Biotech Daily

Thursday September 30, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: TELIX UP 7%; RESONANCE DOWN 7%**

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*** MICHELLE WING INCREASES, DILUTED TO 9% OF RHYTHM**

MARKET REPORT

The Australian stock market recovered 1.88 percent on Thursday September 30, 2021, with the ASX200 up 135.5 points to 7,332.2 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell and seven traded unchanged. All three Big Caps were up.

Telix was the best, up 39 cents or 6.9 percent to $6.03, with 696,473 shares traded. Amplia climbed five percent; Impedimed improved 4.2 percent; Antisense, Clinuvel, Cynata, Pro Medicus and Uscom were up more than three percent; CSL, Nanosonics, Oncosil and Universal Biosensors rose two percent or more; Cyclopharm, Mesoblast, Next Science, Orthocell, Paradigm, Polynovo and Resmed were up one percent or more; with Avita, Cochlear, Medical Developments and Neuren up by less than one percent.

Resonance led the falls, down 0.7 cents or 7.2 percent to nine cents, with 2.8 million shares traded. Nova Eye fell 4.8 percent; Actinogen, Alterity and Prescient were down more than three percent; Optiscan and Patrys shed more than two percent; Genetic Signatures, Immutep, Opthea and Osprey were down more than one percent; with Kazia and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: AROA BIOSURGERY

By TIM BOREHAM

ASX code: ARX

Share price: $1.04; **Shares on issue**: 341,862,816; **Market cap:** $355.5 million

Founder and chief executive officer: Dr Brian Ward

Board: James (Jim) McLean (chair), Dr Ward, Steve Engle, Phil McCaw, John Pinion, John Diddams

Financials (year to March 31, 2021*): revenue $NZ22.3 million (down 11%), product revenue $NZ21.5 million (down 2%), underlying loss $3.28 million (previously a $2.2 million profit), reported net loss after tax $NZ19.2 million (previously $NZ5.96 million), cash of $NZ81 million**

* One $NZ = $A0.96
** Post July's $A47 million capital raising

Identifiable major holders: Dr Ward 9.7%, Phil McCaw 5.7%, Richard Abbott 3.8%, Aspire NZ Seed Fund 3.8%, Washington H Soul Pattinson 2.8%, (The venture capitalist Movac Fund 3 held 6% but distributed its holding to its investors).

As with Oliver Twist, Aroa chief Dr Brian Ward and his board are not afraid to ask for more.

Having raised $45 million ahead of listing on July 24 last year, the Kiwi-based wound healing device outfit put its hands up for a further $47 million in July this year.

Rather than whacking the company with a gruel ladle, institutions were happy to stump up the dough, even though the placement was struck at a mere 1.7 percent discount to the prevailing price ($1.165 a share).

(As usual, retail shareholders were far more reticent, with the follow-on share purchase plan raising less than $400,000 of the targeted $5 million.)

With its coffers engorged, Aroa is embarking on an expansion drive with new approved devices in myriad geographies.

Auckland-based Dr Ward is unfazed about being on a small island at the bottom of the world - especially when the pandemic has negated the tyranny of distance, anyway.

With underarm bowling controversies possibly still fresh in his mind, Dr Ward notes that New Zealand is not the only Anzac (Australia and New Zealand Army Corps) member with a minute footprint on the world stage.

“It’s the same as being an Australian company,” he says.

“We’ve been in the US for more than 10 years and have got used to working there. It was pretty scary at the beginning, but like other businesses we have adapted to it and learnt how to do a whole lot of things better.”

The story to date

Aroa’s foundation product is its extracellular matrix platform technology that has nothing to do with Keanu Reeves but everything to do with promoting new tissue growth and blood supply.

The sheep stomach-based material dissolves in the body after it has done the job.

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

Other iterations are Myriad Matrix (soft tissue reconstruction), Myriad Morcells (a granulated variant), Ovitex (reinforced scaffold for abdominal wall reconstruction) and Ovitex PRS (plastic surgery such as breast reconstruction).

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

Aroa was founded by Dr Ward, a veterinarian with a keen interest in the use of biologic materials and scaffolds for soft tissue regeneration.

Being a Kiwi, his work centred on sheep and he discovered that the gut lining of the ruminants was an ideal material, given their thick extracellular matrices and secondary ‘signalling’ molecules that promote cell growth.

With $NZ1.5 million of seed capital, Dr Ward founded Mesynthes in 2008 and employed two research scientists.

Way back in 2010, the US Food and drug Administration approved Endoform Natural for non-healing wounds. First sales flowed in 2013.

The products are made at Aroa’s Auckland factory, which is about to be augmented with a new facility across the road - due to be finished by December and commissioned in March next year.

How’s it going bro?

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

“We had predicted we would be down by 50 percent, 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.”

Aroa has regulatory clearance in 49 countries, compared with 37 at the time of listing, with approvals covering Germany, Italy, Austria, Switzerland, the UK, the Middle East and South East Asia.

“We are just getting started in these markets,” Dr Ward says. “We have also just been approved in India. There are some fantastic hospitals there and the top end of the market is a big opportunity.”

In July 2020, the US Food and Drug Administration green-lighted Symphony, a skin substitute product for complex wounds.

In April this year, the US regulator approved Myriad Morcells, having approved Myriad Matrix in June 2017.

About half of Aroa’s revenue derives from its US partnership with the Nasdaq-listed Tela Bio.

The alliance is a licencing arrangement that involves revenue sharing, with Tela Bio responsible for clinical trial costs for new products.

The duo collaborated to develop Ovitex, Aroa’s first surgical product which the FDA approved for hernias in 2013.

Where’s it going bro?

Aroa is working on a new platform for dead space management, which is not about cemetery administration but dealing with the cavities that remain after soft-tissue surgery.

The company is emphasizing the use of Myriad Morcells for soft tissue reconstruction, including trauma and inflammatory conditions.

In a revamp of its sales approach, Aroa directly appointed 20 sales reps in February. This supplements an existing relationship with Tela Bio.

“The sales reps have been focused solely on developing Myriad and we see that as the biggest growth driver over the next 24 to 36 months,” Dr Ward says.

“The Endoform products are more mature and growth rates are slower.”

He says Aroa now has a “really good” portfolio and will be banking on existing brands for sales growth, rather than new approvals, over the next three years.

“It’s all about sales and marketing execution.”

Meanwhile, the new factory will lift annual revenue capacity from $NZ35 million to $NZ100 million - and all for a circa $NZ4 million investment.

Let's get clinical

Aroa has just published the results of a 'real word' study pertaining to Endoform and diabetic ulcers.

Covering 1,150 wounds, the study found a "significant reduction" in healing time relative to the standard-of-care (collagen products). The wounds took 1.9 to 5.6 fewer weeks to heal, a time saving of 11 percent to 21 percent.

Aroa is now carrying out a 12-patient complex wounds pilot study for Symphony in the US, which hopefully will extend into a broader 100 to 200 patient effort.

Meanwhile, Tela Bio is kindly funding several prospective studies of the use of Ovitex for simple and complex ventral hernias.

Data from the first 50 patients after 24 months shows "significantly better outcomes" compared to the market leading products.

Hernias are formed after abdominal surgery, with a recurrence rate of 10 percent to 30 percent. Many patients require repeat surgery. Full data is expected by the end of the year.

Finances and performance

Aroa posted product revenue of $NZ21.5 million in the 12 months to March 2021, two percent lower but creditable in these Covid-ravished times.

The net loss after tax almost tripled to $NZ19.2 million.

Management is chirpy enough provide revenue guidance of $NZ30 million to $NZ33 million for the current year, despite the "Delta dip" that resulted in elective surgeries being cancelled, especially in Florida and Texas.

"Hospitals are managing things better and not delaying so many surgeries," Dr Ward says. "By the time we get to November things will be at a similar level to the first part of this year."

Aroa's initial public offer raised $45 million at 75 cents apiece. The shares softened in July this year after a large wad of vendor-held shares came out of escrow.

Management rustled up buyers for any share overhang, but there were few sellers and that girded the company to launch the follow-up capital raising.

The share price also endured a decision by the Kiwi venture capital fund Movac to make an in-specie distribution of its Aroa stake to its investors.

Movac principal Phil McCaw retains a direct Aroa stake of just over five percent – and a board seat.

Did someone mention Polynovo?

Okay, Polynovo has a synthetic rather than biologics-based product. But Polynovo and Aroa aren't exactly chalk and cheese either, and thus their relative valuations make for a telling comparison.

In the 2020-'21 year, Polynovo generated $29.3 million of revenue and $25.5 million of product revenue, not dissimilar to the $NZ30 million to $NZ33 million Aroa guidance.

Polynovo made a slim $300,000 net profit in the 2020-21 year. Aroa is not expected to be in the black this year.

Polynovo is valued at $1.28 billion, while Aroa commands a circa $355 million valuation.

Biologics-based scaffolds tend to be more expensive than the synthetic ones - and they both have their place in the surgery. Synthetic matrixes are more durable, but the natural ones have superior regenerative qualities.

Dr Boreham's diagnosis:

With $NZ60 million of cash in its lambswool-lined kitty, Aroa is in a sturdy financial position - especially as most of the development work has been done and dusted.

Given the circumstances, Dr Ward is chuffed about how the first 12 months have panned out for Aroa as a listed beast.

"When we listed, we were in that Covid 'fog', not really knowing how things would turn out," he says.

"Things have come back strongly this year and the business has really responded to that."

Despite Aroa's geographic reach we shouldn't forget that the US market accounts for 95 percent of revenue.

Given the $US1.5 billion US addressable market for Aroa's current products and a further $US1 billion for its products in development, this is unlikely to change in a hurry.

Last week Woolworths was selling the Kiwi delicacy, chocolate-coated pineapple lumps (Mrs Crucible's favorite treat) for $1.08 a bag, almost two-thirds off the usual price.

Like the luscious lumps, Aroa shares are trading hands at a similar discount. Just don't remind our trans-Tasman allies that since 2018 all pineapple lumps have been imported from Australia.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He finds ovine-themed New Zealand jokes distasteful, especially the one about the Kiwi bloke who couldn't take his girlfriend to the rugby because she'd eat all the grass.

ENA RESPIRATORY

Ena says it will conduct phase II trials of INNA-051 nasal spray in a 420-patient Covid-19 post-exposure prophylaxis clinical study and a 120-patient influenza challenge.

Ena said it had hired the Wilmington, North Carolina-based Pharmaceutical Product Development (PPD) Inc for a multi-country Covid-19 prophylaxis trial and London's Hvivo for the UK influenza challenge.

The company said that the INNA-051 self-administered nasal spray was being developed to stimulate the innate immunity in the nose, where most respiratory viral infections begin.

Ena said it had "encouraging preliminary results from the ongoing phase I study" for the prevention of Covid-19, at Scientia Clinical Research in Sydney (BD: Jul 20, 2021).

The company said that PPD would conduct a phase II, randomized Covid-19 post-exposure anti-viral prophylaxis study, to determine whether INNA-051 reduced the incidence and severity of symptomatic Covid-19 following close contact with Covid-19 positive individuals.

Ena said the study would evaluate whether the nasal spray reduced the magnitude and duration of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) nasal shedding, to understand potential broader public health benefits.

The company said the study would be conducted in several countries and would initially recruit adults ages 18 to 55 years who had recent exposure to someone with confirmed Covid-19, with recruitment expected to begin in January 2022.

Ena said that Hvivo was part of Open Orphan plc and would begin a phase IIa influenza challenge pre-exposure prophylaxis study in UK adults aged 18 to 55 years, to evaluate the safety and efficacy of INNA-051 in reducing the total viral load of treated participants versus placebo, expected to begin in January 2022.

The company said the phase I safety and tolerability study of INNA-051 was expected to report interim results by the end of this year and be completed by April 2022.

Ena chief executive officer Dr Christophe Demaison said that Sars-Cov-2 variants including the Delta variant continued to spread around the world, and at the same time other respiratory viruses like respiratory syncytial virus (RSV) had seen a resurgence in some countries.

"There continues to be an urgent need for treatments that will work alongside vaccines, especially for those at high risk of complications or those who do not mount an adequate immune response to vaccines, such as the elderly, patients with chronic respiratory diseases and the immunocompromised," Dr Demaison said.

"These phase II studies will take us closer to understanding whether our nasal spray can prevent illness and reduce the risk of community spread of common respiratory viruses," Dr Demaison said.

Ena is a private company.

ADHERIUM

Adherium says it has received $369,652 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Adherium said the rebate related to research and development expenditure for the year to June 30, 2020.

The company said that "with the increasing Australian-based investments to expand the Hailie sensor portfolio and software platform, Adherium expects the R&D Tax Incentive to increase substantially for [the] 2021 financial year".

Adherium was unchanged at 1.6 cents with 2.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says Tokyo's Fujifilm will pay $US5 million ($A6.9 million) and relinquish rights while manufacturing Cymerus mesenchymal stem cells for graft-versus-host disease.
Cynata said the two companies had 90 days to negotiate a manufacturing services agreement for Cymerus mesenchymal stem cell products derived from induced pluripotent stem cells for clinical trials and commercial applications.
The company said that under the now-terminated September 2019 licence agreement, Cynata regained all rights to CYP-001 for graft-vs-host disease and Fujifilm would pay Cynata US$5 million (BD: Sep 18, 26, 2019).
Today, that Fujifilm agreed to a new voluntary escrow for its 8.1 million share-holding for 90 days, to be extended for up to 15 months on execution of the agreement.
Cynata chief executive officer Dr Ross Macdonald told Biotech Daily that the immediate priority was a US graft-vs-host disease trial, with Japan and other countries to follow.
In the ASX announcement, Dr Macdonald said Fujifilm Cellular Dynamics Inc developed the original induced pluripotent stem cells line used in its Cymerus manufacturing process.
"We look forward to the extensive experience in cell therapy manufacture among the Fujifilm group being of significant long-term benefit to Cynata as we advance the development of our unique [mesenchymal stem cell] therapeutic products," he said.
Cynata was up two cents or 3.6 percent to 58 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the first of up to 12 Brazilian patients has been dosed in its phase II trial of pentosan polysulfate sodium (PPS) for muco-poly-saccharidosis type 6 (MPS-VI).
Paradigm said the first patient with MPS-VI, also known as Maroteaux-Lamy syndrome, was dosed at the Hospital de Clinicas de Porto Alegre with the study also being conducted at the Hospital Universitário Alcides Carnerio.
The company said the Federal University of Rio Grande do Sul's Dr Roberto Giugliani was the principal investigator in the trial which would evaluate PPS compared to a placebo.
Paradigm said the phase II trial "will be the largest clinical trial conducted using PPS in any MPS population".
Paradigm said MPS-VI was an orphan disease, and classified as a "rare autosomal recessive, inherited lysosomal storage disorder caused by a deficiency of Nacetyl galactosamine 4–sulfatase, leading to physical manifestations associated with accumulation of [glycosaminoglycans] in the lysosomes".
The company said the study was designed to enrol patients with MPS-VI who were currently receiving enzyme replacement therapy (ERT) and exhibited pain and functional deficiency due to musculoskeletal symptoms associated with the underlying disease.
Paradigm said the primary objective would be to evaluate safety and tolerability of PPS in subjects with MPS-VI at six, 12 and 24 weeks, with secondary and exploratory endpoints including the effect of PPS on "pain and function, mobility, urinary [glycos-amino-glycan] levels, mobility, quality of life, activities of daily living, subject/parent global impression of response to therapy, and pulmonary function".
Last year, Paradigm said it had dosed the first of 10-patients in its 48-week, phase II trial of pentosan poly-sulphate sodium for muco-poly-saccharidosis type-I at Adelaide's Women's and Children's Hospital (BD: Nov 12, 2020).
Today, Paradigm said preliminary data from its ongoing Australian phase II study in MPS-I was "very promising" and "…provide a foundation for the development of PPS to address the unmet medical need of chronic pain and limited function in MPS-VI patients".
Paradigm was up three cents or 1.4 percent to $2.20.

RECCE PHARMACEUTICALS

Recce says it has registered an 80-subject, phase I safety and pharmaco-kinetics trial of intravenous R327 with the Australian New Zealand Clinical Trial Registry.

Recce said registration was “one of the final administrative stages” for the trial, which would administer a single one-hour intravenous infusion of R327 across eight dose cohorts of 10 persons each, starting at 50mg of R327 in eight subjects and placebo in two subjects.

The company said ethics approval was underway for the randomized, placebo-controlled, double-blinded, single-dose, first-in-human study, with patient dosing expected to begin in November at Adelaide’s CMax clinical trial facility.

Recce said that R327 was “the only synthetic polymer drug candidate and the only clinical stage antibiotic for the indication of sepsis, globally”.

Recce was up two cents or 2.1 percent to 98 cents.

AMPLIA THERAPEUTICS

Amplia says research by Sydney’s Garvan Institute supports the use of focal adhesion kinase (FAK) inhibitors prior to chemotherapy for pancreatic cancer.

Amplia said the paper titled, ‘Intravital imaging technology guides FAK-mediated priming in pancreatic cancer precision medicine according to Merlin status’, was published in the journal Science Advances and led by the Garvan’s Prof Paul Timpson, with the full article available at: https://doi.org/10.1126/sciadv.abh0363.

Amplia chief executive officer Dr John Lambert told Biotech Daily that the research did not involve Amplia’s AMP945, but the focal adhesion kinase inhibitor study provided further validation for the company’s proposed phase II pancreatic cancer trial.

In the media release to the ASX, Dr Lambert said there had been “several publications over the last two years that have highlighted the potential of FAK inhibitors in pancreatic cancer, including their ability to work synergistically with chemotherapy agents”.

“This latest study from our collaborators at the Garvan Institute is particularly exciting as its replicates the approach that we are taking to treat first line pancreatic cancer patients in our recently announced phase II clinical trial,” Dr Lambert said.

“We believe that making an established standard of care, namely chemotherapy with gemcitabine/Abraxane, more effective offers a very promising approach for improving the outcomes for these patients,” Dr Lambert said.

Amplia was up one cent or five percent to 21 cents.

CLARITY PHARMACEUTICALS

Clarity says the Springfield, New Jersey-based Evergreen Theragnostics Inc will manufacture the copper isotope products for its US clinical trials.

Clarity said Evergreen would manufacture and distribute Cu-67 Sartate for its neuroblastoma study currently underway at multiple sites across the US and Cu-64 SAR-Bombesin for the planned trials for cancer in the US.

The company said the proximity of the manufacturing facility to major transport hubs and “the optimal half-lives of Cu-64 and Cu-67” would enable Evergreen to efficiently distribute the copper isotope products to hospitals across North America and Europe.

The value of the contract was not disclosed.

Clarity was up 10 cents or 8.1 percent to $1.34.

IMPEDIMED

Impedimed says Brisbane's Icon Group will install 13 Sozo units for lymphoedema screening services for breast cancer patients in Australia and New Zealand.
Impedimed said the initial units were scheduled to be installed "over the coming weeks".
Impedimed chief executive officer Richard Carreon said the agreement with Icon "opens the door to thousands of patients to participate in a state-of-the-art lymphoedema prevention program aimed at stopping chronic lymphoedema before it starts".
Impedimed rose half a cent or 4.2 percent to 12.5 cents with three million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it will provide the Austin, Texas-based Natera's Empower hereditary cancer test for breast cancer to its US customers.
Volpara said it would integrate Natera's test into its breast health platform to provide "additional access for women to comprehensive genetic testing services".
The company said its breast cancer risk assessment software was used to triage patients for supplemental imaging and/or genetic testing based on personalized risk.
Volpara said that risk assessments were "required by many US insurance companies before additional testing".
Volpara chief executive officer Dr Ralph Highnam said by adding Natera to Volpara's breast health platform "we continue to build our integrations with best-of-breed genetic testing companies in order to offer our customers greater options".
Volpara fell half a cent or 0.4 percent to $1.185.

RACE ONCOLOGY

Race says its Zantrene, or bisantrene dihydrochloride, kills melanoma cells that produce fat mass and obesity associated protein (FTO), in-vitro.
Race said the study with the New South Wales' University of Newcastle aimed to identify drug combinations and melanoma subtypes that showed improved treatment responses, with a focus on treatment-resistant melanomas.
Race chief scientific officer Dr Daniel Tillett said the interim results were "highly encouraging and support our clinical plans for Zantrene, with the correlation between FTO overexpression and sensitivity to Zantrene suggesting a strong anti-FTO therapeutic opportunity".
"The high sensitivity of many of the melanoma cell lines to Zantrene as a single agent at concentrations well below chemotherapeutic doses is unexpected and may offer new treatment options for melanoma patients," Dr Tillett said.
Race was up 12 cents or 3.55 percent to $3.50 with 607,425 shares traded.

ARGENICA THERAPEUTICS

Argenica says it has appointed Perth's Linear Clinical Research for a 32-volunteer, phase I, safety trial of its proposed stroke drug ARG-007.
Argenica said the randomized, placebo-controlled, double-blind trial would assess "the safety, tolerability and pharmacokinetics of single ascending doses of ARG-007".
The company said participants would receive either ARG-007 or a placebo on day one, with pathology samples and data collected at multiple points over the following eight days.
Argenica said data from the trial would inform a phase II trial in stroke patients.
Argenica was up 2.5 cents or 6.7 percent to 40 cents.

ANTISENSE THERAPEUTICS

Antisense says the European Medicines Agency paediatric committee supports its paediatric investigation plan for ATL1102 for Duchenne muscular dystrophy.
Antisense said a paediatric investigation plan was a development plan to ensure the necessary data was obtained through studies in children and approval was required to support the authorization of a medicine for children in the EU.
The company said it was planning a European phase IIb trial of ATL1102 for non-ambulant boys with Duchenne muscular dystrophy.
Antisense said the paediatric committee draft opinion "may not reflect the adopted … opinion" and the final opinion was expected following the October 15, 2021 committee meeting.
Antisense was up 0.75 cents or 3.8 percent to 20.5 cents with 1.9 million shares traded.

MGC PHARMACEUTICALS

MGC says distribution partner AMC Holdings Inc has placed an initial order for 1,000 units of Cimetra for sale in the US.
Last month, MGC said it had a supply and distribution deal with the Tampa, Florida-based AMC with minimum orders of $US24 million ($A33.1 million) for its marijuana and artemisinin products over three years (BD: Aug 27, 2021).
Today, MGC said AMC was working with Tampa's University of South Florida and Fort Lauderdale's Holy Cross Hospital, to submit applications for Cimetra and the marijuana based Cognicann for trial approvals.
MGC was up 0.3 cents or 5.2 percent to 6.1 cents with 29.75 million shares traded.

MICRO-X

The Sydney-based Regal Funds says it has reduced its shareholding in Micro-X from 41,062,795 shares (8.93%) to 35,943,205 shares (7.82%).
Regal Funds said it bought and sold shares between July 30 and September 27, 2021, with the single largest sale 1,054,787 shares for $311,162 or 29.50 cents a share.
Micro-X fell 1.5 cents or 4.35 percent to 33 cents.

RHYTHM BIOSCIENCES

Michelle Wing says she has increased and been diluted in Rhythm Biosciences from 11,000,000 shares (10.23%) to 19,182,261 shares (9.19%).
Ms Wing said the shares were held by Ferndale Securities Pty Ltd and Northern Star Nominees Pty Ltd, but did not cite the consideration paid for the shares as required under the Corporations Act 2001.
Earlier this month, Rhythm said its rights offer at 85 cents a share raised $4,296,130 and it would place further shares to raise $1,275,000 (BD: Sep 7, 2021).
Rhythm was up five cents or 4.05 percent to $1.285.