

Biotech Daily

Friday December 20, 2024

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: CURVEBEAM UP 9%; MESOBLAST DOWN 21%
- * AVITA: FDA OKAYS COHEALYX FOR FULL-THICKNESS WOUNDS
- * MEDADVISOR EXPECTS H1 REVENUE DOWN 25-30%
- * LUMOS STARTS FEBRIDX BARDA STUDY, \$1.5m MILESTONE
- * CYCLOPHARM: 17 US TECHNEGAS INSTALLATIONS
- * EPSILON PLACEMENT RAISES \$720k
- * ANATARA SHARE PLAN RAISES \$275k OF \$500k; TOTAL \$1.0m
- * LITTLE GREEN TO BUY HEALTH HOUSE FOR \$1.25m
- * RADIOPHARM PHASE I RAD-202 FOR HER2 TUMORS TRIAL APPROVED
- * MEMPHASYS STARTS ROXSTA CATTLE REPRODUCTION STUDY
- * ANTERIS \$9.15m FOR OBSIDIAN CONVERTIBLE NOTES
- * IDT TAKES \$20m SCOTTISH PACIFIC LOAN
- * RHYTHM REQUESTS 'ACQUISITION' TRADING HALT
- * ISLAND BOARD SPILL, 3m DIRECTOR OPTIONS EGM
- * VISIONEERING VOLUNTARY DELISTING MEETING, DATE CHANGES
- * PHILLIP ASSET INCREASES, DILUTED TO 10.3% OF ACRUX
- * PLATINUM REDUCES FROM 9.6% TO 0.9% OF PERCHERON
- * CURVEBEAM CEO GREG BROWN INCREASES, DILUTED BELOW 5%
- * HYDRIX PROMOTES FINANCE HEAD GARETH EVANS TO CFO
- * 4D MEDICAL DIRECTOR JOHN LIVINGSTON TO NON-EXECUTIVE
- * BLUECHIIP CHAIR IAIN KIRKWOOD REPLACES CO SEC PATRICIA VANNI

MARKET REPORT

The Australian stock market fell 1.24 percent on Friday December 20, 2024, with the ASX200 down 101.2 points to 8,067.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and one was untraded. All four Big Caps fell.

Curvebeam was the best, up one cent or 8.7 percent at 12.5 cents, with 340,882 shares traded. Imugene and Micro-X were up more than five percent; Opthea improved 4.55 percent; Compumedics climbed 3.9 percent; Cynata, Medical Developments, Paradigm and SDI rose more than two percent; with Avita, EBR, Proteomics and Resonance up by more than one percent.

Yesterday's 54 percent best, Mesoblast (see yesterday's edition), led the falls, down 63 cents or 20.7 percent to \$2.42, with 39.7 million shares traded; followed by Medadvisor (see below), down 5.5 cents or 20.4 percent to 21.5 cents with 4.4 million shares traded. Universal Biosensors lost 12 percent; Clarity was down 8.45 percent; Nova Eye and Syntara shed more than six percent; 4D Medical, Neuren, Polynovo and Telix were down three percent or more; Aroa, Emvision and Starpharma shed two percent or more; Clinuvel, Dimerix and Immutep were down more than one percent; with Cochlear, CSL, Orthocell, Pro Medicus and Resmed down by less than one percent.

AVITA MEDICAL

Avita says it has US Food and Drug Administration 510(k) clearance for its Cohealyx collagen-based dermal matrix for treating full-thickness wounds.

In August, Avita said it would pay \$US5 million (\$A7.7 million) for rights to sell the New Jersey-based Regenity Bioscience's collagen-based dermal matrix in the US, as well as potentially Europe, Australia and Japan (BD: Aug 1, 2024).

Today, the company said Cohealyx for full-thickness wounds used a cow-based collagen to facilitate cellular migration and blood vessel formation.

Avita said pre-clinical studies in pigs, showed that "Cohealyx generated robust tissue, capable of consistently supporting a split-thickness skin graft in a two-stage procedure earlier than leading dermal matrices in the study".

The company said animal model results did not necessarily translate to clinical results but that the expedited treatment time was expected "to lead to quicker wound closure and streamlined clinician workflows, resulting in shorter hospital stays, reduced treatment costs, and better patient outcomes".

Avita said Cohealyx would be offered with its existing Recell and Permeaderm products and was expected to "generate significant revenue as we penetrate the full-thickness skin defect market".

The company said it expected to conduct a post-market, clinical study for Cohealyx "in early 2025" with commercialization to begin in "the second quarter of 2025".

Avita chief executive officer Jim Corbett said Cohealyx was "a strategic addition to our Recell-centric portfolio, unlocking the powerful synergies of Recell and Cohealyx to address full-thickness wounds".

"This expansion to our product portfolio strengthens our ability to deliver superior patient outcomes and significantly expands our commercial potential in burns," Mr Corbett said. "By equipping clinicians with more comprehensive treatment options, we strengthen our competitive position, drive new growth opportunities, and further our commitment to advancing regenerative medicine," Mr Corbett said.

Avita was up five cents or 1.35 percent to \$3.75 with 274,070 shares traded.

MEDADVISOR

Medadvisor says it expects revenue for the six months to December 31, 2024 to be down 25-to-30 percent from the record \$75.5 million in the prior corresponding period.

Earlier this year, Medadvisor said revenue from its medication and vaccine adherence programs and digital pharmacy platform network for the six months to December 31, 2023 was up 17.9 percent to \$75,549,535 (BD: Feb 29, 2024).

Today, the company said the revenue fall was due to lower-than-expected vaccination rates amongst pharmacy customers in the US influenza season and it expected "to see a significant shift of revenue from the first half to the second half in its US business". Medadvisor said Australian operations were "performing well" in line with expectations and it expected earnings before interest, taxation, depreciation and amortization (Ebitda) "to remain positive for the first half and full year 2024-'25".

Medadvisor managing-director Rick Ratliff said the company had diversified its pipeline and customer base which was "expected to drive increased revenue for the remainder of the financial year and allow us to mitigate revenue volatility".

Medadvisor fell 5.5 cents or 20.4 percent to 21.5 cents with 4.4 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it has a \$U\$925,217 (\$A1,486,000) milestone payment following the opening of its up-to 800-patient, US trial of Febridx finger-prick blood test for infections. In October, Lumos said it received \$U\$2,984,571 (\$A4,350,000) from the US Biomedical Advanced Research and Development Authority (BARDA) (BD: Oct 3, 2024). At that time, the company said the funds would be used for a clinical laboratory improvement amendments (CLIA)-waiver study to support a US Food and Drug Administration filing for its Febridx, point-of-care, finger-prick blood test to differentiate bacterial from viral respiratory infections.

Today, Lumos said starting the study and testing the first patient triggered the milestones. The company said it expected the trial to continue through the 2025 US Spring season, after which a formal submission would be prepared for the FDA.

Lumos managing-director Doug Ward said that "achieving CLIA-waived status would enable Febridx to reach a broader market".

Lumos was unchanged at 3.6 cents with 1.4 million shares traded.

CYCLOPHARM

Cyclopharm says it has 17 operational installations of its Technegas for lung imaging in the US following US Food and Drug Administration approval (BD: Oct 2, 2023). Earlier this year, Cyclopharm said that Connecticut's Yale University and the California-based Stanford University would use its Technegas for diagnosing respiratory diseases (BD: Jan 29, Mar 19, 2024).

Later, the company said it had an agreement to supply 120 US Government Veterans Health Administration hospitals with Technegas for lung imaging (BD: Oct 3, 2024). Today, Cyclopharm said further installations included Boston's Massachusetts General Hospital, the Long Island Jewish Medical Center and New York Presbyterian Hospital. Cyclopharm managing-director James McBrayer said the use of Technegas at "these world-renowned US healthcare and educational institutions marks a significant milestone in our mission to improve patient outcomes through innovation in pulmonary diagnostics ... [and was] a testament to its clinical and commercial value". Cyclopharm was unchanged at \$1.515.

EPSILON HEALTHCARE

Epsilon says it has "firm commitments" to raise \$720,000 at 1.6 cents a share in a placement of 45,000,000 shares.

Epsilon said the placement would "provide key capital to the company as it recovers from voluntary administration, which has had a significant effect on the company's finances". In June, the company's then administrator said a creditors meeting had adopted a deed of company arrangement (DOCA) proposed by founder Alan Beasely (BD: Jun 5, 2024). Today, Epsilon said the funds raised were about equal value to its net tangible assets at October 31, 2024.

In August, the ASX suspended the company from quotation for not paying its annual listing fees, under Listing Rule 17.6 (BD: Aug 22, 2024).

Today, Epsilon said it was "addressing outstanding matters requiring remediation in order to satisfy ASX requirements in order to lift the suspension as soon as practicable". Epsilon was in a suspension and last traded at 2.4 cents.

ANATARA LIFESCIENCES

Anatara says a share plan has raised \$274,500 of a hoped-for \$500,000 at five cents a share, taking the total raised with the placement to \$1,024,500.

Last month, Anatara said it had "commitments" for \$750,000 at five cents a share, a 10 percent discount to the 30-day volume weighted average price, in a placement, with a share purchase plan for up-to \$500,000 to follow (BD: Nov 15, 18, 2024).

Today, the company said the funds raised would be used to complete its pivotal phase II study of gastro-intestinal reprogramming, or Garp, as a complementary medication for irritable bowel syndrome and for further readiness for manufacturing.

Anatara did not disclose any plans to raise the outstanding \$225,500 shortfall.

Anatara fell 0.05 cents or one percent to 5.05 cents.

LITTLE GREEN PHARMA

Little Green Pharma says it has a binding letter of intent to acquire the Perth-based marijuana distributor Health House Australia Pty Ltd for \$1.25 million in cash. Little Green said Health House had been its medical marijuana distribution partner in Australia since 2019 and that the acquisition aligned with its "strategy of capitalizing on current market conditions to acquire sustainable medicinal cannabis businesses at attractive valuations".

The company said Health House was a "cashflow breakeven business generating approximately \$7.5 million in annual revenue".

Little Green said the Health House had granted it an exclusivity period until January 31, 2025 to complete due diligence, and that it would pay a non-refundable deposit of \$50,000 and a refundable deposit of \$25,000, which would be applied to the final acquisition price at the agreement's close.

Last year, the then Creso Pharma, later Melodiol Global Health, said it had shareholder and Supreme Court of Western Australia approval to acquire Health House International for \$4,630,388 in shares and options (BD: May 3, 8, 2023).

In October, the ASX said that Melodiol was removed from the official list under Listing Rule 17.12, following its suspension relating to fees (BD: Aug 29, Oct 29, 2024). Little Green was up one cent or eight percent to 13.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has ethics approval to begin its phase I trial of Lutetium-177 RAD-202 for the treatment of HER2-expressing solid tumors.

Earlier this year, Radiopharm said that its RAD-202 had "indicated a rapid tumor uptake and high tumor-to background ratio" as a therapy and diagnostic for solid tumors, in mice (BD: Oct 23, 2024).

At that time, the company said it would begin an open-label, dose escalation, phase I study of RAD-202 in Australia before 2025, which would evaluate the safety and preliminary activity of the radio-therapeutic in patients with HER2-positive solid tumors. Today, Radiopharm managing-director Riccardo Canevari said RAD-202 had "the potential to address an unmet treatment gap in HER2-positive metastatic patients that are refractory to or unable to tolerate current standard-of-care treatments".

"With RAD-202, we hope to provide an alternative strategy that can improve clinical outcomes for patients with HER2-positive advanced cancers, while potentially preserving their quality-of-life," Mr Canevari said.

Radiopharm was up 0.3 cents or 14.3 percent to 2.4 cents with 16.8 million shares traded.

MEMPHASYS

Memphasys says it has begun its study of Roxsta anti-oxidant system for use in bovine, or cattle, reproductive performance.

Earlier this month, Memphasys said it would begin a trial of the Roxsta system at a New South Wales cattle operation and collect blood and plasma samples from 50 heifers about one-month post-artificial insemination (BD: Dec 5, 2024).

Today, the company said "the milestone marks an essential step in advancing the company's research into oxidative stress thresholds and their impact on bovine reproductive performance".

Memphasys fell 0.1 cents or 16.7 percent to half a cent with 3.7 million shares traded.

ANTERIS TECHNOLOGIES GLOBAL CORP (FORMERLY ANTERIS TECHNOLOGIES)

Anteris says it will redeem all outstanding convertible notes under its draw-down equity facility with Obsidian Global Partners for \$US5,700,263 (\$A9,151,433) in cash. Last month, Anteris said it had a \$25 million draw-down equity facility with New York's Obsidian Global to support its US re-domicile and Nasdaq listing (BD: Nov 1, 2024). At that time, the company said it had drawn-down an initial \$7.5 million, with additional drawdowns to be made in increments of \$5.0 million and that each convertible note had a face value of \$US1.15 (\$A1.75).

On Tuesday, Anteris said it had raised \$US88.8 million (\$A138.4 million) at \$US6.00 (\$A9.42) a share in its initial public offer to list on the Nasdaq; and resumed trading on the ASX under the code 'AVR' (BD: Dec 17, 2024).

Today, the company said it would pay Obsidian an additional \$300,000 in lieu of the options required to be issued in connection with the initial draw-down.

Anteris said following the redemption no convertible notes would be outstanding under the facility and the facility would remain available for future drawdowns pursuant to its terms. Anteris fell nine cents or one percent to \$8.95.

IDT AUSTRALIA

IDT says it has taken a \$20 million, asset-based loan with Sydney's Scottish Pacific Business Finance Pty Ltd at 10.60 percent per annum to support sales.

IDT said the loan replaced its current \$4.7 million facility with the National Australia Bank (NAB) and would be used to scale its operations in response to increased demand for its pharmaceutical manufacturing services.

The company said the loan was repayable within 36 months with the potential to roll into an ongoing term, subject to mutual agreement, and was secured against its assets. IDT was unchanged at 10 cents.

RHYTHM BIOSCIENCES

Rhythm has requested a trading halt "pending ... a proposed acquisition". Trading will resume on December 24, 2024, or on an earlier announcement. Rhythm fell 0.4 cents or 4.8 percent and last traded at eight cents.

ISLAND PHARMACEUTICALS

Island says following the approval of a board spill investors will vote to re-elect directors Phillip Lynch and Albert Hansen and issue 3,000,000 options to Mr Lynch.

Last month, Island said 92.2 percent of its annual general meeting voted a remuneration report second strike with the board spill approved by 98.43 percent (BD: Nov 19, 2024). Earlier this month, the company said an extraordinary general meeting would vote on a board spill, to be held on January 28, 2025 (BD: Dec 3, 2024).

Today, Island said the meeting would vote to issue Mr Lynch 3,00,000 options exercisable at 15 cents each within three years, in addition to his \$150,000 yearly pay.

The meeting will be held at K&L Gates, 31/1 O'Connell Street, Sydney on January 28, 2025, at 11am (AEDT).

Island was up half a cent or 2.9 percent to 18 cents.

VISIONEERING TECHNOLOGIES

Visioneering says a special meeting will vote to approve the removal of the company from the official list of the ASX.

Last week, Visioneering said it requested it be removed from the ASX official list due to its "low trading price", with delisting expected on February 10, 2025 (BD: Dec 10, 2024).

Today, the company said shareholders at the record date of December 16, 2024 would vote on the scheme, with its delisting expected on February 14, 2025.

The meeting will be held online on January 14, 2025 at 9am (AEDT).

Visioneering fell 0.3 cents or 6.1 percent to 4.6 cents with 719 shares traded.

ACRUX

Melbourne's Phillip Asset Management Ltd says it has increased and been diluted in Acrux from 31,147,134 shares (15.09%) to 37,561,419 shares (10.32%).

Phillip Asset said as trustee for Bioscience Managers Translational Fund it was diluted on December 12 due to the issue of shares and bought 5,714,285 shares in a placement on December 19, 2024 for \$200,000, or 3.5 cents a share.

Earlier this month, Acrux said it raised \$2.65 million at 3.5 cents a share (BD: Dec 5, 2024). Acrux was up 0.1 cents or three percent to 3.4 cents with 1.1 million shares traded.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Sydney's Platinum Investment Management says it has reduced its substantial holding in Percheron from 101,464,483 shares (9.57%) to 10,000,000 shares (0.92%).

Platinum said that between December 11 and 18, 2024 it sold 91,464,483 shares for \$882,024, or 0.96 cents a share.

On Wednesday, Percheron fell as much as 91.5 percent on news that its 48-patient, phase IIb trial of avicursen for Duchenne muscular dystrophy did not meet its primary endpoint (BD: Dec 18, 2024).

Percheron was unchanged at 0.7 cents with 33.4 million shares traded.

CURVEBEAM

Curvebeam chief executive officer Gregory Brown says he has increased his substantial shareholding in the company and been diluted below five percent.

The Melbourne-based Mr Brown said that between December 4 and 10, 2024 he bought 310,407 shares at prices ranging from 11 cents to 14 cents a share and acquired 166,667 salary sacrifice shares on December 13, 2024 for 18 cents a share.

In August, Curvebeam said it raised \$1.64 million at 18 cents a share in a rights offer, taking the total raised to \$11.54 million, with a shortfall of \$2 million (BD: Aug 28, 2024). Curvebeam was up one cent or 8.7 percent to 12.5 cents.

HYDRIX

Hydrix says it has appointed head of finance Gareth Evans as its chief financial officer, effective from January 1, 2025.

Hydrix said Mr Evans had more than 14 years of experience in finance in the public, health and medical technology sectors.

According to his Linkedin page, Mr Evans held a Bachelor of Economics from England's University of Exeter.

Hydrix was up 0.1 cents or 9.1 percent to 1.2 cents.

4D MEDICAL

4D Medical says executive director John Livingstone will "revert to a non-executive director position with the company", effective from January 1, 2025.

4D Medical fell 1.5 cents or 3.3 percent to 44 cents.

BLUECHIIP

Bluechiip says it "has appointed lain Kirkwood as company secretary in conjunction with his role as chair", replacing the resigning Patricia Vanni, effective from today.

Bluechiip said the appointment was "part of its cost containment program".

Bluechiip was in a suspension and last traded at 0.3 cents.