



# Biotech Daily

Friday July 24, 2020

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market fell 1.16 percent on Friday July 24, 2020, with the ASX200 down 70.5 points to 6,024.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and one was untraded.

Universal Biosensors was best, up 3.5 cents or 15.9 percent to 25.5 cents, with 931,607 shares traded. Cynata climbed 9.4 percent; Osprey rose 6.5 percent; Immutep improved five percent; Actinogen, Kazia, Nova, Optiscan, Pharmaxis and Proteomics were up four percent or more; Amplia, Avita and Genetic Signatures were up more than three percent; Next Science rose 2.6 percent; with Opthea and Starpharma up more than one percent.

Cyclopharm led the falls, down nine cents or six percent to \$1.41, with 2,000 shares traded. Antisense and Neuren fell four percent or more; LBT lost 3.3 percent; Paradigm, Pro Medicus, Telix and Uscom shed more than two percent; Clinuvel, Cochlear, CSL, Impedimed, Medical Developments, Orthocell, Polynovo and Volpara were down more than one percent; with Mesoblast and Nanosonics down by less than one percent.

## DR BOREHAM'S CRUCIBLE: AROA BIOSURGERY

**By TIM BOREHAM**

**ASX code:** ARX

**Share price:** IPO at 75 cents, closed today at \$1.35 (see separate article below)

**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 and 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 Hollister, 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 study called Bravo, for the use of Ovitex for 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 [three months] 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.***

## AROA BIOSURGERY

Aroa opened up 86.7 percent above its initial public offer price of 75 cents at \$1.40, hitting \$1.56 in early trade.

The Auckland, New Zealand-based Aroa said that the oversubscribed \$30 million placement and \$15 million sell-down from existing investors would fund the development and commercialization of its Endoform soft tissue regeneration products.

The company said it had five commercial products based on Endoform, which was derived from sheep stomach, which acted as a scaffold to grow new tissue lost or damaged through disease or injury, eventually replaced by the patient's own tissue.

Aroa said the five products included Endoform Natural, a tissue matrix for stalled chronic wounds, Endoform Antimicrobial, an antimicrobial tissue matrix for stalled chronic wounds, Myriad, a biological graft for dermal and implantable soft tissue reconstruction, Ovitex, a reinforced biological scaffold for abdominal wall reconstruction for hernia and Ovitex PRS, a reinforced biological scaffold for plastic and reconstructive surgery.

The company said revenue of \$NZ22 million (\$A20.5 million) for the 12 months to March 31, 2020, came from direct sales of its five commercial products, from its Appulse joint-venture with Hydrofera LLC and distribution partner, the Pennsylvania-based Tela Bio Inc. Aroa said its Endoform had been used in more than four million procedures to date, it had regulatory clearance in more than 37 countries, had sales with more than 600 US hospitals and had 10 patents and 25 pending patent applications.

The company said it also had a pipeline of additional products in development, based on the Endoform technology, including Symphony, a skin substitute for closing wounds for severely impaired healing and a single-use negative pressure wound therapy.

The company said Bell Potter Securities and Wilsons were joint lead managers to the offer.

Aroa climbed as much as 81 cents or 108.0 percent to \$1.56 before closing up 60 cents or 80.0 percent at \$1.35, with 17.3 million shares traded.

## IMMURON

Immuron says it has raised \$US20 million (\$A28.1 million) in the placement of 1,066,668 American depositary shares (ADSs) at \$US18.75 (\$A26.36) each.

Immuron said each ADS represented 40 ASX shares at 65.9 cents each.

The company said the funds would be used for research and development, preclinical and clinical programs, marketing initiatives for Travelan and for ongoing working capital.

Immuron said H C Wainwright & Co was the placement agent for the offer.

Immuron fell three cents or 5.7 percent to 49.5 cents with 5.7 million shares traded.

## EMVISION

Emvision said it has "binding commitments from institutional and sophisticated investors" to raise \$9 million in a placement at \$1.42 a share.

Emvision said the placement share price was a 16.0 percent discount to the last closing price of \$1.69 a share and a 12.7 percent discount to the 15-day volume weighted average share price.

The company said the funds raised would be used for ongoing product development, including the commercialization of the company's first-generation portable brain scanner, corporate administration, and general working capital.

Emvision said Bell Potter Securities was the lead manager for the placement.

Emvision was up 11 cents or 6.5 percent to \$1.80 with 927,899 shares traded.

## UNIVERSAL BIOSENSORS

Universal Biosensors says that revenue for the six months to June 30, 2019 fell 73.3 percent to \$1,063,446 with net loss after tax up 29.2 percent to \$4,523,102.

Universal Biosensors said that revenue from sales of its Xprecia Stride coagulation analyzer test strips to Siemens was down 63.8 percent to \$829,859.

The company said that revenue from services was down 86.1 percent to \$233,587 compared to the previous corresponding period.

Universal Biosensors said it spent \$6,994,361 for the six months to June 30, 2019, down 10.3 percent compared to the previous corresponding period.

The company said that diluted loss per share was up 50 percent to 0.3 cents compared to the previous period's 0.2 cents.

Universal Biosensors said that net tangible asset backing per share was down 11.5 percent to 23 cents a share.

Universal Biosensors said that it held cash and cash equivalents of \$32,146,365 at June 30, 2020 compared to \$50,553,981 at June 30, 2019.

Universal Biosensors was up 3.5 cents or 15.9 percent to 25.5 cents.

## ALCIDION GROUP

Alcidion says the Lanarkshire National Health Service will pay GBP848,000 (\$A1,520,000) for its Patientrack bedside monitoring system.

Alcidion said the NHS Lanarkshire five-year contract covered the use of Patientrack across its network, which included three district general hospitals and smaller community hospitals with a total of 1,250 beds.

The company said the NHS Lanarkshire, headquartered in Kirklands, Scotland, would use Patientrack to electronically record observations, produce charts, automatically calculate patient early warning scores, generate clinical alerts and document a range of clinical assessments.

Alcidion said that NHS Lanarkshire would use Patientrack in its command centre to generate "a real time overview of the status of all patients across all hospitals."

Alcidion was up one cent or 6.7 percent to 16 cents with 2.3 million shares traded.

## VISIONEERING TECHNOLOGIES

Visioneering says it had secured the first Canadian sales of its Naturalvue multifocal 1-day contact lenses for the control of near-sightedness progression.

Visioneering said it had completed the training and accreditation of its first cohort of eye care professionals in Canada, several of which had prescribed and sold Naturalvue to patients.

In March, the company said Health Canada had approved a medical device licence to market and sell its Naturalvue (BD: Mar 13, 2020).

Visioneering chief executive officer Dr Stephen Snowdy said that the launch was "yet another important milestone".

"We are very pleased that we have cleared the regulatory and operational hurdles to enter this market and can now provide a solution for near-sighted children and over-45 adults in the country," Dr Snowdy said.

Visioneering fell 0.1 cents or 5.6 percent to 1.7 cents with 5.2 million shares traded.

## DIMERIX

Dimerix says it has completed dosing in its 40-patient, randomized, controlled, phase II study of DMX-200 for diabetic kidney disease and expects results in four to six weeks. Dimerix said the cross-over study enrolled diabetic kidney disease patients that were taking irbesartan and dosed them with 12 weeks of DMX-200 and 12 weeks of placebo. The company said the primary endpoint was a change from baseline over 24-hours of the ratio of albumin, a protein made by the liver, to creatinine, a chemical waste product produced by muscle metabolism, after 12-weeks of treatment. Dimerix said the study was “statistically powered” to resolve a 30 percent reduction in proteinuria, based on 40 patients completing the study in line with the protocol. Dimerix was unchanged at 38 cents with 1.3 million shares traded.

## FACTOR THERAPEUTICS

Factor says it has a term sheet agreement with Longmile Veterinary to acquire veterinary products and technology and will appoint Dr David Brookes as chairman. In 2018, Factor fell as much as 97.3 percent to 0.2 cents on news that its 157-patient trial of VF001 for venous leg ulcers “failed to meet all endpoints” (BD: Nov 14, 2018). Today, the company said the agreement with the Rockville, Maryland-based Longmile Veterinary positron emission tomography (PET) Imaging, a subsidiary of Brain Bioscience, provided 120 days exclusivity to complete due diligence and negotiate formal transaction documents for the acquisition of the rights to Longmile’s veterinary product portfolio. Factor said it would pay Longmile \$US25,000 (\$A35,290) for the exclusivity period and a further \$US25,000 on the conclusion of the acquisition. The company said the acquisition was conditional on due diligence, transfer pricing, manufacturing capacity, on-going product development, Factor to demonstrate at least \$3 million in cash for commercialization, staff changes and regulatory approval. Factor said the transaction would be subject to ASX approval “in terms of demonstrating continuity of business operations and/or requirements under chapter 11 of the ASX listing rules regarding change in nature or scale of the Company’s operations, including to re-comply with chapters 1 and 2 of the ASX listing rules”, and its securities would be suspended until the transaction was concluded and it satisfied all ASX requirements. Factor chair Dr Cherrell Hirst said that veterinary imaging technologies had become a standard part of oncology, infection and rheumatology care in human medicine and there was a growing unmet need to deliver similar capabilities in veterinary medicine, “against the backdrop of rapid growth in the global animal insurance market”. “Uniquely, the Longmile team have demonstrated a solid scientific foundation and commercial application of the use of imaging diagnosis and treatment management in both large and small animals, with a stellar reputation for innovation and novel product development,” Dr Hirst said. Separately, Factor said it would appoint director Dr David Brookes as chair, following Dr Hirst’s retirement at the close of the company’s annual general meeting on July 30, 2020. The company said Dr Brookes joined Factor in May 2019 and had experience in the health and biotechnology industries, including as a director of Anantara, Tali and the Better Medical Group, and previously was chairman at Reproductive Health Sciences. “The signing of the term sheet with Longmile opens the door for an exciting and successful future for Factor as a veterinary imaging company providing innovative and market leading devices to the world,” Dr Brookes said. Factor remained in a suspension and last traded at 0.5 cents.



## ADHERIUM

Adherium's extraordinary general meeting passed all resolutions, but with up to 20 percent opposition to 20,000,000 options to the chief executive officer and chairman.

Adherium said the ratification and issue of 10,000,000 options exercisable at 4.0 cents each to chief executive officer Mike Motion was opposed by 44,251,421 (19.88%) votes with 178,304,930 votes (80.12%) in favor, while the ratification and issue of 10,000,000 options to chairman James Ward-Lilley was opposed by 45,048,132 (20.19%) votes and approved by 178,108,219 (79.81%) votes.

The company said the motion to issue 83,333,333 options to Bioscience Managers Translation Fund-1 as part of the recent \$5 million capital raising was opposed by 31,434,030 (14.04%) votes, with 192,487,422 (85.86%) in favor.

Adherium said the ratification of 104,000,000 shares and 62 million addition shares to Bioscience Managers, the approval of the executive share option plan, the issue of issue 1,500,000 options each to directors Bryan Mogridge and Dr William Hunter and the issue of 500,000 employee share plan loan shares to director Bruce McHarrie passed more easily.

The company's most recent Appendix 2A new issue announcement said that Adherium had 601,906,334 shares on issue, meaning that the votes against the issue of options to Mr Ward-Lilley amounted to 7.48 percent of the company, sufficient to requisition extraordinary general meetings.

Adherium was up half a cent or 20.8 percent to 2.9 cents with 2.9 million shares traded.

## BIONOMICS

Bionomics says it will vote on ratification of 135,833,000 shares to Apeiron and approve a 52 percent acquisition by Apeiron and Christian Angermayer.

Last month, Bionomics said it hoped to raise \$22 million in a raising at four cents a share, including \$5,433,320 from the Malta-based Apeiron Investment Group, the family officer of Mr Angermayer, and a \$15,000,000 rights offer underwritten by Apeiron, subject to shareholder approval (BD: Jun 2, 2020).

Today, the company said it proposed to issue Apeiron and Mr Angermayer securities totalling 52.004 percent of the company, including 53,330,000 shares under the rights offer, 250,000,000 shares for underwriting the offer and 150,000,000 warrants, exercisable at six cents each within 36 months of the meeting.

Bionomics said shareholders would vote to elect Aaron Weaver as a director, who was appointed as one of two Apeiron directors, as well as increase the director fee pool from \$500,000 to \$750,000 a year to accommodate new directors (BD: Jul 3, 2020).

The company said it would vote to issue 12,000,000 options to executive chairman Dr Errol De Souza, with 6,000,000, exercisable at four cents each within five years.

The meeting will be held online on August 26, 2020 at 9am (AEST).

Bionomics was unchanged at seven cents.

## PRESCIENT THERAPEUTICS

Australian Ethical Investment says it has reduced its substantial shareholding in Prescient from to 32,331,536 shares (8.20%) to 25,551,534 shares (6.48%).

The Sydney-based Australian Ethical said that between June 2 and July 22, 2020 it sold 6,780,002 shares for \$462,808 or an average of 6.83 cents a share.

Prescient last traded at 6.6 cents.

### [PRESCIENT THERAPEUTICS](#)

Prescient has requested a trading halt “requested pending an announcement by the company to the market regarding a capital raising”.

Trading will resume on July 28, 2020 or on an earlier announcement.

### [MGC PHARMACEUTICALS](#)

MGC has requested a voluntary suspension to follow the trading halt “in relation to safety and toxicity pre-clinical study results for Artemic” (BD: Jul 22, 2020).

Trading will resume on July 27, 2020 or on an earlier announcement.

MGC last traded at 2.4 cents.

### [MESOBLAST](#)

Mesoblast says it has appointed Dagmar Rosa-Bjorkeson as chief operation officer, based in New York, ahead of its first US potential launch.

Mesoblast said Ms Rosa-Bjorkeson had more than 25 years’ experience in the pharmaceutical industry and previously was an executive at Novartis, Baxalta and Mallinckrodt Pharmaceuticals.

Mesoblast fell three cents or 0.85 percent to \$3.51 with 3.9 million shares traded.

### [OPTHEA](#)

Opthea says it has appointed Lawrence Gozlan as a non-executive director, effective from July 24, 2020.

Opthea said Mr Gozlan was the life sciences investment manager at Jagen Pty Ltd, the family office of Bori Liberman, which held 7.31 percent of Opthea (BD: Dec 4, 2018).

The company said Mr Gozlan was currently a director of Australian and US companies and previously worked for the Queensland Investment Corporation, Foster Stockbroking and Deloitte, and held a Bachelor of Science from the University of Melbourne.

Opthea was up five cents or 1.9 percent to \$2.72 with 783,980 shares traded.

### [BARD1 LIFE SCIENCES](#)

Bard1 says it has appointed Dr Peter French as chief scientific officer, effective from August 17, 2020, replacing Dr Irmgard Irminger-Finger.

Bard1 said Dr Irminger-Finger would transition to the role of founding scientist and would work with Dr French.

The company said Dr French would lead the company’s research and development program, which broadened since the acquisition of Sienna Diagnostics and its cancer diagnostic tests (BD: Apr 9, 2020).

Bard1 said Dr French had more than 40 years’ experience in cell and molecular biology and had provided consultancy services to both Bard1 and Sienna.

The company said Dr French was currently the chairman of Mediland Pharm and Penao, and previously held roles at Ausdiagnostics Pty Ltd, Bioxyne, Benitec and Cryosite.

Bard1 was up 0.1 cents or 3.2 percent to 3.2 cents with 1.9 million shares traded.