Biotech Daily

Wednesday December 4, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 38%; RESONANCE DOWN 8%**

*** FEDERAL GOVERNMENT MONASH, MODERNA mRNA VACCINE FACTORY**

*** MICRO-X CONFIRMS $12.75m US CT SCANNER GRANT**

*** QIMR '15-YEAR DATA SHOWS T-CELLS TREAT VIRAL INFECTIONS'**

*** ACRUX: FDA APPROVES NITRO-GLYCERIN ANAL FISSURE OINTMENT**

*** ADHERIUM, TENOVI RESPIRATORY MONITORING AGREEMENT**

*** ALTERITY COMPLETES PHASE II ATH434 MSA TRIAL, DATA IN 2025**

*** ANATARA ENROLS PHASE II GARP IBS TRIAL, PAUSES RECRUITMENT**

*** 4D MEDICAL TO SUBMIT CT VQ TO FDA IN 'MID 2025'**

*** NOXOPHARM APPOINTS UNNAMED CRO FOR SOF-SKN TRIAL**

*** CHIMERIC EGM 40.5% OPPOSE CHAIR PLACEMENT OPTIONS**

*** SYNTARA PLEADS 'NEXT WEEK'S DATA' TO 44% ASX PRICE QUERY**

*** CYNATA REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** PRO MEDICUS DR SAM HUPERT, ANTHONY HALL SELL 2m SHARES**

*** PLATINUM REDUCES TO 13.8% OF SYNTARA**

*** ANGUS WALKER, MWP TAKE 11.6% OF ISLAND**

*** DORSAVI APPOINTS LEIGH TRAVERS DIRECTOR**

*** SERVATUS APPOINTS DR ANTHONY NOBLE DIRECTOR**

*** JOSHUA LIGHT REPLACES MEDLAB DIRECTOR MATT HUDSON**

MARKET REPORT

The Australian stock market fell 0.38 percent on Wednesday December 4, 2024, with the ASX200 down 32.6 points to 8,462.6 points. Thirteen of the Biotech Daily Top 40 companies were up, 17 fell, eight traded unchanged and two were untraded.

Micro-X was the best for the second day in a row (see below), up 2.7 cents or 38.0 percent to 9.8 cents, with 5.1 million shares traded. Paradigm climbed 17.2 percent; Orthocell was up 15.3 percent; 4D Medical rose 13.5 percent; Imugene improved 10.5 percent; Universal Biosensors was up 4.2 percent; Aroa and Avita rose more than two percent; Dimerix, Medadvisor, Medical Developments, Pro Medicus and Telix were up more than one percent; with Cyclopharm and Resmed up by less than one percent.

Resonance led the falls, down 0.5 cents or 7.9 percent to 5.8 cents, with 361,782 shares traded. Genetic Signatures, Mesoblast and Starpharma fell more than four percent; Alcidion, Neuren, Opthea and Proteomics lost more than three percent; Emvision and Syntara shed more than two percent; Clarity, EBR, Immutep, Impedimed, Percheron and Polynovo were down more than one percent; with Cochlear, CSL and Nanosonics down by less than one percent.

FEDERAL GOVERNMENT, VICTORIA GOVERNMENT, MODERNA AUSTRALIA

The Federal Government says the Moderna mRNA vaccine manufacturing facility has been opened at Monash University in Clayton, Melbourne.

In 2021, the Victoria Government said it had an agreement with the Federal Government and the Cambridge, Massachusetts-based Moderna to establish an mRNA vaccine manufacturing plant, and last year, said construction had reached “the halfway mark, ahead of schedule” (BD: Dec 14, 2021; Sep 18, 2023).

Today, a media release from the Minister for Health and Aged Care Mark Butler said that the facility made “Australia one of very few countries in the world, and the only country in the Southern Hemisphere, with an end-to-end mRNA manufacturing capability”.

The Federal Government said the factory would have the capacity to produce up to 100 million vaccine doses each year for respiratory diseases including influenza, respiratory syncytial virus and Covid-19.

A media release from Victoria Premier Jacinta Allan said that the State Government’s “record investment of more than $1 billion in medical research has cemented the state as an international hub for medical research, with a workforce of over 30,000 driving incredible breakthroughs in treatment and patient care”.

Mr Butler said opening the site was “a major step forward in helping protect Australians against future pandemics, while creating highly skilled jobs, supporting local industry, and promoting research collaboration”.

“Covid-19 taught us how important it is to have the capability to manufacture the latest vaccines here in Australia,” Mr Butler said.

“The Federal Government is building Australia’s future with this world leading facility, ensuring we have the sovereign manufacturing capability Australia needs to produce the latest vaccines,” Mr Butler said.

Ms Allan said that the facility was “is exactly what economic growth looks like, more investment, more jobs and more opportunity for all”.

“There are now three world-leading centres of medical research, Boston, London and Victoria,” Ms Allan said. “I’m proud that our state will make vaccines that Australia and the world can rely on.”

MICRO-X

Micro-X says it has won a $US8.15 million ($A12.75 million) from the US Advanced Research Projects Agency for Health to develop a portable full-body CT scanner.
Yesterday, Micro-X said it was aware that a US Government website reported it had won a $US8,153,718 ($A12,750,000) development contract (BD: Dec 3, 2024).
Today, the company said it would develop a lightweight and portable, full-body computed tomography (CT) scanner over two years, using its existing baggage CT and head CT technology.
Micro-X said the five-year development agreement was based on a fixed milestone schedule in three phases, with the $US8.2 million committed in the first two-year phase.
The company said, subject to the project meeting technical objectives after two years, the contract would be extended for three more years through to US Food and Drug Administration 510(k) submission.
Micro-X chief executive officer Kingsley Hall said the company was “incredibly excited by this award and the opportunity to develop a portable full-body CT using our proprietary [nano electronic x-ray] technology”.
Micro-X was up 2.7 cents or 38.0 percent to 9.8 cents with 5.1 million shares traded.

QUEENSLAND INSTITUTE OF MEDICAL RESEARCH BERGHOFER

The Queensland Institute of Medical Research says 15-year data shows its T-cell immunotherapy for viral infections improved 46 of 71 immuno-compromised patients.
QIMR said the immunotherapy was available to immune-compromised patients through an Australian Therapeutics Goods Administration special access scheme, which allowed “patients to access unapproved therapeutic goods as a last resort for treatment”.
The Institute said it had supplied the cellular immunotherapy to Australian clinicians, and an analysis showed the therapy could “treat complex disease in seriously ill patients”.
The research paper, titled ‘Compassionate access to virus-specific T cells for adoptive immunotherapy over 15 years’ was published in the journal Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-024-54595-2.
QIMR said the therapy targeted uncontrolled viral infections stemming from common viruses, such as Epstein–Barr virus, cytomegalovirus, BK polyomavirus, John Cunningham virus and adenovirus.
The Institute said viral complications were “a leading cause of death in patients such as children who have had a stem cell transplant to treat leukaemia, organ transplant recipients” and anyone with a genetic disorder reducing their ability to fight infection.
QIMR said cellular therapy, also known as adoptive immunotherapy, was “a highly effective tool to treat cancer, autoimmune diseases, and infectious diseases” but had not been approved for the treatment of severe viral infections.
The Institute said it was the “sole supplier of this therapy for compassionate use in Australia”, which it produced at its Brisbane cell therapy manufacturing factory.
QIMR said funding was “needed to sustain this immunotherapy access program” and open clinical trials to collect the data needed to gain TGA approval.
QIMR Berghofer researcher and therapy co-developer Prof Rajiv Khanna said the cellular therapy had “minimal side effects and has been effective in saving the lives of many children and adults who had otherwise run out of options”.
“Many patients are coming to us at a very late stage of disease and have undergone multiple treatments, so the success rate is around 65 percent,” Prof Khanna said.
“We believe more lives could be saved if patients received the therapy earlier,” Prof Khanna said.

ACRUX

Acrux says the US Food and Drug Administration has approved its generic Rectiv, or 0.4 percent nitro-glycerin ointment, for pain associated with chronic anal fissure.
Acrux said the abbreviated new drug application (ANDA) would allow it to sell its generic version of the topical treatment for moderate to severe pain due to anal fissure in the US, where annual sales generated by the branded product and generic competitor were more than $US23 million ($A36 million).
Acrux was untraded at 4.5 cents.

ADHERIUM

Adherium says it will integrate its Hailie smart inhaler with Tenovi's cellular gateway technology for remote respiratory disease patient management.
Adherium said the Portsmouth, New Hampshire-based Tenovi had "an advanced technology platform that integrates with medical devices and software to deliver real-time health data to healthcare providers".
The company said Tenovi's cellular gateway technology allowed the connection of a range of US Food and Drug Administration-approved devices, including blood pressure monitors, glucose meters, pulse oximeters and smart weight scales.
Adherium said the partnership would integrate its Hailie smart inhaler with Tenovi's cellular gateway device in the US market first "offering a clinically proven technology platform to support both patient outcomes and the payor models".
The company said the deal would provide a medication adherence device for difficult-to-treat and severe asthma patients to improve "remote monitoring capabilities which can be extended into payer programs and support a cost-effective monitoring ecosystem that helps to reduce the overall cost of respiratory care".
Adherium did not disclose the commercial terms of the agreement.
Adherium was unchanged at 1.1 cents.

ALTERITY THERAPEUTICS

Alterity says it has completed its 77-patient, phase II study of ATH434 for multiple system atrophy (MSA), with results expected in "late January or early February 2025".
Last year, Alterity said it treated the first patient in Australia in the randomized, blinded, controlled, phase II ATH434 for MSA trial; and previously said it had enrolled patients in the UK, US, Italy and New Zealand (BD: Jun 2, 2022; Mar 8, 16, Apr 4, May 10, 2023).
Today, the company said the trial would evaluate the effect of the treatment on neuro-imaging and protein biomarkers to show efficacy, in addition to assessments of safety.
Alterity said patients were treated for 12 months, which would provide "an opportunity to detect changes in efficacy endpoints to optimize design of a definitive phase III study".
Alterity managing-director Dr David Stamler said the last patient completing all clinical evaluations was "the final milestone that starts the clock to reporting top-line data in this rare neuro-degenerative disease".
"The completion of our ATH434-201 trial represents a major accomplishment for Alterity, and I would like to recognize the trial participants for their involvement in the study," Dr Stamler said.
"Throughout the course of the trial, we have had tremendous interest from our clinical sites, doctors and patients around the globe as we seek a treatment that could potentially slow the progression of this devastating disease," Dr Stamler said.
Alterity was unchanged at 0.4 cents with 26.0 million shares traded.

ANATARA LIFE SCIENCES

Anatara says it has enrolled the minimum 60 patients in stage two of its phase I/II trial of gastro-intestinal re-programming (Garp) for irritable bowel syndrome.
Last year, Anatara said it had dosed all 70 first stage patients (BD: Aug 31, 2023).
Earlier this year, Anatara said it opened five sites in the 60-to-100-patient, second stage of the up-to 140-patient phase II trial, with 36 patients recruited (BD: Apr 9, Oct 8, 2024).
Today, Anatara said it had reached its minimum number of patients for stage two, with trial sites continuing to screen participants but enrolments closed from December 13, 2024.
The company said a further group of more than 25 participants were in final screening to determine suitability to enter the trial, and it expected recruitment to be completed this year with the headline results readout later by April 2025.
Anatara executive chair Dr David Brookes said the company was “extremely pleased to progress towards and beyond the minimum number of 60 participants … for stage two”.
“We intend to pause recruitment at the end of next week and will decide about any need for resumption early in the New Year,” Dr Brookes said.
Anatara fell 0.7 cents or 12.3 percent to five cents.

4D MEDICAL

4D Medical says it expects to submit its computed tomography (CT)-based ventilation perfusion (VQ) imaging device to the US Food and Drug Administration “in mid-2025”.
Earlier this year, 4D Medical said the Federal Government granted it $1.9 million for its non-nuclear CT VQ imaging device, which measured both the regional motion and local density changes of lung tissue (BD: Oct 23, 2024).
Today, 4D Medical said it presented the CT VQ at the Radiological Society of North America meeting in Chicago, and early results showed the opportunity to improve healthcare equity and accessibility not addressed by nuclear VQ diagnostic imaging.
4D Medical managing-director Prof Andreas Fouras said the company was “well advanced in the completion of its [US Food and Drug Administration] submission”.
Prof Fouras said that the recent funding from the Federal Government would “facilitate expansion and acceleration of the clinical evidence required to empower physicians to immediately substitute nuclear VQ scans for 4D Medical’s CT VQ”.
4D Medical was up 6.5 cents or 13.5 percent to 54.5 cents with 5.2 million shares traded.

NOXOPHARM

Noxopharm says it has appointed an unnamed “highly experienced Australian contract research organization” for its first in-human trial of SOF-SKN for auto-immune diseases.
Earlier this year, Noxopharm said it planned to start its first human trial of its Sofra drug candidate SOF-SKN for cutaneous lupus erythematosus-related skin disease in early 2025 (BD: Aug 19, 2024).
Today, Noxopharm said the contract research organization would be responsible for data management, pharmaco-vigilance, statistical analysis and post-trial reporting.
Noxopharm managing-director Dr Gisela Mautner said that an experienced contract research organization was “another essential step forward in building the team that will support the … trial”.
“We have already worked with them and know the high-quality services they can deliver,” Dr Mautner said. “In addition, we are currently moving ahead with selecting a phase I unit for the trial and expect this to be completed in due course.”
Noxopharm was unchanged at 10 cents.

CHIMERIC THERAPEUTICS

Chimeric says its extraordinary general meeting has passed all resolutions with up-to 40.46 percent against the issue of placement options to executive chair Paul Hopper.
In October, Chimeric said it had “commitments” to raise $5 million at 0.8 cents a share, with one option for every share purchased (BD: Oct 31, 2024).
At that time, the company said Mr Hopper had subscribed for 125 million shares, or $1 million of the $5 million placement, subject to shareholder approval, and that the second tranche of 555,000,000 shares and options were subject to approval at an extraordinary general meeting.
Today, Chimeric said Mr Hopper’s options were opposed by 27,372,299 votes (40.46%) with 40,287,606 votes (59.54%) in favor.
The company said the issue of Mr Hopper’s shares was opposed by 31.53 percent, with the approval to issue advisor options and placement options facing 14.99 percent and 14.88 percent dissent, respectively.
Chimeric said the resolutions to ratify the issue of first and second tranche placement shares were passed with up-to 89.35 percent of the meeting in support.
According to its most recent filing, Chimeric had 995,140,820 shares on issue, meaning that the 27,372,299 votes against Mr Hopper’s options amounted to 2.75 percent of the meeting, not sufficient to requisition extraordinary general meetings.
Chimeric was up 0.1 cents or 10 percent to 1.1 cents with 7.35 million shares traded.

SYNTARA

Syntara has told the ASX that “anticipation by certain investors of the release of … interim data” from its phase II trial of SNT-5505 could explain recent trading.
The ASX said the company’s share price rose 43.75 percent from a low of 4.8 cents to a high of 6.9 cents “in the last few days”, and noted the “significant increase” in the volume of shares traded between November 29 and December 3, 2024.
Syntara said that on November 6, 2024 it announced that it would present interim data from its phase II trial of SNT-5505 with ruxolitinib for bone marrow cancer myelofibrosis at an American Society of Hematology meeting on December 10, 2024 (AEDT).
The company said the interim data was “currently only known to a limited number of people on a confidential basis … [and it] has no reason to believe that any of the interim data has ceased to be confidential”.
Syntara said it was “confident that the interim data remains confidential and therefore the information in the interim data is not the reason for the recent trading in its securities”.
The company said that it considered “recent trading activity could have been impacted by the initiation of coverage by a major broker on December 2, 2024 and increased investor relations activities by Syntara over recent months”.
Syntara fell 0.2 cents or 2.9 percent to 6.7 cents with 10.8 million shares traded.

CYNATA THERAPEUTICS

Cynata has requested a trading halt “in relation to a pending announcement of the results of the phase I clinical trial in diabetic foot ulcers”.
Trading will resume on December 6, 2024, or on an earlier announcement.
Cynata last traded at 21.5 cents.

PRO MEDICUS

Pro Medicus says co-founders chief executive officer Dr Sam Hupert and executive director Anthony Hall have sold 1,000,000 shares, each.
Pro Medicus said Dr Hupert and Mr Hall said that on December 4, 2024 they each sold 1,000,000 shares on-market at $256.73 a share.
Pro Medicus said that the sale was “in response to strong approaches from a number of high-quality funds and was done before market at the previous day’s closing price”.
Pro Medicus said that Dr Hupert retained 24,137,660 shares (23.10%), Mr Hall retained 24,144,000 (23.11%) and that they “do not intend to sell any further shares in Pro Medicus in the foreseeable future”.
Last year, Pro Medicus said Dr Hupert and Mr Hall sold 1,000,000 company shares, each, at $88.02 a share (BD: Nov 21, 2023).
Pro Medicus was up $4.51 or 1.8 percent to $261.24 with 321,146 shares traded.

SYNTARA

Platinum Investment Management Ltd says it has reduced its substantial shareholding in Syntara from 204,352,115 shares (14.88%) to 189,403,942 shares (13.79%).
The Sydney-based Platinum said it sold shares between October 21 and November 28, 2024, with the single largest sale 3,028,062 shares on November 27 for $140,460, or 4.6 cents a share.

ISLAND PHARMACEUTICALS

MWP Partners Ltd and its director Angus Walker say they have increased their holding in Island from 11,870,151 shares (7.70%) to 20,891,365 shares (11.56%).
The Hong Kong-based MWP Partners and Mr Walker said that on December 4, 2024 they bought 9,021,214 shares in a placement for $631,485, or seven cents a share.
Earlier this year, Island said it had raised $3.5 million in a placement at seven cents a share (BD: Oct 3, 2024).
Island was unchanged at 17 cents.

DORSAVI

Dorsavi says it has appointed “blockchain and technology executive” Leigh Travers as a non-executive director, effective from December 4, 2024.
Earlier this month, Dorsavi said it had begun a “strategic feasibility study to incorporate ‘blockchain technology’ into its core data platform” for data collected by its wearable sensors (BD: Nov 20, 25, 2024).
Today, the company said Mr Travers was currently director of emerging markets for the Hong Kong-based Animoca Brands and had been chief executive officer of Binance Australia and Digitalx as well as serving on the board of Blockchain Australia.
The company said Mr Travers held a Bachelor of Commerce from the University of Western Australia.
Dorsavi was unchanged at 1.3 cents with 13.4 million shares traded.

SERVATUS

Servatus says it has appointed Dr Anthony Noble as a director, effective from March 1, 2025.

Servatus said Dr Noble had “close to two decades of experience in the biotechnology and healthcare” and was managing-director of the ASX-listed Calmer Co, formerly Fiji Kava.

According to his Linkedin profile, Dr Noble held a Bachelor of Science and a Doctor of Philosophy from the Queensland University of Technology, a Master of Information Technology from the University of Queensland and a Master of Business Administration from Philadelphia’s University of Pennsylvania.

Servatus is a public unlisted company.

MEDLAB CLINICAL

Medlab says it has appointed Joshua Light as a non-executive director following the resignation of director Matt Hudson.

Medlab said Mr Light worked in corporate finance and had managed and facilitated merger and acquisition transactions and capital raising in Australia and North America.

The company said Mr Light held a Bachelor of Science from Perth’s Edith Cowan University.

Medlab thanked Mr Hudson for “his time and diligent efforts in managing the company on a care-taker mode since [the] … trading suspension” (BD: Aug 22, 2023).

Last year, the company said its extraordinary general meeting approved the sale of its subsidiary Medlab Pty Ltd and intellectual property to chair Dr Sean Hall, but with 32.4 percent opposition (BD: Dec 22, 2023).

Medlab was in a suspension and last traded at a post-consolidation $6.60.