



Biotech Daily

Tuesday November 24, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: TELIX UP 11%; COMPUMEDICS DOWN 5%**
- * **VICTORIA BUDGET \$13b FOR HEALTH, INNOVATION**
- * **TELIX: US FDA ACCEPTS TLX591-CDx PROSTATE CANCER NDA**
- * **ANALYTICA: PERICOACH COSTS 'SIGNIFICANTLY LESS' THAN PHYSIO**
- * **IMUGENE ADDITIONAL DATA FOR HER-VAXX GASTRIC CANCER CLAIM**
- * **RACE: BISANTRENE COMBO BREAST CANCER EFFICACY, IN-VITRO**
- * **UNIVERSAL BIOSENSORS: WINE ANALYZER ACCURACY STUDY**
- * **BOD RECEIVES \$1m H&H HEMP SEED OIL ORDER FOR ITALY**
- * **ADHERIUM HAILIE INHALER SENSOR AT 8 US CENTRES**
- * **MGC, MERCER \$3.5m DRAW DOWN CONVERTIBLE NOTE**
- * **SUDA RECEIVES \$662k R&D TAX INCENTIVE**
- * **IMMURON RECEIVES \$358k R&D TAX INCENTIVE**
- * **RESAPP TAKES US FDA 510(k) PATH FOR SLEEPCHECK**
- * **AZURE: 36% REM REPORT 1st STRIKE, 37% PLACEMENT CAPACITY LOSS**
- * **CANN AGM 27% DEFEAT 10% PLACEMENT CAPACITY**
- * **CYNATA: AGM 24% OPPOSE DIRECTOR OPTIONS**
- * **MAYNE: AGM 13.6% OPPOSE ELECTION OF CHAIR ROGER CORBETT**
- * **MESOBLAST: AGM 10.6% OPPOSE DONAL O'DWYER ELECTION**
- * **CRESO 198m BLUMENTHAL, EVERBLU SHARES, 109m OPTIONS EGM**
- * **HERAMED RELEASES 40m ASX ESCROW SHARES, 20m OPTIONS**
- * **AUSTRALIAN ETHICAL TAKES 8.4% OF IMMUTEP**
- * **SANDON CAPITAL TAKES 10% OF IDT**
- * **PERENNIAL BELOW 5% IN MEDADVISOR**
- * **OVENTUS: SUE MACLEMAN REPLACES CHAIR DR MEL BRIDGES**

MARKET REPORT

The Australian stock market was up 1.26 percent on Tuesday November 24, 2020, with the ASX200 up 82.5 points to 6,644.1 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, 12 fell and seven traded unchanged.

Telix was the best, up 31 cents or 10.9 percent to \$3.15, with 2.1 million shares traded. Imugene and LBT improved more than eight percent; Volpara climbed 6.3 percent; Optiscan was up five percent; Mesoblast and Orthocell were up more than four percent; Nanosonics and Oncosil were up more than three percent; Cynata and Neuren rose more than two percent; Antisense, Clinuvel, Genetic Signatures, Next Science, Nova, Pharmaxis and Prescient were up one percent or more; with Cochlear, CSL, Cyclopharm, Polynovo and Starpharma up by less than one percent.

Compumedics led the falls, down three cents or 5.2 percent to 55 cents, with 139,848 shares traded. Osprey fell 4.35 percent; Amplia, Kazia, Resonance and Universal Biosensors shed more than two percent; Dimerix, Medical Developments, Opthea, Paradigm and Pro Medicus were down more than one percent; with Proteomics and Resmed down by less than one percent.

VICTORIA GOVERNMENT

Victoria Treasurer Tim Pallas has committed \$2 billion to a Breakthrough Victoria Fund, \$9.0 billion to support the state health system and \$2 billion in tax deferrals.

In his Budget speech, Mr Pallas said that the efforts to contain the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) pandemic “put our health care system under enormous pressure”.

Mr Pallas said that in the past six years, the State Government had invested more than \$109 billion in output funding for health, “the biggest investment in health in Victorian history ... [and the] Budget continues that legacy of investment, providing an additional \$9.0 billion for our health system ... [to] keep managing coronavirus while also opening up more beds, carrying out elective surgery and building our health care capacity”.

Mr Pallas said that a \$2 billion Breakthrough Victoria Fund was “an Australian first ... [to] drive investment in research, innovation and commercial outcomes”.

He said the Government would provide low-interest loans to Victorian enterprises to maintain their cashflow and continue to undertake research and development.

The Treasury Budget papers said that Breakthrough Victoria Fund would “position Victoria as an international leader in research and technology ... support new Victorian jobs, driving investment in research, innovation and ... breakthroughs over the next 10 years ... [and focus on] medical research, health and life-sciences, agri-food, advanced manufacturing, clean energy and digital technologies”.

“The fund will also help support research and development, adoption and commercialization, supporting 15,700 jobs over the next 10 years,” the Budget papers said.

The Budget papers said that \$210 million would be provided for medical research, there would be more than \$2 billion in tax deferrals, including allowing businesses with payrolls of up to \$10 million to defer their 2020-'21 payroll tax liabilities for up to 12 months, representing a \$1.7 billion cash flow boost to businesses in 2020-'21.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has accepted its new drug application for TLX591-CDx for prostate cancer imaging.

Telix said it had requested a priority review for TLX591-CDx, or 68-gallium-prostate-specific membrane antigen-11 (68-Ga-PSMA-11) in the submission and expected to be notified of the outcome around December 10, 2020.

Telix chief executive officer Dr Christian Behrenbruch said the company was “delighted to have achieved this significant milestone with the FDA’s acceptance for filing of the first commercial NDA for PSMA imaging in the US”.

“From acquiring ANMI and its advanced chemistry platform in December 2018, to successfully filing an NDA less than two years later, represents an extraordinary achievement by the Telix team,” Dr Behrenbruch said.

Telix was up 31 cents or 10.9 percent to \$3.15 with 2.1 million shares traded.

ANALYTICA

Analytica says its Pericoach intra-vaginal device is “on-par” with standard-of-care physiotherapy sessions for urinary incontinence and costs “significantly less”.

Last week, Analytica said an independent 48-patient trial showed its Pericoach bio-feedback device demonstrated “non-inferiority to in-clinic pelvic floor physical therapy” for stress incontinence (BD: Nov 20, 2020).

Today, the company said Pericoach was priced at \$US299 (\$A409) for a once only cost, compared to between \$US150 (\$A205) and \$US200 (\$A274) per physiotherapy session in the US, which could require between four and 12 sessions.

The clinical trial’s lead investigator Dr Lauren de Winter said that “use of the Pericoach system significantly improves the quality of life with women with [stress urinary incontinence] and mixed urinary incontinence and is non-inferior to the current standard of care”.

“The system costs significantly less to both patients and payers for similar treatment success and may prevent or delay women from needing expensive surgical treatments,” Dr de Winter said.

Analytica fell 0.1 cents or 33.3 percent to 0.2 cents with 8.7 million shares traded.

IMUGENE

Imugene has detailed the numbers of gastric cancer patients missing from yesterday’s claim of “statistical significance” for HER-Vaxx in combination with chemotherapy.

Yesterday, Imugene said that an interim analysis of its 68-patient, phase II trial of HER-Vaxx with chemotherapy for gastric cancer showed “statistically significant” benefit, but did not disclose the number of patients.

The company said that the interim analysis of the trial in Eastern Europe and India, found a “hazard ratio” of 0.418 meaning that HER-Vaxx reduced the risk of death by 58.2 percent and the analysis resulted in “a statistically significant one-sided p-value of 0.083” (BD: Nov 23, 2020).

Today, the company said in an “Investor Presentation” that of the 13 patients in the chemotherapy alone arm, eight had died, with four dead in the 14-patient arm receiving HER-Vaxx and chemotherapy.

Imugene was up one cent or 8.7 percent to 12.5 cents, with 78.4 million shares traded.

RACE ONCOLOGY

Race says an in-vitro study found that Bisantrone combined with cyclophosphamide has similar efficacy to the standard-of-care for breast cancer.

Race said the research program, conducted in collaboration with the New South Wales University of Newcastle, aimed to identify combinations of breast cancer drugs that when paired with Bisantrone reduced the serious side effects compared to the doxorubicin and epirubicin standard-of-care treatments.

The company said it found that Bisantrone alone showed similar cytotoxic or cell killing effects to the standard-of-care in a range of breast cancer subtypes and was able to kill some cancer types that were resistant to both doxorubicin and epirubicin.

Race said it found a near identical additive benefit in combination with cyclophosphamide as with doxorubicin and epirubicin and showed that the combination of drugs observed no antagonism between them.

The company said the results provided the necessary pre-clinical evidence to advance Bisantrone into human breast cancer clinical trials.

Race chief scientific officer Dr Daniel Tillett said the results “show that Bisantrone is compatible with existing treatment regimes and can be combined with standard chemotherapy drugs”.

Race was up 25 cents or 15.6 percent to \$1.85, with 2.3 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says an independent comparison validation study has confirmed that its hand-held wine analyzer Sentia is accurate and reliable.

Universal Biosensors has previously developed and commercialized the Onetouch Verio blood glucose test for Johnson & Johnson and the Xprecia Stride coagulation analyzer for Siemens Healthcare (BD: Feb 21, 2011; Dec 9, 2014; Oct 5, 2016).

Today, Universal Biosensors said the wine study, conducted at the California State University at Fresno, assessed 200 still white and red wine samples to compare free sulfur dioxide (SO₂) results compared to the most common methods in the US.

The company said the study found that Sentia was flexible, easy to use and “can provide the same level of accuracy and reliability that could be expected from a standard laboratory method”.

Universal Biosensors said that based on the results, Sentia could be recommended for use in finished and clarified still wines.

Universal Biosensors chief executive officer John Sharman said the company used its biosensor platform technology to develop the Sentia test, to be launched in early 2021. “In addition to free SO₂, we are working on total acid, malic acid, glucose and fructose tests, which we expect to be launched during 2021 and early 2022,” Mr Sharman said. Universal Biosensors fell one cent or 2.3 percent to 43 cents.

BOD AUSTRALIA

Bod says the Health & Happiness Group has ordered \$1 million worth of four Swisse Wellness hemp seed oil products for sale in Italy.

Bod said that with Health & Happiness, it would launch its marijuana products in more than 4,000 Italian pharmacies and through Swisse’s ecommerce channels.

The company said the products were in soft gel cap form for sleep, energy levels, stress and general wellness.

Bod was up 10.5 cents or 20.8 percent to 61 cents, with 1.4 million shares traded.

ADHERIUM

Adherium says Monaghan Medical Corporation will introduce its Hailie inhaler for asthma and chronic obstructive pulmonary disease at eight US respiratory centres.

In April, Adherium said it had a sales agreement with Trudell Medical US subsidiary Monaghan Medical Corp for its Hailie inhaler sensor (BD: Apr 29, 2020).

Today, the company said it had completed feasibility testing and internal training with Monaghan and would move to a pilot phase for the operational and commercial programming, which it expected to complete by April 2021.

Adherium was up 0.3 cents or 10.7 percent to 3.1 cents, with 2.9 million shares traded.

MGC PHARMA

MGC says it will raise \$3.5 million through its draw down convertible note with the New York-based Mercer Street Global Opportunity Fund.

In September, MGC said it had an up to \$15 million drawdown facility with Mercer, with \$2.25 million to be received up front (BD: Sep 10, 2020).

Today, MGC said it would issue 3,850,000 convertible notes, valued at \$1 each.

MGC fell 0.1 cents or 4.55 percent to 2.1 cents, with 7.1 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has received \$662,009 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Suda said the rebate related to expenditure for the year to June 30, 2020.

Suda fell 0.1 cents or 2.4 percent to four cents with 1.5 million shares traded.

IMMURON

Immuron says it has received \$358,280 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Immuron said the rebate related to expenditure for the year to June 30, 2020.

Immuron was up half a cent or 1.9 percent to 26.5 cents.

RESAPP HEALTH

Resapp says that following advice from the US Food and Drug Administration, it will pursue a 510(k) regulatory pathway for its Sleepcheck sleep apnoea application.

Resapp said the 510(k) approach was the fastest route to market for its Sleepcheck mobile application and following the pre-submission meeting with the FDA, it would begin a US human factors study in January 2021 to assess the product user interface design.

The company said it expected to lodge a 510(k) submission by April 2021, with a decision expected from the FDA within 90 days and if successful, Sleepcheck would be made available through a direct-to-consumer telemedicine visit.

Resapp said an over-the-counter approval would require additional clinical and human factor studies and it would begin a US sleep laboratory-based clinical study by June 2021.

Resapp fell 0.2 cents or 2.2 percent to 8.9 cents with 2.2 million shares traded.

AZURE HEALTHCARE

Azure says it received a remuneration report first strike with 36.19 percent of annual general meeting votes opposed and 36.72 percent dissent to the placement capacity. Azure said there were 73,196,758 votes (36.19%) opposed to the remuneration report, with 129,064,531 votes (63.81%) in favor.

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 is required to vote on a board spill and if passed the directors must stand for re-election.

The company said 74,078,011 votes (36.72%) opposed the 10 percent placement capacity, which requires a 75 percent majority, with all other resolutions passed more easily, including the name change to Austco Healthcare Limited.

Azure's most recent Appendix 2A new issue announcement said the company had 284,188,951 shares on issue, meaning that the votes against the placement capacity amounted to 26.07 percent of the company, sufficient to call extraordinary meetings. Azure was unchanged at nine cents.

CANN GROUP

Cann Group says its 10 percent placement capacity failed with 15,676,270 annual general meeting votes (26.69%) opposed and 43,054,266 votes (73.31%) in favor.

Cann said all other resolutions passed more easily with up to 3.56 percent dissent.

According to Cann Group's most recent Appendix 2A new issue announcement, the company had 269,910,378 shares on offer, meaning the votes against the placement capacity amounted to 5.81 percent, sufficient to call extraordinary general meetings.

The placement capacity is a special resolution requiring 75 percent to pass.

Cann Group was up 15.5 cents or 44.3 percent to 50.5 cents, with 27.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says its annual general meeting voted up to 23.90 percent dissent against the issue of 300,000 incentive options to independent director Dr Paul Wotton.

Cynata said there were 9,452,385 votes (23.90%) opposed to the options for Dr Wotton, with 30,102,645 votes (76.10%) in favor.

The company said there was a similar vote against the issue of 1,500,000 options for managing director Dr Ross Macdonald, 300,000 options for independent director Dr Stewart Washer and 100,000 options for company secretary Peter Webse.

Cynata said all other votes passed with dissent but more easily, with 16.91 percent opposed to the remuneration report.

According to Cynata's annual report, the company had 117,124,004 shares on issue, meaning the votes against the issue of options for Dr Wotton amounted to 8.07 percent, sufficient to call extraordinary general meetings.

Cynata was up two cents or 2.4 percent to 86 cents.

MAYNE PHARMA GROUP

Mayne says 107,399,040 annual general meeting votes (13.57%) opposed the election of chair Roger Corbett as a director, with 683,945,148 votes (86.43%) in favor.

The company said the remaining three resolutions to re-elect Nancy Dolan, adopt the remuneration report and issue shares passed more easily with up to 6.77 percent dissent. According to Mayne's annual report, the company had 1,679,068,131 shares on issue, meaning the votes against the re-election of Mr Corbett amounted to 6.40 percent, sufficient to call extraordinary general meetings.

Mayne was unchanged at 35.5 cents with 5.0 million shares traded.

MESOBLAST

Mesoblast says 26,139,352 annual general meeting votes (10.63%) opposed the re-election of director Donal O'Dwyer, with 219,869,452 votes (89.37%) in favor.

Mesoblast said that resolutions to adopt its remuneration report, issue options to chief executive Prof Silviu Itescu and ratify the prior issue of shares were passed more easily.

According to Mesoblast's most recent Appendix 2A new issue announcement, the company had 586,586,780 shares on issue, meaning the votes against Mr O'Dwyer's re-election amounted to 4.46 percent, not sufficient to call extraordinary general meetings.

Mesoblast was up 19 cents or 4.4 percent to \$4.47, with 22.7 million shares traded.

CRESO PHARMA

Creso says investors will vote to issue up to 197,841,090 shares and 108,884,142 options to director Adam Blumenthal, Everblu Capital and Suburban Holdings.

Creso said that its extraordinary general meeting would vote to issue the shares and options, including up to 42,955,327 shares and 10,738,832 options to Suburban Holdings to cancel and settle 1,666,667 convertible notes.

The company said Suburban Holdings was a related party of the company by being controlled by Alvin Blumenthal, the father of director Adam Blumenthal.

Creso said it would vote to issue up to 137,457,045 shares and 34,364,262 options to Adam Blumenthal and 17,428,718 shares and 63,781,048 options to Everblu, which was controlled by Mr Blumenthal.

The company said it would vote to issue 3,346,427 shares and 13,745,708 options to Azalea Consulting and up to 30,000,000 options to strategic advisor Bruce Linton.

Creso said it would also vote to ratify the prior issue of shares and to approve future placement shares of up to \$6,000,000.

The virtual meeting will be held on December 23, 2020 at 2pm (AEDT) at:

<https://web.lumiagm.com/?fromUrl=373050859>.

Creso was up 0.1 cents or 3.3 percent to 3.1 cents, with 12.6 million shares traded.

HERAMED

Heramed says it will release 39,939,721 shares and 19,949,504 options from ASX escrow and 1,628,126 shares from voluntary escrow on December 12, 2020.

Heramed said a further 8,277,494 shares would be released from voluntary escrow on December 5, 2020.

According to Heramed's most recent Appendix 2A, the company will have 150,038,908 shares on issue following the release of shares.

Heramed was up half a cent or 4.55 percent to 11.5 cents.

IMMUTEP

Australian Ethical says it has increased its substantial shareholding in Immutep from 32,000,000 shares (6.56%) to 41,583,333 shares (8.44%).

The Sydney-based Australian Ethical said that on November 20, 2020 it acquired 9,583,333 shares for \$2,300,000 or 24.0 cents a share.

Immutep was unchanged at 27 cents with four million shares traded.

IDT AUSTRALIA

Sandon Capital says it has increased its substantial shareholding in IDT from 21,085,119 shares (8.8%) to 24,069,512 shares (10.1%).

The Sydney-based Sandon said that between September 10 and November 19, 2020 it acquired 2,984,393 shares for \$541,709 or 18.2 cents a share.

IDT was unchanged at 19 cents.

MEDADVISOR

Perennial Value Management says it has ceased to be a substantial shareholder in Medadvisor.

Last week, the Sydney-based Perennial said that it had become substantial in the company with 13,157,895 shares or 5.31 percent (BD: Nov 19, 2020).

Medadvisor was up half a cent or 1.3 percent to 39 cents.

OVENTUS MEDICAL

Oventus says Sue MacLeman will replace Dr Mel Bridges as non-executive chair and non-executive director Sharad Joshi has retired.

Oventus said Dr Bridges would continue as a non-executive director.

The company said Mr Joshi had left the company "to focus on his role as [chief executive officer] of US emerging clinical diagnostics company Nanodiagnostics" and Ms MacLeman had been a director of the company since 2015.

Oventus was up half a cent or 2.2 percent to 23.5 cents.