# Biotech Daily

Tuesday September 27, 2022

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: PROTEOMICS UP 8%; PATRYS DOWN 9%**

*** FEDERAL CONSULTATION ON SCIENCE STATEMENT, PRIORITIES**

*** VICTORIA, PFIZER mRNA FELLOWSHIP**

*** SEER WINS FDA 510(k) OKAY FOR AMBULATORY EPILEPSY MONITORING**

*** FEDERAL $2.6m FOR WEHI GENOMICS PRECISION MEDICINE PROJECT**

*** FEDERAL $5.4m FOR CARTHERICS CANCER NATURAL KILLER CELLS**

*** COMPUMEDICS PAYS $372k FOR 50% OF ALPHA TRACE**

*** ORTHOCELL RECEIVES 1st STRIATE+, REMPLIR ORDERS**

*** PROTEOMICS OESOPHAGEAL CANCER TEST 'STRONG PERFORMANCE'**

*** RACE STARTS FTO, ALKBH5 INHIBITORS PROGRAM**

*** RECCE: R327 FOR SEPSIS, UTIs, DIABETIC FOOT ULCERS**

*** PYC ADDS PHELAN-MCDERMID SYNDROME TO PIPELINE**

*** CORRECTION: MICRO-X**

*** MICROBA TO RELEASE 58m VOLUNTARY ESCROW SHARES**

*** POLYNOVO 1.2m DIRECTOR DR DAVID MCQUILLAN OPTIONS AGM**

*** ALCIDION EX-CHAIR RAY BLIGHT REDUCES, DILUTED TO 7.3%**

*** VIBURNUM REDUCES, DILUTED TO 8.2% OF ADHERIUM**

*** JM FINANCIAL TAKES 9.4% OF IMEX**

*** MERCHANT FUNDS TAKES 7.7% OF HEXIMA**

*** CYCLOPHARM APPOINTS PROF GREGORY KING DIRECTOR**

## MARKET REPORT

The Australian stock market was up 0.41 percent on Tuesday September 27, 2022, with the ASX200 up 26.8 points to 6,496.2 points. Twelve of the Biotech Daily Top 40 companies were up, 22 fell, four traded unchanged and two were untraded.

Proteomics was the best, up seven cents or 7.45 percent to $1.01, with 232,245 shares traded. Volpara climbed 6.5 percent; Imugene improved 5.6 percent; Alcidion, Orthocell and Starpharma were up four percent or more; Neuren and Polynovo rose more than two percent; Antisense, Genetic Signatures and Medical Developments were up more than one percent; with Emvision and Resmed up by less than one percent.

Patrys led the falls, down 0.2 cents or 9.1 percent to two cents, with 11.4 million shares traded.

Impedimed shed 7.7 percent; Oncosil and Resonance retreated more than five percent; Compumedics fell four percent; Dimerix and Immutep lost more than three percent; Kazia, Micro-X, Nanosonics, Next Science, Nova Eye and Prescient shed more than two percent; Atomo, Clinuvel, Cynata, Mesoblast and Pharmaxis were down more than one percent; with Avita, Cochlear, CSL, Cyclopharm, Pro Medicus and Telix down by less than one percent.

## FEDERAL GOVERNMENT

The Federal Government says the Chief Scientist Dr Cathy Foley will consult to develop a “revitalized priorities and science statement”.
A media release from the Federal Minister for Industry and Science Ed Husic said that Dr Foley would be supported by a taskforce established within the Department of Industry, Science and Resources.
The media release said that the work to revitalize Australia’s Science and Research Priorities and National Science Statement would include extensive consultation with science, research and industry stakeholders, as well as the public.
Mr Husic said the Government was “committed to supporting the best science and research framework possible”.
“Australia’s current priorities and the National Science Statement were published in 2015 and 2017, respectively,” Mr Husic said.
“Both these policy frameworks, which set the Government’s direction and vision for Australian science, are out-of-date and require renewal,” Mr Husic said.
“The Albanese Government has put science back into government,” Mr Husic said.
“We are focused on evidence-based policy and for that we need a scientific framework that is fit for purpose,” Mr Husic said.
“The current priorities do not mention First Nations knowledge, do not properly acknowledge climate change and fail to adequately engage with emerging critical technologies, which are essential for national prosperity and our wellbeing,” Mr Husic said.
He said the Government recognized that “a strong science system, with clear priorities, is critical to maintain high levels of sustainable economic and social prosperity”.
The media release said that more information would be released “shortly” including the terms of reference and the framework incorporating the revitalized National Science and Research Priorities would be finalized within 12 months.

## VICTORIA GOVERNMENT, PFIZER

The Victoria Government says that applications are open for the Pfizer Fellowship Program, supported by mRNA Victoria.

A media release from the Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said the State Government and Pfizer would offer a fellowship for one Victorian researcher to spend up to nine months working at Pfizer's emerging science and innovation unit RNA accelerator in Cambridge Massachusetts, next year.

The media release said that the mRNA Victoria and Pfizer Joint Industry Fellowship was open to early career researchers working at a Victorian university or research institute in a related field with a strong RNA background.

The Government said that the successful applicant would have the chance to "gain valuable knowledge and skills at Pfizer's recently established accelerator centre, specifically set up to advance potential applications of mRNA technology".

The State Government said that mRNA Victoria and Pfizer would cover a portion of the costs including travel, accommodation and living expenses for the nine months.

For details, go to: https://djpr.vic.gov.au/medical-research/initiatives/mrna-victoria.

## SEER MEDICAL

The Carlton, Melbourne-based Seer Medical says the US Food and Drug Administration has cleared its Seer Home for accurate epilepsy diagnosis.

The Melbourne and Rochester Minnesota-based Seer Medical said the device's FDA 510(k) approval allowed for the diagnosis of epilepsy through multi-day video-electro-encephalogram (EEG) and electro-cardiogram (ECG) monitoring.

In July, the Victoria Government said it would give an undisclosed amount of money to Seer, saying that it operated more than 20 clinics across Australia including permanent and visiting "to support the company's expansion in overseas markets" (BD: Jul 8, 2022).

The State Government said that Seer had developed an at-home diagnosis and monitoring technology for epilepsy, which reduced patient waiting times from six to 18 months to within one to six weeks, diverting "more than 179 years of in-patient hospital bed monitoring, freeing-up hospital beds for urgent care and making critical care available to regional patients".

Today, Seer said that epilepsy affected more than 3.4 million Americans and more than 65 million people worldwide, with 150,000 people in the US diagnosed each year.

The company said that Seer Home was an ambulatory electro-encephalograph (EEG) system designed to be used at the patient's home for week-long studies.

Seer said the Seer Sense wearable device was worn around the shoulders, with electrodes connected to the skull and chest to record brain and heart signals, with the recordings wirelessly transmitted to a monitoring hub, which stored the data and recorded video footage synchronized to the EEG-ECG data, providing context and information to the reviewing physician, such as body movement artifacts, to assist in diagnosis of the neurological condition.

The company said that on completion of the study, the technology is returned to Seer and the collected data is reviewed and annotated by a qualified physician, producing a report for the referring doctor.

Seer chief executive officer Dr Dean Freestone said that the FDA approval mean thte company could "offer a new pathway to diagnosis for Americans with epilepsy, one that does not require a hospital stay and one that will give doctors the data they need to more accurately diagnose and monitor neurological disorders".

Seer Medical is a private company.

## THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has a $2.57 million Federal grant for a genomics project to advance precision medicine and personalized cancer treatment.

WEHI said the Medical Research Future Fund's Genomics Health Futures Mission funding would support research into genomic data "to improve diagnosis and inform clinical care for all patients who have undergone genetic or genomic testing in Australia".

The Institute said that a team of researchers and clinicians would be led by its computational biologist Dr Alan Rubin to address the barriers holding back the use of genomic data in clinical care and gain insights into blood, breast and ovarian cancers.

WEHI said that the research would focus on rapid clinical translation, enabling clinicians to easily use information gained from the latest genomic research to improve patient health.

Dr Rubin said that biological databases contained "a wealth of genetic information but combining the data and interpreting it accurately was a major challenge".

"Diagnosing genetic diseases is difficult because subtle changes can be harmful but we don't always know which changes are benign and which ones may contribute to disease," Dr Rubin said.

"More than half of the genomic variants catalogued in clinical databases can't be used to inform diagnosis and treatment because we don't have enough information to say whether they're significant for a patient's health or not," Dr Rubin said.

"With new technologies we can now examine every possible change in a single gene in one experiment, but what we're missing is an easy way to share this data and cross-reference it with what we see in patients," Dr Rubin said. "This project will bridge that critical gap."

WEHI said the team included researchers from the Queensland Institute of Medical Research, Adelaide's Centre for Cancer Biology, Melbourne's Peter MacCallum Cancer Centre, the University of Washington and New South Wales Health Pathology.

The Institute said the team would "develop technology to link two vital data platforms to enable rapid clinical translation, use the technology to investigate cancer-related genes and educate clinicians across Australia on how to interpret and apply the data to improve patient health".

WEHI said that multiplexed assays of variant effect (MAVE) had "revolutionized our ability to understand the function of genes and their roles in disease" and offered a way for researchers to systematically measure the impact of tens of thousands of individual genetic variants on the function of a gene in a single well-controlled experiment.

"Data obtained from MAVEs has many applications, from understanding the fundamentals of how a gene or protein functions to measuring the potential role of genetic variants in a disease," Dr Rubin said. "But the data can be difficult to access and interpret, so the information is not widely used and MAVEs are still slow to impact clinical care".

Dr Rubin said that the three-year project would link MaveDB, the first dedicated repository of MAVE data, with Shariant, a platform for sharing clinical variant interpretations between Australian clinical molecular pathology laboratories, and connecting the two platforms would enable laboratories to use the data to improve genetic diagnosis across diseases.

Dr Rubin said the project would also provide support for variant curation tools and integrate with other Australian genomic resources.

WEHI said that the project would generate data to help classify patient variants and inform treatment options for blood, breast and ovarian cancers.

The Institute said the research would focus on genetic variants in blood cancer genes RUNX1 and GATA2, as well as PARPi, a class of targeted cancer therapeutics rapidly emerging as the standard of care in ovarian cancer, and work to overcome resistance, a key issue with PARPi.

## CARTHERICS

Cartherics says a Federal $5.4million grant will support its program to enhance cancer therapy by using the patients' own immune system to complement Car cell therapy.
Cartherics said the Medical Research Futures Fund grant would support work with Melbourne's Australian Regenerative Medicine Institute at Monash University, the Peter MacCallum Cancer Centre, Central Adelaide Local Health Network and Cell Therapies Pty Ltd to advance clinical research for its immunotherapy product in solid cancers.
The company said the project would develop "off-the-shelf functionally enhanced natural killer cells to treat many patients with a single product and … also engage the patient's own macrophages in their immune system in tumor destruction".
Cartherics said that, to date, it had raised more than $30 million from investors, and more than $8 million in grant funding.
Cartherics is a private company

## COMPUMEDICS

Compumedics says it has paid EUR250,000 ($A371,870) for 50 percent of Dr Grossegger & DRBAL GmbH, renamed Compumedics Alpha Trace GmbH.
Compumedics said the Vienna-based Alpha Trace had sold neurological monitoring equipment in Southern Germany, Austria and Switzerland for more than 40 years.
The company said the acquisition would allow it to "strengthen the selling infrastructure in this part of Europe as Alpha Trace and use its electro-myography neuro-muscular diagnostic technology in its existing neuro-diagnostic product range.
Compumedics said that it would work with Alpha Trace founder Dieter Grossegger as equal owners for up to three years, which would allow it to sell the neuro-muscular technology exclusively, subject to approvals, and allow Alpha Trace to sell Compumedics existing range of products in its markets.
Compumedics said that it could purchase the remainder of Alpha Trace for EUR150,000 either during the three-year period, or at the end of the period for the same price and a share of the profits over the period.
The company said it expected the acquisition would contribute up to EUR2 million in additional annual revenues within 18 months.
Compumedics fell one cent or four percent to 24 cents.

## ORTHOCELL

Orthocell says it has received the first orders for Striate+ dental membrane for bone and tissue repair product and its Celgro-based Remplir for peripheral nerve repair.
In July, Orthocell said it received $21,420,144 from the Birmingham, Alabama-based Biohorizons for a licence to the intellectual property for Striate+ (BD: Jul 21, 2022).
Today, the company said that Biohorizons had made it first orders since the agreement and that it would promote Striate+ at a conference in Phoenix Arizona in late October.
Orthocell said that Device Technologies had made its first orders of Remplir, and that it would exhibit Remplir at conferences in the coming two months.
Orthocell managing-director Paul Anderson said the company was "delighted to be working with … [its] partners to grow adoption and establish our products as best in class medical devices for dental bone regeneration and nerve repair procedures".
"These first orders represent a significant commercial milestone for Orthocell," Mr Anderson said.
Orthocell was up 1.5 cents or 3.95 percent to 39.5 cents.

## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a 302-patient study of its oesophageal adenocarcinoma test shows "strong diagnostic performance", with up to 90 percent detection rate.
Proteomics said a study, titled 'Establishing a Mass Spectrometry based diagnostic Test for Oesophageal Cancer' was presented at the International Society for Diseases of the Esophagus meeting in Tokyo from September 26 to 28, 2022.
The company said the prototype test was an easy-to-use test using biomarkers, or protein 'fingerprints' in the blood, and could be used to target Barrett's oesophagus, a pre-malignant condition associated with increased risk of oesophageal adenocarcinoma.
Proteomics said the study first analyzed a development cohort of samples from 253 people with either oesophageal adenocarcinoma, Barrett's oesophagus, Barrett's oesophagus with high grade dysplasia, and healthy controls to attain optimal performance.
The company said the prototype was then tested in the validation cohort of 49 patient samples and found that the test had 90 percent sensitivity and 64 percent specificity, and for Barrett's oesophagus versus oesophageal adenocarcinoma positive by endoscopy, it had 80 percent sensitivity and 89 percent specificity.
The company said its test "demonstrated that the biomarkers added statistically significant ($p < 0.05$) performance to the clinical models, with the validated performance for sensitivity of 76 to 90 percent across the key categories, with specificity of 64-89 percent".
Proteomics said the validation cohort was "relatively small" so further work in additional patient samples was required to confirm the statistical significance of the results.
Proteomics managing-director Dr Richard Lipscombe said the next steps were to further develop statistically modelling to improve the test's sensitivity and specificity, refine the reproducibility of the biomarker measurements to produce tests suitable for regulatory pathways, demonstrate diagnosis and treatment outcomes and confirm performance.
"These results form the basis for a simple blood test for the disease… it's a significant step towards diagnosing this cancer earlier without the need for an endoscopy," he said.
Proteomics was up seven cents or 7.45 percent to $1.01.

## RACE ONCOLOGY

Race says is starting a drug discovery program for novel drugs that inhibit the m6A RNA demethylases fatso/fat and obesity associated and ALKBH5 proteins.
Race said it had contracted Melbourne's Monash University Fragment Platform to complete the program, with Prof Martin Scanlon to lead the project.
The company said changes in expressions of fatso/fat and obesity associated (FTO) or ALKBH5 proteins had "a profound impact on cancer growth, spread and resistance to treatment" and inhibiting FTO or ALKBH5 activity had the potential to "kill or slow the growth of a wide range of cancers".
Race said its Zantrene, or bisantrene, was a potential inhibitor of FTO and was the only m6A RNA demethylases inhibitor and RNA epi-transcriptomic drug in the clinic.
Race said the Monash Fragment Platform would "complete a fragment screening campaign using the latest techniques in nuclear magnetic resonance spectroscopy (NMR)" and the project expected to report results over the coming 12 months.
The company said that the total cost of the project was $286,786 and was expected to be eligible for its research and development tax incentive.
Race principal scientist Prof Mike Kelso said "the discovery and patenting of new FTO and ALKBH5 inhibitors will greatly strengthen Race's drug development pipeline and add valuable assets to our expanding [intellectual property] portfolio".
Race fell half a cent or 0.3 percent to $1.92.

## RECCE PHARMACEUTICALS

Recce says it has expanded and accelerated its clinical programs of R327 for sepsis, urinary tract infections and diabetic foot ulcers.

Recce said that its 60-volunteer, phase Ia, one-hour, single dose, intra-venous study of R327 found it to be safe and well-tolerated, supporting its 12-month, phase Ib/IIa, multi-dose, early-stage sepsis efficacy study, expected to begin dosing this year.

The company said that data from its ongoing phase I trial showed high concentrations of R327 residing in urine in the bladder of healthy volunteers, which was consistent with pre-clinical, in-vivo kidney and urinary tract infection bacterial infection studies, suggesting opportunities for therapeutic activity in the human urinary tract.

Recce said it was finalizing the study protocol for a phase II clinical trial expected to begin dosing in the early part of next year.

The company said that it had designed a phase II study of diabetic foot ulcer infections to assess R327 as a spray-on, broad-spectrum, antibiotic therapy for mild skin and soft tissue diabetic foot ulcers, with dosing to begin by December 2022.

Recce chief executive officer James Graham said “the significant progress Recce has made in the last 12 months continues to strengthen and build out the company’s anti-infective platform, paving the way to new and considerable infectious disease programs across a range of unmet medical needs”.

“With good safety and encouraging signs of efficacy, we look ahead to new indications that can best adapt to physician and patient needs,” Mr Graham said.

“We have therefore established an ambitious development plan, aiming to get new anti-infective therapies into market as expediently possible,” Mr Graham said.

Recce was up 3.5 cents or 5.4 percent to 68.5 cents.

## PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says it has added Phelan-McDermid syndrome to its program, following in-vitro results of an RNA therapeutic which corrected faulty gene expression.

PYC said that the cause of Phelan-McDermid syndrome in the majority of patients was due to the deletion or mutation affecting one copy of the Shank3 gene, causing a 50 percent decrease in expression of the Shank3 protein.

The company said that it “designed and validated an RNA therapeutic capable of increasing SHANK3 expression in cells by about two-to-three-fold” and that “the extent of protein upregulation observed in these in vitro studies is sufficient to correct the underlying SHANK3 protein deficiency that causes [Phelan-McDermid syndrome]”.

PYC was unchanged at seven cents.

## CORRECTION: MICRO-X

Last night’s edition incorrectly described Dr Brian Gonzales as the “Micro-X chief executive officer”.

Dr Gonzales is the chief executive officer of the US division - Micro-X Inc.

Peter Rowland is the managing-director and chief executive officer of Micro-X Limited.

The error was made by the junior sub-editor attempting to edit beyond her abilities.

She has been reassigned to show-bag duties at Melbourne’s Royal Agricultural Show, and has not been hurt in making this correction.

Micro-X fell half a cent or 2.9 percent to 17 cents.

## MICROBA

Microba says it will release 57,690,639 shares from voluntary escrow on October 5, 2022.
A spokesperson from Microba told Biotech Daily that following the release of shares it would have about 171 million shares available for trading, with 48,031,314 shares in ASX escrow and about 55 million shares in voluntary escrow.
Microba fell half a cent or 2.6 percent to 19 cents.

## POLYNOVO

Polynovo says its annual general meeting will vote to issue former director and current chief technical and scientific officer Dr David McQuillan 1,200,000 million options.
Polynovo said Dr McQuillan had resigned as a non-executive director on September 1, 2022, but because the options were offered within six months of Dr McQuillan resigning as a non-executive director, the issue of options was subject to shareholder approval.
The company said that the options would be exercisable at the 30-day volume-weight average price prior to employment, vest in three equal tranches, with 800,000 options expiring by May 30, 2025 and the remainder by May 30, 2026.
Polynovo said the meeting would vote to re-elect directors David Williams and Leon Hoare, and approve the remuneration report.
The meeting will be at Minter Ellison, Level 20, 447 Collins Street, Melbourne on October 28, 2022 at 1pm (AEDT), and virtually at: https://meetnow.global/MLPKM5M.
Polynovo was up 3.5 cents or 2.5 percent to $1.43 with 1.3 million shares traded.

## ALCIDION

Former Alcidion chair Ray Blight says he has reduced his holding and been diluted from 101,871,831 shares (8.34%) to 92,678,438 shares (7.31%).
In January, Alcidion said it had raised $11.6 million in a one-for-10.5 retail rights offer at 25 cents a share (BD: Jan 16, 2022).
Today, the Adelaide-based Mr Blight said he had been diluted by 0.31 percent following the issue of shares on January 4, 2022, and that between March 30 and September 15, 2022 he sold 9,193,393 shares for $1,448,488 or an average of 15.755 cents a share.
Alcidion was up half a cent or 4.2 percent to 12.5 cents with 1.8 million shares traded.

## ADHERIUM

Viburnum Funds Pty Ltd says it has reduced and been diluted in Adherium from 219,057,245 shares (9.94%) to 208,970,039 (8.16%).
The Perth-based Viburnum said that between January 20 and 21, 2022 it sold 10,087,206 shares for $151,308 or an average of 1.5 cents a share, and that it was diluted on September 26, 2022 due to the issue of shares.
Earlier this month, Adherium said it had “commitments” for $13.5 million in a placement at 0.5 cents a share and would offer a share plan at the same price, subject to shareholder approval (BD: Sep 16, 2022).
Adherium was unchanged at 0.6 cents.

## IMEX HEALTH SERVICES

Melbourne's JM Financial says it has increased its holding in Imex from 2,697,764 shares or 7.74 percent to 3,651,263 shares or 9.37 percent.
JM Financial said that between August 11 and 30, 2022 it bought and sold shares as well as participated in placements, with the single largest purchase 1,011,961 shares in the placement for $485,741 or 48 cents a share.
Earlier this month, Imex said its rights offer at 48 cents a share raised $1,975,112 taking the total raised with the placement to about $4 million (BD: Sep 1, 2022).
Imex fell half a cent or one percent to 50 cents.

## HEXIMA

Merchant Funds Management Pty Ltd says it has increased its substantial holding in Hexima from 9,000,000 shares (5.39%) to 12,880,000 shares (7.71%).
The Perth-based Merchant Funds said that on September 23, 2022 it bought 3,880,000 shares for $51,991 or 1.34 cents a share.
In July, Hexima said it was winding-up after lead candidate HXP124 failed its nail fungus trial and the share price fell 85 percent to four cents (BD: Jun 24, Jul 11, 2022).
Hexima was unchanged at 1.5 cents.

## CYCLOPHARM

Cyclopharm says it has appointed Prof Gregory King as a non-executive director, effective immediately.
Cyclopharm said Prof King had more than 25 years of experience as a clinician, educator and researcher, currently working as a professor of respiratory medicine and practitioner at the Northern Central Clinical Schools of the University of Sydney, at Royal North Shore Hospital as medical director of respiratory investigation unit, as well as at the Woolcock Institute of Medical Research.
The company said Dr King was chair-elect to the Asia Pacific Society of Respirology and held a Bachelor of Medicine and Bachelor of Surgery from new Zealand's Otago University and a Doctor of Philosophy from the University of Sydney.
Cyclopharm fell half a cent or 0.4 percent to $1.295.