Biotech Daily

Thursday January 30, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO, MEDICAL DEVEL UP 3.5%;**
- PERCHERON DOWN 11%

*** ALTERITY: 'ATH434 IMPROVES MSA FUNCTION, DAILY LIVING' - UP 138%**

*** MEDADVISOR H1 RECEIPTS DOWN 23% TO $47m**

*** ALCIDION H1 RECEIPTS UP 1.6% TO $15m**

*** ATOMO H1 RECEIPTS UP 49% TO $2.9m**

*** AUDEARA H1 RECEIPTS UP 61% TO $2.3m**

*** CLEVER CULTURE 1st CASH FLOW POSITIVE QUARTER SINCE 2022**

*** MACH7 $5m SHARE BUY-BACK**

*** VICTORIA $800k FOR DIAG-NOSE BREATHING DISORDERS TEST**

*** QIMR, KAZIA PHASE Ib PAXALISIB BREAST CANCER COMBINATION TRIAL**

*** ARGENICA DOSES 79 PHASE II ARG-007 PATIENTS**

MARKET REPORT

The Australian stock market was up 0.55 percent on Thursday January 30, 2025, with the ASX200 up 46.7 points to 8,493.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and one was untraded. The four Big Caps were up.

Medical Developments and Universal Biosensors were the best, both up 3.5 percent or 1.5 cents and 0.3 cents, respectively, to 44 cents and 8.9 cents, respectively, with 104,871 shares and 22,846 shares traded, respectively. Dimerix and Resonance both climbed 3.45 percent; Immutep and Paradigm improved more than two percent; Clinuvel, Cochlear, Impedimed, Opthea and Pro Medicus were up one percent or more; with CSL, Mesoblast, Neuren, Resmed and Telix up by less than one percent.

Percheron led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 886,688 shares traded. Curvebeam lost 9.1 percent; Clarity, Cyclopharm and Medadvisor were down more than seven percent; 4D Medical and Micro-X shed six percent or more; Imugene was down 5.1 percent; EBR and Starpharma fell four percent or more; Polynovo was down 3.2 percent; Amplia, Aroa, Avita, Cynata, Orthocell and SDI shed more than two percent; Alcidion and Compumedics were down more than one percent; with Emvision down by 0.8 percent.

ALTERITY THERAPEUTICS

Alterity rose 137.5 percent on its 77-patient, phase II ATH434 trial showing a “statistically significant improvement” on function and daily living for multiple system atrophy (MSA).
Last year, Alterity said it had dosed the randomized, double-blinded, controlled trial, with results expected in “late January or early February 2025” (BD: Dec 4, 2024).
Today, the company said ATH434 led to an improvement on the modified Unified MSA rating scale (Umsars) part I, a scale used for assessing disability and disease severity.
Alterity said at 52 weeks a 50mg dose of ATH434 showed a 48 percent slowing of clinical progression ($p = 0.03$) and the 75mg dose led to a 29 percent slowing of clinical progression ($p = 0.2$), compared to placebo, with the 75mg dose group showing a 62 percent slowing of progression at 26 weeks ($p = 0.05$).
Alterity said the improvement in Umsars scores for both groups of patients receiving ATH434 were “clearly separated from placebo”.
The company said that “trends of improved motor performance were observed on the Parkinson’s plus rating scale and overall benefit was shown on the clinical global impression of severity at the 50mg dose ($p=0.009$)”.
Alterity said the primary endpoint was reduced or stabilized iron content in key brain areas affected by multiple system atrophy, with the 50mg dose reducing iron accumulation in the substantia nigra, putamen and globus pallidus significantly at 26 weeks ($p = 0.025$) and approaching statistically significant at 52 weeks ($p = 0.08$).
The company said the 75mg dose reduced iron accumulation in the globus pallidus.
Alterity said 26 patients received 50mg, 25 patients received 75mg and 26 patients were administered placebo.
The company said ATH434 was well-tolerated with similar adverse event rates in the treatment and placebo groups and most adverse events mild-to-moderate in severity.
Alterity chief executive officer Dr David Stamler said statistical significance on the Umsars was “extremely meaningful because it assesses the functional areas affected in MSA and is the endpoint needed to support … approval by the US Food and Drug Administration”.
“Based on the strength of these phase II data, we look forward to engaging with the FDA as quickly as possible to discuss the path forward for accelerating the development of ATH434 given the tremendous unmet need for treating MSA,” he said.
Alterity climbed as much as 1.1 cents or 137.5 percent to 1.9 cents before closing up one cent or 125 percent to 1.8 cents with 638.2 million shares traded.

MEDADVISOR

Medadvisor says receipts from customers for the six months to December 31, 2024 were down 22.6 percent to $47,094,000, compared to the prior corresponding period.
Medadvisor said receipts from sales of its patient medication management software for pharmacies for the three months to December 31, 2024 were down 53.3 percent to $19,597,000, compared to the previous corresponding period, while US sales fell 43.7 percent in the three months to $25.3 million, “primarily due to deferrals in vaccine-related health programs from two key [pharmacy] clients”.
The company said it began a restructure in January 2025, which was expected to result in annual cost savings of at least $5.0 million by June 30, 2026, and it expected “a stronger second half through a diversified US pipeline for various health programs, as well as a number of new customer accounts currently being finalized”.
Medadvisor said it had a $4,038,000 cash burn in the quarter, with cash and equivalents of $12,398,000 at December 31, 2024 compared to $22,535,000 the prior year.
Medadvisor fell 1.5 cents or 7.5 percent to 18.5 cents.

ALCIDION GROUP

Alcidion says receipts from customers for the six months to December 31, 2024 were up 1.6 percent to $15,342,000, compared to the previous corresponding period.

Alcidion said its receipts from customers for its Miya electronic patient record system and other patient monitoring software for the three months to December 31, 2024 were up 4.2 percent to $9,061,000, compared to the prior corresponding period.

Alcidion managing-director Kate Quirke said the three months to December 31, 2024 was "a very active period … delivering $13.1 million of new and renewal sales, with the majority being from new customers".

"Heading into the second half of the financial year, 2024-'25 contracted revenue stands at approximately $30.8 million … [and] we maintain our position of [earnings before interest, taxation, depreciation and amortization] breakeven occurring upon achieving revenue of approximately $36.0 million and as result of our continued sales progress we expect to be Ebitda and cashflow positive for 2024-'25," Ms Quirke said.

"Furthermore, with the addition of several larger new contracts we continue to build our annually recurring revenue base which is increasingly valuable given the critical nature of our technology offering and longstanding nature of our customer relationships," Ms Quirke said.

The company said that it had a $259,000 cash burn for the three months, with cash and cash equivalents of $7,681,000 at December 31, 2024 compared to $7,914,000 at December 31, 2023.

Alcidion fell 0.1 cents or 1.5 percent to 6.6 cents with 1.6 million shares traded.

ATOMO DIAGNOSTICS

Atomo says customers receipts for the six months to December 31, 2024 were up 49.0 percent to $2,888,000, compared to the previous corresponding period.

Atomo said receipts from sales of its finger-prick, HIV self-test for the three months to December 31, 2024 were up 57.1 percent to $1,723,000, compared to the prior corresponding period.

The company said during the three months it "onboarded 41 new pharmacies in Australia and progressed launch activities for New Zealand with commercial launch through a leading national pharmacy chain scheduled for April this year".

Atomo said it had a positive cash flow of $308,000 for the three months, with cash and cash equivalents of $2,896,000 at December 31, 2024 compared to $6,510,000 at December 31, 2023.

Atomo was unchanged at 1.8 cents with 1.1 million shares traded.

AUDEARA

Audeara says receipts from customers for the six months to December 31, 2024 were up 60.5 percent to $2,307,000, compared to the prior corresponding period.

Audeara said receipts from sales of its ear buds and other hearing health and audio products for the three months to December 31, 2024 rose 69.6 percent to $1,126,000, compared to the previous corresponding period.

The company said it had a cash burn of $578,000 for the three months, with cash and cash equivalents of $1,714,000 at December 31, 2024 compared to $1,650,000 at December 31, 2023.

Audeara was untraded at 3.7 cents.

CLEVER CULTURE SYSTEMS (FORMERLY LBT INNOVATIONS)

Clever Culture says it has a $511,000 positive cash flow for the three months to December 31, 2024 for the first time since September 30, 2022.
A spokesperson for the company told Biotech Daily that the last positive cash flow period was $357,000 for the then LBT in the three months to September 30, 2022.
Today, Clever Culture said receipts from sales of its automated plate assessment system (Apas) for analyzing microbiology culture plates for the six months to December 31, 2024 were up 170.0 percent to $1,617,000, compared to the prior corresponding period.
The company said receipts for the three months were up 244.0 percent to $1,008,000, with cash and cash equivalents of $1,700,000 at December 31, 2024 compared to $3,242,000 at December 31, 2023.
Clever Culture was unchanged at 1.7 cents with 2.05 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it intends to buy-back and cancel up-to $5 million worth of its shares, or about 14,705,882 shares based on its last closing price of 34 cents.
Mach7 said it considered the on-market buy-back “to be an efficient use of capital given the strength of Mach7’s balance sheet and strong cash inflows to date” and that it had a cash balance of $25.3 million at January 29, 2025.
The company said the price paid per share would be no more than a five percent premium to the five-day volume weighted average price of shares prior to purchase.
Mach7 said the number of shares purchase would not exceed 10 percent of the shares on issue and would not require shareholder approval.
Mach7 was up three cents or 8.8 percent to 37 cents with 1.3 million shares traded.

VICTORIA GOVERNMENT, BREAKTHROUGH VICTORIA, DIAG-NOSE MEDICAL

The Victoria Government says Breakthrough Victoria has invested $800,000 in Diag-Nose Medical for its Rhinomap diagnostic tool for chronic respiratory disorders.
A media release from the Minister for Economic Growth and Jobs Danny Pearson said the Melbourne-based Diag-Nose had developed Rhinomap using artificial intelligence “to map the biological makeup of a patient’s respiratory system so the most effective treatment for patients can be quickly determined”.
The Victoria Government said the tool could reduce costs for patients and improve health outcomes and would be used to “treat chronic respiratory conditions like asthma, chronic obstructive pulmonary disorder and chronic sinusitis, which affect almost 9.0 million Australians and more than 450 million people around the world”.
The Government said Breakthrough Victoria’s investment was in addition to a $50,000 Launchvic grant for Diag-Nose Medical through its Medtech Market Growth Program, which supported medical technology “start-ups and scale-ups giving them the skills, services and resources they need to push their life-saving medical products to market”.
Mr Pearson said the government was “backing Diag-Nose so they can get their life-saving products into market to help people in Australia and around the world who are living with these conditions”.
Diag-Nose Medical co-founding chief executive officer Eldin Rostom said “together with the new biologics medicines, our Rhinomap platform will bring us one step closer towards the holy grail of respiratory medicine, helping patients become completely free of symptoms”.
Diag-Nose is a private company.

QUEENSLAND INSTITUTE OF MEDICAL RESEARCH, KAZIA THERAPEUTICS

The Queensland Institute of Medical Research Berghofer says with Kazia it will conduct a 24-patient, phase Ib trial of paxalisib with standard-of-care for breast cancer.
In 2022, Kazia said that with QIMR, it would conduct pre-clinical studies of paxalisib in solid tumors; and last year, said it had licenced the Institute's PI3K-inhibitor-related intellectual property, which included paxalisib (BD: Dec 15, 2022, Sep 13, 2024).
Today, the Brisbane-based Institute said it would be the first clinical trial of paxalisib, which would study the safety and efficacy of the treatment in combination with pembrolizumab, marketed as Keytruda, or Olaparib, marketed as Lynparza, in 24 women with metastatic, triple-negative breast cancer.
QIMR said paxalisib was able to cross the blood-brain barrier, which was "significant for metastatic triple-negative breast cancer because the brain is one of the common sites the cancer spreads to when disease progresses".
The Institute said the multi-centre, open-label, phase Ib study was sponsored by Kazia and would treat patients for up-to 12 months at sites in Queensland.
QIMR Berghofer's Prof Sudha Rao said the hope was to prolong survival of patients through the combination therapy, which targeted dormant cancer cells that drove the spread and recurrence of the disease and helped the immune system fight the cancer.
On the Nasdaq, Kazia fell 3.0 US cents (4.8 Australian cents) or 2.1 percent to $US1.38 ($A2.21) with 83,656 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has dosed 79 of 92 patients in its phase II trial of ARG-007 for acute ischaemic stroke and has approval to continue the trial with "no modifications".
Last year, Argenica said it had dosed the first cohort in the study of ARG-007 for acute ischaemic stroke, with no adverse events reported (BD: Apr 10, 2024).
Later, the company said it would conduct a final safety review following the dosing of 74 patients "at the end of January" (BD: Dec 10, 2024).
Today, Argenica said the independent data safety monitoring board had recommended the trial "continues with no modification to the study protocol".
The company said the data reviewed by the safety board included information on one serious adverse event that was deemed by investigators at the clinical trial site "possibly related to the study drug administration".
Argenica said trial site investigators "noted in their assessment that other concomitant medication the participant was on could have also caused the [serious adverse event] and therefore deemed only possibly-related".
The company said the trial was double-blinded, so it was unknown if the patient received placebo or ARG-007.
Argenica said due to the strong rate of recruitment overall it expected dosing to be completed in around April 2025, with topline data to be "provided within weeks of the final 90-day follow-up of last patient dosed".
Argenica managing-director Dr Liz Dallimore said that the final review was "a significant milestone".
Argenica was up four cents or 6.1 percent to 69.5 cents.