



Biotech Daily

Friday July 26, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.76 percent on Friday July 26, 2024, with the ASX200 up 60.1 points to 7,921.3 points. Fifteen of the Biotech Daily Top 40 companies were up, 14 were down, 10 traded unchanged and one was untraded.

Actinogen was the best, up 0.5 cents or 6.25 percent to 8.5 cents, with 14.4 million shares traded. Avita climbed 4.7 percent; Cyclopharm and SDI were up more than three percent; Cynata rose two percent; Cochlear, Compumedics, Immutep, Nanosonics, Opthea, Percheron, Resonance and Starpharma were up one percent or more; with CSL, Neuren, Polynovo and Telix up by less than one percent.

Yesterday's 61.3 percent best, Amplia, led the falls, down 1.2 cents or 12.0 percent to 8.8 cents, with 8.2 million shares traded. Universal Biosensors lost 8.1 percent; Next Science was down 5.2 percent; Prescient fell 4.4 percent; Paradigm was down 3.8 percent; Clarity, Emvision, Mesoblast and Syntara shed two percent or more; 4D Medical, Dimerix and Impedimed were down one percent or more; with Medadvisor, Pro Medicus and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: AROA BIOSURGERY

By TIM BOREHAM

ASX code: ARX

Share price: 63 cents

Shares on issue: 344,207,834

Market cap: \$216.9 million

Founder and chief executive officer: Dr Brian Ward

Board: James (Jim) McLean (chair), Dr Ward, Darla Hutton, Phil McCaw, John Pinion, John Diddams, Dr Catherine Mohr

Financials (year to March 31, 2024): revenue \$NZ69.1 million (\$A62.1 million) (up 9%), reported net loss after tax \$NZ10.6 million (previously \$NZ396,000 loss), cash of \$NZ11,522,000

(Three months to June 30, 2024): receipts \$NZ17,834,000 (up 17.7%), cash burn \$NZ3,645,000, cash \$NZ23,889,000 (\$NZ38,526,000 previously), 7.0 quarters cash.

Identifiable major holders: Dr Ward 9.7%, First Cape Group (Harbour Capital Management) 7.23%, Phil McCaw 5.75%, Acorn Capital 5%

While investor sentiment in the biotech sector continues to improve after valuations were hammered in the Great Post Pandemic Letdown of late 2021, some revenue-generating exponents are yet to feel the love.

Take the Auckland-based wound-care house Aroa Biosurgery, which the market values at a tad over \$210 million compared with \$355 million when we last visited the company in September 2021.

Since then, revenues have trebled to just under \$NZ70 million, although profitability has proved elusive.

"I feel we are very undervalued at the moment but conditions have been tough for small caps generally," says Aroa founder and CEO Dr Brian Ward.

Of course, every CEO says the same thing, but Dr Ward has a point given the nearest ASX peer Polynovo is valued at \$1.7 billion, having reported first-half revenue of \$48 million.

In the meantime, some pundits claim the company would be better off merging with its Nasdaq-listed US distribution partner, Tela Bio (see below).

About Aroa

Aroa develops and commercializes matrix-based wound healing products based on its proprietary ovine forestomach matrix (OFM) technology (a.k.a sheep guts).

The material promotes new tissue growth and blood supply and dissolves in the body after it has done its job.

“We get fast regrowth and very well revascularized tissue,” Dr Ward says. “We don’t seem to see the infection complications or adverse immune responses seen with other products.”

To date, Aroa’s products have been applied to more than six million wounds.

Aroa’s first product, Endoform, has been used for non-healing wounds such as diabetic and venous foot ulcers.

Other iterations include Myriad Matrix and Myriad Morcells (soft tissue reconstruction and complex wounds), Ovitex (reinforced scaffold for abdominal wall reconstruction) and Ovitex PRS (plastic and reconstructive surgery - such as breast reconstruction).

The Ovitex scaffolds work as a surgical mesh to reinforce and/or repair soft tissue where weaknesses exist.

Then there’s Symphony, a skin substitute for lower diabetic foot ulcers and venous leg ulcers.

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

Biologics-based scaffolds tend to be more expensive than the synthetic ones - and they both have their place in the surgery

“For the high-load bearing products such as hernia, you need additional strength and synthetics provides that,” Dr Ward says.

The story to date

With a keen interest in biologic materials and scaffolds for soft tissue regeneration, Kiwi veterinarian Dr Ward founded the company - then called Mesynthes - with \$NZ1.5 million of seed capital in 2008.

Through his veterinary work he had found that the gut lining of ruminants was an ideal material, given its thick extracellular matrices and secondary ‘signalling’ molecules that promote cell growth.

Aroa listed on July 24, 2020, having raised \$45 million at 75 cents apiece. The company raised a further \$47 million at \$1.165 a share in July 2021.

While Aroa's devices are sold in 15 countries, the company is focused on the key US market which accounts for more than 90 percent of its sales.

In 2010, the US Food and Drug Administration (FDA) approved Endoform Natural for non-healing wounds. First sales flowed in 2013.

In July 2020, the US FDA green-lighted Symphony and in April 2021 it approved Myriad Morcells, having approved Myriad Matrix in June 2017.

The products are made at Aroa's Auckland factory, which has been augmented with a new facility.

'Telaroa'?

Aroa alliance with the Nasdaq-listed Tela Bio covers the Ovitex range and accounts for about half of Aroa's revenue.

Under the compact, Aroa receives \$27 for every \$100 of product and Tela bears the cost of relevant clinical trials and selling costs.

However, Aroa shares some cost of development - usually equally - for product extensions.

In a recent report, broker Wilsons refers to long-standing speculation that Tela and Aroa will do the obvious thing and merge their operations.

Valued at around \$US110 million, Tela last year made revenue of \$US76 million and lost \$US40.5 million.

"The current stage of the two companies and [the] position of both stocks make the idea of a merger more plausible than ever," Wilsons opines.

Dr Ward says Aroa's direct sales are becoming a bigger component relative to Tela - sourced revenue, which is nice because Aroa derives the full value of the products (despite bearing the full costs).

That said, the Tela alliance is also fruitful because the 27 percent cut pretty much goes straight to the bottom line.

Bravo to hernia management

In the case of hernias, a company-funded study - dubbed Bravo - produced "fantastic" results.

"In hernia procedures, recurrences are a big problem, especially with ventral and complex hernias," Dr Ward says.

“Typical recurrence rates are in the 10 to 30 percent range, but with Bravo and Ovitex the recurrence was less than three percent.”

The company expects a number of studies to report this year, including a 130-patient prospective study of lower limb salvage.

The company is running a 120-patient Symphony trial for diabetic and venous leg ulcers. An interim report from the randomized, controlled effort is due by November 2024, with final analysis in March-April next year.

This year, the company also expects to report interim results from a 130-patient trial for lower limb salvage.

“We have some quite key studies coming through,” Dr Ward says. “Once again, the key themes are more rapid repair and lack of complications.”

What's next?

Management is most excited about its novel device for tissue apposition in development, called Enivo.

Tissue apposition refers to bringing the tissue edges, or sides, of the wound next to each other for proper healing.

It's also called 'dead space' management, which refers to closing infection-prone cavities post-surgery.

The Enivo device consists of an implant and a catheter and pump. A vacuum is delivered into dense soft tissue, enabling it to be held together while healing takes place.

“It will be used where surgeons have dissected tissue to access a surgical site, or have removed tissue in cancer surgery,” Dr Ward says.

In January, Aroa reported the results of a pilot study of patients who had undergone a unilateral mastectomy. Six of the 10 patients had completed follow-up care with no “clinically relevant” seromas (fluid build-up) or other complications.

Initiated in Auckland in July last year, the study has been expanded to a site in picturesque Whangarei on the North Island.

Dr Ward says the company is also eyeing the prospect of using Myriad in combination with negative pressure wound therapy in trauma procedures.

“These products aren't typically used in combination, but we think there's a great opportunity to reduce time in hospital and complications,” Dr Ward says.

Eyeing the competition

Aroa does not have the market to itself, with the nature and ferocity of competition varying between product categories.

In the hernia market, Tela and Aroa are disrupting a virtual duopoly market competed by BD (Becton, Dickinson and Co) and Abbvie.

“With hernias, it tends to be the large established players with pretty old portfolios,” Dr Ward says.

“Ovitex is a new type of product, combining biologics and synthetics so it brings something new to the market.”

The breast is dominated by biologics products.

Dr Ward adds that breast reconstruction usually involves applying human acellular dermal matrices (the thick bit below the surface of the skin) which are not ideal because they stretch and big pieces are hard to find.

And there is competition in the soft tissue market primarily from Integra Life Sciences.

Finances and performance

Aroa reported revenue of \$NZ69.1 million in the half year to March 2024, 12 percent higher than previously.

Sales were driven by the growth in Myriad sales, up 73 percent to \$NZ23.3 million.

Ovitex revenues declined seven percent to \$32.6 million, because of inventory issues since rectified in the second half.

Sales of Endoform - a mature product - were flat at just over \$NZ10 million.

While Aroa made an underlying (Ebitda) loss of \$NZ3.09 million, Dr Ward says the company would have been profitable, excluding Enivo development costs.

“We are now through a big part of the expenditure and this year we will transition to being profitable even with that investment,” he says.

Management has guided to revenue of \$NZ80 million to \$NZ87 million for the current financial year and Ebitda of \$NZ2 million to \$NZ6 million.

Dr Ward says the company’s new Auckland facility supports annual revenue of \$NZ200 million, which means the company can more than double output without any more investment.

“Over the next two to three years we should get to the stage where we are using a good deal of that capacity.”

Over the last 12 months, Aroa shares have traded between 48 cents (mid-May this year) and 96 cents (late July last year).

Since listing, they have traded as high as \$1.52 (mid-October 2020).

Dr Boreham’s diagnosis:

Management cites a total US addressable market of \$US3 billion, including \$US1 billion for Symphony and ulcers and \$US730 million for Myriad.

Plastic surgery is a \$US700 million opportunity.

“So, we are only scratching the surface,” Aroa chair Jim McLean told Tuesday’s annual general meeting in Auckland.

He adds that because of the challenges faced by clinicians and hospitals in replacing existing products “the rate of uptake for our products is not easy to predict.”

Dr Ward says while the company plans product extensions in its existing portfolio, Enivo is the “stand-out opportunity” given the \$US1 billion total addressable market.

Despite the sagging share price Aroa is happy to remain listed on the ASX, given the strong support from the top end of town that sees institutions account for 80 percent of the register.

While Dr Ward remains the biggest shareholder, instos on board include Harbour and Acorn.

Dr Ward is clearly unimpressed by the share valuation, it’s a case of ‘onwards and upwards’.

“We will just focus on delivering on the plan,” he says.

Fortunately, the plan includes achieving consistent profitability - a key step to salving the share price wound.

Wilson forecasts a \$NZ6.7 million net profit in 2025-'26, rising to \$NZ9.3 million in 2026-'27.

A merger with Tela could unlock value more quickly, but even the most ‘obvious’ unions have a habit of not happening for a range of reasons.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He remains laser-focused on delivering the plan.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$19 million for six projects researching mRNA vaccines for cancer and urinary tract infections.

A media release from the Minister for Health and Aged Care Mark Butler said the Medical Research Future Fund funds were awarded to the University of Queensland, the Australian National University, the Hudson Institute of Medical Research, the University of Technology Sydney and two Monash University projects.

The Government said the University of Technology Sydney team received \$1.8 million to develop an mRNA vaccine to prevent recurrent urinary tract infections caused by *Escherichia coli* bacteria.

A media release from the University of Queensland said it had received \$3.3 million to open a laboratory to design and manufacture mRNA cancer vaccines at the Australian Institute for Bioengineering and Nanotechnology at its Brisbane campus.

The University said the hub was expected to be operating "by late 2024".

The Federal Government said the University of Queensland team was one of five projects funded by the National Critical Research Infrastructure Initiative, which sought to build out the infrastructure required to safely develop, test and evaluate mRNA therapies and vaccines.

A separate announcement from Monash University said it had received \$4 million to open "Australia's first National Centre for Biopharmaceutical Optimisation of mRNA Therapeutics".

Monash University said the facility would "focus on a critical step in the development process for mRNA medicines, which is to evaluate delivery and biodistribution in the body, informing the plausibility of the candidate to progress toward human studies".

The University said the facility, at its Monash Institute of Pharmaceutical Sciences in Parkville, Melbourne, would collaborate with Moderna, Icamuno, the Walter and Eliza Hall Institute of Medical Research, the Australian National University, the University of Melbourne, the University of New South Wales and the University of Queensland.

Mr Butler said the projects aimed "to improve the health and wellbeing of Australians through world-class health and medical research".

"Cancer affects so many families, and mRNA vaccines are a promising new approach," Mr Butler said.

"As antibiotics are becoming ineffective because of anti-microbial resistance, finding a new way to treat recurring infections like [urinary tract infections] would be a major breakthrough for patients here in Australia, but also in neighboring countries in the Asia-Pacific," Mr Butler said.

Further details of the recipient projects are available at: <https://bit.ly/3WnyMFX>.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it hopes to raise \$10.0 million at 38.0 cents a share in a fully-underwritten \$5.5 million placement and a \$4.5 million one-for-7.35 rights offer.

Medical Developments said the issue price was a 20.9 percent discount to the five-day volume weighted average price of 48.1 cents.

The company said the funds would be used for the commercialization of its inhaled analgesic Pentrox.

Medical Developments said the retail entitlement offer had a record date of July 30, would open on August 2 and close on August 22, 2024.

Medical Developments said Bell Potter was sole lead manager and underwriter.

Medical Developments was in a trading halt and last traded at 48.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says unaudited revenue for the year to June 30, 2024 was up 2.7 percent to \$33.2 million, compared the previous corresponding period.

Last year, Medical Developments said revenue for the year to June 30, 2023 was up 47.4 percent to \$32,337,000, with an underlying loss before interest and taxation of \$18.3 million (BD: Aug 31, 2023).

Today, the company said underlying loss before interest and taxation was expected to be \$11.6 million, down 36.6 percent due to higher average Pentrox prices and lower costs.

Medical Developments said customer receipts from sales of Pentrox for the year to June 30, 2024 were \$34,762,000, with record three-month sales of \$8,322,000.

The company said it had a cash burn of \$381,000 for the three months, with cash and equivalents of \$9,735,000 at June 30, 2024 compared to \$24,661,000 at June 30, 2023.

ACRUX

Acrux says customer receipts for the year to June 30, 2024 were down 32.9 percent to \$5,604,000, compared to the previous corresponding period.

Last year, Acrux said revenue was primarily from a licencing deal and sales of its generic pharmaceuticals, with Gedeon Richter PLC to buy the future royalties of its Lenzetto oestradiol transdermal spray for menopause symptoms for EUR4.10 million (\$A6.80 million) (BD: Jul 27, 2023).

Today, the company said receipts from sales of its topical pharmaceutical products including Lidocaine and Prilocaine creams, Dapsone gel and Evamis for the three months to June 30, 2024 was \$659,000, up from no receipts in the prior corresponding period.

Acrux said it had a cash burn of \$3,811,000 for the three months, with cash and cash equivalents of \$2,945,000 at June 30, 2024 compared to \$6,232,000 at June 30, 2023, meaning it had 0.8 quarters of available funding.

The company said its operating cash outflow was "unusually high due to payment of \$2,437,000 for raw materials in the form of active pharmaceutical ingredients" in the three months to June 30, 2024 and that it had a short-term loan with Radium Capital as an advance on its expected research and development tax incentive.

Acrux fell 0.3 cents or 4.35 percent to 6.6 cents.

PACIFIC EDGE

Pacific Edge says it received no updates from Novitas regarding the expected finalization of changes to local coverage determination for its Cxbladder cancer test.

Last year, Pacific Edge said its Medicare administrative contractor Novitas had warned its Cxbladder tests would cease to be covered by Medicare in the US because it did not consider the tests "medically reasonable and necessary"; and later, said Novitas had delayed implanting changes (BD: Jul 6, 28, 2024).

Later, the company said submissions on the draft local coverage determination (LCD) for non-coverage of Cxbladder, with Novitas and First Coast Service Options would take up to a year from the July 27 date to withdraw or finalize the decision (BD: Sep 11, 2023).

Today, Pacific Edge said it had approached Novitas and was told it was "currently in discussion with the [US] Centers for Medicare and Medicaid Services regarding this proposed LCD [... and] a timeframe for finalization is not available at this time".

The company said its Cxbladder tests continued to receive reimbursement from Medicare, it expected Novitas to finalize the LCD, but the timeframe was unknown.

Pacific Edge was untraded at 7.8 cents.

ONEVENTURES, BIVACOR

Oneventures says Bivacor has implanted its first, in-human, total artificial heart as part of a US Food and Drug Administration early feasibility study.

Sydney venture capital firm Oneventures said Bivacor's total artificial heart was a titanium bi-ventricular rotary blood pump with a single moving part that used magnetic levitation technology and had no valves or flexing ventricle chambers.

The company said the total artificial heart's non-contact suspension provided "large blood gaps minimizing blood trauma and eliminating mechanical wear to offer a durable, reliable, and bio-compatible heart replacement".

Oneventures said the procedure was performed at Houston's Texas Medical Center, with four additional patients to be enrolled in the study, which aimed to evaluate the safety and performance of the total artificial heart as a "bridge-to-transplant" for patients with end-stage heart failure.

Texas Heart Institute chief executive officer and Bivacor trial principal investigator Prof Joe Rogers said a 57-year-old man awaiting a heart transplant received the Bivacor heart on July 9, 2024, the device provided blood flow sufficient to maintain normal vital signs and normal organ function, it allowed the patient to be liberated from the ventilator on post-operative day-3 and ambulate 150 metres on post-operative day-7.

"After eight days of support on the Bivacor device a suitable donor heart was identified ... and he's undergone successful transplantation," Prof Rogers said.

Oneventures said it first invested in Bivacor in 2018, continued to support the company, and expected a financing round in 2025 following completion of the early feasibility study.

Bivacor founder and chief technology officer Prof Daniel Timms said that using the achievement "would not have been possible without the courage of our first patient the magnetic levitation technology, the total artificial heart "brings us one step closer to providing a desperately needed option for people with end-stage heart failure who require support while waiting for a heart transplant".

Oneventures founder and Bivacor director Dr Paul Kelly said Bivacor was "an Australian medical success story, showcasing the ingenuity and perseverance of our local talent".

"Their groundbreaking work is a shining example of how Australian innovation can lead to global medical advancement and demonstrates how collaboration between pioneering founders and committed investors can turn ideas into life-changing realities," Dr Kelly said.

RADIOPHARM THERANOSTICS

Radiopharm says it expects to list on the Nasdaq following US Securities Exchange Commission approval, expected "by late August", and will remain listed on the ASX.

Last year, Radiopharm said it began the process of a secondary listing on the Nasdaq to begin trading in March, 2023 under the code RADX (BD: Feb 14, 2023).

Today, the company said due to "market conditions" it had delayed the process.

Last month, Radiopharm said it had "firm commitments" to raise about \$62.5 million at 4.0 cents a share in a placement, taking the total with a previous placement to Lantheus to \$70 million (BD: Jun 25, 2024).

Today, the company said as part of the \$70 million capital raising it had agreed with "certain US institutional investors to seek a listing of its ordinary shares in the form of American depositary shares (ADS) on Nasdaq by the end of 2024".

Radiopharm said its Nasdaq listing would be a level 2 American depositary receipt program, with each American depositary share equal to 200 Australian shares.

The company said Deutsche Bank was depositary, custodian and registrar.

Radiopharm fell 0.1 cents or 2.8 percent to 3.5 cents with 3.7 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says chief executive officer Simon Morriss will resign, it has cut costs, hopes to raise \$3.85 million in a rights offer and will take an \$800,000 loan.

Genetic Technologies said it would implement a “capital light operations model” following a review showing it should focus on increasing sales, particularly in the US, and moving its operations from its in-house Melbourne laboratory to an out-sourced third-party approach. The company said Mr Morriss would “transition out of the organization” in September as part of a board “restructuring” that would focus its leadership team on increasing US opportunities, with the redundancy costs to be covered by its loan.

Genetic Technologies said the board agreed to defer their director fees “until year end, at the earliest” and take the fees in equity, subject to shareholder approval.

The company said it hoped to raise \$3.85 million through a two-for-three rights issue at four cents, with one attaching option for every share issued, exercisable at four cents.

Genetic Technologies said the offer was a 13.85 percent discount to the five-day volume weighted average price and had a record date of August 7, would open on August 12 and close on September 2, 2024.

The company said its board and “others” had committed to underwrite the first \$500,000 of the offer, based on a minimum \$2 million being raised.

Genetic Technologies said it had “received commitments” for a short-term loan of \$800,000, secured partly on its expected research and development tax incentive “due late September” at an interest rate of 20 percent a year.

The company said the lenders included board members, who had committed “to apply part or all of their loan entitlements to the first \$500,000 under the entitlement offer”.

Genetic Technologies was unchanged at 4.4 cents.

MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

Melodiol has requested a trading halt pending an announcement “regarding a capital raising”.

Trading will resume on July 30, 2024, or on an earlier announcement.

Melodiol last traded at 0.4 cents.

COCHLEAR

Cochlear says chief financial officer Stuart Sayers will replace Asia Pacific, Latin America head Anthony Bishop, who replaces EMEA head Richard Brook on January 1, 2025.

Cochlear said Mr Sayers would be responsible for Asia Pacific and Latin America while Anthony Bishop, would be the head of Europe, Middle East and Africa following Mr Brook’s resignation.

The company said Mr Brook had been head of Europe, Middle East and Africa for more than 20 years.

Cochlear chief executive officer Dig Howitt said Mr Brook had “overseen a period of substantial growth for [Europe, Middle East and Africa], with an eight-fold increase in revenue during that time”.

“I would like to express my deepest gratitude for his dedication and leadership which has contributed to Cochlear’s growth and success,” Mr Howitt said. “His contributions will have a lasting impact and he leaves behind a strong legacy of achievement that will guide us into the future [... and] we wish him all the best in the future,” Mr Howitt said.

Cochlear said it had begun a search for a new chief financial officer.

Cochlear was up \$4.29 or 1.3 percent to \$339.87 with 153,439 shares traded.

ORTHOCELL

Orthocell says it has appointed Vik Malik as its chief commercial officer.

In an email not announced to the ASX, Orthocell said the Perth-based Mr Malik had more than 25 years of “senior sales and marketing experience ... and a proven track record of driving significant revenue growth”.

The company said Mr Malik had had led product launches and market development strategies and had “a deep understanding of the US healthcare market and his extensive network of orthopaedic and plastic reconstructive surgeons ... will be particularly beneficial as we prepare to launch Remplir ... in the US”.

The company said Mr Malik would oversee sales, marketing and business development as well as market expansion for Striate+ and Remplir and support the development and commercialization of its regenerative medicines.

On Wednesday, Orthocell said it would expand regulatory approvals to additional territories for its Striate+ collagen barrier membrane for dental implants and Remplir collagen wrap for nerve repair damage (BD: Jul 24, 2024).

According to his LinkedIn profile, Mr Malik held a Bachelor of Science from the Carbondale’s Southern Illinois University.

The company did not disclose the effective date of Mr Malik’s appointment.

Orthocell was unchanged at 38.5 cents.