Biotech Daily

Wednesday March 5, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PERCHERON UP 10%; OPTHEA DOWN 13%**

*** COMPUMEDICS: FDA CLEARS FALCON HOME SLEEP TEST**

*** ATMO GAS CAPSULE VALIDATED, READIES FOR FDA RE-APPLICATION**

*** VAXXAS MOUSE STUDY BACKS HD-MAP FOR DNA VACCINES**

*** ENLITIC: GE HEALTHCARE'S GENESIS TO INCLUDE ENSIGHT SUITE**

*** ECHO IQ: BETH ISRAEL IMPLEMENTS ECHOSOLV-AS**

*** CLARITY PHASE I/II CU-67 TRIAL EXPANDS TO 24 PATIENTS**

*** CLARITY, UNIVERSITY OF QUEENSLAND CU-64 SUPPLY DEAL**

*** RACE $8.6m FOR GEORGE CLINICAL RC220 PHASE I CARDIO-PROTECTION TRIAL**

*** IMMURON TO DISTRIBUTE CALMINO PRO-IBS TREATMENT**

*** INVION TERMINATES, REPAYS LIND FACILITY**

*** ALCIDION CEO KATE QUIRKE SELLS 5m SHARES**

*** ADALTA $425k RADIUM RDTI LOAN**

*** ACORN TAKES 11% OF MICRO-X**

*** ARGENT MOVES EU MANUFACTURING TO NORTH MACEDONIA'S ECC PHARM**

*** GARY HERMON REPLACES ARGENT DIRECTOR LEIGHTON MILLS**

MARKET REPORT

The Australian stock market was down 0.7 percent on Wednesday March 5, 2025, with the ASX200 down 57.0 points to 8,141.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 22 fell and seven traded unchanged. The four Big Caps were mixed.

Percheron was the best, for the second day in a row, up 0.1 cents or 10 percent to 1.1 cents, with 2.4 million shares traded. Clinuvel climbed 6.1 percent; Cyclopharm, Mesoblast, Prescient and Starpharma improved more than four percent; Clarity was up 3.4 percent; Avita, Cochlear and Pro Medicus rose one percent or more; with Emvision, Nanosonics and Neuren up by less than one percent.

Opthea led the falls, down 11.5 cents or 13.3 percent to 75 cents, with 13.1 million shares traded. Cynata, Medadvisor and Syntara lost six percent or more; Immutep was down 5.1 percent; Aroa, Curvebeam, Genetic Signatures, Nova Eye, Orthocell and Resonance fell more than four percent; Actinogen and EBR were down more than three percent; Alcidion, Amplia, Impedimed, Paradigm, Polynovo and Resmed shed more than two percent; 4D Medical, Dimerix, Proteomics and Telix were down one percent or more; with CSL down by 0.2 percent.

COMPUMEDICS

Compumedics says the US Food and Drug Administration has cleared its Falcon home sleep testing (HST) device for sale.

Compumedics said the Falcon HST would complement its other approved product, the Somfit platform, which was “gaining commercial traction” in the US, with the Falcon HST designed to be set up and worn by patients to record data as they sleep.

The company said the home sleep testing market in the US was estimated to be between $US100 million ($A160 million) to $US200 million ($A319 million) a year, with 3,000 sleep centres and 15 major independent diagnostic testing facilities.

Compumedics said it hoped to “achieve between 10 percent and 30 percent of the addressable market over the next 24 months” and had already begun sales of Somfit in the US, with initial sales in the last six months of about $1 million.

The company said it had sold more than 100 Falcon HST devices in Australia since its release in October 2024.

Compumedics executive chair Dr David Burton said that “following FDA clearance for the Falcon HST device in the US, Compumedics can further accelerate our HST commercialization strategy to capitalize on this high growth sleep market segment”.

Compumedics

ATMO BIOSCIENCES

Atmo says that a 213-participant study validates its ingestible gas-sensing capsule for gut health for gastro-intestinal transit times to assist with the diagnosis of disorders.

Atmo said the study validated the capsule “for assessing whole and regional gastro-intestinal transit times to assist with the diagnosis of highly prevalent motility disorders such as gastro-paresis (delayed emptying from the stomach) and slow transit constipation”.

Last year, Melbourne’s Atmo said the study met its primary endpoint (BD: Apr 9, 2024).

Today, the company said that the subjects at 12 trial sites in the US and Australia ingested the Atmo Gas Capsule and a predicate device, the Wireless Motility Capsule, to test the comparative ability of Atmo to assess the primary endpoints of gastric emptying time, that is, emptying from the stomach, and colonic transit time, the transit time in the large bowel, to assist with diagnosis of gastro-paresis and slow transit constipation.

Atmo said all endpoints were met.

The research article, titled ‘The Assessment of Gastrointestinal Transit by the Atmo Capsule: A Comparison With the Smart Pill Capsule’ was published in the journal Clinical Gastroenterology and Hepatology and the complete article is available at: https://www.cghjournal.org/article/S1542-3565(25)00069-2/fulltext.

Atmo said the data would support a US Food and Drug Administration regulatory submission for an initial indication to evaluate whole and regional gut transit to assess common gastrointestinal motility disorders.

Massachusetts General Hospital principal investigator Dr Braden Kuo said “the Atmo gas capsule correlated well with the other technology on assessments of gastric emptying time and colonic transit time … [and the] results demonstrate that the Atmo Capsule is a clinically useful method for evaluating gastrointestinal transit”.

Atmo chief executive officer Mal Hebblewhite told Biotech Daily that the company would re-apply for US regulatory approval “next month and then it’s up to the FDA”.

Mr Hebblewhite said that the sole competitor and comparator product was Medtronic’s Smartpill which had been discontinued.

Atmo is a public unlisted company.

VAXXAS

Vaxxas says a mouse study supports the use of its high-density microarray patch (HD-MAP) technology to deliver DNA-based vaccines.

Vaxxas said its high-density microarray patch delivered a dry formulation of vaccine encoding the for the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) spike protein to immune cells below the skin surface.

The company said University of Queensland researchers studied the HD-MAP delivery of a DNA-based Covid-19 vaccine candidate, developed by the Melbourne-based Technovalia, to mouse skin.

Vaxxas said the study, titled 'Skin patch delivery of a Sars-Cov-2 spike DNA vaccine produces broad neutralising antibody responses', was published in Heliyon and was available at: https://www.sciencedirect.com/science/article/pii/S2405844025009132.

Vaxxas is a private company.

ENLITIC

Enlitic says Chicago's General Electric (GE) Healthcare's Genesis imaging program will include its Ensight Suite program for medical imaging.

Enlitic said Ensight would enable the Genesis imaging portfolio to conduct large-scale, artificial intelligence-powered medical imaging migrations, transmitting standardized, high-quality imaging data through Amazon web service's digital cloud network.

The company said it would work with Amazon web service (AWS) to enable its technology to transmit data to Amazon web services' cloud network.

Enlitic chief executive officer Michael Sistenich said the company was "fully engaged with GE HealthCare and AWS to bring this innovative solution to market".

The company said financial terms, details and conditions were being finalized and would be disclosed "in due course".

Enlitic

ECHO IQ

Echo IQ says Boston's Harvard Medical School Beth Israel Deaconess Medical Centre has become the fourth US hospital to use Echosolv-AS

Last year, Echo IQ said five US hospitals would use its artificial intelligence-based Echosolv decision support software for assessing aortic stenosis with echo-cardio-graphy, including the Beth Israel Deaconess Medical Center (BD: Nov 18, 2024).

Echo IQ chief executive officer Dustin Haines said that "following FDA Clearance for our technology … the team at Echo IQ has stayed committed to the disciplined execution of our broader commercialization strategy for Echosolv-AS in the US healthcare market".

"In the first two months of 2025, we have continued to build a very strong integration pipeline, which now exceeds over 60 individual sites and a number of large groups, all with multiple hospitals in their respective networks," Mr Haines said.

"Advanced discussions are ongoing with a number of integration partners that provide image and [picture archiving and communication system] software solutions for hospital systems," Mr Haines said. "This has been undertaken while advancing the use of Echosolv-AS with our flagship deployment site, Beth Israel."

"The company has taken key steps towards approval for a designated [current procedural terminology] code for our technology, as well as … additional research and development … [to] provide valued insight into the health economics of Echosolv," Mr Haines said.

Echosolv

CLARITY PHARMACEUTICALS

Clarity says its ‘Secure’ phase I/II trial of copper-67 Sar-bis-PSMA can expand its 8GBq (giga-becquerels) dose cohort from 14 to 24 patients, and increase dose cycles.

Clarity said that, following recommendations from its safety review committee, it had amended the trial protocol to dose participants at earlier stages of their disease, including pre-chemotherapy, with the safety review committee recommending it increase the number of dosage cycles from four to up-to six.

The company said that 12 of 13 patients (92.3%) who had not received chemotherapy “had prostate specific antigen drops of 35 percent or more” predominantly with single doses of Cu-67 Sar-bis-PSMA, with reductions of 80 or more percent in “almost half of these patients”.

In 2022, the company said it treated the first patient in its ‘Secure’ phase I/IIa trial of Cu-67 Sar-bis- prostate specific membrane antigen (PSMA) for metastatic non-resectable prostate cancer and in 2023 said it had treated the first cohort in the trial and would increase the dose to 8GBq in cohort two (BD: Oct 7, 2022; May 24, 2023).

In 2024, Clarity said the first patient treated with two doses of 8.0GBq of Cu-67 Sar-Bis-PSMA had a “complete response” and later said data from three patients in cohort four of its 44-patient phase I/IIa trial showed copper-67 Sar-bis-PSMA to be safe and potentially reduce prostate-specific antigen (BD: Apr 30, Sep 12, 2024).

Today, the company said its meeting with the safety review committee confirmed the end of the dose escalation phase of its trial and that it would begin the cohort expansion phase, and in doing so move to its phase II component.

Clarity said that despite only 77 percent of patients only receiving a single dose, 68 percent of total participants showed reductions in prostate-specific antigen (PSA) levels, with a complete response in a participant in cohort four following two doses of 12GBq and PSA levels continued to drop in the three participants from cohort four to more than 79 percent.

The company said most adverse events had been resolved.

Clarity

CLARITY

Clarity says the University of Queensland will supply it copper-64 to manufacture its Cu-64-Sar-Bis-PSMA product for its various trials.

Clarity said the product would be used for its phase III ‘Clarify’ and ‘Amplify’ trials, its investigator-initiated trial ‘Co-PSMA’ at Sydney’s St Vincent’s Hospital and its ‘Secure’ trial, as well as its pre-clinical program, including its Sar-Bis-Fap and Sar-trastuzumab programs.

Clarity executive chair Dr Alan Taylor said “this agreement with the University of Queensland Australian Institute for Bioengineering and Nanotechnology not only builds on years of close ties between Clarity and the Australian scientific and clinical communities but also reflects our strong focus on continued partnership and synergies that can be derived from these important collaborations”.

“We are dedicated to continuing to work with the leading research and development organizations in Australia and giving back to the scientific and clinical community in our country in order to get closer to our ultimate goal of improving treatment outcomes for people with cancer,” Dr Taylor said. “University of Queensland advanced imaging has been a long-standing collaborator of Clarity through a number of [research and development] initiatives, including being an active participant in the Australian Research Council Hub for Advanced Manufacture of Targeted Radiopharmaceuticals”.

RACE ONCOLOGY

Race says it will pay contract research organization George Clinical International $8,582,115 for a 53-patient, phase I trial of RC220 bisantrene for advanced tumors.

In 2024, Race said it would pay Sydney's George Clinical $1,071,067 to be the contract research organization for a 34-patient, phase Ia/Ib trial of RC220 bisantrene in solid tumor patients, with additional payments on milestones (BD: Jun 20, 2024).

At the time, the company said the phase I, open-label trial would be in Australia, Hong Kong and South Korea, with the phase Ia stage to study ascending doses of RC220 bisantrene for safety, tolerability, pharmacokinetics, n6-methyladenosine RNA effects and the maximum tolerated dose alone and with the anthracycline chemotherapy doxorubicin.

In December, Race said it had submitted an ethics application for an up-to 40-patient, phase I trial of RC220 bisantrene with doxorubicin for solid tumors at Sydney's Southside Cancer Care Centre and would file for locations in Hong Kong and South Korea by April 2025 (BD: Dec 5, 2024).

Today, Race said the study would provide human safety and pharmaco-kinetic data, determine the maximum tolerated combined dose of RC220 and doxorubicin, and yield initial clinical data on the cardio-protective, anticancer and RNA activity of RC220.

The company said the contract covered "all out-sourced trial-related services, investigator grants, and pass through costs" for a dose-escalation and expansion stage of the trial in Australia, Hong Kong and South Korea, with the final cost to depend on the number of patients and other variables of the trial's execution.

Race managing-director Dr Daniel Tillett told Biotech Daily that all the announcements related to the same trial.

Race

IMMURON

Immuron says it will sell the Gothenburg, Sweden-based Calmino Group AB's Pro-irritable bowel syndrome (IBS) treatment in Australia and New Zealand.

Immuron said its "fee-free", five-year exclusive distribution deal with Calmino included all marketing and sales of Pro-IBS, and said it would fund the collaboration.

The company said Calmino would retain intellectual property rights and there was a possibility to extend the contract for an additional five years, subject to standard commercial conditions.

The company said Calmino previously conducted a study of Pro-IBS among users that found it was "helpful" for 94 percent of users, with 91 percent experiencing an "improvement in daily life" and 90 percent saying they would recommend it to others.

Immuron said the product contained AVH200 "derived from the plant Aloe barbadensis" (Aloe vera), was safe and had no known interactions with other medications.

Immuron chief commercial officer Flavio Palumbo said that "following the rapid growth of Travelan in pharmacy as the leading product for the prevention of traveler's diarrhea, we have identified a great opportunity with Pro-IBS to further expand our digestive health portfolio by providing pharmacists a proven premium efficacy product that delivers unique benefits to their customers".

"With Pro-IBS, we are able to provide an innovative and European certified medical device for the treatment of symptoms related to IBS," Mr Palumbo said.

"The product has been on the Swedish pharmacy market for more than a decade," Mr Palumbo said. "Because it is backed by science and recommended by physicians and dietitians, we can promote Pro-IBS with absolute confidence."

Immuron

INVION

Invion says it has terminated its share purchase agreement with Lind Global Fund II LP and will repay the last $250,000 installment at a five percent premium.

Last year, Invion said it had a $2.4 million to $6.8 million draw-down equity facility with New York's Lind Partners, with $1.2 million upfront in a share deal and a $100,000 draw-down (BD: Jun 27, 2024).

At the time, the company said it would draw-down 11 monthly tranches of $100,000, with tranches to increase by agreement to up-to $500,000, or reduced to $25,000, in subsequent months.

Invion said Lind had the option to acquire shares for 0.75 cents each until September 30, 2024, and then had the option to buy shares at either that price or 90 percent of the average of the three lowest daily volume weighted average prices during the 20 days prior to each subscription date, limited to $70,000 a month, that could be increased to $150,000 a month, if monthly tranches under the private placements did not occur.

Yesterday, the company said it raised $2.0 million at 14 cents, a 2.5 percent premium to the 30-day volume weighted average price, in a placement to support its phase I/II trials (BD: Mar 4, 2025).

Today, Invion said it "would like to thank Lind for the support it has provided over the past several months, which was instrumental in helping fund the initiation of the phase I/II non-melanoma skin cancer trial, as well as other research and development programs".

Invion

ALCIDION GROUP

Alcidion says chief executive officer Kate Quirke has sold 5,000,000 shares through a "pre-market block trade" for $425,000 or 8.5 cents each to "diversify her family's assets".

Alcidion said Ms Quirke retained 43.6 million shares or 3.2 percent of the company and was diversifying her family's assets to "meet various financial commitments".

The company said Ms Quirke "no intention to sell any further shares".

Alcidion

ADALTA

Adalta says it has a loan of $424,600 from Melbourne's Radium Capital at 15.0 percent monthly interest against its expected Federal Research and Development Tax Incentive.

Adalta said the loan was 80 percent of its expected Federal Government Research and Development Tax Incentive for the year to June 30, 2025 and the loan would be repaid in October 2025, coinciding with receipt of its tax incentive.

Adalta

MICRO-X

Melbourne's Acorn says it has increased its substantial holding in Micro-X from 45,097,950 shares (9.29%) to 71,089,457 shares (10.85%).

Acorn said between November 6, 2024 and February 13, 2025, it bought and sold Acorn shares, with the largest purchase 11,428,571 shares for $800,000, or 7.0 cents a share.

In February, Micro-X said it raised $3.3 million in a placement and institutional rights issue at 7.0 cents a share, with a further $2.7 million to be raised in a retail rights issue (BD: Feb 10, 2025).

Micro-X was up 0.75 cents or six percent to 13.25 cents.

ARGENT BIOPHARMA (FORMERLY MEDICAL GRADE CANNABIS)

Argent says it will move manufacturing of its marijuana products Cannepil and Cognicann to the North Macedonia-based ECC Pharm for Europe and the UK.

Argent said it would focus on clinical development, medical advancement and regulatory expansion while moving manufacturing from its own European facilities to ECC Pharm's European Union good manufacturing practice-certified facility in North Macedonia.

Argent

ARGENT BIOPHARMA (FORMERLY MEDICAL GRADE CANNABIS)

Argent says Gary Hermon will replace non-executive director Leighton Mills, effective from today.

Argent said Mr Hermon had more than 30 years of experience in telecommunications, electrical systems and infrastructure rollout, including with Hewlett-Packard, the Victoria State Government, British Petroleum, Exxon-Mobil and Haumea.