

Biotech Daily

Tuesday February 11, 2025

Daily news on ASX-listed biotechnology companies

- * ASX EVEN, BIOTECH DOWN: PERCHERON UP 14%; PARADIGM DOWN 7%
- * CSL RECORD H1 REVENUE UP 5% TO \$13.5b, PROFIT UP 7% TO \$3.3b
- * ENA FLU LAB \$8m FOR INNA-051
- * ALCIDION \$5.5m WELSH MIYA CONTRACT
- * FEDERAL \$4m FOR AUSTRALIA-INDIA RESEARCH
- * CLARITY: CU-64, CU-67 SAR-TRASTUZUMAB FOR BREAST CANCER
- * MEMPHASYS COMPLETES LAST FELIX IVF TRIAL PATIENT VISIT
- * VISIONEERING TO DELIST ON FRIDAY
- * VITURA REQUESTS 'ACQUISITION, CAPITAL RAISING' TRADING HALT
- * CANN: NAB EXTENDS LOAN DATES
- * AUSTRALIAN ETHICAL DILUTED TO 15% OF NOVA EYE
- * DOUG RATHBONE REPLACES CANN CHAIR DR JULIAN CHICK
- * VISIONEERING PROMOTES HEAD OF FINANCE JEFF PRUETT TO CFO

MARKET REPORT

The Australian stock market edged up 0.01 percent on Tuesday February 11, 2025, with the ASX200 up 1.2 points to 8,484.0 points. Eleven of the Biotech Daily Top 40 companies were up, 20 fell, eight traded unchanged and one was untraded.

Percheron was the best, up 0.1 cents or 14.3 percent to 0.8 cents, with 2.1 million shares traded. Genetic Signatures climbed 4.8 percent; Actinogen, Alcidion and Immutep were up more than three percent; Pro Medicus and Universal Biosensors rose more than two percent; Amplia, Aroa, Emvision and Syntara were up more than one percent; with SDI up by 0.55 percent.

Yesterday's best, Paradigm, led the falls, down four cents or 7.4 percent to 50 cents, with 2.7 million shares traded. Clarity, CSL, Medadvisor and Micro-X lost five percent or more; 4D Medical fell 4.8 percent; Cyclopharm, Medical Developments, Neuren and Opthea were down three percent or more; Cochlear, Imugene, Nanosonics, Polynovo, Proteomics and Telix shed more than two percent; Clinuvel, Dimerix, EBR, Mesoblast, Orthocell and Starpharma were down one percent or more; with Resmed down by 0.2 percent.

CSL

CSL says record revenue for the six months to December 31, 2024 was up 5.3 percent to \$US8,483,000,000 (\$A13,524,000,000), with record net profit after tax up 7.1 percent to \$US2,056,000,000 (\$A3,278,000,000).

CSL said that research and development expenditure fell 3.6 percent to \$US646 million for the six months to December 31, 2024, or 7.6 percent of total revenue, compared to 8.32 percent of total revenue for the six months to December 31, 2023.

The company said the reduced research and development expenditure reflected "the cessation of several [research and development] programs" and that research and development expenses were expected to be about 10 percent of revenue for the full year. CSL said \$US5,743,000,000 in revenue was from its Behring business, including immunoglobulin, albumin and haemophilia products, \$US1,661,000,000 was generated through its Seqirus business for sales of its vaccines and \$US1,079,000,000 was from sales of its Vifor business' iron deficiency products.

CSL managing-director Dr Paul McKenzie said the company "delivered a solid result for the first half of the 2025 financial year led by CSL Behring".

"Strong demand for many of our market-leading therapies has translated into sales growth, particularly in our core [immune-globulin] franchise," Dr McKenzie said. "We continue to advance key initiatives to improve gross margin, which is tracking according to our plans," Dr McKenzie said.

"CSL Seqirus was negatively impacted by significantly low influenza immunization rates, particularly in the US," Dr McKenzie said.

"CSL Vifor grew sales, underpinned by robust iron volumes in Europe and the expansion of our nephrology products," Dr McKenzie said.

The company reaffirmed its guidance for the year to June 30, 2025, with revenue expected to be up between five and seven percent "at constant currency" and net profit after tax to be \$US3.2 billion and \$US3.3 billion.

CSL said an interim unfranked dividend up 9.2 percent to \$US1.30, would be paid on April 9, for a record date of March 11, 2025.

The company said diluted earnings per share rose 5.4 percent to \$US4.13 and that it had cash and cash equivalents of \$US1,524,000,000 at December 31, 2024 compared to \$US1,017,000,000 at December 31, 2023.

CSL fell \$13.38 or 4.95 percent to \$256.96 with 2.4 million shares traded.

ENA RESPIRATORY

ENA says it has received \$US5 million (\$A8 million) from San Francisco's Flu Lab for development of its intra-nasal, dry powder INNA-051 for viral respiratory infections. ENA said Flu Lab was founded to "advance innovative approaches for the prevention and treatment of influenza" and the investment would fund its phase II proof-of-concept community infection study of the safety and potential efficacy of INNA-051 in reducing the incidence and duration of symptomatic infections caused by common respiratory viruses, including influenza.

Last month, ENA said it was planning a phase II community infection study by the end of 2025 to assess the safety and potential efficacy of INNA-051 (BD: Jan 23, 2025). ENA chief executive officer Dr Christophe Demaison said there was "an urgent need for new approaches to reduce the enormous burden of serious viral respiratory infections including influenza, and this investment from Flu Lab will allow us to accelerate our clinical program".

ENA is a private company.

ALCIDION GROUP

Alcidion says it has a \$5.5 million, five-year contract with the Carmarthen, Wales-based Hywel Dda University Health Board for its Miya patient monitoring system.

Alcidion said the contract was its first in Wales and included the option to extend to seven years, taking the total contract value to up-to \$7.7 million.

The company said its Miya Precision patient flow, observations and assessment and smart-page would support the Hywel Dda University Health Board's "care delivery across various services, including real-time patient flow management and alerting users to deteriorating patients".

Alcidion said Hywel Dda University Health Board provided primary, secondary, community and dental health services to about 380,000 people in west Wales and was responsible for four acute hospitals, five community hospitals, two integrated care centres and general practices, dental practices, pharmacies and in-home care.

Alcidion managing-director Kate Quirke said the contract was "won in a competitive tender process ... [and] the first contract we have secured with a health board in Wales, which is a deeply established and respected model of tertiary healthcare in the northern hemisphere".

"We are honored to support the [Hywel Dda University] Health Board on their important 10-year journey of digital transformation," Ms Quirke said.

Alcidion was up 0.3 cents or 3.9 percent to eight cents with 4.6 million shares traded.

FEDERAL GOVERNMENT

The Federal Government says it will award \$4 million to researchers under the Australia-India Strategic Research Fund (AISRF), including research in RNA vaccines.

A media release from the Federal Minister for Industry and Science Ed Husic said Australian researchers would receive grants worth between \$200,000 and \$1,000,000 through round 16 of the AISRF.

The Government said collaborations could include joint research projects, workshops, fellowships and institutional partnerships, and that the AISRF had supported more than 370 collaborative activities since it was established in 2006.

The Federal Government said eligible applicants must address priority areas and challenges common to both Australia and India, including RNA vaccines and biotherapeutics, such as immuno-therapies, and biotechnology for improved agricultural productivity and climate resilience.

The Government said other priority areas included critical minerals processing technologies and methods, quantum computing and communications, remanufacturing and electronic waste recycling and biomanufacturing for industrial and consumer products, including biochemicals, biofuels and novel bio-based minerals.

The Federal Government said the AISRF was jointly administered by Australia's Department of Industry, Science and Resources and the Indian Government's Department of Science and Technology and Department of Biotechnology.

Mr Husic said "countries that work together to solve common problems become closer, as this successful program has shown in spades for almost two decades".

"The \$4 million on the table today will focus collaboration on some of the biggest challenges facing both of our countries: critical minerals, recycling, quantum, modern vaccines and biotech," Mr Husic said.

"This is our biggest bilateral science program for good reason, and I want to see it grow even stronger into the future," Mr Husic said.

The release said applications were open until April 11, 2025 at: https://bit.ly/3Qd6CKR.

CLARITY PHARMACEUTICALS

Clarity says it will develop copper-64 and copper-67 Sar-trastuzumab as a diagnostic and therapeutic for patients with HER2-expressing breast cancers.

Clarity said that with the University of Melbourne it had combined the trastuzumab antibody with its Sar chelator and radio-labelled with copper-64 for diagnostic imaging and copper-67, forming a radio-immuno-therapy.

The company said trastuzumab was an antibody that targeted human epidermal growth factor receptor 2 (HER2), which was expressed in many cancers, including some types of lung, gastric and breast cancers.

Clarity said copper-64 Sar-trastuzumab "was shown to target HER2-positive cancer cells to a very high level pre-clinically ... [and] copper-67 Sar-trastuzumab was shown to significantly reduce the growth of HER2-expressing tumors in a dose-dependent manner, as well as to improve the survival of mice treated with the product".

The company said it signed a supply agreement with Taipei, Taiwan's Eirgenix Inc for the clinical development and future commercial supply of a clinical-grade good manufacturing practice trastuzumab biosimilar, called EG12014.

Clarity said the supply would allow it to develop a radio-labelled product using its Sar technology, and that it would initially focus on breast cancer.

The company said it hoped to conduct a phase I/IIa study with copper-64 diagnostic and copper-67 therapeutic Sar-trastuzumab in HER2-positive breast cancer patients. Clarity executive chair Dr Alan Taylor said the company was "also committed to progressing our Sar-Bombesin, Sartate and Sar-Bis-[prostate specific membrane antigen] products in breast cancer, complementing the existing focus on prostate cancer, neuro-blastoma and neuro-endocrine tumors".

Clarity fell 18 cents or 4.95 percent to \$3.46 with 2.15 million shares traded.

MEMPHASYS

Memphasys says it has completed the last in-vitro fertilization (IVF) patient visit in its pivotal trial of the Felix sperm separation system, with results expected next month. In 2022, Memphasys said that with the Monash IVF Group, it had enrolled and treated the first couple in the 104-couple study of its Felix device (BD: Jun 28, 2022).

Last year, the company said its trial of the Felix electrophoresis-based sperm separation device for in-vitro fertilization (IVF) procedures had "90 percent completion, with fewer than 20 patients remaining" (BD: Oct 24, 2024).

At that time, Memphasys said it would pursue Conformité Européenne (CE) mark registration for its Felix sperm separation device "as soon as practicable, following clinical trial completion".

Today, the company said all required patient visits, including pregnancy outcomes were completed and that data lock was expected in about two weeks.

Memphasys said the data would be incorporated into the CE mark submission which would enable market entry into Europe, with other jurisdictions including Australia and India "to follow shortly after".

Memphasys managing-director Dr David Ali said that with "all patient data now collected, our team is focused on ensuring every data point is verified and ready for statistical analysis".

"It's a meticulous process, but a necessary one as we prepare for regulatory approvals and commercial discussions," Dr Ali said.

"We look forward to sharing the trial results very soon," Dr Ali said.

Memphasys was up 0.1 cents or 14.3 percent to 0.8 cents with 2.3 million shares traded.

VISIONEERING TECHNOLOGIES

on February 12, 2025, pending delisting.

Visioneering says its last day of trading on the ASX will be tomorrow February 12, with its removal from the official list expected to be completed on Friday February 14, 2025. Last year, Visioneering said it filed a request to the ASX to be removed from the official list due to its "low trading price" and last month, an extraordinary general meeting approved the scheme to delist with 94.1 percent support (BD: Dec 10, 2024; Jan 19, 2025). Today, Visioneering said it would enter into a voluntary suspension at the close of trading

Visioneering was up 0.1 cents or 1.5 percent to 6.7 cents.

VITURA HEALTH

Vitura has requested a trading halt "pending the release of announcements by the company about a potential acquisition and capital raising".

Trading will resume on February 13, 2025, or on an earlier announcement. Vitura last traded at 7.9 cents.

CANN GROUP

Cann says the National Australia Bank will extend the maturity dates of its construction and working capital loans from May 31 to September 30, 2025.

Last year, Cann said it had extended its fully-drawn \$15.6 million NAB loan to March 31, 2025, and NAB agreed to defer the quarterly repayment of the principal loan amounts of its \$49.4 million construction facility to May 2025 (BD: Mar 18, 2024).

Later, the company said NAB would defer \$900,000 in quarterly interest and facility fee payments, which was due November 22, 2024 (BD: Nov 27, 2024).

Today, Cann said NAB had consented to the capitalization of a further two quarters of interest payments, totaling about \$1.8 million for its construction loan, with the next quarterly interest payment due August 2025.

The company said it was "currently in discussions with its private credit fund lender to provide similar assistance".

Cann was up 0.1 cents or 3.3 percent to 3.1 cents with two million shares traded.

NOVA EYE MEDICAL

Australian Ethical says its substantial 40,113,310 share-holding in Nova Eye has been reduced from 17.53 percent to 15.24 percent, due to a capital raise.

Last month, Nova Eye said it expected to raise \$6.6 million at 12 cents a share in a placement to institutional and sophisticated investors (BD: Jan 31, 2025). Nova Eye was unchanged at 13.5 cents.

CANN GROUP

Cann says Dr Julian Chick has resigned as chair, with non-executive director Doug Rathbone filling the role as interim chair, effective from yesterday, February 10, 2025. Cann said Dr Chick's "workload in his full-time executive role at Renerve has expanded considerably and requires frequent international travel, such that he does not have the capacity to dedicate to the role of chair of Cann at the present time".

The company said it would recruit a new chair and had "identified several suitable external candidates".

VISIONEERING TECHNOLOGIES

Visioneering says it has promoted head of finance Jeff Pruett to the role of chief financial officer, effective immediately.

Last year, Visioneering said it appointed Mr Pruett as head of finance, with chief operating officer and chief financial officer Brian Lane to resign (BD: Sep 13, 2024).