Biotech Daily

Thursday April 3, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDADVISOR UP 21%; 4D MEDICAL DOWN 9%**

*** US 10% TARIFFS; PRIME MINISTER; CSL, COCHLEAR, FISHER & PAYKEL**

*** BIOXYNE $7m MARIJUANA MANUFACTURING, SUPPLY DEAL**

*** IMEX PLACEMENT RAISES $2.5m; $1m SHARE PLAN TO GO**

*** ECHO IQ MEETS FDA FOR MAYO CLINIC ECHOSOLV HEART FAILURE TRIAL**

*** MESOBLAST REQUESTS FDA REVASCOR HEART FAILURE MEETING**

*** IMUGENE PHASE I ONCARLYTICS I-V HIGHER DOSE APPROVAL**

*** RACE OPENS PHASE I RC220 TUMOR TRIAL**

*** ARGENT GERMAN MARIJUANA CANNEPIL SPECIAL ACCESS**

*** CANN TO SELL MARIJUANA PRODUCTS AT 11 QUEENSLAND PHARMACIES**

*** ACRUX TAKES $1.7m RADIUM RDTI LOAN**

*** ORTHOCELL REQUESTS 'FDA CLEARANCE' TRADING HALT**

*** MEMPHASYS ROXSTA CATTLE INSEMINATION STUDY**

*** ALGORAE APPOINTS VISHAL SHAH CCO**

*** BIOXYNE APPOINTS PROF MICHAEL BARNES ADVISOR**

MARKET REPORT

The Australian stock market fell 0.94 percent on Thursday April 3, 2025, with the ASX200 down 74.8 points to 7,859.7 points. Just three of the Biotech Daily Top 40 companies were up, 25 fell, nine traded unchanged and three were untraded.

Medadvisor was the best, up two cents or 21.05 percent to 11.5 cents, with 479,284 shares traded. Percheron climbed 10 percent; Pro Medicus rose two percent; CSL was up one percent; with Cochlear and Nanosonics up by less than one percent.

Yesterday's best, 4D Medical, led the falls, down 2.5 cents or 8.9 percent to 25.5 cents, with 2.3 million shares traded. EBR and Prescient lost more than eight percent; Alcidion and Imugene shed more than six percent; Avita, Clarity, Cynata, Starpharma and Syntara were down more than five percent; Dimerix fell 4.6 percent; Amplia, Compumedics, Medical Developments, Micro-X, Polynovo and Proteomics were down three percent or more; Clinuvel, Cyclopharm, Neuren, SDI and Universal Biosensors shed more than two percent; Immutep and Resmed were down more than one percent; with Emvision and Telix down by less than one percent.

US WHITE HOUSE, CSL, COCHLEAR, FISHER & PAYKEL HEALTHCARE

The US White House says President Donald Trump will use emergency powers to "impose a 10 percent tariff on all countries", effective from April 5, 2025.

The White House said that under the International Emergency Economic Powers Act (1977) Mr Trump enacted a 10 percent tariff baseline on all countries which he believed would "address the national emergency posed by the large and persistent trade deficit that is driven by the absence of reciprocity in our trade partners".

The White House website said Mr Trump would "impose an individualized reciprocal higher tariff on the countries with which the US has the largest trade deficits" with all other countries to be subjected to the 10 percent tariff baseline.

The White House said the tariffs would "remain in effect until such a time as Mr Trump determines that the threat posed by the trade deficit and underlying non-reciprocal treatment is satisfied, resolved, or mitigated".

The release said that today's order contained "modification authority, allowing Mr Trump to increase the tariff if trading partners retaliate or decrease the tariffs if trading partners take significant steps to remedy non-reciprocal trade arrangements and align with the US on economic and national security matters".

The White House said that "some goods will not be subject to the reciprocal tariff … [including] copper, pharmaceuticals, semi-conductors and lumber articles, all articles that may become subject to future section 232 tariffs, bullion and energy and other certain minerals that are not available in the US".

In a media conference, Prime Minister Anthony Albanese said the "[US] tariffs have no basis in logic and they go against the basis of our two nation's partnership".

"Our Government will not be seeking to impose reciprocal tariffs, we will not join a race to the bottom that leads to higher prices and slower growth" Mr Albanese said.

Mr Albanese said the Federal Government would expand trade with the UK, EU and Indonesia and had cleared more than $20 billion in trade impediments with China.

"We will provide $50 million to affected sectors …. backed by five new business and investment missions to priority markets within the first 100 days of our second term … [and] provide $1 billion in zero-interest loans for firms to capitalize on new export opportunities," Mr Albanese said.

Vaccine and blood products manufacturer CSL said "at this stage pharmaceutical products are not subject to the reciprocal tariffs".

The company said it was "continuing to assess the broader impact of the tariffs and will monitor further announcements by the US Government".

Cochlear said there were "complexities in understanding the application of the new tariff … [and it had] long been importing its products under a chapter of the Harmonized Tariff Schedule of the US that provides for duty-free importation on a range of products into the United States, including hearing implants".

Cochlear said it was "expecting further detail in the US Customs and Border Protection Notice of Implementation … to be published in the next week".

Fisher & Paykel said it did not expect "a material impact from the US tariffs on its net profit after tax" for the year to March 31, 2025.

In February, the company said it expected its costs would "likely increase" due to the US 25 percent tariff imposed on Mexico given 43 percent of revenue for the six months to September 30, 2024 was from sales of its products and sleep apnoea devices in the US and 60 percent of US volumes were supplied from Mexico (BD: Feb 3, 2025).

Today, the company said for the year to March 31, 2026 its costs would "likely increase due to the new tariffs, acknowledging the economic environment, global response to US tariffs and foreign currency movements may be fluid over this period".

BIOXYNE

Bioxyne says it has a minimum $7 million manufacturing and supply agreement with Brisbane's Nectartek Australia for pastille, vape and flower marijuana products.
Bioxyne said it had been appointed exclusive manufacturer of all Nectartek's marijuana products for distribution in Australia, the UK and Germany, with the agreement expected to generate at least $7 million in revenue for the year to June 30, 2026.
The company said the contract included minimum orders volumes of $3,600,000 of pastilles, $2,500,000 of packed flower products, $500,000 of vapes and $500,000 of oral mucosal oils and other products, with the minimum order a 200 percent increase on historical orders from Nectartek and that actual order volumes may exceed minimums.
The company said it expected to secure "additional long-term contracts following a substantial increase in manufacturing capacity across all product categories with the potential to generate revenue of over $100 million per year".
Bioxyne fell 0.1 cents or 3.6 percent to 2.7 cents with six million shares traded.

IMEX HEALTH SERVICES

Imex says it has raised $2.5 million at 35 cents a share in a placement, with a further $1.0 million, non-underwritten share purchase plan to follow.
Imex said the issue price was a 13.2 percent discount to the five-day volume weighted average price and a 11.4 percent discount to its closing price on April 1, 2025.
The company said the funds would be used to "provide working capital and drive growth in Aquila+ [picture archiving communications system] sales".
Imex said $1.5 million of the placement was raised from sophisticated and institutional investors, with an additional $1.0 million placed to directors and subject to shareholder approval at its annual general meeting.
The company said the placement was managed by Morgans Corporate.
Imex said the share plan had a record date of April 2, would open on April 14 and close on May 2, 2025.
Imex was in a trading halt and last traded at 39.5 cents.

ECHO IQ

Echo IQ says it has met with the US Food and Drug Administration to verify the design of an Echosolv heart failure validation trial with Rochester, Minnesota's Mayo Clinic.
Echo IQ said it had "positive engagement with the regulator" and would advance the proposed study design of a clinical trial for its artificial intelligence (A.I.)-based Echosolv heart failure clinical decision support system.
The company said it had a collaboration deal with the Mayo Clinic Platform to undertake the study, with the Clinic able to use Echosolv for heart failure at its 30 hospitals as well as integrate and co-brand the product with its existing software.
Echo IQ said the study would begin by July and was expected to be completed "mid-year", with a formal submission to the FDA for regulatory approval expected by 2026.
Echo IQ chief executive officer Dustin Haines said the company's "meeting with the FDA was very encouraging and has provided Echo IQ with a clear path towards regulatory clearance for Echosolv [heart failure]".
Mr Haines said the agreement with the Mayo Clinic "leaves the company incredibly well positioned to advance its planned validation study, progress regulatory clearance and generate better patient health outcomes".
Echo IQ was up half a cent or 1.7 percent to 30 cents with 3.7 million shares traded.

MESOBLAST

Mesoblast says it has requested a meeting with the US Food and Drug Administration to discuss the approval pathway for Revascor for ischaemic chronic heart failure.

In 2020, Mesoblast said a 537-patient, phase III trial of Revascor showed a statistically significant reduction in heart attacks or strokes ($p = 0.002$) and death from cardiac causes ($p = 0.037$) but did not meet the primary endpoint of a "reduction in recurrent non-fatal decompensated heart failure events" (BD: Dec 15, 2020)

Last year, the company said further data showed Revascor, or rexlemestrocel-L "significantly lowered the risk of cardiovascular death" in 303 reduced ejection fraction patients ($p = 0.003$) (BD: Dec 3, 2024).

At that time, Mesoblast managing-director Prof Silviu Itescu said the company had FDA feedback supporting an accelerated approval pathway in end-stage ischemic heart failure with reduced ejection fraction patients with a left ventricular assist device.

Today, the company said that at a meeting last year the FDA noted a single confirmatory trial in class II/III patients with ischemic heart failure with reduced ejection fraction and inflammation would need to be completed after any accelerated approval was granted.

Mesoblast said the next meeting would obtain FDA feedback on relevant chemistry, manufacturing and controls, alignment on potency assays for commercial product release and its proposed design and primary endpoint for the confirmatory trial.

The company said it expected the meeting to be held by July 2025.

Mesoblast was unchanged at $1.875 with 9.3 million shares traded.

IMUGENE

Imugene says it has approval to begin dosing the next cohort with a higher dose of intra-venous infused Oncarlytics in its up-to 50-patient, phase I trial for solid tumors.

In 2023, Imugene said it had dosed the first combination patient in the intra-tumoral arm of its phase I trial of Oncarlytics and blinatumomab (BD: Oct 26, 2023).

Last year, the company said it had dosed the first patient in the intra-venous combination arm of the phase I trial (BD: Jun 24, 2024).

Today, Imugene said that it successfully completed the safety observation period for the intra-venous combination arm and would progress to a higher dose level of its CD19-expressing oncolytic virus Oncarlytics with monoclonal antibody blinatumomab.

The company said the study was being conducted at seven sites in the US, with the potential to open a total of 10 sites

Imugene fell 0.2 cents or 6.7 percent to 2.8 cents with 39.0 million shares traded.

RACE ONCOLOGY

Race says it has begun enrolling its 53-patient, phase I trial of RC220 bisantrene with doxorubicin for advanced solid tumors at Sydney's Southside Cancer Care Centre.

Last month, Race said it had ethics approval to begin the safety, tolerability and pharmaco-kinetics trial of RC220 at Southside Cancer Care Centre, and earlier this week, said it had approval to open the trial at two more sites (BD: Mar 14, Apr 1, 2025).

Race was up one cent or 0.9 percent to $1.155.

ARGENT BIOPHARMA (FORMERLY MGC PHARMACEUTICALS)

Argent says Germany has approved its marijuana cannabinoid-based Cannepil for refractory epilepsy under a special access scheme.
Argent said the approval meant Cannepil was available for prescription by qualified physicians in Germany, with patients eligible for health insurance depending on physician recommendation and case assessment.
The company said it would begin physician education programs in Germany, expand Cannepil distribution and access through its partners, continue regulatory efforts for approval in other European countries and monitor uptake and patient outcomes.
Argent managing-director Roby Zomer said the approval was “a significant milestone for Argent Biopharma and the patients who rely on innovative treatments for epilepsy”.
“This marks our continued expansion in Europe and reinforces our commitment to improving lives through cutting-edge cannabinoid-based medicine,” Mr Zomer said.
Argent was up 6.5 cents or 50 percent to 19.5 cents.

CANN GROUP

Cann says 11 Chemist Warehouse pharmacies in Queensland will sell its Botanitech range of prescription medical marijuana products on request per outlet.
Cann said its products would be supplied to customers at the pharmacies in connection with scripts issued under the Australian Therapeutic Goods Administration’s Special Access Scheme and/or Authorised Prescriber Scheme.
The company said the agreements between its subsidiary Cannoperations Pty Ltd and each of the franchise business owners of 11 individual Chemist Warehouse pharmacies in Queensland were for an initial two-year term, automatically renewing for a further term unless otherwise terminated.
Cann said the financial benefit of the deals would “ultimately depend on the volume of orders placed for its medicinal cannabis products”.
The company said the contracts were “material due to the prominence of the Chemist Warehouse brand, its extensive market reach, and the potential for expanding to more outlets over time”.
Cann chief executive officer Jenni Pilcher said the deal was “the beginning of a promising relationship, and we look forward to working closely with Chemist Warehouse and their network of franchisees to drive mutual success and growth”.
Cann was up 0.4 cents or 17.4 percent to 2.7 cents with 17.7 million shares traded.

ACRUX

Acrux says it has a $1.73 million loan from Melbourne’s Radium Capital against 80 percent of its expected Federal Government Research and Development Tax Incentive.
Acrux did not cite the cost of the loan nor the maturity date; and said it expected to receive its Federal Government Research and Development Tax Incentive “later in 2025”.
Acrux was unchanged at 2.3 cents.

ORTHOCELL

Orthocell has requested a trading halt “pending an announcement by the company … regarding the results of the US FDA 510(k) clearance application”.
Trading will resume on April 7, 2025, or on an earlier announcement.
Orthocell last traded at $1.435.

MEMPHASYS

Memphasys says its Roxsta pilot study “did not demonstrate a statistically significant correlation between anti-oxidant levels and pregnancy outcomes in heifers”.
Last year, Memphasys said it began its 50-heifer study of Roxsta anti-oxidant assay system for use in bovine reproductive performance at a New South Wales cattle operation (BD: Dec 5, 20, 2024).
The company said “the analysis revealed no statistically significant difference in antioxidant levels between pregnant and non-pregnant animals”.
Memphasys said the study showed that the “Roxsta system operated as intended and accurately measured anti-oxidant activity in the samples”.
The company said the pilot study identified “more targeted oxidative stress applications” including in bulls, where oxidative stress had a more pronounced and measurable impact on reproductive health, as well as in dairy cattle.
Memphasys managing-director Dr David Ali said Roxsta continued to show “its versatility as a scientifically robust and commercially scalable diagnostic tool”.
“These trials have seen Roxsta used in a commercial agricultural farm and proven that the system operates simply, easily and offers reliable results,” Dr Ali said.
“While only a small pilot study, the results are encouraging with the research team able to determine further target areas for future application, namely in bulls as well as mastitis in the dairy industry,” Dr Ali said.
Memphasys was unchanged at 0.8 cents with 6.3 million shares traded.

ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has appointed Vishal Shah as its chief commercial officer.
Algorae said Mr Shah had worked for Australian pharmaceutical wholesaler Ebos and been head of Australia and New Zealand Pharmaceuticals at Baxter Healthcare.
According to his Linkedin profile, Mr Shah held a Bachelor of Pharmacy from New Delhi’s Lallubhai Motilal College of Pharmacy as well as a Master of Applied Science and a Master of Business Administration from Western Sydney University.
Algorae was unchanged at half a cent.

BIOXYNE

Bioxyne says it has appointed Prof Michael Barnes to its advisory board.
The company said Prof Barnes was previously an advisor to US marijuana-based medicines company GW Pharmaceuticals and was currently president of the Cannabis Industry Council and UK Medical Cannabis Clinicians Society.
Bioxyne said it would use “Prof Barnes’ experience in registering medicines for marketing authorization, which will allow it to distribute its products through traditional prescriber channels, without the need for special access or authorized prescriber pathways”.