Biotech Daily

Friday December 6, 2024

Daily news on ASX-listed biotechnology companies

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*** PETERS INVESTMENTS TAKES 27% OF OPTISCAN**

MARKET REPORT

The Australian stock market fell 0.64 percent on Friday December 6, 2024, with the ASX200 down 54.0 points to 8,420.9 points. Fifteen of the Biotech Daily Top 40 companies were up, 19 fell, four traded unchanged and two were untraded.

Syntara was the best, up 0.6 cents or 9.4 percent to seven cents, with 12.3 million shares traded. Resonance rose 7.9 percent; Immutep improved 6.45 percent; Proteomics was up five percent; Cynata and Starpharma climbed more than four percent; Actinogen, EBR and Impedimed were up more than three percent; Emvision and Opthea rose more than two percent; SDI and Telix were up more than one percent; with Aroa, Neuren and Pro Medicus up by less than one percent.

Orthocell led the falls, down 12 cents or 11.2 percent to 95 cents, with 5.75 million shares traded. Amplia and Genetic Signatures lost more than five percent; Percheron fell 4.1 percent; Avita, Clinuvel, Curvebeam and Medadvisor were down more than three percent; Cyclopharm, Imugene, Medical Developments, Micro-X, Prescient and Resmed shed two percent or more; 4D Medical, Clarity, Cochlear, Compumedics, Nanosonics and Polynovo were down one percent or more; with CSL and Mesoblast down by less than one percent.

DR BOREHAM'S CRUCIBLE: AVITA MEDICAL

By TIM BOREHAM

ASX code: AVH (Chess depositary instruments); **Nasdaq code:** RCEL (US shares)

CDI equivalents on issue: 131,088,145; **CDI price:** $3.86; **Market cap:** $506.0 million

Chief executive officer: James (Jim) Corbett

Board: Lou Panaccio (chair), Mr Corbett, Jeremy Curnock Cook, Prof Suzanne Crowe, Jan Reed, Robert McNamara, Cary Vance

Financials (September quarter 2024): revenue $US19.5 million (up 44%), loss of $16.2 million (previously an $US8.7 million deficit), cash and equivalents of $US44.4 million (down 50%). ($US1.00 = $A1.56)

Identifiable major holders: Vanguard Group 4.5%, Pura Vida Investments 3.4%, Black Rock Institutional Trust Company 1.85%, Michael Perry 1.4%, Thorney Investments 0.5%.

When it comes to medical devices, improving the lives of clinicians is just as important as improving the lives of patients. If both these aims can be achieved, that's the sweet spot.

In the case of Avita, the company's approved spray-on skin burns treatment Recell has the runs on the board.

To date, 400 to 500 US burns surgeons are using Recell, with indications expanded to traumatic and surgical wounds and vitiligo.

Avita CEO Jim Corbett notes an American Burns Association appraisal that showed patients left hospital 30 percent faster. He cites the experience of one patient with 85 percent total body surface area (TBSA) wounds.

"The doctor said she would be lucky if she were in [the intensive care unit] for a year and then die. She walked out at six months."

(The patient now advocates for Recell under the auspices of the Burns Survivor foundation).

Management's priority is now making Recell easier to prepare and apply, with an automated 2.0 device called Recell Go that eliminates about 90 percent of the training requirements.

"It's a better use of [surgeons'] time to be doing something for the patient, other than scraping skin," Mr Corbett says. "It is going to make substantial changes to the business."

Specifically, he expects Avita's share of the burns market to double, while it also makes the full-thickness burns indication expansion easier to obtain.

A slow-burn story

A battery-operated autologous cell harvesting device, Recell involves taking a small skin sample from the body and mixing the cells into a liquid spray, for use in 30 minutes.

Recell competes in the main with traditional skin grafts, but the one Recell kit can cover 80 times the area of a graft.

Avita's Recell technology evolved from the pioneering work done by legendary Perth burns surgeon and Australian of the Year, Prof Fiona Wood, which she famously used on Bali burns victims after the 2002 terrorist attack.

Originally known as Clinical Cell Culture, Avita was founded in 1992 and merged with Visiomed to become Avita in 2008. Its American depositary shares traded on the over-the-counter exchange, and then on the Nasdaq from October 2019.

Avita was headquartered in Perth, but a corporate rejig in 2020 saw the company migrate to the US.

Recell was approved in Europe and launched there in 2005, and was available in Australia a year later. It is also approved in Japan.

In September 2018, the US Food and Drug Administration (FDA) approved Recell as a class-three device, to treat second and third-degree thermal burns in adults. And in June 2021, the FDA expanded this indication to paediatric third-degree burns, which account for about one-quarter of all US burns injuries. Recell was then approved for wounds and full-thickness skin defects.

In 2019, Avita forged an alliance with M3 Group subsidiary Cosmotec to market and distribute Recell in Japan, the second biggest healthcare market. Cosmotec launched the product there in September 2022.

These days, Avita is based in California's orange capital of Valencia.

An Avita director since June 2021, Mr Corbett replaced Mike Perry as CEO in September 2022. Brought up in St Louis, Missouri, Mr Corbett was CEO of the Nasdaq-listed Micro Therapeutics Inc, Ev3 Inc and Alphatec Spine, and had helmed three private biotechs and has had roles at Baxter, Scimed Life Systems and Boston Scientific.

It's Go time

Recell Go consists of a battery-powered processing device and a single-use cartridge (containing the requisite enzymes and other goodies). The automated device scrapes the skin samples and mixes them with the liquid ingredients.

About the size of a blender, Recell Go ameliorates the need for sales agents to spend many hours training nurses and clinicians on how to prepare the kits.

In late May this year, the FDA approved Recell Go and the product was launched in June.

“It’s Go time for a new era in wound care,” Mr Corbett said at the time.

“By streamlining processes and enhancing operational efficiency with Recell Go, clinicians can now treat a greater number of patients and more broadly experience the proven benefits of Recell technology.”

Mr Corbett said the device will reduce training time from about 50 minutes to five minutes and make Avita’s sales force 50 to 70 percent more productive.

In June this year, the first burns patient was treated with Recell Go, at the clunkily-monikered Joseph M Still Burn Center at Doctors Hospital of Augusta, Georgia.

Recell Go applies to burns covering up to 10 percent of the body, or up to 1,920 square centimetres. The company expects FDA approval for a variant, Recell Go Mini, for burns up to 2.5 percent of the body or up to 480 square centimetres.

Bringing it home

While Recell is approved locally the company hasn’t been selling actively, for want of decent reimbursement.

But in November the company entered an exclusive distribution agreement with Revolution Surgical Pty Ltd, covering Australia and New Zealand.

The deal includes Recell Go, pending regulatory approval. Mr Corbett says the deal “reintroduces Avita to its place of origin” a reference to Prof Wood’s ground-breaking work

Layer upon layer

In July 2024 Avita entered a five-year partnership with Regenity Biosciences to develop a collagen-based dermal matrix called Cohealyx (so called because of the collagen’s helical structure).

The idea is that the matrix goes on the bed of the wound and Recell goes on top. The matrix promotes the growth of cell fibre tissue and re-vascularation (in other words: healing).

Under the deal, Regenity will make the scaffold and it will be sold by Avita’s sales team under the Avita moniker. The revenue is shared equally in the first two years; thereafter Avita pockets 60 percent.

Avita also holds the exclusive US rights to market, sell and distribute Permeaderm, a biosynthetic wound dressing that goes on top.

Mr Corbett says Permeaderm has “microporous variability”, which means it can be stretched to make it bigger or smaller, while ensuring the pus exits the wound – and that’s a good thing.

In animal models, the company tested 18 formulations from 10 different companies.

“In our pre-clinical data, we got graft-ready somewhere between five and seven days faster than the closest [product],” Mr Corbett says. “We don’t have human data but it is a validated porcine model.”

The company estimates per patient revenue from the combined devices at $US28,000 to $US55,000 per procedure.

Tackling the ‘Michael Jackson disease’

Meanwhile, Avita is working on a Recell cartridge to treat vitiligo, the genetic disorder that results in loss of pigmentation and skin turning white (the late Michael Jackson was a famous sufferer).

The FDA approved Recell for vitiligo last year, but management did not feel the data from a previous 23-patient trial was strong enough and carried out a 109-patient post-market study called Tone.

The six-month data is yet to be released - it should be published in early 2025 - but Mr Corbett says the results showed 80 percent better re-pigmentation than the earlier data presented to the FDA. A health economics study also shows it is cheaper, which will be handy for reimbursement options.

Current therapies include phototherapy or melanocyte transplants, which are either ineffective, long and/or expensive.

In the US, 50,000 vitiligo patients are currently seeking therapy, of a total affected populace of three million to 6.5 million. There are about 70 million vitiligo sufferers, globally.

Finances and performance

Avita posted September (third) quarter revenue of $US19.5 million, 44 percent higher than previously.

The loss came in at $US16.2 million, compared with a $US8.7 million deficit previously and attributable mainly to increased sales and marketing costs.

Management has guided to current (December) quarter revenue of $US23.2 million at the midpoint, 65 percent higher year-on-year.

Full year (calendar 2024) guidance is for revenue of $US68 million to $US70 million, 37 to 41 percent higher.

Management has also guided to cash flow breakeven and profitability under Generally Accepted Accounting Principles (GAAP) by the end of the September quarter 2025. Put that one in your diary folks!

At the end of September, the company had net cash and equivalents of $US44.4 million, 50 percent lower.

Avita's development is being funded substantially by a $40 million loan from healthcare investor Orbimed.

Mr Corbett says the company could have raised equity, but given the "undervalued" shares it would have diluted shareholders by an unacceptable 15 percent.

In November, the company agreed to forego an extra $US50 million available from Orbimed, in return for Orbimed dropping a revenue-related covenant requirement.

Over the last 12 months, Avita's ASX-listed shares have traded between $5.51 (February 2, 2024) and $2.37 (July 5 2024). The stock peaked at $16.30 in February 2020.

Dr Boreham's diagnosis:

Mr Corbett says more than 75 percent of Avita's Recell customer base has transitioned to Recell Go.

With the anticipated launch of Cohealyx in 2025 "we are positioned to address a broad continuum of wound care needs".

In March 2023, Mr Corbett attributed the company's lowly share price to its own performance - rather than the overall market - and "how we express ourselves to investors".

He said investors would "kill' him if his definitive deadlines and targets were not met.

It now looks like Mr Corbett will spare being slayed - metaphorically speaking, of course - because the shares have lifted 50 percent over the last six months.

"The sun is coming up and we can see it," he says.

The company cites a total addressable market in the US as 127,000 annual procedures, including 120,000 traumatic wounds and 900 surgical procedures.

Expanding indications would take the tally to 271,500, including 136,000 cancer excisions (Avita's material also mentions 1,500 gunshot wounds, which surely is an underestimate).

So, there's clearly a large addressable market. All Avita needs to do now is to execute its commercial rollout and demonstrate consistent profitability - something it has struggled with in the past.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is still snoozing when the sun comes up, so can't see it.

CYNATA THERAPEUTICS

Cynata says it has “firm commitments” to raise $8,115,000 at 18 cents a share in a non-underwritten placement.
Cynata said the issue price was a 17.2 percent discount to the 10-day volume weighted average price, a 17.7 percent discount to the five-day volume weighted average price and a 16.3 percent discount to the last closing price.
The company said that the placement included $115,000 at the same price from its directors.
Cynata said the funds would be used for regulatory discussions for its CYP-006TK for diabetic foot ulcers, CYP-001 for acute graft versus host disease and kidney transplant and CYP-004 for knee osteo-arthitis, as well as progressing potential licencing partnerships, manufacturing activities and working capital.
The company said Euroz Hartleys was the sole lead manager and bookrunner, with Becketts Lawyers its legal adviser.
Cynata was up one cent or 4.65 percent to 22.5 cents.

CLEVER CULTURE SYSTEMS (FORMERLY LBT INNOVATIONS)

Clever Culture says it has an Astrazeneca order worth $3.1 million for four additional automated plate assessment systems (Apas), taking the total to nine systems.
In August, the then LBT said it had an up-to $4.1 million contract with Astrazeneca for five of its Apas systems for imaging microbiology culture plate (BD: Aug 7, 2024).
Later, the company said it installed the first Apas system for reading 90mm settle plates and 55m contact plates at Astrazeneca’s UK facility (BD: Oct 24, 2024).
Yesterday, Clever Culture said the four additional instruments were expected to be delivered by July 2025, with revenue recognized this financial year.
The company said that with the inclusion of annual maintenance and support fees for each instrument, the order was expected to be worth more than $US2.0 million ($A3.1 million), over seven years.
Clever Culture said the first order of five instruments had been delivered to multiple Astrazeneca facilities.
The company said Astrazeneca was expected to finalize “their internal validation of Apas for environmental monitoring and start progressively integrating Apas Independence into routine operation for drug manufacturing over the coming months”.
Clever Culture said a total of 12 Apas sales had been made to pharmaceutical customers since the Apas Pharma QC launch in March 2024, which underpinned “the potential for a cash flow positive result for full 2024-’25”.
Clever Culture managing-director Brent Barnes said the company was “pleased to have delivered the first five instruments to multiple Astrazeneca facilities over the past three months as planned”.
“This additional order of four Apas instruments allows expanded standardization of Apas to additional Astrazeneca global sterile drug manufacturing locations,” Mr Barnes said.
“The addition of contact plates to the Apas platform was a key factor for this additional commitment of roll-out, enabling Astrazeneca extended functionality to automate another test performed during route environmental monitoring,” Mr Barnes said.
“We expect to complete the deliveries and installations in the first half of … 2025 and look forward to continuing our collaboration with the Astrazeneca sites to embed the Apas platform throughout their global network,” Mr Barnes said.
Clever Culture was unchanged at two cents with 5.2 million shares traded.

BREAKTHROUGH VICTORIA

Breakthrough Victoria says it is providing $2 million to Umps Health for the development of wearable sensors and artificial intelligence (A.I.) for home aged care.

The Victoria Government-funded Breakthrough Victoria said Umps Health had spent six years developing its “smart home platform”, called Link.

Breakthrough Victoria said since the platform was launched in 2023, the company had “grown to support thousands of households across Australia”.

The organization said that Umps Health founder Adam Jahnke named the company “Umps” after his nickname for his grandfather.

Breakthrough Victoria said the technology was “easily installed in the homes of older adults and uses data collected from proprietary wearables, sensors and A.I. to generate real-time insights about declines in health and wellbeing”.

The organization said, if required, Umps’ device connected users to an emergency response centre or family caregivers, “providing earlier and proactive support at home”.

The fund said that by 2030 there was predicted to be a shortage of more than 100,000 aged care workers in Australia and Umps aimed to “alleviate this shortage in the face of increased demand for care by augmenting existing aged care workers with technology”.

Breakthrough Victoria said Umps’ products were currently offered under the Home Care Package Program, Commonwealth Home Support Program and National Disability Insurance Scheme.

The fund said other investors included Intervalley Ventures, Sprint Ventures, the Cerebral Palsy Alliance, the 5Point Foundation and Agnes Health.

Breakthrough Victoria said its investment would “accelerate ongoing research, development and commercialization of the technology, creating up-to 40 jobs over the next two years”.

Breakthrough Victoria chief executive officer Lauren Morrey said that “the health benefits that Umps’ innovative technology generates are multi-fold, across families, society, the aged care sector and to the wider economy”.

“Every person gets another option at ageing with dignity; this is why Breakthrough Victoria is investing in Umps Health,” Ms Morrey said. “By supporting start-ups to develop, trial and manufacture medical technology in Victoria, we can ensure these life-saving technologies benefit and prioritize local patients, increase jobs and investments in the state.”

Umps Health chief executive officer Adam Jahnke said the company believed “that enabling more timely, person-centred care at home is the biggest opportunity we have to reduce demand on an already stretched care system and enable better health outcomes for older adults”.

“Every year, there are more than 500,000 hospitalizations that could have been prevented if older adults received care earlier,” Mr Jahnke said.

“These health incidents are often a catalyst for a loss of independence,” Mr Jahnke said. “A.I. has the potential to address this by enabling proactive care at scaling, alleviating pressure on an already stretched system while improving the health and wellbeing of older adults,” Mr Jahnke said.

“The capital raised will allow us to accelerate our market reach within Australia and scale Umps’ technology to support tens of thousands of Australians,” Mr Jahnke said.

Victoria Minister for Economic Growth, Danny Pearson said the State was “backing innovative companies like Umps” for local services, jobs and to increase the economy”.

“This investment will provide more options to maintain healthy independent lifestyles for older Victorians and help reduce the physical workload of our brilliant care workers,” mr Pearson said.

Umps is a private company.

MICRO-X

Micro-X says it expects a Medical Research Future Fund $500,000 milestone payment after first images were taken with its head computed tomography (CT) device for stroke.
In 2021, Micro-X said it had an $8 million agreement with the Australian Stroke Alliance to develop a stroke diagnostic after the Alliance received $40 million from the Federal Government's Medical Research Future Fund (BD: Sep 23, 2021).
In 2022, the company said it expected to receive a $900,000 milestone payment following the submission of data to the Australian Stroke Alliance (BD: Mar 25, 2022).
Today, Micro-X said it had "delivered CT images taken by its head CT test bench showing the skull and soft tissue structure of the brain of an anthropomorphic head phantom" - a model of the human head and brain.
The company said clinical leads at the Australian Stroke Alliance had determined the images showed detail of the sulci, ventricles and vascular anatomy in the supra-tentorial compartment.
Micro-X said the images were a "significant milestone achievement in the head CT project, with an associated payment of $500,000".
The company said it was building hospital test benches that would support an application to the Royal Melbourne Hospital's ethics committee for a clinical trial, expected "in early 2025".
Micro-X said radiation measurements showed the effective dose to a patient from its head CT imaging was "around one third of a conventional head CT dose", which was below annual radiation exposure limits for members of the general public.
Micro-X chief executive officer Kingsley Hall said the "significance of this achievement in developing a world-first, mobile head CT device should not be underestimated".
"The value of this technology goes beyond head imaging, enabling future opportunities including the next generation of full body CT imaging," Mr Hall said.
Micro-X fell 0.2 cents or 2.1 percent to 9.4 cents with one million shares traded.

ADHERIUM

Adherium says its Hailie inhaler sensor will be included on the New York-based AMC Health remote patient monitoring system for "managing chronic respiratory diseases".
Adherium said AMC Health managed the pulmonary monitoring of 10,000 patients.
The company said the partnership would help patients "manage their conditions through medication reminders, adherence analysis, and real-time monitoring".
Adherium said the inclusion of its Hailie sensors on AMC Health's virtual care system would give healthcare providers "actionable insights for proactive care management".
The company said with the agreement AMC expected "significant expansion of their [chronic obstructive pulmonary disease] and asthma programs".
Adherium said the deal was "a significant step forward in healthcare innovation, paving the way for improved efficiency, precision, and patient-focused solutions".
Adherium chair Lou Panaccio said the partnership reflected "a shared commitment to improving health outcomes by equipping providers and payers with the data they need to support adherence and treatment".
Mr Panaccio said AMC Health's "digital and clinical services bridge communication gaps, enabling patients to manage chronic conditions from the comfort of their homes while maintaining strong connections with their care teams".
Adherium fell 0.2 cents or 16.7 percent to one cent with 1.7 million shares traded.

EBR SYSTEMS

EBR says its day-100 pre-market approval meeting for its Wise system with the US Food and Drug Administration has been scheduled for December 20, 2024.
In January, EBR chief executive officer John McCutcheon told Biotech Daily that he was hoping for FDA approval of the wireless stimulation endocardially (Wise) heart pacer system "early in 2025" (BD: Jan 29, 2024).
Later, the company said it had filed the final pre-market approval application module for its Wise cardiac re-synchronization therapy system to the FDA (BD: Aug 29, 2024).
Today, EBR said the purpose of the meeting was to discuss the review status of its pre-market approval application and clarify any additional information or documentation required by the FDA.
The company said following the meeting, the FDA "may take up-to 15-days to confirm the official meeting minutes, subject to holiday delays".
EBR said the FDA had noted an onsite biomedical monitoring audit would "not likely be a requirement prior to final approval" but that a manufacturing, pre-approval inspection was a milestone to approval.
EBR was up 2.75 cents or 3.1 percent to 91.5 cents.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has received $1,031,073 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Trivarx said the incentive related to the research and development costs of its phase II sleep analysis of major depressive episode study in the year to June 30, 2024.
Trivarx was up 0.1 cents or 5.9 percent to 1.8 cents with 2.9 million shares traded.

LTR PHARMA

LTR has requested a trading halt "pending a material announcement relating to a capital raise".
Trading will resume on December 10, 2024, or on an earlier announcement.
LTR last traded at $1.05.

VISIONEERING TECHNOLOGIES

Visioneering has requested a trading halt "pending an announcement concerning an application to be made for the company to be removed from the official list".
Trading will resume on December 10, 2024, or on an earlier announcement.
Visioneering last traded at 13.5 cents.

HYDRIX

Hydrix director Paul Lewis says he has increased his substantial shareholding from 14,875,000 shares (6.45%) to 20,423,334 shares (7.49%).
The Melbourne-based Mr Lewis said with Invia Custodian Pty Ltd he bought 1,708,334 shares for six cents a share under a shortfall offer on December 7, 2022 and received 3,840,000 shares in lieu of directors' fees on December 3, 2024.
In 2022, Hydrix said it raised $1,292,822 in a one-for-two retail rights offer and shortfall facility at six cents a share, taking the total raised to $3,366,409 (BD: Oct 20, 2022).
Hydrix was unchanged at one cent.

OPTISCAN IMAGING

Peters Investments Pty Ltd says it has increased its substantial shareholding in Optiscan from 214,750,000 shares (25.708%) to 223,413,544 shares (26.745%).

The Perth-based Peters Investments said that it bought 8,663,554 shares on-market between May 1 and December 4, 2024 for $1,456,805, or 16.8 cents a share.

Optiscan was up one cent or 6.25 percent to 17 cents.