Biotech Daily

Tuesday February 25, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACTINOGEN UP 8%; CYCLOPHARM DOWN 20%**

*** CYCLOPHARM REVENUE UP 5% TO $28m; LOSS UP 181% TO $13m**

*** BTC GROUP H1 REVENUE UP 8.5% TO $5m; PROFIT TRIPLES TO $5m**

*** QIMR WINS $6m NHMRC GRANTS**

*** ATSE: FEDERAL $6m FOR INTERNATIONAL PARTNERSHIPS**

*** AVASA TO RAISE $4.5m FOR ARTERIAL COUPLER**

*** DEMENTIA AUSTRALIA $4m FOR 24 PROJECTS**

*** CONTROL BIONICS RAISES $2m**

*** NEXT SCIENCE FDA WARNING LETTER**

*** CAMBIUM FDA PHASE III ELATE OCULAR PROTOCOL APPROVED**

*** PERCHERON RECEIVES 2nd BOARD SPILL CALL**

*** 4D MEDICAL CT LVAS CANADA APPROVAL**

*** HERAMED 3-YEAR GARMIN SMARTWATCH DATA DEAL**

*** ARCHER TO TRIAL BLOOD POTASSIUM TEST BIOCHIP IN 2026**

*** TELIX TO REPORT FINANCIALS IN US DOLLARS**

MARKET REPORT

The Australian stock market fell 0.68 percent on Tuesday February 25, 2025, with the ASX200 down 56.3 points to 8,251.9 points. Eight of the Biotech Daily Top 40 stocks were up, 24 fell, seven traded unchanged and one was untraded. The Big Caps were mixed.

Actinogen was the best, up 0.3 cents or 8.1 percent to four cents, with 10.7 million shares traded. Medadvisor and Proteomics were up more than three percent; Syntara and Telix rose more than two percent; Immutep was up 1.6 percent; with CSL, Medical Developments, Nanosonics and Pro Medicus up by less than one percent.

Cyclopharm led the falls, down 38 cents or 20 percent to $1.52, with 930,614 shares traded. Polynovo lost 17.65 percent; Curvebeam fell 10.7 percent; Amplia and Percheron were down more than seven percent; Atomo, Dimerix and Orthocell fell more than five percent; Alcidion, Aroa, Avita, Cynata, Mesoblast, Paradigm and Universal Biosensors were down four percent or more; Neuren lost three percent; Impedimed, Imugene and Micro-X shed more than two percent; Clarity, Clinuvel and Opthea were down one percent or more; with Cochlear, EBR, Emvision and Resmed down by less than one percent.

CYCLOPHARM

Cyclopharm says revenue for the year to December 31, 2024 was up 4.7 percent to $27,572,581, with net loss after tax up 180.75 percent to $13,197,618.
Last year, Biotech Daily reported Cyclopharm revenue for the year to December 31, 2023 including other revenue but has not included that today (BD: Feb 28, 2024).
Today, Cyclopharm said revenue was primarily from sales of its imaging products, including $15,209,759 from its Technegas lung imaging generators and patient administration sets and $12,362,822 from "third-party distribution", a combination of capital works projects and ongoing sales from consumables and service support.
The company said diluted loss per share rose 153.1 percent to 12.83 cents, net tangible assets per share fell 17.9 percent to 33 cents, and it had cash and cash equivalents of $20,567,898 at December 31, 2024 compared to $11,726,424 at December 31, 2023.
Cyclopharm fell 38 cents or 20 percent to $1.52 with 930,614 shares traded.

BTC HEALTH

BTC says that group revenue for the six months to December 31, 2024 was up 8.55 percent to $5,342,276, with net profit after tax up 199.1 percent to $4,938,024.
BTC said revenue was from sales made by its investee businesses, including sales of BTC Specialty Health's pain infusion pumps, down 39.5 percent to $2.6 million "due to the discontinued Ambit infusion pumps".
The company said sales of BTC Pharma's Bronchitol and Aridol respiratory products were up 10.3 percent to $640,000 and sales of BTC Cardio cardio-pulmonary and extra-corporeal life support systems were $2.1 million compared to $100,000 in the prior corresponding period.
BTC said diluted earnings per share rose 175.5 percent to 1.46 cents, net tangible assets were up 84.4 percent to 3.08 cents, with cash and cash equivalents of $794,679 at December 31, 2024, compared to $2,119,172 at December 21, 2023.
BTC was unchanged at 6.6 cents.

FEDERAL GOVERNMENT

AUSTRALIAN ACADEMY OF TECHNOLOGY SCIENCES AND ENGINEERING

ATSE says it will award $6,300,000 through grants of $100,000 to $1,000,000 for Australian researchers and businesses partnering with "priority partner countries".
The Australian Academy of Technology Sciences and Engineering (ATSE) said the funds were from the second round of the Federal Government's $40 million Global Science and Technology Diplomacy Fund, delivered with the Australian Academy of Science
The organization said partner countries included Indonesia, Malaysia, Singapore, Thailand, Vietnam, New Zealand, Japan, the Republic of Korea and Brazil.
ATSE said the focus was on RNA and messenger RNA vaccines and therapies, advanced manufacturing, artificial intelligence (A.I.), quantum computing and hydrogen production.
ATSE chief executive officer Kylie Walker said the grants linked Australian science, technology, engineering and mathematics with "global partners, building new technologies from a foundation of international collaboration".
"A grant through this scheme will boost the capabilities of researchers, industries and new businesses across many countries, all while strengthening international science and technology cooperation," Ms Walker said.
ATSE said applications were open and would close on May 4, 2025, with expressions of interest to be submitted at: https://glodip.org.au/.

QUEENSLAND INSTITUTE OF MEDICAL RESEARCH BERGHOFER

The Queensland Institute of Medical Research (QIMR) says the National Health and Medical Research Council (NHMRC) has awarded it three grants worth $6,011,000.
QIMR said the recipients included its population health program deputy director Prof Rachel Neale, who would use the funds for two programs on sun exposure and pancreatic cancer mortality.
The institute said that its endometrial cancer association consortium's Prof Tracy O'Mara would continue work on endometrial cancer genetics.
QIMR said the emerging viral diseases laboratory's Dr Daniel Rawle would work on ways to combat pathogenic arboviruses.
The Institute said that "the funding would support research that would change how clinicians understood and treated disease and bring immeasurable benefits to Queenslanders, Australians and patients globally".
QIMR chief executive officer Prof Fabienne Mackay said that the grants reflected "both the quality and importance of the research being conducted at QIMR Berghofer".
"The impactful discoveries made by our scientists continue to advance human health through pioneering intellect and originality," Prof Mackay said.
The National Health and Medical Research Council chief executive officer Prof Steve Wesselingh said grants funded "investigator-led research where Australia's highest performing health and medical researchers set out to achieve ambitious goals of improving the health and wellbeing of the Australian community".

AVASA

Avasa says it hopes to raise between $NZ4.5 million ($A4.1 million) to $NZ5 million ($A4.5 million) in series A funding to develop its arterial coupler for micro-surgery.
The Auckland, New Zealand-based Avasa, an Auckland Bio-engineering Institute spin-out, said it had finalized the design of its "world-first arterial coupler" for connecting small arteries and veins in micro-surgery, using hooks on vessel inserts.
The company said the current method of manually suturing arteries was "time-consuming, requiring 40 minutes per connection and highly specialized skills".
Avasa said pre-clinical studies showed its coupler device simplified and expedited the process, reducing procedure time by 80 percent with a 100 percent success rate.
The company said the device had undergone pre-submission review with the US Food and Drug Administration, which indicated it could be eligible for a 510(k) pathway and faster approval.
Avasa said that by reducing operating times and complications, hospitals could save $US1,000 ($A1,577) per procedure and increase service delivery.
The company said "several million dollars" had already been committed by existing and additional investors, and once it had completed the raise would begin "the necessary testing for FDA clearance in the next 12 months".
Avasa chief executive officer Dr Nandoun Abeysekera said finalizing the device's design was "a really exciting milestone … [and] it has taken years of unrelenting design and testing to get here".
"With a validated pre-production device, successful preclinical trials, and conclusive guidance from the FDA, we can now execute on the formal testing needed for FDA clearance and bring this important technology into the hands of surgeons," Dr Abeysekera said.
Avasa is a private company.

DEMENTIA AUSTRALIA RESEARCH FOUNDATION

Dementia Australia says its Research Foundation has awarded 24 projects $3.7 million to support dementia researchers.

Dementia Australia said the grants included $700,000 to the University of Wollongong's Dr Simon Maksour for a five-year project to "enhance the brain's inbuilt defence mechanism against Alzheimer's disease", with $400,000 awarded to Monash University's Dr Marianne Coleman for research to improve eye care for people in residential aged care facilities.

Dementia Australia said that since its grants program began in 2000, more than $35 million in funding had supported more than 400 projects.

Dementia Australia Research Foundation chair Prof Graeme Samuel said there were "an estimated 433,300 Australians living with dementia and it is increasingly being understood as the public health, disability and aged care challenge facing Australia".

"The diversity and range of projects selected, from those focused on supporting timely diagnosis and support, to research to improve the quality of care, shows we have a very exciting future for dementia research," Prof Samuel said.

The organization said a full list of recipients was available at: http://bit.ly/4hTVeQo.

CONTROL BIONICS

Control Bionics says it has raised $2.0 million at 4.5 cents a share in a placement to existing shareholders Nightingale Partners Pty Ltd and Phoenix Development Fund.

Biotech Daily calculated the 4.5 cents issue price as a 7.1 percent premium to the last closing price of 4.2 cents.

Control Bionics said the funds would be used to support revenue for core operations and expansion into "high-potential markets", including its Neuronode Only and Neurostrip.

Control Bionics was up 0.1 cents or 2.4 percent to 4.3 cents.

NEXT SCIENCE

Next Science says it has received a warning letter from the US Food and Drug Administration related to issues including marketing and labelling claims.

Next Science said the FDA inspected its Jacksonville, Florida facility between August and September 2024 and found it did not have "pre-market approval pertaining to certain product marketing and labelling claims related to Xperience, Blastx and Surgx".

The company said the FDA inspection "found that the methods used in, or the facilities or controls used for, the products' manufacture, packing, storage or installation did not conform with the current good manufacturing practice requirements of the quality system regulation".

Next Science said that the letter stated it had "failed to timely submit reports to the FDA regarding information that suggested a device marketed by the company may have contributed to serious injury".

The company said it had submitted a written response addressing the FDA's observations, including corrective actions that "had already been undertaken as well as further actions underway", and would regularly update the FDA.

Next Science said its products were "safe and effective for their cleared intended uses" and it was "committed to the highest standards of compliance and is giving the utmost attention to comprehensively addressing and correcting as quickly as possible any open actions regarding the matters raised in the FDA's warning letter".

Next Science fell one cent or 8.3 percent to 11 cents with two million shares traded.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it has US Food and Drug Administration protocol approval for two 400-patient, phase III trials of its Elate Ocular for moderate-to-severe dry eye disease.

Last year, the then Regeneus said it merged with the Atlanta, Georgia-based Cambium Medical Technologies for its Elate Ocular dry eye disease treatment in exchange for shares and 5.5 percent of future royalties (BD: Feb 14, Apr 5, 8, 2024).

Later, Cambium said it had FDA fast track designation for Elate Ocular, or CAM-101, for the treatment of dry eye disease, which would support the opening of two, phase III trials by July 2025 (BD: Dec 9, 2024).

Today, the company said the phase III program included two identical registration-enabling trials designed to meet FDA requirements for a biologics licence application, with the trials to be conducted at sites “in Australia, the US and select other countries”.

Cambium said the randomized, placebo-controlled trials would enrol 400 patients, each, with primary endpoints including change in total corneal fluorescein staining score and change in eye discomfort score.

The company said patients would be treated for nine weeks, with a subset of patients to participate in a 43-week, long-term safety follow-up.

Cambium said subject to additional financing first patients were expected to be enrolled in mid-2025, with top-line data in mid-2026 and a biologics licence application submitted following successful completion of the trials.

Cambium chief executive officer Karolis Rosickas said that FDA approval for the phase III protocol was “a pivotal milestone in Elate Ocular’s development journey”.

“The trial design reflects extensive consultation with regulatory experts and key opinion leaders to ensure we meet the FDA's requirements for registration,” Mr Rosickas said.

“With fast-track designation now secured, and the protocol approved, we are well-positioned to advance Elate Ocular through its final stages of clinical development,” Mr Rosickas said.

Cambium was up 7.5 cents or 19.2 percent to 46.5 cents.

PERCHERON THERAPEUTICS

Percheron says it has notices from shareholder Powerhouse Ventures Ltd calling for a general meeting to vote on the replacement its board of directors.

Last month, Percheron said it would hold a meeting on March 4, 2025 to vote on a board spill requisitioned by shareholders including Gregory Peters, former chair of the then Antisense Robert Moses, Dale Reed, David Kinley, Statemoor, Xcelerate Nominees and XEC Partners (BD: Jan 19, 24, 2025).

At that time, the company said the resolutions included the removal of directors Dr Charmaine Gittleson and Dr James Garner and the appointment of Mr Peters and Gennadi Koutchin as directors.

Last week, the Brisbane-based Powerhouse Ventures said it held 10,000,000 shares, or 10.12 percent, of Percheron (BD: Feb 21, 2025).

Today, Percheron said Powerhouse Ventures had called for a meeting to vote on the removal of Dr Gittleson, Dr Garner and Dr Ben Price as directors, the removal of Mr Peters and Mr Koutchin as directors if appointed prior to the meeting, and the appointment of Doran Eldar, Renerve managing-director Dr Julian Chick and Richard Hamersley as directors.

Percheron said that its board encouraged “shareholders to vote against all resolutions at that meeting”.

Percheron fell 0.1 cents or 7.7 percent to 1.2 cents with 12.15 million shares traded.

4D MEDICAL

4D Medical says Health Canada has approved its computed tomography lung ventilation analysis software (CT-LVAS) for diagnosing lung diseases.
4D Medical said its lung density analysis (LDA), lung texture analysis (LTA) and lung nodules were already approved in Canada and it had applied for approval of its CT ventilation-perfusion (VQ) imaging technology.
4D Medical managing-director Prof Andreas Fouras said “with the vast majority of Canadians living near the north-east corner of the US and with easy travel and shared culture, no region is more accessible to our US-based sales team”.
“In the last [six months] we grew our number of sites by 24 percent, scans per site at over 10 percent and average fee per scan by 12 percent,” Prof Fouras said.
“With our team having cracked the code on how to drive adoption, now is a great time to have CT Lvas approved in Canada,” Prof Fouras said.
4D Medical was unchanged at 42 cents with 1.2 million shares traded.

HERAMED

Heramed says it has a three-year deal with Garmin Health to integrate Garmin’s smartwatch data into Heracare for remote pregnancy and foetal heart monitoring.
Heramed said that with the Olathe, Kansas-based Garmin Health’s application programming interface (API) pregnant women could share health and fitness activity data to a Garmin smartwatch, which could then collect and integrate the data into the Heracare platform, including heart rate, sleep pattern and fitness activity level metrics.
The company said the agreement with the smartwatch and global position system (GPS)-enabled products was “dedicated to research and data rather than commercial … [and] does not involve any direct financial consideration between the companies”.
Heramed chief executive officer Anoushka Gungadin said “by incorporating Garmin's high-quality sensor data into Heracare, we're expanding and enhancing our ability to provide continuous, real-time health insights to expectant mothers and their healthcare providers”.
Heramed was up 0.3 cents or 17.65 percent to two cents with 31.0 million shares traded.

ARCHER MATERIALS

Archer says it has improved its biochip’s accuracy for detecting potassium as an at-home chronic kidney disease blood test, with clinical trials expected to begin in 2026.
Archer said it had reduced the variability of test results between graphene field effect transistors (GFETs) on one of its biochips from 15 percent to 1.5 percent and would transition to testing human blood samples.
The company said it hoped to test the biochip with human blood and develop a first prototype cartridge system “at the end of 2025”.
Archer chair Greg English said the company reducing the variability on a single biochip was “a significant achievement in the development of the biochip and allows us to progress to the next stage of development”.
“The team is now looking towards testing human blood samples and integrating it into a prototype cartridge system,” Mr English said.
“These are important steps before we engage in clinical trials,” Mr English said.
Archer was up 1.5 cents or 4.55 percent to 34.5 cents.

TELIX PHARMACEUTICALS

Telix says it will change its reporting currency from Australian to US dollars, for its results for the six months to June 30 and year to December 31, 2025.

Telix said changing its reporting currency allowed it to “align to the predominant currency used for reporting of revenue, costs and corresponding cash flows, which are primarily generated in the US and denominated in US dollars”.

Telix was up 81 cents or 2.7 percent to $31.14 with 4.2 million shares traded.