Biotech Daily

Tuesday December 17, 2024

Daily news on ASX-listed biotechnology companies

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

*** ANTERIS US IPO RAISES $138.4m; RESUMES ASX**

*** QUEENSLAND UNI SPINS-OUT CERETAS ALZHEIMER'S ULTRASOUND**

*** CONTROL BIONICS EXPECTS H1 US REVENUE UP 15%**

*** CORRECTION: CONTROL BIONICS**

*** BOTANIX SHIPS 1st US SOFDRA ORDERS**

*** FEDERAL $300m FOR RESEARCH; $16m FOR COMMERCIALIZATION**

*** IMMUTEP: 'IMP761 SAFE IN HEALTHY VOLUNTEERS'**

*** NEURIZON EU NUZ-001 FOR ALS ORPHAN STATUS**

*** DORSAVI, 'SECRET NETWORK' TESTS BLOCKCHAIN DATA ENCRYPTION**

*** RACE RECEIVES $5.25m FEDERAL R&D TAX INCENTIVE**

*** PRESCIENT APPOINTS JAMES MCDONNELL CEO, ON $390k PA**

*** BIO-MELBOURNE: 3 MEDTECH MANUFACTURING ALLIANCE MEMBERS**

*** HERAMED APPOINTS VIVEK KRISHNAN ADVISOR**

*** RENERVE CHAIR STEPHEN COOPER, ZETLAND ROAD TAKE 7.25%**

MARKET REPORT

The Australian stock market was up 0.78 percent on Tuesday December 17, 2024, with the ASX200 up 64.5 points to 8,314.0 points. Twenty of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and one was untraded. All four Big Caps rose.

Actinogen was the best, up 0.2 cents or 7.7 percent to 2.8 cents, with 9.3 million shares traded; followed by Nova Eye and Prescient up 7.4 percent and 7.5 percent to 14.5 cents and 4.3 cents, respectively, with 257,491 shares and 440,851 shares traded, respectively. Mesoblast climbed six percent; Paradigm was up 5.6 percent; Genetic Signatures and Medadvisor were up more than three percent; Compumedics, Pro Medicus and Resmed rose two percent or more; Amplia, Avita, Cochlear, Dimerix, EBR, Emvision, Nanosonics, Polynovo and SDI were up one percent or more; with Clarity, Clinuvel, CSL, Proteomics and Telix up by less than one percent.

Micro-X led the falls, down 0.6 cents or 7.9 percent to seven cents, with 416,788 shares traded. Syntara lost 6.8 percent; Starpharma fell 4.8 percent; Alcidion, Curvebeam and Impedimed were down more than three percent; 4D Medical, Cyclopharm, Cynata and Orthocell shed more than two percent; Neuren was down 1.05 percent; with Aroa down by 0.8 percent.

ANTERIS TECHNOLOGIES GLOBAL CORP (FORMERLY ANTERIS TECHNOLOGIES)

Anteris says it has raised $US88.8 million ($A138.4 million) in its initial public offer to list on the Nasdaq; and has resumed trading on the ASX under the code ‘AVR’.

Earlier this year, Anteris said it had shareholder and court approval to redomicile to the US and list on the Nasdaq through the Delaware-based Anteris Technologies Global Corp (ATGC) with final ASX trading on December 5 (BD: Nov 13, Dec 3, 5, 2024).

Yesterday, the company said that US holding company ATGC hoped to raise $US88,800,000 ($A139,397,000) at $US6.00 ($A9.42) a share in an initial public offer of 14,800,000 shares to list on the Nasdaq (BD: Dec 10, 16, 2024).

Today, Anteris said an additional 2,220,000 shares were issuable through the underwriters’ option to purchase further securities, if exercised in full.

The company said it had listed its Chess depository interests, equally to one ordinary US share, on the ASX.

Anteris fell $1.68 or 15.9 percent to $8.86.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has licenced its ultrasound therapy for Alzheimer's disease brain function to the Ceretas spin-out, start-up.

The University of Queensland said the therapeutic ultrasound technology was developed by Prof Jürgen Götz from its Queensland Brain Institute and would be progressed to clinical use by Ceretas.

The University said Ceretas was formed by its Uniquest commercialization arm, in partnership with early-stage investors and co-founders Ryan Laws and Sam Wetzler.

A Uniquest spokesperson told Biotech Daily Ceretas was a private company “with a view to potentially list in the future” and that “only a small amount of initial capital will be raised through investment from a small group of [high net-worth] investors”.

The University of Queensland said the company would aim “to validate the system to treat Alzheimer's and other neuro-degenerative diseases”.

The University said that the technology used “targeted pressure waves from sound to activate the brain's ability to increase neuronal signaling and clear pathological proteins that accumulate in people with Alzheimer's disease”.

The University of Queensland said a first human safety trial of the ultrasound therapy was completed in 2024, with results expected “in early 2025”.

In 2022, the University said it began a 12-patient, 12-month safety trial of its ultrasound device to treat Alzheimer’s disease and restore memory functions following Prof Götz’s 2015 discovery “that ultrasound could clear the toxic amyloid-beta plaque build-up, the hallmark of Alzheimer’s disease and … restore memory functions” (BD: Dec 13, 2022).

Today, Prof Götz said current medications target disease progression and symptoms but don't offer patients a cure.

“The therapy increases neuronal signaling and thereby restores memory and cognition by enhancing communication between brain cells,” Prof Götz said.

“But it also targets and clears the build-up of the proteins toxic amyloid and tau by activating the brain's intrinsic clearance mechanism,” Prof Götz said.

“The treatment could also potentially be personalized across multiple neurological disorders including frontotemporal dementia, amyotrophic lateral sclerosis, disorders caused by brain tumours and mental disorders,” Prof Götz said.

Ceretas co-founder Ryan Laws said “taking the therapeutic ultrasound treatment further was an exciting prospect”.

CONTROL BIONICS

Control Bionics says it expects US revenue for the six months to December 31, 2024 to "exceed the corresponding period in 2023-'24 by more than 15 percent".
Earlier this year in its half yearly report and accounts, Control Bionics said that US revenue for the six months to December 31, 2023 was $2,650,527.
Today, the company said the increased US revenue reflected "increasing demand for our solutions, the new Neuronode only sales enabled by the new HCPCS code and growing market penetration".
In August, Control Bionics said its Neuronode had a US Centers for Medicare and Medicaid Healthcare Common Procedure Coding System (HCPCS) code qualifying it for $US4,299.75 ($A6,432) in reimbursement, from October 1, 2024 (BD: Aug 19, 2024).
Today, the company said it expected revenue in the six months to December 31, 2024 to be "almost 30 percent higher than the first six months of 2024" due to a "significant new customer, which made the first of what we expected will be meaningful orders".
Control Bionics said despite National Disability Insurance Scheme approvals remaining inconsistent and well outside service guarantee timelines, it expected Australian revenue in the six months to December 31, 2024 to be up 20 percent compared to the six months to June 30, 2024.
The company said that it had reduced US costs by about $700,000 a year.
Control Bionics fell 0.3 cents or 4.55 percent to 6.3 cents.

CORRECTION: CONTROL BIONICS

Last night's edition incorrectly said Control Bionics' Neurostrip trained athletes to increase their vertical leap "by five-to-15 cm … in just eighty sessions".
In fact, the Neurostrip electro-myography wearable sensors used by Neuro Elite Athletics trained athletes to increase their vertical leap "by five-to-15 cm … in just eight sessions".
The error was made by the fat-fingered Monday sub-editor who is damn lucky it's the week before Christmas or she would have been terminated on the spot.
She continues under probation.
Biotech Daily apologizes unequivocally. It's just hard to get good hired help, these days.

BOTANIX PHARMACEUTICALS

Botanix says it has shipped the first Sofdra topical gel prescriptions for excessive sweating to patients following tele-medicine diagnosis and insurance approvals.
Earlier this year, Botanix said the US Food and Drug Administration had approved Sofdra, or sofpironium bromide topical gel, for excessive underarm sweating in adults and children aged nine years and older (BD: Jun 20, 2024).
Last month, the company said the Roseland, New Jersey-based US payer organization Ascent Health would cover Sofdra for excessive sweating (BD: Nov 14, 2024).
Today, Botanix said the first orders were "a significant milestone for the company as it transitions into a revenue generating commercial stage pharmaceutical company with the full commercial launch of Sofdra" expected by April 2025.
The company said it had increased its sales team to 25 personnel from 10 employees at the time of Sofdra approval and was "finalizing coverage with the last of the commercial payers in advance of launch".
Botanix said it was "already seeing Sofdra prescriptions being reimbursed in line with the pricing and restrictions already contracted or previously negotiated with payers".
Botanix was unchanged at 38 cents with 10.6 million shares traded.

FEDERAL GOVERNMENT

The Federal Government says the National Health and Medical Research Council will provide $300 million for medical research, with $16 million for commercialization.
A media release from the Federal Minister for Health and Aged Care Mark Butler said the $16 million would be invested through the National health and Medical Research Council (NHMRC) development grants scheme to support the commercialization of research.
The Government said $274 million would be shared by 223 researchers through the NHMRC ideas grants scheme and the remaining $10 million would be issued to medical graduates as part of the NHMRC post-graduate scholarship scheme.
Mr Butler said the projects were “driving … research innovation and carving out pathways to commercialization of health and medical research”.
The full list of NHMRC grant recipients is available at: https://bit.ly/4gH3fqZ.

IMMUTEP

Immutep says its first in-human, up-to 49-patient, phase I study of IMP761 for autoimmune disease shows no treatment-related adverse events.
In July, Immutep said the Leiden, Netherlands’ Centre for Human Drug Research would conduct a 49-participant, phase I trial assessing the safety, pharmaco-kinetics and pharmaco-dynamics of IMP761 LAG-3 agonist antibody for autoimmune disease; and later, said it had dosed the first healthy volunteer (BD: Jul 17, Aug 14, 2024).
In October, the company said it dosed all five volunteers in the single dose, part A portion of the study, with no safety issues, and that it would begin dosing the 30-participant, part B, dose escalation cohort (BD: Oct 17, 2024).
At that time, Immutep said that subject to no safety issues in the second group, the trial would then continue to a multiple ascending dose cohort of 14 volunteers, in which pharmaco-kinetics would be further evaluated.
Today, the company said the safety data was from “the first three of five single ascending dose cohorts in healthy participants” but did not state the number of patients included in the data.
Immutep said it expected additional safety data and efficacy data “in the first half of 2025”.
Immutep chief scientific officer Dr Frédéric Triebel said the company was “very encouraged by the safety data generated to date for IMP761, the world’s first LAG-3 agonist antibody, in this phase I setting”.
Immutep was unchanged at 34 cents with four million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has European Medicines Agency orphan medicinal product designation for NUZ-001 for amyotrophic lateral sclerosis (ALS).
Neurizon said the status provided “a robust framework of benefits, including reduced regulatory fees, free protocol assistance, and market exclusivity for 10 years in the [European Union] upon product approval”.
Neurizon managing-director Dr Michael Thurn said the designation was “a significant achievement for Neurizon … [bolstering] our position in Europe … [and] complements the orphan drug designation previously granted by the US Food and Drug Administration, providing global market exclusivity across key territories”.
In May, the then Pharmaust said the FDA granted orphan drug designation to the then monepantel for motor neuron disease, also known as ALS (BD: May 17, 2024).
Neurizon was up one cent or 6.1 percent to 17.5 cents.

DORSAVI

Dorsavi says it will test whether the data collected from its devices can be encrypted using Secret Network's encrypted smart contract blockchain platform.
Last month, Dorsavi said it began a proof-of-concept study "to tokenize and securely share clinical device data" generated by its wearable sensor devices and video techniques (BD: Nov 20, 25, 2024).
Today, the company said the Secret Network was "the first blockchain platform designed to enable privacy-preserving smart contracts, ensuring data remains confidential and secure while allowing decentralized applications across multiple industries".
Dorsavi said the partnership would "assess the use of various data tokenization methods, including issuing non-fungible tokens which represent ownership and secure access to confidential data".
The company said Secret Network would provide software development resources at no cost to complete the proof-of-concept but did not state further commercial terms.
Dorsavi quoted Secret Network Foundation executive director Lisa Loud saying her group was "thrilled to collaborate with Dorsavi on this proof of concept",
According to her Linkedin page Ms Loud is a New York-based "fintech influencer".
According to its Linkedin page the Secret Network Foundation is "internet" based.
Dorsavi was up 0.1 cents or 8.3 percent to 1.3 cents with 3.4 million shares traded.

RACE ONCOLOGY

Race says it has received $5,254,557 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Race said the incentive related to expenditure for the year to June 30, 2024.
The company said it was issued an advance and overseas finding from Ausindustry, which would cover up-to $20,081,627 in overseas development activities over three years.
Race was unchanged at $1.41.

PRESCIENT THERAPEUTICS

Prescient says it has appointed James McDonnell as its chief executive officer on $390,250 a year, effective from January 20, 2025.
Earlier this year, Prescient said founding director Steven Yatomi-Clarke would resign as chief executive officer, remain until the end of February 2025 (BD: Sep 12, 2024).
Today, the company said Mr McDonnell had more than 25 years of experience in the pharmaceutical industry, including in blood disorders and haematological malignancies such as myeloma, myelodysplasia and chronic myeloid leukaemia.
Prescient said Mr McDonnell had been US head of marketing at Pharmion and CSL Vifor head of Australia and New Zealand and head of patient blood management.
The company said Mr McDonnell would be paid $390,250 a year in fixed remuneration, inclusive of superannuation, and would receive 24,000,000 options exercisable at a 75 percent premium to the five-day volume weighted average price prior to the grant date within five years of issue.
Prescient said Mr McDonnell would receive short-term incentives equal to 30 percent of his base salary and long-term incentives, subject to performance milestones.
Prescient was up 0.3 cents or 7.5 percent to 4.3 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it has appointed three additional industry members to its Australian Medtech Manufacturing Alliance.

Earlier this year, the Bio-Melbourne Network said it would partner with industry bodies to form the Australian Medtech Manufacturing Alliance, with Victoria Government seed funding (BD: Oct 3, 2024).

At that time, the Network said members included Ausbiotech, MTP Connect, the Australian Manufacturing Technology Institute Ltd (AMTIL) and the Industry Capability Network Victoria.

Today, Bio-Melbourne said Pathology Technology Australia (PTA), the Association of Healthcare Supply and Procurement Officers (AHSPO) and the Medical Technology Association of Australia (MTAA) had been added.

The Network said the additional members would “bolster Australia’s vision to see more local [small and medium enterprise] health technology procured domestically”.

Bio-Melbourne chief executive officer Karen Parr said that “with industry and health two sides to the same coin, it’s critical to the Alliance’s success to have both perspectives in the room to drive meaningful outcomes”.

“It adds even greater strength to our vigorous advocacy for systemic improvements in procurement pathways and market access for locally made ‘medtech’ products,” Ms Parr said.

HERAMED

Heramed says it has appointed Vivek Krishnan as a member of its advisory board, effective immediately.

Heramed said Mr Krishnan was formerly chief technology officer of Alcidion and currently founding managing-director of Agilemed.

The company said Mr Krishnan's expertise aligned with its “four-point strategic plan, particularly in areas of technology integration, data analytics, generative [artificial intelligence] and analytics, and strategic partnerships”.

According to his Linkedin profile, Mr Krishnan held a Bachelor of Mathematics from India’s University of Delhi and a Master of Information Technology from Melbourne’s Deakin University.

Heramed fell 0.1 cents or 4.55 percent to 2.1 cents with 2.5 million shares traded.

RENERVE

Renerve chair Reginald Stephen Cooper says he has increased his substantial holding in the company from 10,170,788 shares (7.17%) to 10,281,158 shares (7.25%).

The Melbourne-based Mr Cooper said with Zetland Road Pty Ltd he purchased 110,370 shares on December 13, 2024 for $16,511, or 15.0 cents a share.

Renerve was up half a cent or 3.6 percent to 14.5 cents.