Biotech Daily

Wednesday February 5, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CURVEBEAM UP 30%; MEDICAL DEVEL DOWN 10%**

*** WEHI: 'EYE MAPPING LINKS RETINA THINNING TO DISEASES'**

*** HUDSON STARTS 1st E.V. TRIAL FOR CROHN'S, IBD**

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*** CYNATA: 'IPSC STEM CELLS BEAT OTHER STEM CELLS', IN VITRO**

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*** AUSBIOTECH FEBRUARY VICTORIA BIOCHEERS**

MARKET REPORT

The Australian stock market was up 0.51 percent on Wednesday February 5, 2025, with the ASX200 up 42.9 points to 8,416.9 points. Sixteen of the Biotech Daily Top 40 companies were up, 15 fell, seven traded unchanged and two were untraded.

Curvebeam was the best, up 3.5 cents or 30.4 percent to 15 cents, with 3.6 million shares traded. Orthocell was up 12.2 percent; Clarity climbed 10.1 percent; Syntara was up 8.3 percent; Alcidion rose 7.25 percent; Actinogen was up 6.9 percent; Proteomics improved 5.8 percent; Cynata and Neuren were up more than four percent; Avita, Medadvisor and Prescient rose two percent or more; Immutep, Opthea and Pro Medicus were up more than one percent; with Clinuvel and Nanosonics up by less than one percent.

Medical Developments led the falls for the second day in a row, down 7.5 cents or 10.2 percent to 66 cents, with 402,400 shares traded. Universal Biosensors lost 9.6 percent; Mesoblast was down 5.3 percent; Amplia and Cyclopharm fell more than four percent; Aroa and EBR were down more than three percent; Dimerix and Impedimed shed two percent or more; CSL, Paradigm and Telix were down more than one percent; with Cochlear, Emvision, Genetic Signatures, Polynovo, Resmed and SDI down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says a study mapping more than 50,000 eyes has linked “retinal thinning to a range of diseases” using artificial intelligence (A.I.).

WEHI said the study used artificial intelligence to create 50,000 maps with measurements at more than 29,000 locations in the retina, identifying “retinal thinning relating to 294 genes that play an important role in disease”.

The Institute said it had developed the “most detailed maps of the retina ever produced”.

WEHI said the maps linked retinal thinning to a range of diseases as well as identifying genetic factors that influenced retinal thickness, which opened “new possibilities for using routine eyecare imaging as a tool to screen for and manage diseases, much like mammograms have for breast cancer”.

The Institute said the research, with UK Biobank, the University of Washington, Moorfields Eye Hospital and the University College London, was funded by the Lowy Medical Research Institute, and reinforced oculomics as a non-invasive way for predicting and diagnosing diseases, including type 2 diabetes, dementia and multiple sclerosis.

WEHI said the study, titled “Multi-omic spatial effects on high-resolution AI-derived retinal thickness” was published in the journal article Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-024-55635-7.

WEHI lead researcher Dr Vicki Jackson said the findings broadened retinal imaging as a doorway into the central nervous system, to help manage disease.

“We’ve shown that retinal imaging can … [detect] associations with neurological disorders like multiple sclerosis and many other conditions,” Dr Jackson said. “This research underscores the potential for retinal thickness to act as a diagnostic biomarker to aid in detecting and tracking the progression of numerous diseases.”

THE HUDSON INSTITUTE OF MEDICAL RESEARCH

The Hudson Institute says it has begun a 15-participant, trial of extracellular vesicles (EVs) for Crohn’s disease and ulcerative colitis, or inflammatory bowel disease (IBD).

The Hudson said it used extracellular vesicles, or membrane-bound particles related to cell communication and transportation, derived from human amniotic epithelial cells to “deliver the same benefits as stem cell treatments at a greatly reduced cost”.

The Institute said the trial was its first in-human study of the drug candidate and was being conducted at Melbourne’s Monash Health in collaboration with Monash University and would be the “first use of [extracellular vesicle] therapy for Crohn’s disease worldwide and the second human [extracellular vesicle] trial in Australia”.

The Hudson said the trial would administer extracellular vesicles to 15 participants with complex refractory Crohn’s perianal fistulas and assess the safety of the vesicles and whether it was “effective in healing perianal fistulae and improving patient quality-of-life”.

The Institute said the trial was being run by its spin-off company Exosome Biosciences Pty Ltd, which was developed to commercialize its intellectual property.

The Hudson Institute said the trial was funded by a $1.5 million grant from Brandon Biocataylst and the Federal Government’s Medical Research Future Fund.

Monash Health gastro-enterologist and trial lead Dr Charlotte Keung said the goal was “to increase treatment accessibility for a debilitating condition without other options, by developing a therapy with significant manufacturing cost reductions and improved commercialization potential”.

Dr Keun said extracellular vesicles derived from human amniotic epithelial cells as a therapy reduced “the significant manufacturing, cold chain logistics, clinical administration and cost limitations associated with live cell treatment.”

AUDEARA

Audeara says it has a $US917,000 ($A1,480,000) second mass production order from the Norwell, Massachusetts-based Avedis Zildjian for its hearing impairment devices.
Last year, Audeara said it had a $2.1 million maiden mass production order from Avedis Zildjian for its hearing devices (BD: Feb 27, 2024).
Today, the company said the timing and scale of any further orders would "be determined by the product's market performance, with Audeara remaining focused on leveraging its proprietary technology for long-term commercial success".
Audeara said the revenue from the order would "be recognized in accordance with accounting policies after shipment of the products".
Audeara managing-director Dr James Fielding said the follow-up purchase order "marks a validation of the commercial application of Audeara's healthy hearing technology when incorporated into market-leading products with global commercial partners".
Dr Fielding said Audeara was showing the potential of its technology division "to scale across multiple addressable market segments".
Audeara was up 0.8 cents or 21.6 percent to 4.5 cents with 1.2 million shares traded.

CYNATA THERAPEUTICS

Cynata says in-vitro studies show its IPSC-derived mesenchymal stem cells (MSC) outperform donor tissue-derived MSCs in a range of functions.
Cynata said the studies by Melbourne's Monash University compared the proteins released by mesenchymal stem cells, called 'secretomes' derived from either induced pluripotent stem cells or a donor tissue source, including bone marrow, adipose tissue or umbilical cord.
The company said the study, titled 'Proteomic profiling of iPSC and tissue-derived MSC secretomes reveal a global signature of inflammatory licensing' was co-authored by Cynata managing-director Dr Kilian Kelly, published in NPJ Regenerative Medicine and available at: https://www.nature.com/articles/s41536-024-00382-y.
Cynata said IPSC-derived and umbilical cord-derived mesenchymal stem cells "resulted in significantly faster wound closure than bone marrow or adipose tissue-derived MSCs".
The company said its IPSC-derived stem cells showed a greater ability to balance the immune system than mesenchymal stem cells derived from any donor tissue source.
Cynata said the studies showed its IPSC-derived cells had less variability and could release more unique proteins compared to donor tissue-derived stem cells.
The company said its IPSC-based mesenchymal stem cells and umbilical cord-derived stem cells showed features consistent with younger cells, suggesting a sustained ability to avoid ageing.
Cynata said the "strong regenerative potential of IPSC-derived and umbilical cord-derived MSCs but not bone marrow or adipose tissue-derived MSCs, was maintained under both resting and inflammatory conditions".
Dr Kelly said the studies provided "further support for our view that our IPSC-based Cymerus platform provides the ideal means of producing MSC with a high level of potency and functionality, in a consistent and scalable manner".
"It is particularly notable that Cynata's IPSC-derived MSC displayed very impressive immune-modulatory and wound-healing properties compared to MSC from other sources," Dr Kelly said. "These findings have clear relevance to our product candidates in acute graft-versus-host disease and diabetic foot ulcers, both of which have already shown very promising safety and efficacy outcomes in completed clinical trials."
Cynata was up one cent or 4.3 percent to 24.5 cents.

LITTLE GREEN PHARMA

Little Green Pharma says its acquisition of Health House Australia Pty Ltd and its medical marijuana distribution business is scheduled to complete today.

Last year, Little Green said it would acquire the Perth-based marijuana distributor Health House Australia Pty Ltd for $1.25 million in cash (BD: Dec 20, 2024).

The company said Health House had been its long-term distribution partner and generated about $7.5 million in annual revenue.

Little Green said it would acquire Health House's property, plant and equipment, inventory and intellectual property.

The company said the acquisition scheduled for later today following satisfaction of standard closing conditions and provision of deliverables and that it would "work closely with Health House's team to ensure a seamless transition, including the integration of operations, systems, and personnel".

Little Green chief executive officer Paul Long said that the "acquisition was a significant step in strengthening our supply chain and margin capture capacity".

"The integration of Health House into Little Green's operations enhances our distribution portfolio and opportunities for synergies, positioning us strongly as the industry continues to consolidate," Mr Long said.

Little Green was up one cent or 9.1 percent to 12 cents.

BLINKLAB

Blinklab says it has opened the first US site in its 1,000-children, registrational trial of its smartphone platform autism diagnostic at Dayton, Ohio's Primed Clinical Research.

Last year, Blinklab said the US Food and Drug Administration confirmed the study design needed for a 510(k) clearance of its autism diagnostic (BD: Dec 19, 2024).

Today, the company said Primed Clinical Research LLC was the first site selected to conduct a 100-patient, initial phase of the trial, with first participants expected to be enrolled "early this month".

Blinklab said Primed's paediatric division provided primary care for 30,000 children in Southwest Ohio.

Blinklab chief executive officer Dr Henk-Jan Boele sad the company was "very excited to announce the official initiation of our FDA work".

"By partnering with the best clinical institutions, Blinklab is committed to delivering breakthrough, accessible [artificial intelligence]-driven technology that is expected to transform early autism detection and provide families with faster, more reliable diagnoses," Dr Boele said.

Blinklab was up 2.5 cents or 6.25 percent to 42.5 cents with 3.5 million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says the US Patent and Trademark Office has granted it a patent protecting the method of use of its NUZ-001 for amyotrophic lateral sclerosis.

According to the US Patent and Trademark Office website, the patent was titled 'Use of aminoacetonitrile compounds for the treatment of infection and disease' and the lead inventor was former Pharmaust chair Dr Roger Aston (BD: May 9, 2024).

Today, Neurizon said the patent would protect its intellectual property until 2039.

Neurizon was up two cents or 16 percent to 14.5 cents with 1.2 million shares traded.

QBIOTICS GROUP

Qbiotics says the UK Veterinary Medicines Directorate has approved the extended use of its tigilanol tiglate, or Stelfonta, as a treatment of cancer in dogs.

Qbiotics said veterinarians would be able to prescribe Stelfonta to treat mast cell tumors if they do not consider surgery the best option, and that previously Stelfonta was restricted to the treatment of non-resectable mast cell tumors.

In 2020, Qbiotics said the European Medicines Agency registered its small molecule, tigilanol tiglate, or Stelfonta, as a drug for mast cell tumors in dogs (BD: Jan 20, 2020).

The company said the approval covered the use of Stelfonta in dogs with cutaneous mast cell tumors located anywhere and subcutaneous mast cell tumors "located at or distal to the elbow or the hock".

Qbiotics said the extended marketing authorization was applicable in Great Britain, meaning England, Scotland and Wales.

Qbiotics managing-director Stephen Doyle said the company was "delighted with the … approval to expand Stelfonta's indication for Great Britain".

"This milestone provides veterinarians with greater scope to offer a patient centric approach to cancer treatment," Mr Doyle said. "Ultimately more dogs in Great Britain are now eligible to receive Stelfonta, an effective non-surgical mast cell tumor treatment."

"This expansion not only strengthens Stelfonta's market presence but also aligns with our broader mission to elevate patients' quality of life worldwide, while treating challenging conditions," Mr Doyle said. "As we continue to advance tigilanol tiglate in phase II human clinical trials, we remain committed to developing cutting-edge solutions that improve health outcomes for people and animals."

Qbiotics is a public unlisted company.

GENETIC TECHNOLOGIES

Genetic Technologies administrators say they have reconvened a second creditors meeting to decide the company's future.

Last year, FTI Consulting said Ross Blakeley and Paul Harlond were appointed as voluntary administrators of Genetic Technologies (BD: Nov 20, 2024).

Today, the administrators said the meeting would vote to execute a deed of company arrangement, whether the administration should end, or the company be wound up.

The administrators said that as the company was "insolvent with no funds to pay its debts and no proposal for a [deed of company arrangement] has been received, the administrators consider it is in creditors' interests for the company to be wound up".

The meeting will be held online on February 12, 2025 at 11.30am (AEDT).

Genetic Technologies was in a suspension and last traded at 3.9 cents.

INHALERX

Inhalerx says its extraordinary general meeting will vote to approve the appointment of related party Ingenu CRO Pty Ltd as its contract research organization.

Inhalerx said Ingenu was a subsidiary of substantial shareholder Cannvalate Pty Ltd and that Inhalerx chief executive officer Darryl Davies and medical advisor Dr Sud Agarwal were both directors of Ingenu and Cannvalate.

The company said at no stage were Ingenu, Cannvalate, Dr Agarwal or Mr Davies involved in any discussion of the tender and had no involvement in the selection.

The meeting will be held online on March 6, 2025 at 4pm (AEDT).

Inhalerx was untraded at 2.2 cents.

OPTHEA

Regal Funds Management Pty Ltd says it has reduced its substantial shareholding from 404,818,462 shares (32.88%) to 392,175,492 shares (31.852%).
The Sydney-based Regal Funds said that it bought and sold shares between July 29, 2024 and January 31, 2025, with the single largest sale 27,000,000 shares on September 23 for $19,710,000, or 73 cents a share.
Opthea was up two cents or 1.85 percent to $1.10 with 7.6 million shares traded.

ARGENT BIOPHARMA

Argent says non-executive director Layton Mills “has tendered his resignation, … effective upon the appointment of a suitable Australian replacement”.
Argent said it was “currently in advanced discussions with the several highly qualified candidates and will provide an update to shareholders as soon as an appointment is finalized”.
Argent was unchanged at 14 cents with 60 shares traded.

CORRECTION: AUSBIOTECH, MTP CONNECT

Last night’s article on Ausbiotech and MTP Connect calling for a national life sciences strategy and council incorrectly said Ausbiotech was “Federally-funded”.
Ausbiotech is member funded.
The error was made by the Tuesday sub-editor who has been terminated.

AUSBIOTECH

Ausbiotech says it will host its Victoria Biocheers event on February 27, 2025 in partnership with the Commonwealth Scientific and Industrial Research Organisation.
Ausbiotech said the event was open to members and non-members in the life sciences, including therapeutics, medical technology, digital health, and agri-biotech sectors.
The organization said the informal networking event provided “an opportunity to catch-up with friends and colleagues, share ideas, build relationships and make new connections in Victoria's thriving biotechnology community”.
Ausbiotech said the event was free for members and $100 for non-members, with the venue, drinks and food to be supplied by host partner CSIRO.
The organization said the event would be held at the central reception of CSIRO’s research institute on Research Way in Clayton from 5pm to 7.30 pm (AEDT), with registration available at: https://bit.ly/3Q13LVs.