



Biotech Daily

Tuesday October 18, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: POLYNOVO UP 12%; IMPEDIMED DOWN 6%**
- * **CSL: VIFOR TAKES FORECAST PROFIT UP-TO \$2,800m**
- * **TELEX TRIALS TLX250-CDX FOR BREAST, BLADDER CANCER**
- * **AROA: ENIVO 'PROMOTES POST-SURGICAL WOUND HEALING', IN SHEEP**
- * **RADIOPHARM RAD101 'SIGNIFICANT BRAIN TUMOR UPTAKE'**
- * **WOKE, SYDNEY UNI TRIAL PSILOCYBIN WP002 FOR ALCOHOL USE DISORDER**
- * **RECCE R327 'SIGNIFICANTLY REDUCES SARS-COV-2', IN HAMSTERS; CSIRO**
- * **EMYRIA, UWA SEND 4th MDMA ANALOGUE BATCH TO EUROFINS**
- * **BIONOMICS RECEIVES \$4.6m FEDERAL R&D TAX INCENTIVE**
- * **COCHLEAR AGM FACES 13% DISSENT**
- * **PAINCHEK \$1,050,000 DIRECTOR RIGHTS AGM**
- * **NOXOPHARM 2m CEO GISELA MAUTNER OPTIONS AGM**
- * **MACH7: 723k CEO RIGHTS, 110k DIRECTORS OPTIONS AGM**
- * **RACE PLEADS SCHULTZ, SUPPORT TO ASX 43.5% PRICE QUERY**
- * **PHARMAXIS REQUESTS 'PLACEMENT' TRADING HALT**
- * **NEXT SCIENCE REQUESTS 'US COMMERCIAL DEVELOPMENT' TRADING HALT**
- * **HARBOUR TAKES 13.1% OF VOLPARA**
- * **PROBIOTEC LOSES 8-MONTH DIRECTOR PAUL SANTORO**

MARKET REPORT

The Australian stock market was up 1.72 percent on Tuesday October 18, 2022, with the ASX200 up 114.8 points to 6,779.2 points. Eighteen of the Biotech Daily Top 40 were up, eight fell, 10 traded unchanged and four were untraded.

Polynovo was the best, up 22 cents or 12.4 percent to \$1.995, with 4.7 million shares traded. Nova Eye and Telex climbed more than 11 percent; Dimerix was up 10 percent; Neuren rose 7.1 percent; Clinuvel and Nanosonics climbed more than six percent; Avita, Imugene and Patrys improved five percent or more; Pro Medicus was up 4.2 percent; Immutep and Prescient were up more than three percent; Cochlear, Paradigm and Universal Biosensors rose two percent or more; Resmed was up 1.4 percent; with Cyclopharm, Mesoblast and Starpharma up by less than one percent.

Impedimed led the falls, down 0.4 cents or 5.6 percent to 6.7 cents, with 5.3 million shares traded. Alcidion and Emvision lost three percent or more; Next Science shed 2.6 percent; Antisense, Cynata, Oncosil and Opthea were down one percent or more; with CSL down 0.4 percent.

CSL

CSL says it expects the Vifor acquisition to increase its net profit after tax by 13 to 18 percent to about \$2,700 million to \$2,800 million.

In a presentation on the \$US11.7 billion (\$A16.4 billion) acquisition of the St Gallon, Switzerland-based Vifor Pharma for its renal disease and iron deficiency expertise, CSL said its original net profit after tax guidance was for \$2,400 million to \$2,500 million.

The company said Vifor had a portfolio of products across renal disease and iron deficiency, with “untapped potential in patient blood management, heart failure, women’s health and fatigue”.

CSL fell \$1.13 or 0.4 percent to \$275.70 with 623,100 shares traded.

TELEX PHARMACEUTICALS

Telex says it has expanded the indication of TLX250-CDx beyond kidney cancer after presenting data from studies of patients with breast and bladder cancer.

Telex said it presented the data from two studies of TLX250-CDx for patients with triple-negative breast cancer and non-muscle-invasive bladder cancer at the European Association of Nuclear Medicine annual congress in Barcelona, Spain.

The company said the first study, ‘Imaging Performance Assessment of 89-Zirconium-labelled Girentuximab (89-Zr-TLX250) PET-CT in Metastatic Triple Negative Breast Cancer Patients’ (Opalescence), was a 12-patient, open-label, single-group phase II trial.

Telex said the study’s primary objective was to evaluate how carbonic anhydrase IX (CAIX) targeting imaging with positron emission tomography (PET) could be used for the diagnosis and staging of triple-negative breast cancer and to develop “a deeper understanding of CAIX as a potential therapeutic target in this patient population”.

Telex said that CAIX was a trans-membrane protein that was “highly over-expressed in clear cell renal” and other cancers, making it an “attractive potential target for both new imaging and therapeutic modalities”.

The company said that the preliminary data demonstrated the potential of girentuximab to target CAIX expression in triple-negative breast cancer, with 83 percent of patient lesions having a strong CAIX expression, allowing TLX250-CDx immune-PET detection.

Telex said that three patients had “all of their lesions detected by TLX250-CDx immune-PET” with the best detected metastatic sites were bone.

The company said that the results made TLX250-CDx an “attractive novel investigative targeting agent for [triple-negative breast cancer and a] potential alternative to biopsy and immune-histo-chemistry for staging metastatic disease and targeted radioligand therapy”.

Telex said the second study, titled ‘Assessment of Safety, Tolerability, Radiation Dosimetry, and Imaging Properties of 89-Zr-Labeled Girentuximab (89-Zr-Girentuximab) in Patients with Non-Muscle-Invasive Bladder Cancer’ (Pertinence), was a six-patient, open-label, feasibility pilot phase I trial.

The company said the study’s primary objective was to evaluate the safety profile, bio-distribution and tumor targeting property of TLX250-CDx given directly into the bladder in patients with non-muscle-invasive bladder cancer and to established CAIX as a potential therapeutic target in this condition.

Telex said that data showed “encouraging tumor-targeting and biodistribution with TLX250-CDx, and no systemic distribution of radiation” and that it intended to progress TLX250 labelled with the alpha-emitter astatine-211 into a first-in-human phase I study.

Telex said both studies were investigator-initiated, undertaken by Dr Caronline Rousseau at the Institut de Cancérologie de l’Ouest in St Herblain, France.

Telex was up 62 cents or 11.1 percent to \$6.21 with 1.6 million shares traded.

AROA BIOSURGERY

Aroa says pre-clinical data of its Enivo system to manage post-surgical dead space shows potential for “promoting tissue apposition and reducing seroma formation”, in sheep.

Aroa said the study, titled ‘Evaluation of Tissue Apposition and Seroma Prevention in an Ovine Model of Surgical Dead Space using a Novel Air-Purged Vacuum Closure System’ was published in the journal *Eplasty*, available at: <https://bit.ly/3CDW5Bf>.

The company said that the Enivo system used an external vacuum device with a designed Aroa extra-cellular matrix (ECM) implant device to “draw separated tissue surfaces together and remove excess fluids from the treatment site”.

Aroa said the study assessed the effectiveness of Enivo at preventing seromas and supporting tissue apposition, the re-approximation of separated tissue layers, side-by-side with the use of a closed surgical drain, within a challenging large defect model of surgical dead space management and seroma prevention.

Aroa said Enivo showed “potential for promoting tissue apposition and reducing the formation of seromas” the deep space remaining after surgical separation and excision of soft tissue, with Enivo resulting in “significantly reduced seroma area and seroma volume at days seven and 14” when compared to the closed surgical drain standard-of-care.

Aroa said use of Enivo resulted in “near complete dead space closure at the conclusion of treatment, two weeks post-treatment, with a median seroma area of 2.0 percent and median seroma volume of 1.3mL, compared to an area of 98 percent and volume of 188.5mL for the standard-of-care treatment”.

The company said that about “three times more fluid” was removed by Enivo treatment than the standard-of-care, and at day-28, all nine treatments of tissue defects were judged clinically successful with Enivo, compared to six of 10 for the standard-of-care.

Aroa chief executive officer Dr Brian Ward said the company was “delighted with the evidence that Enivo can promote tissue apposition to reduce the incidence and impact of seromas which are very common after surgery and can lead to extended hospitalization and treatment costs due to the complications they cause”.

Aroa was up half a cent or 0.6 percent to 79.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says a 17-patient, phase IIa trial of its RAD101 for brain metastases shows “significant tumor uptake that was consistent and independent from tumor origin”.

Radiopharm said that the trial of RAD101, or F18-Pivalate, with positron emission tomography (PET) was conducted by the Imperial College London, led by Prof Eric Aboagye, and was presented to the European Organisation for Research and Treatment of Cancer joint meeting in Barcelona, Spain from October 26 to 28, 2022.

Radiopharm said the study showed that “F-18 Pivalate PET showed high uptake regardless of origin of primary tumor”, indicating that Pivalate could be “used to detect and monitor cerebral metastases” and patients without previous external beam radiation showed “higher tumor uptake of the radio-tracer, while previously treated patients show a trend towards lower uptake of the radio-tracer”.

Radiopharm managing-director Riccardo Canevari said the company was “very pleased to see a new molecule and an innovative mode of action showing significant results in brain cancer metastases”.

“F-18 Pivalate and its potential therapeutic variations, currently under development, represent a promising [diagnostic and therapeutic] approach to target brain metastases and potentially other brain tumors,” Mr Canevari said.

Radiopharm was in a suspension for a capital raising and last traded at 16.5 cents.

WOKE PHARMACEUTICALS PTY LTD

Woke says it has an agreement with the University of Sydney to conduct a 60-patient, phase II trial of psilocybin-based WP002 for alcohol use disorder.

Woke said it would finance the trial and providing WP002 and placebo, with Faculty of Medicine and Health Prof Paul Haber and Prof Kirsten Morley to design and lead the trial. The company said that subject to ethics approval, the trial would examine the safety, tolerability and proof of concept efficacy.

Woke said psilocybin was a naturally occurring psychedelic pro-drug produced by more than 200 fungi and when used at a high dose in combination with psychotherapy, a previous 10-participant proof-of-concept study “indicated that psilocybin may be effective for the treatment of patients with alcohol dependence”.

The company said that alcohol misuse led to a large burden of disease, including cardiovascular diseases, mental health conditions, digestive diseases, cancer, and injuries, with about 3.8 percent of all deaths attributable to alcohol.

Woke chief executive officer Nick Woolf said the company expected “to finalize the clinical trial agreement within the next few weeks”.

Woke is a private company.

RECCE PHARMACEUTICALS

Recce says its synthetic anti-infective R327 can “significantly reduce [severe acute respiratory syndrome-coronavirus-2] levels in a dose-dependent manner” in hamsters.

Recce said the study of intranasal R327 on hamsters infected with the the Delta variant of Sars-Cov-2 was conducted by the Netherlands contract research organization, Viroclinics.

The company said hamsters were infected with Sars-Cov-2 prior to being treated twice daily with either low (200mg/kg), mid (400mg/kg) or high (600mg/kg) doses of R327.

Recce said that treatment with R327 “was shown to significantly reduce Sars-Cov-2 levels in a dose-dependent manner” and provided “proof-of-concept that intra-nasal treatment with R327 has the potential to reduce Sars-Cov-2 levels during infection”.

Recce said it had lodged patent applications in Brazil, Canada , China, Israel, India and Vietnam on the composition or method of manufacture of Recce anti-infectives, the use of R327 or R529 for treatment of viruses with a lipid envelope or coat, and the administration of R327 or R529 by oral, injection, inhalation and transdermal dose applications.

The company said that its 2020 investigation into R327 with the Commonwealth Scientific and Industrial Research Organisation “did not fulfil the agreed criteria required for the CSIRO to commence in-vivo animal testing” and investigations had been discontinued.

In 2020, Recce said its Recce-327 and Recce-529 had been selected by the CSIRO and the Doherty Institute as Covid-19 “priority 1 candidates” (BD: Jul 8, 2020).

Later that month, the CSIRO and Doherty Institute said that tier 1 status did not mean a compound would show anti-viral activity against Sars-Cov-2 (BD: Jul 27, 2020).

The CSIRO and Doherty Institute issued a joint statement saying “the groupings did not reflect an opinion that a compound would show antiviral activity against Sars-Cov-2 but rather that the compounds had some of the properties required to potentially show such activity and there were no obvious concerns [that is, they were] insoluble or toxic”.

Today, Recce said that given the Netherlands hamster results it would focus its anti-viral Covid studies overseas.

Recce chief executive officer James Graham said “the data received from Viroclinics indicates the potential of R327’s capabilities as a treatment for viral infections”.

Recce was up three cents or 4.55 percent to 69 cents.

EMYRIA

Emyria says that with the University of Western Australia it has shipped more 3,4 methylene-dioxy-meth-amphetamine (MDMA) analogues to Eurofins for safety screening. Emyria said the 14 compounds in the fourth batch brought its MDMA-like analogue library to more than 140 compounds in its partnership with the University of Western Australia. Last year, the company said Luxembourg's Eurofins would screen its library of MDMA analogs for central nervous system (CNS) activity (BD: Oct 19, 2021). Emyria was unchanged at 21.5 cents.

BIONOMICS

Bionomics says it has received \$4,634,307 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program. Bionomics said the rebate related to research and development expenditure for the year to June 30, 2022. Bionomics fell half a cent or 7.8 percent to 5.9 cents.

COCHLEAR

Cochlear says its annual general meeting passed all resolutions but the election of Karen Penrose faced 12.61 percent opposition. Cochlear said there were 5,941,831 votes (12.61%) against the election of Karen Penrose as director and 41,162,220 votes (87.39%) in favor. The company said that the re-election of director Yasmin Allen was opposed by 4,475,825 votes (9.50%) with 42,635,301 votes (90.50%) in favor, with the remuneration report, the election of director Michael del Prado, financial reports, long-term incentives to chief executive officer Dig Howitt and the increase to the maximum remuneration of non-executive directors, carried by wider margins. According to its most recent filing, Cochlear had 65,780,109 total shares on issue, meaning the votes against Ms Penrose amounted to 9.03 percent of the company, sufficient to requisition extraordinary general meetings. Cochlear was up \$5.44 or 2.8 percent to \$199.07 with 177,828 shares traded.

PAINCHEK

Painchek says its annual general meeting will vote to issue \$1,050,000 in performance rights to managing-director Philip Daffas and four directors. Painchek said shareholders would vote to issue Mr Daffas \$750,000 in performance rights over three years, pending share price targets. The company said it proposed to issue chair John Murray \$120,000 performance rights over three years, with \$60,000 in performance rights over three years to directors Adam Davey, Ross Harricks and Cynthia Payne. Painchek said the meeting would vote to elect directors Mr Davey and Ms Payne, approve the 10 percent placement facility, ratify a prior placement and adopt the remuneration report. The meeting will be held at Suite 401, 35 Lime Street, Sydney on November 23, 2022 at 3pm (AEDT), and shareholders could watch the meeting but not vote, with registration at: https://us02web.zoom.us/webinar/register/WN_UdFk5oEMRmmt0DHasdvlVQ. Painchek was unchanged at three cents.

NOXOPHARM

Noxopharm says its annual general meeting will vote to issue 2,000,000 options to chief executive officer Dr Gisela Mautner, exercisable at 54 cents, within four years.

Noxopharm said Dr Mautner's would vest on the company being purchased, a \$10 million or greater investment, or "a licencing agreement with a large pharmaceutical company".

The company said shareholders would vote to re-elect Boris Patkin as a director, adopt the employee incentive plan, accept the 10 percent placement facility and adopt the remuneration report.

The meeting will be held at Level 5, 126 Phillip Street, Sydney on November 17, 2022 at 1pm (AEDT).

Noxopharm was unchanged at 19 cents.

MACH7 TECHNOLOGIES

Mach7 says its annual general meeting will vote to issue 723,000 performance rights to managing-director Michael Lampron and 110,000 options to directors.

Mach7 said shareholders would vote to issue Mr Lampron 723,000 performance rights for nil consideration, vesting on June 30, 2025 subject to achieving specified total shareholder returns and expiring on September 30, 2025.

The company said investors would vote to issue 35,000 options to chair David Chambers and 25,000 options each to directors Robert Bazzani, Philippe Houssiau and Dr Elliot Siegel, exercisable at the higher of the 30-day volume-weighted average price to the meeting, or the closing price on the date of issue plus 10 percent, vesting in equal tranches over three years and expiring on November 17, 2027, subject to performance hurdles and other long-term incentive conditions.

Mach7 said that shareholders would vote to re-elect Mr Bazzani as director, accept the remuneration report and approve the 10 percent placement facility.

The meeting will be held at Radisson on Flagstaff Gardens, 380 William Street, Melbourne on November 17, 2022 at 10am (AEDT) and virtually with registration at:

https://mach7t.zoom.us/webinar/register/WN_OuAluvN9QYGMrM2Br4AizQ.

Mach7 was up half a cent or 0.9 percent to 53.5 cents.

RACE ONCOLOGY

Race has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 43.5 percent from \$2.00 on October 13 to \$2.87 today, and noted a significant increase in the trading volume.

Race said that on September 27, it announced a collaboration with Monash University, on September 28 it announced an intravenous formulation of Zantrene and on October 7 Merchant Fund's investment manager Andrew Chapman presented Race as one of his "favorite three picks" in an investor webinar presentation.

Race said that on October 17, Pitt St Research began research coverage on it and concluded that it valued the company "at \$3.4 billion base case and \$6.1 billion bull case... [and] adjusting for probability and accounting for future capital raises, this equates to \$6.61 per share base case and \$11.91 per share bull case".

Race said it had also "attracted recent media exposure over the last several months".

Race was up seven cents or 2.7 percent to \$2.65 with 480,204 shares traded.

PHARMAXIS

Pharmaxis has requested a trading halt “pending an announcement... in relation to the outcome of a capital raising by way of a placement”.

Trading will resume on October 20, 2022 or on an earlier announcement.

Pharmaxis last traded at 7.8 cents.

NEXT SCIENCE

Next Science has requested a trading halt “pending an announcement... in relation to a significant new commercial development in the United States”.

Trading will resume on October 20, 2022 or on an earlier announcement.

Next Science last traded down two cents or 2.6 percent to 74 cents.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has increased its holding in Volpara from 30,521,369 shares (12.115%) to 33,056,183 shares (13.115%).

The Wellington, New Zealand Harbour said that between June 20 and October 17, 2022 it bought 2,550,610 shares for \$1,515,622 or an average of 59.4 cents a share and sold 15,796 shares for \$10,868 or an average of 68.8 cents a share.

Volpara was unchanged at 58 cents.

PROBIOTEC

Probiotec says non-executive director Paul Santoro has resigned “due to full-time commitments as chief executive officer of Cygnett”, effective from today.

Probiotec SAID Mr Santoro had business interests and could “no longer commit the necessary time to continue as a non-executive director”.

In January, Probiotec said it had appointed Mr Santoro (BD: Jan 28, 2022).

Probiotec fell three cents or 1.4 percent to \$2.15.