Biotech Daily

Monday March 31, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: COMPUMEDICS UP 3%; PARADIGM DOWN 10%**

*** MESOBLAST 1st RYONCIL US PATIENTS TREATED; CMS COVERAGE**

*** OPTHEA 2nd PHASE III TRIAL MISSES ENDPOINT; ENDS OPT-302 TRIALS**

*** ANTERIS: 100 TREATED, 65 SHOW DURAVR THV BENEFIT**

*** ARCHER, HYLID AT-HOME BIOCHIP KIDNEY DISEASE TEST**

*** INOVIQ, PETER MAC CAR-EXOSOME PRE-CLINICAL CANCER STUDIES**

*** ECHO IQ: SCIMAGE, MEDAXIOM TAKE ECHOSOLV TO 36 US CLINICS**

*** CURVEBEAM FILES PATIENT SCANS, DATA TO VENDOR**

*** NEUROTECH NTI164 EU ORPHAN DRUG STATUS FOR RETT SYNDROME**

*** ZELIRA TAKES $1m AT-THE-MARKET FACILITY**

*** NYRADA DOSES 1st PHASE I NYR-BI03 COHORT**

*** MEDADVISOR REQUESTS 'PLACEMENT, UPDATE' TRADING HALT**

*** BLINKLAB REQUESTS 'STUDY RECRUITMENT' TRADING HALT**

*** ALTERITY EGM 19% OPPOSE PLACEMENT**

*** ALGORAE RECEIVES $451k FEDERAL R&D TAX INCENTIVE**

*** MACQUARIE TAKES 5% OF RECCE**

*** PATRYS LOSES 18-YEAR DIRECTOR MICHAEL STORK**

*** OPTISCAN PROMOTES DARIUS OOI TO CFO; WILLIAMSON, WARD**

*** ANTEOTECH LOSES CHAIR EWEN CROUCH, KATHERINE WOODTHORPE**

*** PETER KOPANIDIS REPLACES CANN DIRECTOR ROBERT BARNES**

*** TRYPTAMINE CFO HAMISH GEORGE REPLACES CO SEC DAVID FRANKS**

MARKET REPORT

The Australian stock market lost 1.74 percent on Monday March 31, 2025, with the ASX200 down 138.6 points to 7,843.4 points.

Just five of the Biotech Daily Top 40 companies were up, 26 fell, seven traded unchanged and two were untraded. All four Big Caps were down.

Compumedics was the best of the five, up one cent or three percent to 34.5 cents, with 81,751 shares traded.

Emvision, Medical Developments and Resonance rose more than two percent; with SDI up by 1.2 percent.

Paradigm led the falls, down 3.5 cents or 9.6 percent to 33 cents, with two million shares traded.

Actinogen lost 8.6 percent; 4D Medical was down 6.9 percent; Avita, Clarity and Orthocell were down five percent or more; Nova Eye, Polynovo, Starpharma and Telix fell more than four percent; Alcidion, Aroa, Dimerix, Immutep, Imugene and Mesoblast were down three percent or more; Amplia, Cynata, EBR, Impedimed, Neuren and Prescient shed more than two percent; Clinuvel, Cochlear, CSL, Nanosonics, Pro Medicus, Proteomics and Resmed were down one percent or more; with Cyclopharm down by 0.9 percent.

MESOBLAST

Mesoblast says the first US steroid-refractory acute graft versus host disease (GvHD) patients will receive Ryoncil this week and it has US Medicaid coverage.

Last year, Mesoblast said the US Food and Drug Administration approved Ryoncil, or remestemcel-L, for GvHD in children aged two months and older (BD: Dec 19, 2024).

Last month, the company said Ryoncil was the first therapy for pediatric patients two months and older in GvHD and would cost $US194,000 ($A308,087) wholesale per intravenous infusion; and last week, said Ryoncil was available purchase in the US through its online patient hub (BD: Feb 27, Mar 27, 2025).

Today, Mesoblast said it entered into the Medicaid National Drug Rebate Agreement (NDRA) with the US Centers for Medicare & Medicaid Services (CMS) for Ryoncil.

The company said the NDRA agreement meant the US Government provided “inpatient and outpatient access for a treatment course of Ryoncil to the approximately 40 percent of US children covered by Medicaid”.

Mesoblast said the remaining US GvHD patients would be covered by private insurance and that individual states had “the option to immediately cover Ryoncil, with mandatory coverage commencing July 1, 2025”.

Today, chief executive Prof Silviu Itescu said the company was “delighted to be commencing treatment with Ryoncil for children suffering with … GvHD and are proud that the product is available to all children in the US irrespective whether they have private insurance or Medicaid”.

“This is a significant commercial achievement by our team and partners who are driven by an overwhelming desire to help children and their families faced with this devastating disease,” Prof Itescu said.

Mesoblast fell six cents or three percent to $1.96 with 8.6 million shares traded.

OPTHEA

Opthea says it will discontinue its wet age-related macular oedema (AMD) trials after its Shore phase III trial of OPT-302 with ranibizumab missed its primary endpoint.

In 2019, Opthea said a 366-patient, phase IIb trial of OPT-302, or sozinibercept, for wet AMD met its primary endpoints with statistical significance between the higher dose 2.0mg OPT-302 with ranibizumab at 24 weeks compared to both a 0.5mg OPT-302 with ranibizumab and ranibizumab alone (p = 0.0107) (BD: Aug 7, 2019).

Last year, the company said it had enrolled all 1,984 patients in its two, phase III trials evaluation the safety and efficacy of OPT-302 with either ranibizumab (Shore) or aflibercept (Coast), compared to ranibizumab or aflibercept alone (BD: May 28, 2024).

Last week, Opthea said its 993-patient, phase III Coast trial of OPT-302 with aflibercept for wet AMD "failed to meet [its] primary endpoint" and it could be required to pay its Development Funding Agreement (DFA) investors amounts that would have a material adverse impact on its solvency (BD: Mar 24, 2025).

Today, the company said the phase III Shore trial of OPT-302 with ranibizumab "did not meet its primary endpoint of mean change in best corrected visual acuity (BCVA) from baseline to week 52".

Opthea said following the negative results from the 'Coast' phase III trial, it "determined that the most appropriate course of action for wet AMD patients, shareholders and other stakeholders was to accelerate the 'Shore' trial topline data readout, including in consultation with its DFA investors".

The company said following negative results from both phase III trials it had agreed with the DFA investors "to discontinue the development of sozinibercept in wet AMD with immediate effect, and that this decision did not constitute a termination event under the DFA resulting in any amount payable by Opthea".

Opthea said that in the 'Shore' trial, 328 patients were dosed with OPT-302 and ranibizumab every four weeks and 326 patients were dosed every eight weeks achieved a mean change in BCVA of 13.3 and 12.6 letters from baseline to week 52, respectively, compared to 14.3 letters in the 331 patients dosed with ranibizumab alone (p = 0.32 and 0.09, respectively).

The company said the OPT-302 combination therapy was well tolerated.

Opthea said it remained possible that under the DFA it might be required to pay a multiple of the amount funded by the DFA investors which "would have a material adverse impact on the solvency of the company".

The company said that termination could "be triggered by a range of events, including, among other things, Opthea's insolvency, in which case Opthea would be obligated to pay a multiple of the amounts funded by the DFA Investors".

Opthea said that had about $US100 million ($A160 million) in unaudited cash and cash equivalents at the end of this month.

Opthea chief executive officer Dr Frederic Guerard said the company was "disappointed that 'Coast' and 'Shore' did not demonstrate the improvements in vision with sozinibercept combination therapy compared to standard of care that we had hoped for".

"In light of the phase III clinical trial results, the company and the DFA Investors will continue to discuss this matter in good faith, and we will provide updates on this matter in the future," Dr Guerard said.

Separately, the ASX said Opthea's financial condition was "not adequate to warrant the continued quotation of its securities and therefore is in breach of Listing Rule 12.2".

The ASX said Opthea would remain in a suspension until it was "satisfied that Opthea is in compliance with the Listing Rules".

Opthea last traded at 60 cents.

ANTERIS TECHNOLOGIES GLOBAL CORP

Anteris says Duravr has been used on more than 100 patients, with 65 patients meeting safety and efficacy endpoints including haemodynamic benefit after 30 days.

Last year, Anteris said 30-day results from its 28-patient, first human study and 15-patient, US early feasibility study showed its Duravr transcatheter heart valve increased orifice area and Doppler velocity index and reduced mean pressure gradient (BD: Mar 12, 2024).

Today, the company said it had treated more than 100 patients with severe aortic stenosis, including first time stenosis cases, valve-in-valve patients and patients with complex anatomies like bicuspid aortic valve.

Anteris said no valve or cardiovascular-related mortality had been recorded after a year of treatment and it was “on track” to begin a pivotal trial by October 2025, pending US Food and Drug Administration approval.

Anteris chief medical officer Dr Chris Meduri said “the excellent haemodynamic performance we are seeing is noteworthy in that it shows that Duravr has the potential to restore natural heart valve function and thereby redefine what success looks like in the treatment of aortic stenosis”.

Anteris chair Wayne Paterson said the results were “a clinical milestone for the company and its investors”.

“Not only have we crossed the threshold of having treated over 100 patients, but we have achieved results that are clinically relevant and significantly differentiated to current therapies,” Mr Paterson said.

Anteris fell 92 cents or 12.4 percent to $6.50.

ARCHER MATERIALS

Archer says with the Ottawa, Ontario-based Hylid Diagnostics it will develop an at-home test for chronic kidney disease using its Biochip.

Archer said Hylid specialized in medical devices for at-home testing of blood samples in North America and Europe and that it would use its potassium sensing Biochip with Hylid’s blood haemolysis sensor technology to develop a prototype system.

Last year, the company said it developed a computer micro-chip to detect the electronic signals from genetic sequence reactions using a single liquid sample, enabling the potential detection of multiple diseases (BD: Jan 23, 2024).

Later, the company said it had designed a smaller version of its Biochip for applications in biotechnology, began experiments to detect and monitor chronic kidney disease by detecting potassium and miniaturized the graphene field effect transistor (gFET) Biochip by a further 97 percent (BD: Aug 27, Nov 7, 2024).

Today, Archer said Hylid would first produce a stand-alone haemolysis sensor that when integrated with its Biochip would meet blood-potassium measurement accuracy requirements.

The company said that it would then work with Hylid to design and manufacture an “integrated cartridge system suitable for early-stage clinical testing and volume production”.

Archer chief executive officer Simon Ruffell said Hylid’s technology aligned well with the company’s “goal of developing a biosensor device for the at-home testing of chronic kidney disease”.

“Hylid staff have significant industry experience in sensing, diagnostics, design, and manufacturing at leading companies such as Siemens and Alere (now Abbott),” Mr Ruffell said.

Archer was up 1.5 cents or five percent to 31.5 cents.

INOVIQ

Inoviq says Melbourne's Peter MacCallum Cancer Centre will conduct in-vitro and in-vivo studies of its chimeric antigen receptor (CAR)-exosome therapy for solid tumors.
Inoviq said the Peter MacCallum Clinic would provide contract research services, with the first study to involve in-vitro research evaluating the tumor killing activity of Car T-cell and CAR natural killer (NK) cell derived exosomes in triple negative breast cancer.
The company said it would pay costs for the study, which it expected to be completed by October 2025, with additional to evaluate the safety, dosing and efficacy of CAR-exosomes for breast cancer in mice, which were expected to be completed by next year.
Inoviq chief executive officer Dr Leearne Hinch said the collaboration was "an important step forward in our mission to revolutionize cancer treatment".
"[Peter MacCallum's] cell therapy expertise and access to … infrastructure will accelerate the development of our CAR-exosome therapy for breast cancer," Dr Hinch said.
"Achieving in-vivo efficacy in a [triple negative breast cancer] mouse model will be a major milestone for our CAR-exosome program … bringing us closer to phase I clinical studies."
Inoviq was unchanged at 40.5 cents.

ECHO IQ

Echo IQ says it has deals with Scimage and Medaxiom to use its Echosolv for aortic stenosis (AS) at 36 affiliated hospitals and cardiology practices in the US.
Echo IQ said the San Jose, California-based Scimage was "[an internet] cloud and integrated workflow management platform with over 1,200 users, specializing in the collation of medical images and secure, real-time access to patient information'.
The company said the Jacksonville, Florida-based Medaxiom was "an American College of Cardiology company and the cardiovascular community's premier source for organizational performance solutions".
Echo IQ said it was in discussions with Scimage to extend the availability of its artificial intelligence (A.I.)-based Echosolv to additional cardiology practices.
The company did not disclose the commercial terms of the agreements.
Echo IQ chief executive officer Dustin Haines said the partnership was "a pivotal milestone in our mission to transform cardiovascular diagnostics in the US".
Echo IQ fell 1.5 cents or 5.2 percent to 27.5 cents with 7.3 million shares traded.

CURVEBEAM A.I.

Curvebeam says it has submitted patient scans and validation data to an undisclosed "key vendor" for its Hirise weight bearing computed tomography scanner.
Last year, Curvebeam said it had filed six patient datasets comparing its Hirise imaging device with standard computed tomography (CT) to be validated with a vendor's robotic surgical system (BD: Nov 19, 2024).
Today, the company said it submitted scans from its artificial intelligence (A.I.)-based Hirise and scans from multi-detector computed tomography (MDCT) showing Hirise images "meeting or exceeding the MDCT metrics that were used as a control".
Curvebeam said it submitted to the vendor "further validation data and substantive accompanying documents, including updated instructions for use to include Hirise".
The company said it was "confident" the submission met the requirements to complete validation, and was awaiting the vendor's review and conclusion, and would advise the market when it had a further update.
Curvebeam was unchanged at 12 cents with two million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has European Commission orphan drug designation for its marijuana-based NTI164 as a treatment of Rett syndrome.
Neurotech said the status meant it could receive development incentives including 10 years of market exclusivity in the European Union, reduced regulatory fees, access to research funding and protocol assistance from the European Medicines Agency.
Last year, the company said the US Food and Drug Administration granted NTI164 orphan drug designation for Rett Syndrome, a rare severe neurodevelopmental disorder that primarily affects girls and causes a progressive loss of motor and communication skills, leading to significant lifelong challenges (BD: Nov 26, 2024).
Today, Neurotech managing-director Dr Anthony Fillippis said the designation was "another powerful validation of our therapeutic approach".
"This decision further strengthens our efforts to bring NTI164 to children and families living with Rett syndrome, a community with significant unmet need and no approved therapies in Europe," Dr Fillippis said.
Neurotech was up 0.2 cents or 6.45 percent to 3.3 cents.

ZELIRA THERAPEUTICS

Zelira says it has a $1 million at-the-market facility with Melbourne's Securities Vault Pty Ltd with no interest in exchange for 550,000 shares at no cost.
Zelira said the agreement allowed it to access up-to $1 million by issuing shares to Securities Vault and had a maturity date of March 30, 2026 which could be extended by mutual agreement.
The company said it would issue 550,000 shares to Securities Vault at no cash consideration, equal to 4.85 percent of its issued capital.
Zelira fell 0.25 cents or 2.3 percent to 10.75 cents.

NYRADA

Nyrada says it has dosed the first cohort of eight participants in its 40-volunteer, phase I trial of intra-venous NYR-BI03 for traumatic brain injury and stroke.
Last year, Nyrada said it completed pre-clinical studies (BD: Oct 16, 2024).
Last month, the company said it had ethics approval for the double-blind, randomized, placebo-controlled trial studying the safety of NYR-BI03 in healthy volunteers, with dosing expected "by the end of March 2025" (BD: Feb 7, 2025).
Today, Nyrada said six participants were dosed with an infusion of NYR-BI03 over three hours and two participants with placebo.
The company said the safety review committee would assess safety and pharmaco-kinetic data after each completed cohort, with subsequent dose cohorts only able to proceed after favorable review and approval by the committee.
Nyrada said final data readouts were expected by October 2025.
Nyrada fell 0.3 cents or 2.7 percent to 10.7 cents.

MEDADVISOR

Medadvisor has requested a trading halt pending an announcement "in relation to a capital raising by way of a placement and an update on the strategic review".
Trading will resume on April 2, 2025, or on an earlier announcement.
Medadvisor last traded at 11 cents.

BLINKLAB

Blinklab has requested a trading halt pending an announcement “regarding recruitment for the [US Food and Drug Administration] regulatory study”.
Trading will resume on April 2, 2025, or on an earlier announcement.
Blinklab last traded at 38.5 cents.

ALTERITY THERAPEUTICS

Alterity says its extraordinary general meeting passed all resolutions with up-to 19.36 percent against the ratification of the issue of 1,165,841,830 placement shares.
Last month, Alterity said it had “commitments” to raise $40.0 million in a placement at 1.1 cents a share, with one attaching option for every share issued (BD: Feb 10, 2025).
Today, the company said the ratification of the prior issue of shares was opposed by 92,513,308 votes (19.36%), with 385,444,309 votes (80.64%) in favor.
Alterity said the issue of shares at 1.29 cents each was opposed by 11.66 percent of the meeting and the issue of shares and options to unrelated investors and three directors had between 3.42 percent and 14.93 percent opposition.
The company said votes to refresh and amend its 2004 ASX plan and 2018 ADS plan were opposed by 97,974,583 votes (9.48%) and 95,983,783 votes (9.28%), respectively.
According to its most recent filing, Alterity had 6,656,848,880 shares on issue, meaning that the 97,974,583 votes against amending the ASX plan amounted to about 1.47 percent of the company, not sufficient to call extraordinary general meetings.
Alterity was unchanged at 0.9 cents with 11.0 million shares traded.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has received $451,359 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Algorae said the incentive related to expenditure for the two years to June 30, 2024.
Algorae was up 0.05 cents or 10 percent to 0.55 cents.

RECCE PHARMACEUTICALS

Sydney’s Macquarie Group says it has become a substantial shareholder in Recce with 12,242,076 shares, or 5.28 percent of the company.
Macquarie Group said that between November 27, 2024 and March 26, 2025 it bought and sold shares at prices ranging from 32 cents to 54 cents a share.
Recce was unchanged at 36 cents.

PATRYS

Patrys says 18-year non-executive director Michael Stork will retire, effective from today.
Patrys said Mr Stork joined the board in 2007, was its longest serving member, held more than 98,000,000 shares and had “played a major role in the development of the company”.
Patrys chief executive officer Dr James Campbell said Mr Stork had “been an outstanding director of Patrys for a sustained period, and his insights and intellect have guided and shaped the governance and oversight of our company”.
“On behalf of the board, I would like to extend my gratitude to Mr Stork, and to wish him well in his retirement,” Dr Campbell said.
Patrys was unchanged at 0.2 cents.

OPTISCAN IMAGING

Optiscan says Darius Ooi has been promoted to chief financial officer, with Belinda Williamson appointed chief commercial officer and Jessica Ward head of US operations.
Optiscan said chief operating officer Brendan Fafiani had “decided to step down from this role to pursue other opportunities”.
The company said its finance manager Mr Ooi had been with the company for nearly three years and had previously worked at a “large multinational medical device company”.
Optiscan said Ms Williamson had worked as a sales manager at Olympus Medical and Johnson & Johnson Medical and previously held sales and marketing roles at Guidant Corp, Boston Scientific, Bard Australia and Zimmer Australia.
The company said Ms Ward would be the US-based director of clinical and regulatory affairs, following the departure of Nicole Williams and Ken Lock.
Optiscan said Ms Ward would initially focus on its clinical trials for US Food and Drug Administration clearance of its surgery and pathology imaging products.
The company said that following the executive changes it would “be better placed to both successfully deliver on its stated transformation, clinical and regulatory strategies, and develop a number of exciting products currently in the pipeline”.
Optiscan was up half a cent or 3.7 percent to 14 cents.

ANTEOTECH

Anteotech says chair Ewen Crouch and non-executive director Dr Katherine Woodthorpe will retire, effective from April 14, 2025.
In 2022, Anteotech said it had appointed Ewen Crouch as its non-executive chair, to succeed Dr Jack Hamilton (BD: Apr 21, 2022).
Today, the company said it would announce its replacement chair “in due course”.
Anteotech fell 0.1 cents or 7.7 percent to 1.2 cents with 16.2 million shares traded.

CANN GROUP

Cann says Peter Kopanidis will replace retiring non-executive director Robert Barnes, effective from March 31, 2025.
Cann said Mr Kopanidis had more than 30 years of experience and had held executive roles at Medibank, Telstra, Treasury Wine Estates and Foster’s Group and was the director and owner of Petra Investor Relations & Debt Advisory Pty Ltd.
According to his Linkedin profile, Mr Kopanidis held a Bachelor of Business from Melbourne’s Monash University.
The company said Mr Barnes had served on its board since September 20, 2022.
Cann was unchanged at 2.5 cents.

TRYPTAMINE THERAPEUTICS

Tryptamine says company secretary David Franks has resigned, effective from today, and will be replaced by its chief financial officer and Bio101 director Hamish George.
Tryptamine was up 0.4 cents or 12.5 percent to 3.6 cents with 3.2 million shares traded.