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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Polynovo

By TIM BOREHAM

ASX Code: PNV

Share price: 36 cents

Market cap: $213.8 million

Shares on issue: 593,974,935

Chief executive officer: Paul Brennan

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

Financials (2016-'17 year): revenue $3.8 million (up 8 percent), loss $5.0 million (up 54 percent), cash $5.5 million (previously $10.7 million).

Identifiable shareholders: The Trust Co (Merchant's Andrew Chapman) 11.6 percent, John Greenwood 2.8 percent, Lateral Innovations (David Kenley) 4.8 percent, Moggs Creek Pty Ltd (David Williams) 1.8 percent, Monash Investment Holdings 1.7 percent, Paul Brennan 1.3 percent.

These days, Polynovo is focused squarely on its non-toxic wound dressing device called the Novosorb biodegradable temporising matrix (BTM), but my, what a circuitous and tortured listed history this corporate has been.

While developed mainly for the $1 billion a year surgical wounds market, Novosorb is intended to be the medical version of the Swiss Army knife in terms of versatility.

Demonstrating Novosorb's multiple uses, the company this week announced a memorandum of understanding with an "innovative global medical device company" to develop devices for the breast reconstruction surgery market.

The potential deal – which is subject to a 90-day exclusive negotiation period – would result in up-front and milestone payments and, ultimately, royalties on any sales.

The news prompted a pneumatic market response, with the shares bounding 25 percent.

Pay attention, you will be tested

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 joint venture with Xceed Biotechnology. Metabolic bought 60 percent of this venture in 2008.

Metabolic was famous (infamous actually), for a massive obesity trial "belly-flop" in 2007 based on the peptide AOD9604.

Or as then chief executive officer Dr Roland Scollay told Biotech Daily at the time: "The trial didn't fail. The trial was very successful. It showed our drug didn't work."

For those who followed the Essendon Football Club (and Cronulla) drugs saga, AOD9604 would be familiar as one of the substances allegedly taken by the unknowing players; and the original target of anti-doping authorities.

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 chief executive officer David Kenley's Lateral Pharma Pty Ltd.

Lateral Pharma is now developing AOD9604 as an osteoarthritis and osteoarthritis pain treatment, with other pain and repair indications also being explored.

This is apt, given the pain the substance caused Essendon.

"By focusing on Polynovo we have become commercial with proper facilities, staffing and infrastructure," chief executive officer Paul Brennan says.

It’s all about Novosorb

Novosorb is a 2.0 millimetre thick biodegradable polymer foam wound scaffolding that is claimed to provide a better result than rival lattice products, or skin grafts from the bum.

“We can make it as a fibre, a solid cardiac stent or films and foams,” Mr Brennan says. “It’s all the same polymer but with different end attributes.”

To the lay person, Novosorb looks like a layer of Aussie Post standard parcel packaging but it 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.

Novosorb contains no aromatic isocyanates or solvents (this is a good thing). It biodegrades through hydrolysis and is excreted via respiration, urine or microphage (blood cell) activity.

Being non-organic, the material is less conducive to infection.

Currently Novosorb is approved for wound and burns use in the US, although burns are only about 10 percent of Polynovo’s target market.

As well as breast reconstruction, Novosorb is also being developed for hernia repair and as a “dermal depot” for islet cell transplants (for type 2 diabetes).

The magic foam mat may also be relevant for repairing bone fractures and damaged cartilages and for subcutaneous drug delivery.

The story to date

In 2015, Polynovo gained US Food and Drug Administration 510k (device) clearance for use in reconstructive and surgical wounds.

The first US patient – a trauma victim with a ‘degloved’ hand and forearm – was treated in February.

The company reports first sales in the US, with good results for trauma, necrosis, burns and reconstructive and plastic surgery.

In short, Polynovo is selling in US, South Africa, Israel, New Zealand and Australia.

The company is progressing through the hospital procurement process at many major US hospitals, with 25 centres of healing nearing the end of their evaluation.

As of September, the company received orders from two large hospitals with a combine invoice value of more than $300,000 and since then has received at least one more, as well as repeat orders.

Polynovo chairman David Williams admits the company had been “over optimistic” about forecast US sales in the past.

“Our conscious decision to build a direct sales model in the world’s biggest market is proving the right strategy,” he chimes.

This month, Polynovo signed AMI Medical Technologies as Israeli distributor.

The company also has a distributorship in South Africa and is also working other Middle Eastern distributorships, as well as eyeing Indian regulatory approval.

It BARDA be good

Polynovo has the advantage of being backed by US mass disaster agency BARDA (Biomedical Advanced Research and Development Agency).

The BARDA-funded full thickness burns feasibility trial in the US involves 10 patients across four hospitals, with four enrolled so far.

The cost? $US18 million, with a further $US30 million for a phase II trial that would involve about 120 patients.

God bless America.

BARDA is also kindly funding a $2.4 million swine study on “degradation and toxicity”.

Off its own bat, the company has commissioned a clinical trial aimed at supporting its application for Conformité Européenne (CE) mark approval, which is expected in 2017.

So far, 18 of 30 patients have been enrolled in the $2.5 million trial, which will take place here and in France.

Dr Boreham’s diagnosis:

Polynovo’s net loss of $5.0 million in 2016-’17 compares with a $3.5 million the year before, but the funds were spent on wholesome development activities.

Polynovo knows how to keep the lights on, raising $13.8 million of equity in 2015 and then $7 million in a recent private placement at 27 cents a share and a share purchase plan is also in train.

Polynovo's receipts of $3.8 million in 2016-'17 derived mainly from BARDA ($3.5 million) as well as a $700,000 Federal R&D Tax Incentive.

Polynovo has better institutional backing than your normal biotech bear, with The Trust Company (formerly the Merchant Group) an 11 per cent holder.

Chairman David Williams is also well known as chair of Medical Developments, which is successfully selling the Penthrox (green whistle) front-line pain relief product globally.

He also runs advisory company Kidder Williams with Bega as a major client.

On the clinical side, leading burns surgeon and 2.5 percent shareholder Prof John Greenwood is a certified Polynovo fan.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has never procured AOD9604, mainly because he has never been seen in a gym.