Biotech Daily

Wednesday October 30, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: RESONANCE UP 6%; CURVEBEAM DOWN 8%**

*** AUSBIOTECH 'BIGGEST' CONFERENCE; HEALTH MINISTER MARK BUTLER**

*** AUSBIOTECH 2024 MILLIS ORATION: BIVACOR CEO DR DANIEL TIMMS**

*** AMPLIA PLACEMENT, RIGHTS TO RAISE $13m**

*** TRYPTAMINE 'COMMITMENTS' FOR $6m PLACEMENT**

*** AMPLIA '15 OF 26 PATIENTS REMAIN ON NARMAFOTINIB TRIAL'**

*** ARGENICA FDA ORPHAN DRUG STATUS FOR ARG-006 FOR HIE**

*** COGSTATE, MEDIDATA PARTNER FOR CNS TRIALS**

*** MACH7 800k M-D MIKE LAMPRON RIGHTS AGM**

*** ECHO IQ WITHDRAWS DIRECTOR RIGHTS AGM RESOLUTIONS**

*** ASX SUSPENDS HEXIMA ON 'CHANGE OF ACTIVITIES APPROVAL'**

*** CSL LOSES DIRECTOR DUNCAN MASKELL**

*** ADHERIUM TO LOSE CEO DR PAUL MASTORIDIS; NEW CEO WANTED**

*** AARON BRINKWORTH REPLACES PROTEOMICS DIRECTOR ROGER MOORE**

*** DR DANIEL TILLETT REPLACES TRYPTAMINE DIRECTOR CLARKE BARLOW**

MARKET REPORT

The Australian stock market fell 0.83 percent on Wednesday October 30, 2024, with the ASX200 down 68.8 points to 8,180.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and one was untraded. All three Big Caps fell.

Resonance was the best, up 0.3 cents or 5.9 percent to 5.4 cents, with 1.1 million shares traded. Actinogen and Medadvisor climbed more than four percent; Emvision and Pro Medicus were up more than three percent; Dimerix and Genetic Signatures rose more than two percent; 4D Medical, Medical Developments and Telix were up one percent or more; with SDI up by 0.5 percent.

Curvebeam led the falls, down one cent or 8.3 percent to 11 cents, with 436,198 shares traded. Universal Biosensors lost 7.4 percent; Syntara shed 6.8 percent; Clarity and Opthea fell more than four percent; Avita, Compumedics, Immutep, Impedimed and Orthocell were down more than three percent; Cynata, Paradigm and Starpharma shed more than two percent; Clinuvel, CSL, Mesoblast, Micro-X, Polynovo and Resmed were down more than one percent; with Cochlear, Cyclopharm, Nanosonics and Neuren down by less than one percent.

AUSBIOTECH

By Jamie Miller

Ausbiotech says its “largest ever” conference began in Melbourne today with more than 1,500 attendees, including 200 delegates from 25 countries.

Ausbiotech said the three-day event, following yesterday’s Ausbioinvest day, was being held at the Melbourne Convention and Exhibition Centre and included more than 200 speakers over three days at more than 60 sessions, as well as a ‘Bioexhibition Hall’ of more than 95 life sciences companies, institutions and organizations.

The industry organization said the event was designed to “inform, connect, educate, and celebrate the sector's success and challenges”.

The event began with a welcome speech by the Federal Minister for Health and Aged Care Mark Butler who discussed the report of the Covid-19 inquiry.

“[The report] very much aligns with the work that Ausbiotech is doing, even if it is in the more narrow field of pandemic response”.

Mr Butler said he was “the first Australian Health Minister to ever address the Ausbiotech conference”.

Mr Butler said he wanted to make clear “the government’s desire to continue to work with Ausbiotech and its industry members to bridge the gap between invention and realization”.

“We need a whole pipeline approach, from discovery to start-up, clinical trials, manufacturing, export, access and reimbursement,” Mr Butler said.

“To the people in this room, from the start-ups, the small to medium enterprises, the research institutes, multinationals, investors and manufacturers I say, we are stronger together,” Mr Butler said. “Our funding, tailored programs and vision reflect our commitment to support and nurture our biotechnology industry.”

Mr Butler said the programs included the Medical Research Future Fund (MRFF), the National Health and Medical Research Council (NHMRC) and the National One Stop Shop for clinical trials and health and medical research.

“Above all else though, you’re the beating heart of this sector because you take great ideas and translate them into health and economic benefits,” Mr Butler said.

Ausbiotech chief executive officer Rebekah Cassidy said “many of the conversations we are having over the three days [of the conference] go to the heart of policy issues” including manufacturing sovereignty and health security.

Ausbiotech said MTP Connect chief executive officer Stuart Dignam spoke about biotechnology advocacy in Australia and the organization’s partnership with Ausbiotech.

The organization said a panel including Ms Cassidy, Vaxxas head of research Angus Foster, Astrazeneca Australia head Benjamin McDonald, Viral Vector Manufacturing chair Sue MacLeman and head of Myeloid Therapeutics Jerome Chal discussed medical manufacturing as part of the Federal Government’s Future Made in Australia program.

Ausbiotech said in the afternoon it conducted an early-stage innovation forum which included up-to 15 emerging technologies.

The organization said the forum allowed these projects from institutes, universities, hospitals and pre-series A funding round companies “to pitch to a panel of industry experts, corporate [venture capitalists] and early-stage investors to continue their commercialization journey”.

Ausbiotech said other sessions involved discussions and presentations on incentives for antibiotic innovation, commercializing radioligand therapies, precision medicines and selling medical technologies.

The Ausbiotech 2024 Conference is being held until Friday, November 1, with the full program available at: https://www.ausbiotechnc.org/ausbiotech-programme-2024.

BIVACOR, AUSBIOTECH

By Jamie Miller

Bivacor founding chief technology officer Dr Daniel Timms says the company hopes to implant at least two of its artificial hearts for end-stage heart failure in Australia this year.
Dr Timms delivered the Ausbiotech conference Millis Oration, dedicated to Prof Nancy Millis' contribution to the industry and sponsored by CSL.
In an address titled 'The Medical Moonshot - A Decades long quest to build an artificial heart' Dr Timms discussed "developing a fully functional artificial heart to replace a failing human heart".
In July, Oneventures said the Los Angeles-based Bivacor had implanted its first total artificial heart in a US Food and Drug Administration feasibility study (BD: Jul 26, 2024).
At that time, Oneventures said the heart was a titanium bi-ventricular rotary blood pump with a single moving part that used magnetic levitation technology.
Today, Dr Timms said that since July, four patients in the US had received a transplant and were able to walk again.
Dr Timms said that, with the support of MTP Connect and the Medical Research Future Fund, the company hoped to successfully complete two transplants in Australia "by the end of the year" at Sydney's St Vincent's Hospital and Melbourne's Alfred Hospital.
Dr Timms said Bivacor's mission was "to make an artificial heart that is as good as a heart transplant, or better" for end stage heart failure.
Dr Timms said he began developing an artificial heart whilst completing his Doctor of Philosophy at the Queensland University of Technology, after his father was diagnosed with heart failure, and his father's death in 2004 "galvanized [his] resolve to develop this technology further".
Dr Timms said there were more than 150,000 Australian's diagnosed with heart failure, but only about 100 transplants a year due to the limited amount of donor organs.

AMPLIA THERAPEUTICS

Amplia says it hopes to raise up-to $13.0 million at 11.5 cents a share in an $8.1 million placement and a $4.9 million, one-for-6.45 institutional and retail rights offer.
Amplia said the issue price was a 22.3 percent discount to the 10-day volume weighted average price of 14.8 cents a share and a 14.8 percent discount to the last closing price.
The company said investors would receive three options for every four shares issued, exercisable at 17.25 cents each by October 31, 2027.
Amplia said the placement would raise $7.8 million, with a further $325,000 to be raised from its directors, subject to shareholder approval, with chair Dr Warwick Tong committing to $80,000, managing-director Dr Chris Burns to subscribe for $40,000 and directors Robert Peach and Jane Bell to take up $125,000 and $80,000, respectively.
Amplia said the funds would be used for its 'Accent' trial of narmafotinib for pancreatic cancer and a US trial combining narmafotinib and the Folfirinox (folinic acid, fluorouracil, irinotecan and oxaliplatin) regime, as well as working capital.
The company said the rights offer would have institutional and retail components, with any shortfall to be placed by lead managers and bookrunners, Bell Potter and Taylor Collison.
Amplia said the entitlement offer's retail component had a record date of November 1, would open on November 6 and close on November 22, 2024.
Separately, Amplia requested a trading halt for "the offer to be undertaken in an orderly manner", with trading to resume on November 1, 2024, or an earlier announcement.
Amplia last traded at 13.5 cents.

TRYPTAMINE THERAPEUTICS

Tryptamine says it has “firm commitments” to raise $6.0 million at 2.0 cents share in a placement, with one attaching option for every two shares issued.
Tryptamine said the placement price was equal to the 30-day volume weighted average price, and the attaching options would be exercisable at four cents each within two years of issue, subject to shareholder approval at a meeting in January 2025.
Tryptamine said the placement was supported by the Merchant Biotech Fund and Race managing-director Dr Daniel Tillett, as well as Dr Bill Garner, Herwig Janssen, Ludwig Criel, chief executive officer Jason Carroll and director Chris Ntoumenopoulos, subject to shareholder approval; with Merchant as lead manager and Mr Ntoumenopoulos to be paid a six percent selling fee on funds raised by him in a separate arrangement with Merchant.
The company said the funds were for “additional, larger clinical trials” of its TRP-8803 intra-venous infused psilocin, the active ingredient of psilocybin.
Tryptamine was up one cent or 43.5 percent to 3.3 cents with 71.9 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it 15 of the 26 patients enrolled in the first part of its 50-patient, phase IIa trial of narmafotinib, formerly AMP945, for pancreatic cancer “remain on trial”.
Last month, Amplia said six of 26 enrolled patients in its 50-patient, phase IIa, trial of AMP945 for pancreatic cancer showed reduced tumor size with no new lesions, allowing it to begin recruitment of the remaining 24 patients (BD: Sep 23, 2024).
Today, the company said that an interim analysis, including data to September 27, 2024, showed six patients with confirmed partial responses, with four partial responses awaiting confirmation and two subsequently recording progressing disease.
Amplia said eight patients had sustained stable disease, with five remaining on study; while three patients recorded progressive disease as best response, and three other patients were considered ineligible or withdrew.
The company said of the 24 evaluable participants, 19 had a decrease in tumor size as best response; and the median duration on trial was 136-days, compared to 117 days for chemotherapy alone; with preliminary analysis showing patients had a “faster response to therapy in terms of tumor reduction, compared to historical data for chemotherapy alone”.
Amplia said it expected to recruit the second cohort of 24 patients by April, 2025.

ARGENICA THERAPEUTICS

Argenica says the US Food and Drug Administration has granted orphan drug and rare paediatric disease status for ARG-006 for hypoxic ischaemic encephalopathy (HIE).
Argenica said ARG-006 was its second neuro-protective drug to receive the FDA designations, after ARG-007, and that it was the L-isomer, or mirror image, of the D-isomer ARG-007; and ARG-006 was considered a different chemical entity.
Argenica said that it had begun piglet studies of the safety, pharmaco-kinetics and therapeutic potential of ARG-006, which could be used to treat brain injury related to hypoxic ischaemic encephalopathy in newborn term infants.
The company said orphan drug designation qualified it for “tax credits for qualified clinical trials, exemption from user fees [and] potential seven years of market exclusivity after approval” while rare paediatric disease designation meant that “upon approval of a new drug application for either ARG-006 or ARG-007 in HIE, the FDA may award a priority review voucher provided that HIE is the first indication for which the drug is approved”.
Argenica was up two cents or 2.8 percent to 74 cents.

COGSTATE

Cogstate says with New York's Medidata it will "provide a fully unified" product for clinical trials relating to central nervous system (CNS) diseases.
Cogstate said Medidata was a provider of clinical trial products and a brand of the Paris-based Dassault Systèmes.
The company said it was marketing the joint offer and the first sales contract with an unnmaed bio-pharmaceutical customer was expected "within the coming days".
Cogstate did not disclose the commercial terms of the agreement.
A media release from Medidata said the agreement would "reshape clinical trials and outcomes measurement for central nervous system diseases across neuro-degenerative, psychiatric, motor, and rare neuro-developmental disorders".
Medidata said the deal would use its electronic clinical outcome assessment platform and Cogstate's digital cognitive assessments to "deliver higher quality data collection with increased efficiency and accuracy".
Cogstate managing-director Brad O'Connor said the ability to deliver precise and reliable data was "critical for understanding and treating complex neurological conditions".
Cogstate was unchanged at $1.00.

MACH7 TECHNOLOGIES

Mach7 says its annual general meeting will vote to issue 800,000 performance rights to managing-director Mike Lampron.
Mach7 said Mr Lampron's rights would vest in four tranches pending milestones, and expire on September 30, 2027.
The company said the rights were equal to 80 percent of Mr Lampron's fixed yearly pay and in addition to his pay, which was $US406,363 ($A621,328).
Mach7 said the meeting would vote to adopt the remuneration report, elect Rebecca Thompson and Robert Bazzani as directors and approve its 10 percent placement capacity.
The meeting will be held online on November 28, 2024 at 10am (AEDT).
Mach7 fell 1.5 cents or 2.9 percent to 50.5 cents.

ECHO IQ

Echo IQ says it has withdrawn three resolutions to issue performance rights to directors at its annual general meeting due to "recent strong share price performance".
Earlier this month, Echo IQ said its annual general meeting would vote to issue chair Andrew Grover 6,500,000 performance rights as well as 4,500,000 rights and 1,000,000 rights to directors Steve Formica and Stephen Picton, respectively, and raise its directors fee pool 25 percent from $400,000 to $500,000 (BD: Oct 7, 2024).
Today, the company said resolutions five, six and seven, relating to Mr Grover, Mr Formica and Mr Picton's rights were withdrawn, with the remaining resolutions including the increase to the director fee pool to remain.
Echo IQ said that "in light of the recent strong share price performance" it was withdrawing the resolutions and the withdrawal would have "no material adverse impact on the company and will not affect the validity of the proxy form provided in connection with [the meeting] or any proxy forms already submitted".
The company said its board was "currently considering a new remuneration structure and will advise shareholders in due course".
Echo IQ was up half a cent or 2.2 percent to 23 cents with 2.7 million shares traded.

HEXIMA

The ASX says it has suspended Hexima from quotation under Listing Rule 17.3 in relation to its “proposed acquisition of Real Thing Entertainment Pty Ltd”.
The ASX said that it required the acquisition to be “conditional on approval by Hexima’s ordinary security holders” under Listing Rule 11.1.2 and 11.1.3, which stated an “entity must get the approval of holders of its ordinary securities … to make a significant change … to the nature or scale of its activities”.
Earlier this year, Hexima said it had a “binding but conditional agreement … to acquire … Real Thing Entertainment Pty Ltd which has developed an artificial intelligence platform that allows used to achieve outcomes using simple voice commands through to complex dialogue” (BD: Jul 24, 2024).
Hexima said the transaction was subject to various conditions, including shareholder approvals and re-complying with Chapters 1 and 2 of the ASX Listing Rules.
The ASX said Hexima would remain suspended until it had recompiled with Chapters 1 and 2 of the Listing Rules.
Hexima last traded at 1.35 cents.

CSL

In an Appendix 3Z, Duncan Maskell says he ceased to be a director of CSL, effective from yesterday.
CSL fell $5.21 or 1.8 percent to $287.46 with 588,357 shares traded.

ADHERIUM

Adherium says chief executive officer Dr Paul Mastoridis’ “employment with the company will end on January 7, 2025” and it will search for a replacement.
Earlier this year, Adherium said Dr Mastoridis replaced chief executive officer Rick Legleiter, on a base salary of $US350,000 ($A533,000) a year (BD: Feb 1, 2024).
Today, the company said Dr Mastoridis was employed for an initial 12-month term and that it had “not been able to agree terms to enable him to continue in his role”.
Adherium said until Dr Mastoridis’ departure he would “be on ‘gardening leave’”.
The company said the business would be managed by its board and management.
Adherium was unchanged at 1.4 cents with 1.5 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says Aaron Brinkworth will replacing Roger Moore as a director, with James Williams to replace Neville Gardiner as chair, effective on November 8, 2024.
Proteomics said Mr Gardiner would stand down from the role of chair at its annual general meeting and continue as a non-executive director.
The company said Mr Brinkworth had 25 years of industry experience, including 22-years at Gilead Sciences and was currently a director of Resonance Health.
According to his Linkedin profile, Mr Brinkworth held a Bachelor of Health Science from Perth’s Edith Cowan University.
Proteomics managing-director Dr Richard Lipscombe thanked Mr Moore “for his considerable contributions to the growth of the company during his eight years on the board, and to Mr Gardiner for his guidance as chair over the past three years”.
Proteomics was unchanged at 71 cents.

TRYPTAMINE THERAPEUTICS

Tryptamine says it Race managing-director Dr Daniel Tillett will replace Clarke Barlow as a non-executive director at its annual general meeting on November 8, 2024.

Tryptamine said Dr Tillett held was the founder and chief executive officer of Nucleics and had been chief scientific officer and executive director of Race before transitioning to managing-director in 2024.

The company said Dr Tillett held a Doctor of Philosophy from Sydney's University of New South Wales.

Tryptamine said Dr Tillett's appointment followed his involvement in its placement (see above) and that he would assist the "ongoing development of the company's clinical trial strategy and commercialization opportunities".

The company said it wished "to thank Mr Barlow for his service and wish him well for future endeavors".