



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Aroa Biosurgery

By **TIM BOREHAM**

**ASX code:** ARX

**Share price:** IPO at 75 cents, closed today at \$1.35

**Shares on issue:** 300,074,950 (198,906,131 held in escrow)

**Market cap:** \$405.1 million

**Founder and chief executive officer:** Dr Brian Ward

**Board:** James (Jim) McLean (chairman), Dr Ward, Steve Engle (Prescient), Phil McCaw, John Pinion, John Diddams (Volpara)

**Financials (year to March 31, 2020\*):** revenue \$NZ25 million (up 7.9%), earnings before interest, tax, depreciation and amortization \$NZ224,000 (down 89%), net loss \$NZ6.1 million (previously \$NZ4.45 million loss), cash of \$NZ2.2 million\*\* (down 43%).

\*One \$NZ = \$A0.93 \*\*\$45 million raised in today's initial public offer

**Identifiable major holders:** Dr Ward 11%, Movac Fund 3 LP 8.6%, Phil McCaw 5.6%.

Aroa chief executive Brian Ward objects to his wound healing device outfit being referred to as a "mini me" version of the \$1.5 billion market cap Polynovo, last year's best ASX performer.

"I would say we are at least equivalent," he quips.

Today, the Auckland-based Aroa joined Polynovo on the Australian bourse, having raised \$45 million in an “over-subscribed” raising.

In a nice touch, the ASX listings folk provided a replica bell for Dr Ward to ring before the first trade, within the safety of the New Zealand Covid-19 free bubble.

Aroa’s Endoform platform indeed is similar to Polynovo’s Novosorb range, in that they are both approved, matrix-based soft tissue repair technologies.

But Aroa’s biologic-based products don’t compete directly with Polynovo’s synthetic ones - or not yet, at least. Polynovo works mainly in the burns sector, while Endoform’s repertoire covers non-healing wounds, diabetic and venous foot ulcers, hernias and breast reconstructions.

“They both have their place and I think both companies have large opportunities in front of them,” Dr Ward says with a feel for diplomacy that would do the United Nations proud.

Aroa currently has five approved products that have been used in four million procedures.

The products are available across 600 hospitals in 37 countries and have US Food and Drug Administration and European Union approval.

## **About Endoform**

Endoform, in essence, is a scaffold that promotes new tissue growth and blood supply.

Eventually the scaffold, like The Who, just f-f-fades away by the body’s natural functions.

Aroa’s products consist of two Endoform iterations (for wounds that won’t heal and microbial wounds), Myriad (soft tissue reconstruction), Ovitex (reinforced scaffold for abdominal wall reconstruction) and Ovitex PRS (plastic surgery such as breast reconstruction).

A pipeline of products in development targets more specific applications.

The company claims its products are 20 percent to 60 percent cheaper than competing biologics-based products. “while offering superior regenerative performance”.

## **From sheep guts to surgery**

Endoform results from 10 years of development work spearheaded by Dr Ward, a former vet (animals, not Vietnam).

There’s a quintessentially Kiwi - that is, ovine - angle to the story, in that Endoform derives from the stomach lining of sheep.

“I saw this field of regenerative medicine unfolding and was really interested in the use of biologic materials and scaffolds,” Dr Ward says. “I was intrigued and curious about how materials could be used for a range of soft tissue regeneration.”

He dusted off his old anatomy books and identified the ruminants’ guts as an ideal material source, given their thick extracellular matrices and high concentration of secondary ‘signalling’ molecules that promote cell growth.

“When you purify it, you are left with this beautiful porous scaffold which has these vascular channels with high concentrations of these signalling molecules.”

Dr Ward founded the company, initially known as Mesynthes in 2008 after rustling up \$NZ1.5 million of seed capital. Initially he deployed two contract research scientists before hiring Barnaby May (now the company’s head of clinical development).

The company expanded into its own purpose-built Auckland facility in 2014.

The FDA approved the first product, Endoform Natural for non-healing wounds, in 2010. The product was launched in 2013 via then distribution partner Hollister Inc.

“I weathered two or three years of pretty lean times, but we have managed to keep the company on track, get products approved and build partnerships with global companies,” Dr Ward says.

## **Better together**

Aroa’s route to market in the US is via two key partnerships: Appulse and Tela Bio.

Formed in 2018 after Aroa re-acquired the distribution rights from Holliser, Appulse is a sales joint venture with the Connecticut-based wounds care house Hydrofera LLC.

Cavorting with the enemy? Not quite: Hydrofera’s wound dressing range is more complementary to Aroa’s rather than replacing them.

“It’s quite common for these products to be used together: Endoform at the base of the wound and then the Hydrofera (product) as a dressing to cover it,” Dr Ward says.

Aroa collaborated with the Nasdaq-listed Tela Bio to develop Ovitex, its first surgical product. The FDA cleared Ovitex for ventral hernia repair and abdominal wall reconstruction in 2013 and the product was launched shortly thereafter.

The Appulse joint venture deploys a shared sales team; with all costs shared. The partners do their billing and back office work separately.

The Tela Bio alliance is a licencing arrangement that involves revenue sharing.

Aroa, meanwhile, is working on non-US distribution arrangements.

## **Raptures over ruptures trial**

Aroa's clinical efforts are centred on a post-market, US-based study called Bravo, for the use of Ovitex for simple and complex ventral hernias.

(Okay: Bravo stands for Bio-scaffold Reconstruction of Abdominal wall and Ventral hernia defect with Open or laparoscopic repair).

The hernias are formed after abdominal surgery, with a recurrence rate of 10 percent to 30 percent. Many patients require repeat surgery.

"Typically, ventral hernias occur after patients have had abdominal surgery and the abdominal incision has failed to heal," Dr Ward says. "Patients require further surgery to repair the hernia and surgeons frequently use mesh to reinforce the abdominal wall.

"The Bravo study investigates the use of Ovitex to reinforce the repair using established surgical techniques."

In the study, 50 patients completed 12 months with one recurrence, but not at the site of the surgery.

"The first 20 patients completed in 24 months, with zero recurrence, which is a phenomenal result," Dr Ward says.

The results from 50 more patients after 24 months are due by the end of this year.

Meanwhile the Food and Drug Administration is mulling whether to approve Symphony, a skin substitute for diabetic and venous ulcers.

## **Finances and performance**

Aroa has not been immune to Covid-19, in that the virus deferred elective surgeries in March and April before they rebounded in May.

"We had predicted we would be down by 50 percent for at least [the three month quarter] but it's turned out to be not as severe as that," Dr Ward says.

"We are quite pleased how things tracked back in May and June, but it is going to be bumpy in the US over the next six months."

The initial public offer raised \$45 million at 75 cents apiece: 30 million from new shares, with an additional \$15 million from a vendor sell down.

But don't worry, these vendor-holders still account for 240 million shares, or 80 percent of the company and 83 percent of these shares are escrowed for up to three years.

In its privately-owned guise, the company posted a net loss of \$NZ6.1 million in the year to March 2020, but generated earnings before interest tax, depreciation and amortization (ebitda) of \$NZ224,000 (down 89 percent).

The company cites a \$US1.5 billion (\$2.1 billion) addressable US market for its current products, with an extra \$US1 billion for its products in development.

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

Aroa is - and continues to be - an American story, with about 95 percent of revenues derived from the US.

While the tarnished nation might have the global standing of Kazakhstan, it's still the superpower market for medical device makers.

"It's one market with one regulator and one reimbursement system in the main, it's certainly a market we're familiar with," Dr Ward says.

He says Aroa has avoided "diluting" its resources by expanding into other markets, but this will change over time. Indeed, the company is selling in Germany, Austria and selected Middle Eastern and Asian countries.

Aroa isn't the only wound scaffold game in town: others include Integra Life Sciences, Mimedix, Organogenesis and Smith+Nephew's Osiris Therapeutics.

But Dr Ward is confident of winning market share on the back of "phenomenal" results and the company's ability to make the product at scale and relatively cheaply.

"We want to crack this nut where we can offer a really fantastic product at an affordable price."

Give Aroa's roomy addressable markets, it's indeed feasible the company could eclipse Polynovo in size and become New Zealand's biggest export success since pineapple lumps and the Finn brothers.

***Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. In pre-bubble times he visited Auckland and was impressed by shear beauty of the harbor, the baas and nightlife - without being fleeced once.***