Biotech Daily

Tuesday October 29, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CYNATA UP 4%; DIMERIX DOWN 8%**

*** FEDERAL $251.7m FOR CENTRE FOR DISEASE CONTROL**

*** AUSBIOTECH AUSBIOINVEST 2024**

*** EXTERNA RAISES $11m FOR RNA CANCER THERAPIES**

*** WEHI: 'VESICLES MAY BE A CANCER BLOOD MARKER, IN MICE'**

*** POLYACTIVA: MULTIPLE DOSES OF PA5108 REDUCES EYE PRESSURE**

*** FEDERAL $4m FOR ANTEOTECH BATTERY ANODE**

*** PAINCHEK TO FILE 'POSITIVE' ADULT STUDY RESULTS TO FDA**

*** EMVISION PLANS US STROKE STUDY**

*** CSL 26% REMUNERATION REPORT 1st STRIKE; 23% OPPOSE M-D SHARES**

*** LBT RECEIVES $953k FEDERAL R&D TAX INCENTIVE**

*** ASX DELISTS MELODIOL ON 'FEES'**

*** BIANCA RINEHART, HANCOCK BELOW 5% OF LITTLE GREEN PHARMA**

*** CK TEO, PYXIS TAKES 8% OF INHALERX**

*** ACTINOGEN APPOINTS ANDREW UDELL CCO**

*** ONCOSIL APPOINTS RACHEL DUGGAN EMEA SALES HEAD**

MARKET REPORT

The Australian stock market was up 0.34 percent on Tuesday October 29, 2024, with the ASX200 up 27.7 points to 8,249.2 points. Eleven of the Biotech Daily Top 40 companies were up, 23 fell and six traded unchanged.

Cynata was the best, up one cent or 4.35 percent to 24 cents, with 45,060 shares traded. Avita, Mesoblast and Opthea climbed more than four percent; Universal Biosensors was up 3.85 percent; Aroa and Percheron rose more than two percent; Medical Developments and Pro Medicus were up more than one percent; with Clinuvel, Cochlear, CSL and Genetic Signatures up by less than one percent.

Dimerix led the falls, down 3.5 cents or 8.1 percent to 39.5 cents, with 3.6 million shares traded. Curvebeam lost 7.7 percent; Syntara slipped 6.4 percent; Actinogen and Resonance were down more than five percent; Atomo, Prescient and Proteomics fell more than four percent; Emvision, Resmed and Telix were down three percent or more; Imugene and Neuren shed more than two percent; 4D Medical, Alcidion, Clarity, Compumedics, Cyclopharm, Immutep, Medadvisor, Micro-X, Nanosonics and Polynovo were down one percent or more; with SDI down by 0.5 percent.

FEDERAL GOVERNMENT

The Federal Government says it has invested $251.7 million to establish an Australian Centre for Disease Control (CDC), to be headquartered in Canberra.
The Federal Minister for Health Mark Butler said Australia was the only Organisation for Economic Co-operation and Development country without a CDC equivalent.
The Government said the Labor Party had committed to “a transparent, trusted and independent CDC” in 2020 and the Government opened an interim CDC in January 2023.
The Government said a CDC would ensure Australia had “a national organization that brings together critical information and experts to deliver coherent, timely, trusted health advice to improve health outcomes for the whole country”.
The Federal Government said the interim CDC had “undertaken considerable work to strengthen Australia’s preparedness levels to respond to future health challenges”, including conducting pandemic drills.
The Government said a CDC strengthened “biosecurity measures against avian influenza which has significant risks to Australia, including our unique wildlife and poultry”.
The media release said the interim CDC would continue to operate as part of the Department of Health and Aged Care until the launch of the independent CDC, which was expected to be on January 1, 2026, subject to approval by Federal Parliament.
Mr Butler said Australia wasn’t prepared for Covid-19 and “because of the lack of planning Australia’s pandemic response to Covid was slow, confused and lacked authority”.
“The Australian CDC will ensure we are prepared next time,” Mr Butler said.

AUSBIOTECH

Ausbiotech says there were more than 260 attendees at today’s Ausbioinvest 2024 event, held at the Park Hyatt Hotel in Melbourne.
Ausbiotech said delegates included venture capital firms, private equity firms and individuals as well as research analysts, brokers, industry executives and stakeholders.
The industry organization said the event helped “Australian life sciences companies connect with international capital markets … to be competitive on a global scale”.
Ausbiotech said an address from San Francisco’s DCVC Bio’s Dr Eric Shiozaki opened Bioinvest, followed by panel discussions with Oneventures’ Sarah Meibusch, Horizon 3 Healthcare’s Matt McNamara and Platinum Asset Management’s Bianca Ogden.
The organization said 23 biotechnology companies presented at the event which was “a significant opportunity for investors and potential partners to connect directly with companies seeking funding and collaborative development”.
Ausbiotech said presenting companies included the ASX-listed Amplia, Arovella, Blinklab, Cambium (formerly Regeneus), EBR Systems, Chimeric, Immuron, Imugene, Invion, Neurizon (formerly Pharmaust), Nyrada and Syntara (formerly Pharmaxis).
The organization said the public unlisted and private companies included Atticus Medical, Biomebank, Carina Biotech, Evithé Biotechnology, Fivephusion, Neurotologix, Novapep, Esfam Biotech, Polyactiva, Servatus and Vaxxas.
Ausbiotech said today was “the beginning of Australia’s biggest week in biotechnology” with its conference starting tomorrow at the Melbourne Convention and Exhibition Centre.
Ausbiotech chief executive officer Rebekkah Cassidy said part of the organization’s role was “knowledge sharing and connection building including with the investment community”.
“Our ‘invest’ events help great Australian companies to attract capital while assisting investors in connecting with innovative Australian companies that may offer high-value returns,” Ms Cassidy said.

EXTERNA, WALTER AND ELIZA HALL MEDICAL RESEARCH INSTITUTE

Melbourne's Externa says it raised $11 million in a seed funding to develop "therapies targeting a unique aspect of RNA processing … to treat cancers and other diseases".
Externa said the funding was led by IP Group Australia, with investments from WEHI Ventures, Hostplus Superannuation, as well as Tanarra Capital and the University of Melbourne's Tin Alley Ventures.
The company said the investment would allow it "to advance its unique platform and lead program, which will harness the potential of small molecules to selectively target and modulate RNA processing pathways that are important to disease".
Externa said it was co-founded in 2024 by the Peter MacCallum Cancer Centre's Prof Vihandha Wickramasinghe and the Walter and Eliza Hall's Prof Guillaume Lessene.
The company said its chair was co-founder of Karyopharm Therapeutics Dr Sharn Shacham and Prof Wickramasinghe was its chief scientific officer.
Externa said RNA processing was "a critical biological process that impacts gene expression and ultimately protein production, which is altered in various conditions, including several cancers of high unmet need, and neurodegenerative disorders".
The company said it targeted pathways that modulated RNA with small molecules, to "target critical disease drivers, to provide new therapeutic options that can significantly alter disease trajectories".
Prof Wickramasinghe said the investors "share our vision of harnessing the vulnerability of cancers to modulation of RNA processing".
Externa is a private company.

WALTER AND ELIZA HALL MEDICAL RESEARCH INSTITUTE

The Walter and Eliza Hall Medical Research Institute says it has found measuring the levels of extracellular vesicles in mouse blood may be used to detect cancer.
WEHI said a study with La Trobe University showed "a link between extracellular vesicles and blood vessel damage caused by blood cancers in animal models".
The Institute said the study "observed [extracellular vesicles] inside the bone marrow of live mice for the first time, and found that monitoring the levels of [extracellular vesicles] in the blood could provide direct insight into the level of tissue damage, critical information that may inform ways to better detect and treat diseases".
The study, titled 'In situ visualization of endothelial cell-derived extracellular vesicle formation in steady state and malignant conditions' was published in the journal Nature Communications, with the full article available at: https://bit.ly/3YGzb8J.
WEHI said the results were being used to further study whether extracellular vesicles could be used as a biomarker in detecting acute myeloid leukemia (AML) patients.
The Institute said extracellular vesicles were dispatched by cells to distribute materials like proteins, fats and genetic information to other cells and helped cells communicate when they were "under stress or dying".
WEHI said it hoped to develop new tools and techniques to determine the impact of disease on healthy tissue, and assess disease progression by analyzing patient samples.
Study co-author Dr Georgia Atkin-Smith said that "no other study in the world has been able to achieve this, so it's a huge win for Australia's scientific community".
"In this study, we've shown that the development of leukaemia can degrade healthy blood vessels in the bone marrow," Dr Atkin-Smith said. "Mice with extensive blood vessel damage in their bone marrow had elevated levels of [extracellular vesicles] in their blood, while healthy mice did not … [showing] for the first time, that there is a link between [extracellular vesicles] in the blood and tissue damage during cancer."

POLYACTIVA

Polyactiva says 17 patients in its phase IIa trial of PA5108 for glaucoma show “statistically significant” changes in intraocular pressure (IOP) ($p < 0.0001$).

Last year, Melbourne’s Polyactiva said its 37-patient, open-label, phase IIa clinical study of its PA5108 ocular implant for glaucoma showed it reduced intraocular pressure by more than 20 percent (BD: Nov 1, 2023).

At that time, the company said the primary objectives of the dose-escalation study of its biodegradable implant of latanoprost, or Xalatan, were to show the minimum effective dose of implant to achieve a more than or equal to 20 percent reduction in intraocular pressure at 12 weeks and to assess the safety and tolerability of the implant.

Today, Polyactiva said the trial “met its efficacy and safety endpoints, representing a significant step forward in the company's vision to provide long-term, reliable drug delivery for glaucoma patients”.

The company said 17 of 37 participants were recruited to receive two PA5108 ocular implants, 21 weeks apart, with 15 patients reaching 48 weeks on study.

Polyactiva said that “statistically significant intraocular pressure (IOP) changes from baseline were observed for each mean diurnal measurement at weeks 12, 21, 33 and 42 ($p<0.0001$)”.

The company said clinically meaningful intraocular pressure reductions over 48 weeks were observed, with mean intraocular pressure reductions between 26 percent and 35 percent as well as 94 percent of participants not requiring additional drop therapy over the 48-week treatment period.

Polyactiva said the PA5108 implant was “safe and generally well-tolerated by trial participants and no adverse impact was observed on corneal endothelium following repeat dosing of PA5108 and 48 weeks of monitoring”.

In 2018, the company said Melbourne’s Brandon Capital and Perth’s Yuuwa Capital had provided $16 million to develop its glaucoma implant PA5108, with a seven-patient phase I trial underway (BD: Sep 4, 2018).

At that time, Polyactiva said it had used its proprietary polymer pro-drug technology to develop ocular implants that, when placed in the eye, provided sustained treatment over a six-month period, compared to current glaucoma treatment where patients often need to administer four eye drops daily.

The company said the implant would provide a constant daily therapeutic dose of latanoprost free acid, the active ingredient of common glaucoma treatment Xalatan, for at least 26 weeks.

Polyactiva said the implant had been designed to biodegrade within 90 days after the treatment period and was capable of being administered in an ophthalmologist’s office using a custom-designed administration device.

Today, the company said it hoped to begin late-stage clinical trials under a US Food and Drug Administration investigational new drug application “in early 2025”.

Polyactiva chief executive officer Vanessa Waddell said glaucoma treatments relied “heavily on patient-administered eye drops, but adherence to this regimen is notoriously poor, with studies showing that 40 percent to 90 percent of patients stop using their drops correctly after just one year".

“Polyactiva has developed proprietary manufacturing processes and PA5108 has been successfully transferred to FDA-approved [contract development and manufacturing organizations],” Ms Waddell said.

“Starting materials and intermediates are produced at [good manufacturing practice] and we are on track to achieve commercial scale,” Ms Waddell said.

Polyactiva is a private company.

ANTEOTECH

Anteotech says it has received $3.99 million from the Federal Government's Australian Renewable Energy Agency (ARENA) for its ultra-high silicon anode for electric vehicles.
Anteotech said the funds would be used for a three-year project to develop and commercialize a second generation "ultra-high silicon anode targeting stationary [power] storage markets and ultra-high performance electric vehicles".
The company said the funds would be used to expand its Brisbane facility for "a small-scale industrial roll-to-roll coating line", and the completion of design enhancements and testing, scale up processes and equipment and validation.
Anteotech managing-director David Radford said it was "our second grant this year and represents the execution of our strategy to pursue non-dilutive funding and supplement our internal resources, to fast track new Anteotech products".
Anteotech was up 0.1 cents or four percent to 2.6 cents with 8.0 million shares traded.

PAINCHECK

Painchek says it will file "positive results" from its validation study of its pain management smartphone application to the US Food and Drug Administration.
Earlier this month, Painchek said that it had "completed the majority" of requirements for an FDA de-novo application for its facial pain assessment and monitoring application for smartphones and tablets (BD: Oct 2, 2024).
At that time, the company said it completed its US clinical validation study for the application in July 2024, which involved 105 volunteers at five aged care homes in Iowa and New York, with results in the process of being included in the report.
Today, Painchek said that it was in the process of submitting the validation study data, along with the other required documentation, to the FDA for de novo regulatory clearance, and it expected to complete its submission "in November 2024".
The company said the results were "consistent with other previous observational pain tool studies" but did not disclose the data.
Painchek was up half a cent or 17.2 percent to 3.4 cents with 3.8 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has "positive engagement" from the US Food and Drug Administration for an up-to 300-patient, validation trial of its brain scanner for stroke.
In March, Emvision said it had enrolled its stage two, 180-patient, multi-site study of its 'Emu' portable brain scanner for stroke and stroke mimic patients in emergency departments (BD: May 29, Jun 29, 2023, Mar 27, 2024).
In May, the company said the study confirmed its artificial intelligence-based Emu algorithm could "help answer the clinical question of ischaemia or not" and earlier this month, told Biotech Daily the next step was a validation (pivotal) trial, aimed at supporting FDA approval under the de-novo regulatory pathway (BD: (BD: May 27, Oct 4, 2024).
Today, the company said the trial would be a multi-centre, prospective, diagnostic performance study at a minimum of five stroke centres, with a minimum of three sites in the US, enrolling up-to 300 adult patients with untreated acute suspected stroke unable to receive computed tomography, or magnetic resonance imaging due to contrast allergy.
The company said the primary objective of the study was to show that "sensitivity and specificity of neuro-diagnostic algorithms exceed FDA targets", with secondary objectives including safety, usability, reliability and limit-of-detection.
Emvision fell six cents or three percent to $1.93.

CSL

CSL says its annual general meeting passed all resolutions but with a 26.4 percent first strike against the remuneration report and 23 percent against managing-director shares.
Last month, CSL said investors would vote to grant managing-director Dr Paul McKenzie performance shares valued at $US7,967,237 ($A11,775,239) (BD: Sep 18, 2024).
Today, the company said the remuneration report was opposed by 79,320,436 votes (26.36%), with 221,635,280 votes (73.64%) in favor.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company with sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill.
If passed the directors must stand for re-election within 90 days.
CSL said the approval to issue Dr McKenzie's performance rights faced 69,894,942 votes (23.14%) opposition, with 232,143,090 votes (76.86%) in support.
The company said the remaining resolutions were all passed easily.
According to its most recent notice, CSL had 484,206,562 shares on issue, meaning that the 79,320,436 votes against the remuneration report amounted to about 16.38 percent of the company, sufficient to requisition extraordinary general meetings.
CSL was up 67 cents or 0.2 percent to $292.67 with 711,943 shares traded.

LBT INNOVATIONS

LBT says it has received $952,735 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
LBT said the incentive related to expenditure for the year to June 30, 2024.
LBT was up 0.1 cents or 7.1 percent to 1.5 cents.

MELODIOL GLOBAL HEALTH (FORMERLY CRESO PHARMA)

After the market closed last night, the ASX said that Melodiol was removed from the official list under Listing Rule 17.12.
In August, the ASX said Melodiol was suspended at the close of trading on Wednesday, 28 August 2024 under Listing Rule 17.3.1 after it had determined the company was unable or unwilling to comply with, or had broken, Listing Rules 2.6 and 16.4, relating to fees (BD: Aug 29, 2024).
Today, the ASX said that Melodiol was advised it would be removed for the Official List if the breaches were not rectified by October 28, 2024.
The ASX said that "having regard to the continued breaches of the ASX Listing Rules by [Melodiol], ASX is of the opinion that [Melodiol] is unable or unwilling to comply with the Listing Rules and that it is appropriate to remove [it] from the Official List".
Melodiol last traded at 0.1 cents.

LITTLE GREEN PHARMA

Bianca Hope Rinehart as trustee of the Hope Margaret Hancock Trust has ceased her substantial holding in Little Green Pharma as a related party of Hancock Prospecting.
On Monday, Perth's Georgina Hope Rinehart with Hancock Prospecting Pty Ltd said she had ceased her substantial shareholding in Little Green, with Biotech Daily calculating she retained about 0.63 percent (BD: Oct 28, 2024).
Little Green was unchanged at 14 cents.

INHALERX

Perth's Pyxis Holdings Pty Ltd says it has increased its substantial shareholding in Inhalerx from 8,909,441 shares (6.61%) to 16,830,286 shares (7.97%).
In a notice signed by director CK Teo, Pyxis Holdings said with Pyxis Equities Pty Ltd it bought shares between December 15, 2021 and October 21, 2024 and converted 3,630,286 convertible notes on October 24, 2024 for $83,497, or 2.3 cents a share.
Inhalerx was unchanged at three cents.

ACTINOGEN MEDICAL

Actinogen says it has appointed the US-based Andrew Udell as its chief commercial officer, effective from October 15, 2024.
Actinogen said Mr Udell had been an executive at Calliditas Therapeutics and previously Neuroderm's head of commercial for North America.
The company said Mr Udell had "significant experience working in depression, Parkinson's disease and other large central nervous system markets".
Actinogen said Mr Udell held a Bachelor of Science from Bethlehem, Pennsylvania's Lehigh University and a Master of Business from Mansfield's University of Connecticut.
Actinogen fell 0.15 cents or 5.9 percent to 2.4 cents with 14.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has appointed Rachel Duggan as its head of sales for Europe, the Middle East and Africa, effective from October 29, 2024.
Oncosil said Ms Duggan was returning to the company "after a brief period pursuing other opportunities" and had more than 15 years of experience in medical devices and pharmaceuticals, including for Serb Pharmaceuticals and Boston Scientific.
Oncosil fell 0.1 cents or 9.1 percent to one cent with 10.6 million shares traded.