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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Polynovo

By TIM BOREHAM

ASX code: PNV

Share price: $1.20

Shares on issue: 690,842,991

Market cap: $829.0 million

Chief executive officer: Swami Raote (potentially, to be replaced by June by Dr Robyn Elliott as interim chief executive officer)

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

Financials (December half 2024): revenue $59.9 million (up 25%), earnings before interest, tax depreciation and amortization $7.25 million (up 276%), net profit $3.3 million (up 24%), cash of $30.4 million (down 33%).

Identifiable major holders: Fidelity Investments 6.5%, David Williams 3%

Corporate chieftains by nature are bemused by negative market reactions to seemingly robust financial results – and there were plenty of surprise movements in the healthcare sector during this year's profit reporting season.

But Polynovo chairman David Williams is simply "flabbergasted".

“I find myself in an extraordinary position to try to explain only a 28 percent growth rate, where in any other company or country you would be pretty happy with that.”

He was speaking after the company’s first (half) results last week, which resulted in the stock being birched by 8.5 percent on the day.

Driving home the point, he adds that sector titans Cochlear and CSL would be applauded for such growth.

The Polynovo evolution

Polynovo’s commercialization has been on the back of Novosorb, its bio-resorbable lattice for complex wounds, burns and reconstructions.

As with so many biotechs, Polynovo evolved from interesting roots, having been known as Calzada and, earlier, Metabolic Pharmaceuticals.

Metabolic owned AOD9604, a peptide that failed a large and very expensive obesity trial. The controversial molecule then became embroiled in a drug scandal at the Essendon Football Club.

AOD9604 is well-loved by bodybuilders and was sold to Lateral Innovations, a company associated with former Metabolic director Dr David Kenley, in April 2015 for $1.5 million.

The completely different Novosorb technology 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, and in 2014, the company appointed David Williams as a director, then chairman and adopted the Polynovo moniker.

The current CEO, Swami Raote replaced Paul Brennan in 2022.

Mr Brennan built the company from minnow to hero but departed because of what Mr Williams dubbed as “increasing differences with the board in relation to Paul’s interaction with the company’s senior management team and his management style”.

The Florida-based Mr Swami had a 30-year career at Johnson & Johnson in roles including over-the-counter goods and pharmaceutical products and devices.

He then headed J&J Vision Care and was a senior advisor supporting the rollout of a digital health platform to Indian citizens.

Polynovo responded to this week’s media speculation regarding corporate governance issues, by announcing the proposed departure of Mr Raote. But we digress.

Burns are only the beginning

In a short commercial life of just over seven years, Polynovo sells Novosorb in 46 countries and has serviced 67,000 patients to date.

The company claims a leading position in difficult burns dressings in the US, the UK, Germany as well as here and in New Zealand.

In 2014, an initial product called Novopore - a dressing for pressure sores - was approved in the US and Europe.

In late 2015, the US Food and Drug Administration approved Novosorb BTM - as in biodegradable temporizing matrix - for reconstructive and surgical applications such as venous and diabetic ulcers and surgical and trauma uses.

A synthetic surgical product, 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 foam itself looks like something you wrap a parcel in and then chuck away – but there’s a lot more to it than that.

In September 2022, the FDA approved the extension product for soft tissue regeneration, Novosorb MTX, which is BTM without the temporizing laminate.

All the way with MTX

MTX (matrix) has wide applications in trauma, plastic and reconstructive surgery - and is the key to the company’s fortunes.

Polynovo launched MTX in the US in April 2024. The product generated $2.1 million in the December half and has racked up $3 million of sales since debut.

The company expects MTX to replace BTM in the next three to five years, but with the addressable market greatly expanded as opposed to BTM sales being cannibalized; and has several entreaties before the FDA to expand the indications for MTX with different thicknesses and sizes.

The company plans to file for Syntrel, a hernia mesh, by March 2026, with a launch that year “if we get the right support from the FDA”.

Syntrix (a plastic reconstructive mesh) is due for filing by June 2026.

Separately, other work is being undertaken for oncological applications, limb salvages and vascular wounds.

Not everything has gone Polynovo’s way: last year the company abandoned a diabetic foot ulcer trial, on the back of what broker Bell Potter describes as “indifferent” results.

BARDA not be a disaster

In its munificence, BARDA is funding a paediatric trial for severe full-thickness burns at a cost of $35 million to $50 million.

BARDA is the US doomsday preparation authority, the Biomedical Advanced Research and Development Authority.

Dubbed CP-003, the trial has enrolled 120 patients, with an FDA pre-market approval application expected to be filed by July 2025. Unless the FDA stops the approval clock for pesky questions, a decision is expected six months later.

“The BARDA trial is the most complex trial anyone could undertake,” Mr Raote says. “It was a very hard trial to execute.”

He says a successfully launched product “will give us enormous traction, not just with burns surgeons but plastic and reconstructive surgeons”.

Finances and performance

Polynovo’s group revenue increased 25 percent to $59.9 million.

The company reported a net profit of $3.3 million - 24 percent higher - having made a maiden profit of $5.2 million in the year to June 30, 2024. The company treated 14,690 patients in the half year, compared to 22,205 in the full 2023-’24 year.

Novosorb sales accounted for $54.1 million of this turnover, with BARDA contributing the remaining $5.4 million (for product used in the trials).

Revenue from the US – the company’s maturest market – grew 28 percent to $41.2 million. ‘Rest of world’ revenue grew 28.6 percent to $12.9 million, albeit with a “bit of a tail-off” in the year to date.

In Europe, where the company leads the market in skin substitute procedures in Germany and the UK, revenue grew an “exceptional” 50 percent. The region accounts for 14 percent of total sales. Europe now outpaces the US in terms of the number of units sold and the variety of procedures.

Asia Pacific revenue grew at a more sedate 10 percent, mainly because of fewer burns procedures in Australia.

Over the last 12 months, Polynovo shares have danced between $1.41 (on May 26 this year) and $2.72 (August 1 last year). The shares peaked at $3.95 on Christmas Eve 2020 – but the Santa rally couldn’t be maintained.

Ten years ago, the stock was worth a mere eight cents and - yep - no-one rang the bell to buy by-the-wheelbarrow load.

Growth avenues

European revenues are inherently lumpy, given variable price mix, the incidence of public tendering and the company's entry into new markets and geographies. Speaking of which, Mr Raote is enthused about the company's prospects in Turkey, despite reimbursement being lower.

The company recently signed up a distributor in Japan, "one of the best markets the company has ever laid its hands on".

Polynovo also plans to enter the Middle Kingdom market and plans to launch a registration process "soon".

To support all this growth, it has invested in a new manufacturing and research and development facility in Port Melbourne.

Operational by the end of the year, the plant will increase Polynovo's capacity to $500 million of annual sales, well above the (underused) $180 million-a-year capacity.

Not losing sleep over Trump tariffs

Given the company makes its gear in Australia, the elephant is in the room is whether Trump's tariffs will stymie Polynovo's growth in its most important market.

The short answer is "no". Mr Williams' intel is that Australia generally is not a Trumpian tariff priority, because we buy more stuff from the Yanks - including drugs and medical devices - than the few jars of Vegemite we send there.

The company also has considerable inventory already in the US.

"If the worst came to the worst … there's a fair bit of distance between us and some of our competitors in terms of pricing," Mr Williams says.

In other words, the company could absorb any tariff impact and remain competitive.

"I'm not losing any sleep over it."

A more pertinent question is whether the shake-out of the FDA will affect the approval process for the expanded indications for which the company has applied (or intends to apply).

"By anyone's standards, the new guy at the FDA (new commissioner Martin "Marty" Makary) is unpredictable and anything can happen."

An unpredictable Trump nominee? Who would have thought?

Mr Williams adds that - if anything - the FDA's bureaucracy-ladened process could be hastened.

Explaining the sell down - sorta

So why the harsh sell down?

The market's reaction is vexing given the company had pre-released its first-half revenue numbers in January.

Wilsons analyst Dr Shane Storey opines that the profit missed expectations, "but not materially".

The real 'culprit' was Polynovo's valuation in the first place.

Historically, the stock has traded at 12 times enterprise value (market capitalization less net cash on hand) to revenue.

This compares with a median 2.8 times for comparative wound care companies.

The firm values the stock at six times revenue, equating to a share price of $1.85.

Macquarie Equities says the company's underlying earnings fell 13 percent, accounting for foreign exchange tweaks and twerks.

The firm's values Polynovo at $2.80 per share, similar to broker Morgans' $2.85 a share appraisal.

Dr Boreham's diagnosis:

Mr Williams says Polynovo's revenue should be seen as only the beginning, as the wound care house expands its repertoire from burns to other procedures such as plastic and trauma reconstruction and hernias.

Polynovo doesn't exactly have the synthetic dressing market to itself, but the growth strategy is simple.

"We are going to continue to take market share," he says.

"In some markets we have gone from nothing a few years ago to number one in the market.

"In many markets where we are number two, number one is coming down the track very quickly."

However, Mr Raote adds Polynovo's strategy is to "grow slow to grow fast", which means winning the hearts and skilled hands of surgeons, incrementally.

Despite the emphasis on other new markets - including the aforementioned Turkey - Mr Raote stresses the US will continue to be the company's prime market.

He says the company's US market share remains a "slither" in the US$1 billion a year "complex care" wounds market.

"We have a big runway for growth and will get there in a structured fashion."

Currently, Polynovo is benefiting from the absence of a key rival, Integra Lifesciences. The FDA identified manufacturing problems in mid-2023 and Integra's dermal matrix Surgimed remains off market until next year.

But Mr Raote says competition is intense, with rivals lurking at every corner.

"Multiple players will come into this space and we just have to cope with that reality," he says.

"We are not resting on our laurels."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is not resting on his laurels and prefers a comfy mattress to a comfy matrix.