



Biotech Daily

Wednesday October 27, 2021

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: PHARMAXIS UP 9%; DIMERIX DOWN 7%
- * AROA H1 REVENUE UP 37% TO \$13.2m
- * IMPEDIMED RAISES \$35m, SHARE PLAN FOR \$5m MORE
- * ANTERIS: L1 CAPITAL \$5m PLACEMENT
- * TALI RECEIVES \$504k R&DTI VICTORIA LOAN
- * EPSILON EXTENDS \$4m LOAN REPAYMENT
- * UNIVERSAL BIOSENSORS RECRUITS 1st XPRECIA PRIME TRIAL PATIENT
- * OVENTUS: ALGORITHM ACCURATE FOR APNOEA; FDA EXVENT TRIAL
- * RHINOMED: RHINOSWAB ST VINCENT'S TRIAL APPROVED
- * RACE, CHAIM SHEBA ANALYZE ZANTRENE FTO BIOMARKERS
- * ADHERIUM AGM 19% OPPOSE REMUNERATION REPORT
- * LBT POTENTIAL 2nd STRIKE SPILL, 1.75m DIRECTORS OPTIONS AGM
- * OPTHEA: CHINA PATENT FOR OPT-302
- * BIOXYNE REQUESTS 'POTENTIAL ACQUISITION' TRADING HALT
- * PERENNIAL REDUCES TO 12.3% IN MEDADVISOR
- * LOUMEA DILUTED BELOW 5% IN RHYTHM
- * REGAL FUNDS BELOW 5% IN BCAL
- * BLACK ROCK TAKES 11% OF IMRICOR
- * ONCOLOGY ONE: PETER MAC CEO PROF SHELLEY DOLAN DIRECTOR
- * SPEEDX, ONKO-INNATE, DAVID BLAKE WIN AUSBIOTECH GONGS
- * AUSBIOTECH: REGENERATIVE MEDICINE FOUNDATIONS LAID
- * BIO-MELBOURNE ADDRESSES FREIGHT LOGISTICS, DELAYS

MARKET REPORT

The Australian stock market edged up 0.07 percent on Wednesday October 27, 2021, with the ASX200 up 5.3 points to 7,448.7 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Pharmaxis was the best, up one cent or 8.7 percent to 12.5 cents, with 532,534 shares traded.

Osprey climbed six percent; Alterity was up 3.45 percent; Amplia and Optiscan rose more than two percent; Cochlear, CSL, Imugene, Orthocell, Proteomics and Resmed were up more than one percent; with Avita, Clinuvel, Next Science and Pro Medicus up by less than one percent.

Dimerix led the falls, down two cents or 7.1 percent to 26 cents, with 1.9 million shares traded.

Antisense lost 6.35 percent, Cynata, Immutep and Resonance fell four percent or more; Actinogen, Nanosonics and Uscom were down three percent or more; Genetic Signatures, Kazia, Medical Developments, Neuren, Paradigm, Starpharma and Universal Biosensors shed two percent or more; Cyclopharm, Opthea Polynovo and Volpara were down more than one percent; with Mesoblast and Telix down less than one percent.

AROA BIOSURGERY

Aroa says revenue for the six months to September 30, 2020, was up 37.0 percent to \$NZ13,868,000 (\$A13,204,560).

Aroa said receipts for the three months to September 30, 2021, were up 92.1 percent to \$NZ8,600,000 primarily from sales of its sheep-stomach based Myriad products for soft tissue repair and Symphony for wound closure

The company said it had cash and cash equivalents of \$NZ 65,291,000 or 23 quarters of funding available.

Aroa was unchanged at \$1.15 with 1.7 million shares traded.

IMPEDIMED

Impedimed says it has completed a \$35 million placement at 15.25 cents a share and hopes to raise \$5 million more through a share plan at the same price.

Impedimed said the share price was a 10.3 percent discount to the last closing price and a 9.8 percent discount to the 5-day volume weighted average price to October 22, 2021.

The company said the funds would support inventory purchases to address growth, global micro-chip shortages, Covid-19-related supply chain issues and transition to Sozo II, as well as Sozo II enhancement, development and commercialization of renal and failure applications and for general working capital.

Impedimed said that the record date for the share plan was October 26, it would open on November 3 and close on November 11, 2021.

The company said that Canaccord Genuity (Australia) and Wilsons Corporate Finance were joint lead managers and bookrunners for the placement.

Impedimed was unchanged at 17 cents with 19.2 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says it has raised \$5 million from Melbourne's L1 Capital Investors in a placement of 625,000 shares at \$8.00 a share.

Anteris said the share price was a five percent discount to the closing spot price.

The company said funds would be used for its Duravr three-dimensional single-piece aortic valve for the treatment of aortic stenosis.

Anteris said it would issue L1 Capital 500,000 options exercisable at \$10.00 each within four months, and a further 330,000 options exercisable at \$15.00 each within two years, pending shareholder approval, and if not approved would pay \$1.25 per option.

Anteris said Evolution Capital was the lead manager to the placement.

Anteris was up 20 cents or 2.4 percent to \$8.60.

TALI DIGITAL

Tali says the Victoria Government will lend it up to \$503,744 as part of the Research and Development Cash Flow Loan Initiative.

Tali said it would receive the loan in two tranches, the first of \$300,000 had been received and the second of up to \$203,744 would be received by March 31, 2021.

The company said the Victoria Government Initiative offered low-interest loans on up to 80 percent of the forecast Federal Research & Development Tax Incentive.

Tali was unchanged at 2.9 cents.

EPSILON HEALTHCARE

Epsilon says Mitchell Asset Management has agreed to a 12-month extension of its loan repayment to October 31, 2022.

Epsilon said the original loan amount was \$4 million and it had made about \$400,000 principal repayments over the first year of the facility.

Epsilon was unchanged at 14 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has recruited the first of more than 200 patients for its US-based Xprecia Prime clinical trial for blood coagulation.

Universal Biosensors said the data generated would be used to support applications to the US Food and Drug Administration and European regulators.

The company said Xprecia Prime would replace Xprecia Stride which was approved for sale in 67 countries throughout the world.

In September 2019, Universal Biosensors said it appointed Promedeus as its Xprecia Stride distributor in the Czech and Slovak Republics and in October 2020, it paid Siemens \$US12.5 million (\$A16.6 million) for rights to its Xprecia Stride coagulation test, strips and products (BD: Sep 23, 2019; Oct 6, 2020).

Today, Universal Biosensors said it had agreements for two clinical trial sites with two more under consideration.

Universal Biosensors chief executive officer John Sharman said the company had "invested millions of dollars developing this next generation product for coagulation and it is exciting to see the project entering the final stage."

"Our new Xprecia Prime device is a significant improvement from Xprecia Stride and we expect it to deliver market leading performance," Mr Sharman said.

Universal Biosensors fell 1.5 cents or two percent to 73 cents.

OVENTUS MEDICAL

Oventus says an algorithm accurately categorized and treated 17 sleep apnoea patients, and the US Food and Drug Administration has requested a trial of its Exvent device. Oventus managing-director Dr Chris Hart told Biotech Daily that the 20-patient Exvent trial was required to confirm that the positive end-expiratory pressure (Peep) valve system improved obstructive sleep apnoea scores from baseline over a 90-day monitoring period, compared to no therapy and the O2Vent Optima without Peep. Dr Hart said he expected the trial to be completed by July 2022, when the company would immediately file its 510(k) application to the FDA, with approval hopefully by the end of 2022.

Dr Hart said that 62 patients with a range of causes for their sleep apnoea were assessed and tested by an algorithm developed through a Co-Operative Research Centre Program (CRC-P) with Neuroscience Research Australia, Flinders university and the Commonwealth Scientific and Industrial Research Organisation.

Dr Hart commended the work on the algorithm by Flinders University's Prof Danny Eckert. Dr Hart said that the algorithm determined the four non-mutually exclusive causes of sleep apnoea, anatomical, muscle control, dysregulated carbon dioxide and arousal threshold issues, with 45 of the patients involved in training the program.

He said that when applied to the remaining 17 patients the algorithm was "100 percent accurate" in diagnosis and predicting which treatment intervention was required.

Dr Hart said that the options included O2Vent Optima, Optima with Exvent and positional therapy, additional oxygen and/or additional 80mg atomoxetine with 5mg oxybutynin (ato-oxy) for poor pharyngeal muscle responsiveness, and/or 10mg zolpidem to manage arousal threshold issues.

"Depending on phenotype, we would tailor the therapy to include Exvent, positional therapy, oxygen and or a drug combination," Dr Hart said.

Dr Hart said that with 11 patients who failed O2Vent Optima therapy, the algorithm resolved all patients, with seven receiving Exvent and sleeping position changes, two received supplemental oxygen, one received ato-oxy and one was given ato-oxy with supplemental oxygen.

He said that Prof Eckert's work in developing the algorithm was based on the Palm scale (critical closing pressure of the upper airway, known as Pcrit; arousal threshold; loop gain; and muscle responsiveness), which Oventus could licence from the Co-Operative Research Centre.

Dr Hart said that the algorithm "only applies to our devices".

"There are multiple patents filed as a result of the CRC-P and all of them are available to Oventus to licence," Dr Hart said.

"The intellectual property related to our own technology we own outright," he said.

In yesterday's announcement to the ASX, Oventus said that US pricing data analysis and coding contractors Palmetto GBA recently recoded the previously approved O2Vent Optima oral appliance as A9270 or "a non-covered item or service".

Oventus said it had reapplied to the contractors for approval of the newly-submitted O2Vent Optima version, designed for US Medicare patients.

The company said that, in the meantime, the Palmetto GBA decisions meant that O2Vent Optima would "not be able to be supplied to Medicare patients in its own right for reimbursement purposes".

Oventus said that to date, Medicare patients represented "a very small percentage of US sales".

Oventus fell half a cent or four percent to 12 cents.

[RHINOMED](#)

Rhinomed says it has ethics approval for a 250-participant trial of its Rhinoswab compared to nasal swabs and saliva testing at Melbourne's St Vincent's Hospital.

Rhinomed said the Rhinoswab was "a novel sampling technology that radically improves the sample collection process".

The company said that "studies have established that eight out [of] 10 people preferred the Rhinoswab over the traditional nasal swab".

Rhinomed said the trial's two key objectives were to determine if the Rhinoswab was more comfortable and convenient for sample collection and to compare the sensitivity, specificity and other measures of polymerase chain reaction (PCR) performance compared to traditional swabs.

Rhinomed said the trial would be conducted over 30 to 50 days and would recruit up to 10 staff "to evaluate Rhinoswab against laboratory handling, process and workflow requirements".

Rhinomed fell one cent or 3.2 percent to 30 cents.

[RACE ONCOLOGY](#)

Race says that Tel Aviv's Chaim Sheba Medical Center will analyze patient samples from the 17-patient trial of Zantrene, formerly bisantrene, for acute myeloid leukaemia.

In August, Race said it dosed the first of up-to 12 patients in its phase Ib/II trial of bisantrene in combination with two other drugs for relapsed or refractory acute myeloid leukaemia (BD: Aug 9, 2021).

Today, the company said the patients would be screened for fat mass and obesity associated (FTO) protein overexpression and related biomarkers.

Race said that biomarker testing would include FTO gene sequencing, protein levels including intracellular staining and flow cytometry, FTO mRNA levels, and analysis of mRNA from patient tumor samples before, during and after treatment with Zantrene.

Race chief executive officer Dr Daniel Tillet said the data from the trial would provide "the first insights into the effect of Zantrene in patients on FTO and ... RNA methylation".

Race fell eight cents or 2.4 percent to \$3.22.

[ADHERIUM](#)

Adherium says all resolutions at its annual general meeting were carried but it faced 18.86 percent opposition to its remuneration report.

Adherium said that 215,863,846 votes (18.86%) opposed the report and 928,788,761 votes (81.14%) were in favor.

The company said the largest number of opposition votes, 220,388,846 votes (13.92%), were against the election of director George Baran, with 1,363,136,204 votes (86.08%) in favor.

Adherium said that the award of "stock appreciation rights" to chief executive officer Rick Legleiter was passed by a similar margin, while all other resolutions including, the 10 percent placement capacity and payment of shares in lieu of directors' fees were passed overwhelmingly.

Adherium's most recent filing said the company had 2,128,247,652 shares on issue, meaning that the opposition to Mr Baran's election amounted to 10.4 percent of the company, sufficient to requisition extraordinary general meetings.

Adherium fell 0.1 cents or 7.1 percent to 1.3 cents with 1.8 million shares traded.

LBT INNOVATIONS

LBT says its annual general meeting will vote on a potential “second-strike” board spill, along with the issue of 1,750,000 options to two directors.

Last year, LBT said the remuneration report earned a first strike with 48,391,303 votes or 40.57 percent against.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings must vote on a board spill.

Today, the company said shareholders would vote to issue 1,250,000 options to chair Joanne Moss, exercisable at 8.1 cents within 10 years, and 500,000 options to non-executive director Brian O’Dwyer exercisable at 13.6 cents a share within 10 years, all vesting two years after the issue date.

LBT said shareholders would vote on the election of directors Ms Moss, Mr O’Dwyer and Damien Lismore, the issue of 126,003 shares to directors Simon Arkell and Mr Lismore in lieu of cash owing for directors’ fees and the approval of a 10 percent placement facility.

The virtual meeting will be held on November 29, 2021 at 11.30am (ACDT).

LBT was unchanged at 10.5 cents.

OPTHEA

Opthea says China has granted a patent covering OPT-302 for a range of diseases, including wet age-related macular degeneration and diabetic macular oedema

Opthea said the patent, titled ‘Ligand Binding Molecules and Uses Thereof’ covered until February 20, 2034.

The company said patents had been awarded for OPT-302 in 15 jurisdictions, with patents pending in three other countries.

Opthea fell 1.5 cents or 1.2 percent to \$1.26.

BIOXYNE

Bioxyne has requested a trading halt pending an “announcement in relation to a potential acquisition.”

Trading will resume on October 29, 2021, or on an earlier announcement.

Bioxyne last traded at three cents.

MEDADVISOR

Sydney’s Perennial Value Management says it has reduced its shareholding in Medadvisor from 51,492,053 shares (13.64%) to 46,492,053 shares (12.32%).

Perennial said it sold 5,000,000 shares on October 22, 2021 for \$1,696,260 or an average of 33.92 cents a share.

Medadvisor fell one cent or 2.6 percent to 37 cents.

RHYTHM BIOSCIENCES

Melbourne’s Loumea Investments says it has been diluted below the five percent substantial share-holder level Rhythm Biosciences following a capital raising.

In September, Rhythm said its rights offer raised \$4,296,130 and it would place further shares to raise \$1,275,000, taking the total to \$5,571,130 (BD: Sep 7, 2021).

Rhythm fell one cent or 0.6 percent to \$1.58.

BCAL DIAGNOSTICS

Regal Funds says it has ceased its substantial shareholding in BCal Diagnostics. Regal said it sold shares between July 28 and October 22, 2021 with the single largest sale 547,800 shares for \$90,551 or 16.5 cents a share. BCal was unchanged at 16 cents.

IMRICOR MEDICAL SYSTEMS

Black Rock Group says it has become a substantial shareholder in Imricor Medical Systems with 15,788,844 shares or 11.02 percent. The company said it bought sold and transferred shares between July 15 and October 21, 2021 at prices ranging from \$1.09 to \$2.00 a share. Imricor fell one cent or 0.7 percent to \$1.43.

ONCOLOGY ONE PTY LTD

Melbourne's Oncology One says it has appointed Peter MacCallum Cancer Center chief executive officer Prof Shelley Dolan as a non-executive director. Oncology One said that prior to joining the Peter MacCallum Center in 2019, Prof Dolan was chief nurse and deputy chief executive at the Royal Marsden Hospital National Health Service Foundation Trust and previously was chief nurse and chief operating officer and acting chief executive at Kings College Hospital NHS Foundation Trust. Oncology one chair Mary Harney said Prof Dolan had "extensive expertise in navigating not only the patient-centric requirements of developing innovative cancer treatments, but essential commercial pathways to ensure this process is supported and successful". Oncology One is a private company

AUSBIOTECH

Ausbiotech says Speedx, Onko-Innate and Bioshares co-founder David Blake won the three Ausbiotech and Johnson & Johnson Innovation Industry Excellence Awards. Ausbiotech said that Sydney's Speedx won the Australian company of the year award for its molecular diagnostics, with 45 products on sale, including for improved infectious disease testing and personalized oncology treatment. The industry organization said that Melbourne's Onko-Innate was the emerging company of the year for its work on how the immune system might be better harnessed to treat cancer. Ausbiotech said that co-founder, editor and publisher of industry publication Bioshares David Blake was the recipient of the industry leadership award. The organization said Bioshares delivered weekly independent investment research, analysis and opinion to stockbrokers, analysts, fund managers, and investors. "David's commitment to seeing the sector flourish is at the heart of his authentic, independent and clear leadership," Ausbiotech said.

AUSBIOTECH

Ausbiotech says three publications on regenerative medicine offer “knowledge and benchmarking, purpose and a firm, unified direction for the industry’s future”.

Ausbiotech said that the Regenerative Medicine Investments Database, the Strategic Roadmap for the Regenerative Medicine Sector and four Case Studies, were “the final foundation stones set for [the] future of Australian regenerative medicine”.

Ausbiotech previously said that regenerative medicine included gene therapies, cell therapies and tissue-engineered products intended to regenerate or replace injured, diseased, or defective cells, tissues, or organs to restore or establish function and structure (BD: Aug 13, 2021).

The industry organization said the Roadmap would support Australian patients accessing regenerative medicine therapies and sought to develop a “value chain” that could discover, develop, and distribute regenerative medicines, employ people, commercialize research, export therapies and attracting foreign therapies for Australian patients.

The Roadmap is available at: <https://www.ausbiotech.org/documents/item/677>.

Ausbiotech said that the Regenerative Medicine Investments Database showed that investment in regenerative medicine increased by 113 percent between 2019 and 2020, with \$394.1 million invested in 2020 accounting for about 23 percent of the overall capital invested into the Australian biotech sector.

The organization said the report explained the types of financing and said Australia was “highly dependent” on placements and capital raisings.

The Database is at: <https://www.ausbiotech.org/documents/item/676>.

Ausbiotech said the four industry case studies included cell, gene, gene modified cell and tissue engineered products, and focused on different aspects of cell and gene therapy and its potential for “addressing and managing patients’ unmet needs”.

The Case Studies are available at: <https://www.ausbiotech.org/documents/item/679>.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network says its November Industry Report will address ‘Assessing pandemic impact on freight and logistics for the Victorian Healthtech Industry’.

The Network said the November 4 event would provide insight into key freight and logistics challenges faced by the Victorian biotechnology industry and the potential risks and impacts that the Covid-19 pandemic had caused.

The Network said guest speakers included Australian Government freight controller Air Vice-Marshal Marg Staib, Victoria Department of Jobs, Precincts and Regions senior policy adviser Erik Schmidt, Deloitte manager Derek Keir, World Courier local business development manager Brent McPherson, Cell Therapies business development manager Nathan Smith and Deloitte partner Sean Chung.

The Bio-Melbourne Network said that the virtual event would be presented in partnership with Global Victoria on November 4, 2021 from 8.30am to 10am (AEST).

For details and registration, go to: <https://bit.ly/3bev4aw>.