Biotech Daily

Thursday December 5, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CURVEBEAM UP 13%; PROTEOMICS DOWN 8%**

*** WEAR OPTIMO OPENS $7m WEARABLE HYDRATION SENSOR FACTORY**

*** CYNATA 'CYP-006TK SAFE, EFFICACIOUS FOR DIABETIC FOOT ULCERS'**

*** COMPUMEDICS $2.15m PLACEMENT**

*** ACRUX PLACEMENT RAISES $2.65m; SHARE PLAN FOR $2m MORE**

*** CAMBIUM RAISES $3m FOR PHASE III ELATE OCULAR TRIAL**

*** AUDEARA $1.35m PLACEMENT**

*** LUMOS FEBRIDX CODE FOR US MEDICARE REIMBURSEMENT**

*** MESOBLAST REVASCOR FDA RMAT STATUS FOR HEART DISEASE**

*** INOVIQ: 'SUB-B2M BLOOD TEST DETECTS BREAST CANCER'**

*** RACE FILES FOR PHASE I RC220 BISANTRENE TUMOR TRIAL**

*** MEMPHASYS FELIX UAE ORDER; ROXSTA FOR CATTLE BREEDING**

*** LITTLE GREEN WELCOMES DENMARK MARIJUANA PROGRAM**

*** MICRO-X RECEIVES $6.4m FEDERAL RDTI; REPAYS $4.6m LOAN**

*** ADHERIUM TAKES $674k ENDPOINTS RDTI LOAN**

*** GOODBYE ANTERIS**

*** PARADIGM REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** RECCE REQUESTS 'TRIAL APPROVAL' TRADING HALT**

*** REGAL FUNDS BELOW 5% OF CARDIEX**

*** RACE M-D DR DANIEL TILLETT TAKES 7.8% OF ISLAND**

*** MICROBIO APPOINTS EX-CSL PAUL PERREAULT ADVISOR**

MARKET REPORT

The Australian stock market was up 0.15 percent on Thursday December 5, 2024, with the ASX200 up 12.3 points to 8,474.9 points.

Fourteen of the Biotech Daily Top 40 companies were up, 20 fell, four traded unchanged and two were untraded.

Curvebeam was the best, up 1.5 cents or 13.0 percent to 13 cents, with 37,651 shares traded.

Amplia was up 10.8 percent; Resonance rose 8.6 percent; Medadvisor climbed 6.6 percent; Orthocell was up 5.4 percent; Percheron improved 4.3 percent; Genetic Signatures was up 3.1 percent; Medical Developments and Pro Medicus rose more than two percent; Alcidion, Clinuvel, Nanosonics and Polynovo were up more than one percent; with Cochlear, EBR and SDI up by less than one percent.

Proteomics led the falls, down 5.5 cents or 8.4 percent to 60 cents, with 205,666 shares traded.

Imugene lost 7.1 percent; 4D Medical and Mesoblast were down more than five percent; Dimerix, Starpharma, Syntara and Universal Biosensors fell four percent or more; Actinogen, Avita, Clarity and Immutep were down more than three percent; Aroa, Cyclopharm, Micro-X and Telix shed two percent or more; Compumedics, Emvision and Opthea were down more than one percent; with CSL, Neuren and Resmed down by less than one percent.

WEAR OPTIMO

Brisbane's Wear Optimo says it has opened a $7 million factory to manufacture its wearable sensors for monitoring hydration for use in aged-care and athletes.

Wear Optimo said the facility was partly funded by a $1 million grant from the Federal Government's Modernisation Manufacturing Fund and would produce up-to 30 million "micro-wearable sensor chips" a year.

The company said it intended to develop sensors for cardiac and renal care as it "advances the next generation of wearable technology".

Wear Optimo said its founding chief executive officer Prof Mark Kendall was the co-chair of the Australian Stem Cell Therapies Mission.

Prof Kendall said hydration was "a critical area of health which can fly under the radar, but which can have serious health implications if it's not monitored and maintained appropriately".

"As an example, it's estimated half of the things that go wrong for people in aged care, including about 25 percent of hospitalizations, can be directly attributed to poorly managed hydration, which can cause problems such as dizziness, falls and infections," Prof Kendall said.

"Part of the issue is that as people age, starting from about age 49, the sensors in the body that tell them they need to hydrate deteriorate," Prof Kendall said.

"So, when seniors don't hydrate properly, it's not because they don't want to drink, it's because their body isn't signaling them to do so," Prof Kendall said.

Wear Optimo is a private company.

CYNATA THERAPEUTICS

Cynata says its 30-patient, phase I trial of topical stem cell wound dressing CYP-006TK met its primary endpoint of “safe and well-tolerated” and showed efficacy.
In 2021, Cynata said it would begin a randomized, 24-week, trial comparing CYP-006TK to standard-of-care for diabetic foot ulcers (BD: Jan 16, 2022).
Today, the company said “no participants withdrew from the trial due to adverse events, and no suspected serious adverse reactions were reported”.
Cynata said “positive efficacy data” from the trial showed improved wound healing for CYP-006TK compared to the standard-of-care control group.
The company said the trial showed a mean decrease from baseline in wound surface area after 12 weeks of 181 sq mm (64.6%) in the CYP-006TK group and an increase of 355 sq mm (22.0%) in the control group.
Cynata said the mean change from baseline in wound surface area at 24 weeks, at the end of the study, was a decrease of 261 sq mm (83.6%) in the CYP-006TK group and an increase of 62 sq mm (47.8%) in the standard-of-care control group.
The company said that the study showed that “larger wounds in particular healed to a greater extent in the CYP-006TK group compared to the standard of care control group”.
Cynata managing-director Dr Kilian Kelly said the company was “very pleased and encouraged by these results”.
“First and foremost, the trial achieved its primary objective of safety,” Dr Kelly said. “Whilst the trial was not powered to show statistically significant efficacy, we believe there is a clear signal indicating improved wound healing compared to standard-of-care treatments.”
Cynata was untraded at 21.5 cents.

COMPUMEDICS

Compumedics says it has “binding commitments” to raise $2.15 million at 26 cents a share in a placement to institutional, professional and sophisticated investors.
Compumedics said the placement price was a 6.8 percent discount to the 15-day volume weighted average price.
The company said the funds would be used to employ four additional US sales staff, for working capital and the May 2025 release of its disposable Somfit device.
Compumedics said PAC Partners Securities was the sole lead manager to the capital raising and would be paid up-to six percent of the funds raised.
Compumedics fell 0.5 cents or 1.85 percent to 26.5 cents.

ACRUX

Acrux says it has “binding commitments” to raise $2.65 million at 3.5 cents a share in a placement, with a further $2 million share purchase plan to follow.
Acrux said the issue price was a 19.35 percent discount to the five-day volume weighted average price of 4.34 cents a share.
The company said investors would receive one option for every share acquired, exercisable at 5.25 cents each within two years.
Acrux said the funds would be used for four projects relating to the development and validation of its topical pharmaceuticals; and the share plan had a record date of December 4, would open on December 6 and close on December 18, 2024.
The company said Evolution Capital and Peak Asset Management were joint lead managers to the placement and would receive 20 options for every $1.00 issued.
Acrux fell 0.4 cents or 8.9 percent to 4.1 cents with 2.7 million shares traded.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says it has raised $3.0 million at a post-consolidation 46.37 cents a share in a placement to fund phase III trials of its Elate Ocular for dry eye disease.
Earlier this year, the then Regeneus said it completed its merger with Cambium, would change its name to Cambium Bio and raised $3.48 million at 0.6 cents share for the phase III trial; and later, said it completed a 100-to-one consolidation (BD: Apr 5, Jul 12, 2024).
Today, Cambium said the issue price was a 25 percent discount to the five-day volume weighted average price.
The company said $1,500,000 was placed with Aventacell Biomedical, $250,000 with major shareholder Zheng Yang Biomedical Technology, $146,000 from its directors and $1,054,000 from its chief executive officer Karolis Rosickas and other investors.
Cambium said it expected to begin its phase III trials by July 2025 and the funds would provide working capital for its ongoing operations.
The company said Lodge Corporate was lead manager to the Australian placement.
Cambium fell 1.5 cents or 2.3 percent to 62.5 cents.

AUDEARA

Audeara says it has commitments to raise $1.35 million at four cents a share, with one attaching option for every three shares issued.
Audeara said the price was a 12.2 percent discount to the 10-day volume weighted average price; and the options were exercisable at 8.0 cents each by January 30, 2027.
The company said chair David Trimboli, managing-director Dr James Fielding and executive director Bill Peng participated in the placement, pending shareholder approval.
Audeara said the funds would be used to increase the capacity of its technology division as well as for stock purchasing and working capital.
The company said Bell Potter Securities was lead manager to the placement and would receive a six percent fee on funds raised.
Audeara was up 0.2 cents or 4.8 percent to 4.4 cents.

LUMOS DIAGNOSTICS

Lumos says the US Centers for Medicare and Medicaid Services will reimburse its Febridx infection test $US41.38 ($A64.33) per test, effective from January 1, 2025.
Last year, Lumos said it had received US Food and Drug Administration clearance to market and sell Febridx; following the FDA's original 2022 rejection of its 510(k) application (BD: Jul 11, Aug 8, Oct 3, 2022; Jul 3, 2023).
Today, the company said the Centers for Medicare and Medicaid Services panel had granted a proprietary laboratory analyses (PLA) code for its Febridx point-of-care, finger-prick blood test to differentiate bacterial from viral respiratory infections.
Lumos said the PLA code would "play a vital role in securing reimbursement for Febridx from government and private insurers".
The company said the reimbursement approval was "a critical step toward enhancing Febridx's accessibility and adoption and is expected to facilitate broader use of the test over time, by making it more affordable".
Lumos said it would "now engage with US private and government payers, as well as other key stakeholders, to establish reimbursement and coverage policies".
Lumos managing-director Doug Ward said that the proprietary laboratory analyses code was a further advance in the US commercialization of Febridx.
Lumos was up 0.9 cents or 29.0 percent to four cents with 31.8 million shares traded.

MESOBLAST

Mesoblast says Revascor has US Food and Drug Administration regenerative medicine advanced therapy (RMAT) status for hypo-plastic left heart syndrome (HLHS).

Earlier this year, Mesoblast said the FDA had granted its allogeneic, stromal cell therapy Revascor, or rexlemestrocel-L, rare pediatric disease and orphan-drug designation for children with the congenital heart disease hypoplastic left heart syndrome (BD: Jan 21, Feb 15, 2024).

Today, the company said regeneration medicine advanced therapy designation provided "all the benefits of breakthrough and fast-track designations, including rolling review and eligibility for priority review on filing of a biologics licence application".

Mesoblast chief executive Prof Silviu Itescu said the company appreciated the "FDA's support in designating Revascor both RMAT and [rare paediatric disease] status, a recognition of the potential impact of our therapy on the long-term adverse outcomes of these desperately ill children".

"Under the RMAT designation, we plan to meet with FDA to discuss a potential approval pathway in this indication," Prof Itescu said.

Mesoblast fell nine cents or 5.1 percent to $1.67 with 18.3 million shares traded.

INOVIQ

Inoviq says its Sub-B2M blood test "detects breast cancer across all stages" with 81 percent sensitivity and 93 percent specificity.

Inoviq has previously said that Sub-B2M was an engineered protein that detected the pan-cancer biomarker Neu5Gc (BD: Sep 16, 2022).

In 2022, the company said a study confirmed the presence of Sub-B2M's binding target, Neu5Gc, in tissue sections including breast, prostate, cervical, ovarian, colorectal and skin, which it said supported its program to develop tests to monitor breast, ovarian, and other cancers (BD: Jul 16, 2022).

Today, Inoviq said the test "specifically detects CA15-3 produced by cancer cells, improving cancer detection and potentially reducing false positives".

The company said the study was designed "to show that the 'neuCA15-3' test was positive and specific for cancer and had low false positives for non-cancer diseases".

Inoviq said the test showed "positive results for breast cancer, with the average CA15-3 concentration being five-fold greater than that observed in healthy individuals".

The company said the results of the test were "negative for 97.4 percent of non-breast cancer samples, confirming the specificity for breast cancer".

Inoviq said commercializing the test would involve transferring the test to an assay for implementation on a high-throughput instrument platform, undertaking an in-clinic breast cancer monitoring study and securing a US accredited laboratory partner.

Inoviq chief executive officer Dr Leearne Hinch said the test was being developed as a laboratory developed test for the US market, initially, and showing the specificity of neuCA15-3 for breast cancer completed "another component of the test validation".

"The next step towards commercializing the neuCA15-3 test is to transfer and optimize the test on a system compatible with high-throughput commercial diagnostic instruments," Dr Hinch said.

Inoviq was up 1.5 cents or three percent to 51.5 cents.

RACE ONCOLOGY

Race says it has submitted an ethics application for an up-to 40-patient, phase I trial of RC220 bisantrene with doxorubicin for solid tumors.
Race said it had submitted a regulatory package to Bellberry human research ethics committee for the trial at Sydney's Southside Cancer Care Centre.
The company said following approval the site would be activate for patient recruitment and institutional approval, with first patient recruitment expected by April 2025.
Race said it would file for locations in Hong Kong and South Korea by April 2025.
The company said the trial would use "a Bayesian statistical design for the dose escalation stage, a design that has proven faster and more efficient than the traditional three plus three dose escalation approach".
Race said the trial would identify the maximum tolerated combination dose of RC220 bisantrene with the doxorubicin, marketed by Pfizer as Adriamycin, as well as the pharmaco-kinetics of RC220 and its effect on a range of exploratory clinical biomarkers.
Race chief medical officer Dr Michelle Rashford said the submission was "a critical milestone".
Race was up 15.5 cents or 12.1 percent to $1.44.

MEMPHASYS

Memphasys says a Dubai, United Arab Emirates clinic will evaluate its Felix sperm separation system for in-vitro fertilization, and it will trial its Roxsta system on cattle.
Memphasys said the Dubai order from laboratory and medical product distributor Panacea Medizintech included one demonstration unit and 30 cartridges and was intended to evaluate the systems suitability for research use only.
The company said the order was "an important initial step in determining the viability of the Felix system within the UAE's regulatory framework".
Separately, the company said it had begun a "scoping analysis to explore the potential of its Roxsta system in determining the threshold levels of oxidative stress in the bovine and its impact on reproductive performance".
Memphasys said the study would begin in December 2024 at a commercial cattle operation in New South Wales and would collect blood and plasma samples from 50 heifers, about one-month post-artificial insemination.
The company said that the primary outcome was conception rate as determined by ultrasound testing on day 90 of pregnancy.
Memphasys was unchanged at half a cent.

LITTLE GREEN PHARMA

Little Green says it welcomes the Danish Government's permanent medical marijuana pilot program and improved marijuana cultivation and export framework.
Little Green said it had production sites for its branded medical marijuana and psychedelic products in Denmark and Western Australia.
The company said proposed changes to the Danish medical marijuana program included the use of pesticides to improve cost-efficiencies and yield, importing cannabis products to improve logistics and reduce costs, use overseas service providers and produce products beyond marijuana flower.
Little Green said Denmark would continue to subsidize up-to 50 percent of medical marijuana, capped at DKK10,000 ($A2,192) a year and improve prescribing practices.
Little Green was up 1.5 cents or 12.5 percent to 13.5 cents.

MICRO-X

Micro-X says it has received $6.41 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Micro-X said the funds included $580,000 relating to an amendment to its incentive from the year to June 30, 2023 as well as $5,830,000 relating to research and development expenditure for the year to June 30, 2024.
The company said it had "previously accessed $4.57 million using an advance funding facility which is repaid as part of the receipt".
Micro-X fell 0.2 cents or two percent to 9.6 cents with 3.8 million shares traded.

ADHERIUM

Adherium says it has a $674,000 loan from Sydney's Endpoints Capital Pty Ltd against its expected Federal Government Research and Development Tax Incentive.
Adherium said the loan was for 80 percent of its accrued incentive for the year to June 30, 2025, and was at an annual interest rate of 16 percent and repayable on receipt of the Tax Incentive.
The company said the funds provided additional working capital as it "scales its patient onboarding and ramps up sales and delivery across a range of customers in the key US remote patient monitoring market".
Adherium was up 0.1 cents or 9.1 percent to 1.2 cents.

ANTERIS TECHNOLOGIES

Anteris says the Supreme Court of Queensland has approved its proposed redomicile to the US, with the last date of trading on the ASX today.
On Tuesday, Anteris said its scheme meeting voted 97.7 percent to redomicile to the US and Nasdaq listing through the Delaware-based Anteris Technologies Global Corp (ATGC) (BD: Nov 13, Dec 3, 2024).
Anteris said the record date for the scheme was December 9, with trading on the Nasdaq expected to begin on December 17, 2024.
Anteris closed up 54 cents or 5.4 percent to $10.54.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested a trading halt "pending an announcement in relation to a capital raising".
Trading will resume on December 9, 2024, or on an earlier announcement.
Paradigm last traded at 58 cents a share.

RECCE PHARMACEUTICALS

Recce has requested a trading halt "pending the release of a material announcement relating to a registrational phase III diabetic foot ulcer infection approval".
Trading will resume on December 9, 2024, or on an earlier announcement.
Recce last traded at 47 cents.

CARDIEX

The Sydney-based Regal Funds Management Pty Ltd says it has ceased its substantial shareholding in Cardiex.
Regal Funds said that it sold shares between October 8 and December 2, 2024, with the single largest sale 301,245 shares on November 19 for $36,149, or 12 cents a share.
Cardiex was up 0.3 cents or 3.2 percent to 9.6 cents.

ISLAND PHARMACEUTICALS

Race Oncology managing-director Dr Daniel Tillett has increased his substantial holding in Island from 8,113,434 shares (5.26%) to 14,127,577 shares (7.82%).
The Sydney-based Dr Tillett said that he bought 6,014,143 shares on December 4, 2024 for $420,990, or seven cents a share in a private placement.
Earlier this year, Island said it had “firm commitments” to raise $3.5 million in an institutional placement at seven cents a share (BD: Oct 3, 2024).
Island was unchanged at 17 cents.

MICROBIO

Brisbane’s Microbio says it has appointed former CSL managing-director Paul Perreault as a strategic advisor.
In 2012, CSL said that head of CSL Behring Mr Perreault would succeed the then managing-director Dr Brian McNamee in July 2013 and that Mr Perreault had joined the company as part of the Aventis Behring acquisition (BD: Aug 3, 2012).
At that time, CSL said that Mr Perreault held a Bachelor’s degree in psychology from Orlando’s University of Central Florida.
Microbio chief executive officer Colin Keating said the company would use Dr Perrault’s “exceptional leadership and capabilities” to support the expansion of its Infectid-BSI bloodstream sepsis-causing bacteria and fungi infection test.
Microbio is a public unlisted company.