

# Biotech Daily

Wednesday June 17, 2020

# Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: OPTHEA UP 11%; PHARMAXIS DOWN 8%
- \* MTP CLAIMS SECTOR 'HIT HARD' BY COVID-19
- \* BIOCURATE, UNISEED JOIN FORCES FOR COMMERCIALIZATION
- \* SPEEDX: ROCHE TO DISTRIBUTE INFECTIOUS DISEASE TESTS
- \* DIMERIX COMPLETES PHASE IIa DMX-200 FOR FSGS TRIAL DOSING
- \* STARPHARMA: DEP-LUTETIUM 'SIGNIFICANT FOR CANCER' IN MICE
- \* ANTERIS (ADMEDUS) HEART VALVE FEASIBILITY PIG STUDY
- \* PRESCIENT: 2 US PTX-200 PATENTS FOR LEUKAEMIA, BREAST CANCER
- \* ZELIRA, LEVIN MARIJUANA FOR ATHLETES WITH CHRONIC PAIN
- \* ZELIRA 150% DIRECTORS FEES HIKE EGM
- \* RHINOMED: FIRB OKAYS WHITNEY GEORGE TO UNDERWRITE \$6.5m
- \* RACE AGREES TO BUY-BACK \$800k DR PETER MOLLOY LOAN SHARES
- \* GI DYNAMICS EXTENDS \$6.6m CRYSTAL AMBER NOTE, AGAIN
- \* KENNETH BIDDICK, AUTHENTICS AUSTRALIA BELOW 5% IN IMMURON
- \* REGAL FUNDS INCREASES, DILUTED TO 10% OF VISIONEERING
- \* CSL TO LOSE CFO DAVID LAMONT
- \* BIO-MELBOURNE NETWORK APPOINTS JEFF MALONE CEO
- \* BIO-MELBOURNE FORUM ON FAST CORONAVIRUS VACCINE PROJECT

#### MARKET REPORT

The Australian stock market climbed 0.83 percent on Wednesday June 17, 2020, with the ASX200 up 49.5 points to 5,991.8 points. Twenty-one of the Biotech Daily Top 40 stocks were up, eight fell and 11 traded unchanged. All three Big Caps were up.

Opthea was the best, up 27 cents or 10.6 percent to \$2.81, with 2.1 million shares traded. Osprey climbed 10 percent; Medical Developments and Starpharma were up nine percent or more; Clinuvel was up 8.1 percent; Patrys rose 7.7 percent; Dimerix was up six percent; Amplia and Uscom improved more than four percent; Actinogen, Immutep, Kazia, LBT, Prescient, Resmed and Volpara were up more than three percent; Impedimed, Polynovo and Pro Medicus rose more than two percent; Cochlear, CSL, Genetic Signatures and Mesoblast were up more than one percent; with Telix up 0.8 percent.

Pharmaxis led the falls, down 0.6 cents or eight percent to 6.9 cents, with 1.7 million shares traded. Cynata lost 3.2 percent; Compumedics, Neuren and Universal Biosensors shed more than two percent; Avita and Next Science were down more than one percent; with Nanosonics down 0.6 percent.

#### MTP CONNECT

MTP Connect says "the Covid-19 health crisis has had a significant negative impact across the medical technology, biotechnology and pharmaceutical sector".

MTP Connect said that the Covid-19 pandemic had affected "startups, [small and middle-sized enterprises], large local and multinational companies, researchers, universities, service providers, industry organizations and investors".

The organization said that there have been "significant hits to company values, the shut-down of critical clinical trials and the drying-up of much needed capital to sustain research and development projects".

The report said that "commercial activity across the sector, as measured by the market capitalization of ASX-listed [medical technology and pharmaceutical] companies, has taken an \$11 billion hit and many companies and organizations across the sector have seen severe declines in revenue and margins".

MTP Connect chair Sue MacLeman told Biotech Daily the \$11 billion figure included Cochlear, CSL and Resmed.

Biotech Daily calculated the three companies collectively lost \$13.4 billion from their record high of \$190.7 billion at January 31 to \$177.4 billion at May 31, 2020, but at December 31, 2019, the three had a collective market capitalization of \$169.6 billion. Last year, Biotech Daily reported record capital raisings of \$1.29 billion, primarily by the 130 ASX-listed biotechnology companies, not including Cochlear CSL and Resmed. To the end of May 2020, Biotech Daily counted \$523.8 million raised – on track to equal last year's record, and not including Cochlear's \$1.1 billion capital raise, nor CSL's \$US750 million (\$A1.2 billion) loan at an average of 2.68 percent over 11 years. While the Biotech Daily Top 40-Index (which does not include the three Big Caps of Cochlear CSL and Resmed) fell in February and March, by the end of May it had recovered all of its pre-Covid-19 losses and was just below the February all-time record high (BD: Mar 2, Apr 1, May 1, Jun 1, 2020).

In a media release, MTP Connect chief executive officer Dr Dan Grant said the sector had been battered while simultaneously fast-tracking vaccine, diagnostic, device and therapeutic research to fight Covid-19 and securing vital medical supplies.

"The medtech, biotech and pharma sector has not been immune to the pandemic," Dr Grant said. "While our start-ups, researchers and companies are significant contributors to the Australian economy, generating more than \$5 billion in gross value add and sustaining nearly 70,000 jobs in 2019, our new report makes it plain that the sector is being tested now like never before," Dr Grant said.

Dr Grant said that the report detailed "concerns from sector leaders that tens of thousands of jobs in universities, research institutes and early stage [medical technology and pharmaceutical] companies are at risk".

"[The report] documents fears that efforts to plug substantial revenue shortfalls at universities will lead to a rationalization of research activities and damage to the commercialization pipeline," Dr Grant said.

"Combined with the impact we've seen on clinical trials, where up to 90 percent of trials have been put on hold, the development and translation of new life saving drugs and devices will inevitably slow," Dr Grant said.

Dr Grant said that the sector had "an enviable track record in delivering life-saving new devices and therapeutics ... [and] as our report demonstrates, the ...sector's role has never been more important in driving Australia's pandemic response and recovery and protecting the health of Australians," Dr Grant said.

The report, titled 'MTP Connect Covid-19 Impact Report' is available at: <a href="https://www.mtpconnect.org.au/Category?Action=View&Category\_id=229">https://www.mtpconnect.org.au/Category?Action=View&Category\_id=229</a>.

#### BIOCURATE, UNISEED

Biocurate says it will collaborate with Uniseed on projects of specific interest and facilitate commercialization of intellectual property at the University of Melbourne.

Biocurate said it was a joint venture between the University of Melbourne and Monash University.

The company said that Uniseed was a 20-year-old "leading Australian commercialization fund" investing in research from the Commonwealth Scientific and Industrial Research Organisation, the University of Melbourne, the University of Queensland, the University of Sydney and the University of New South Wales.

Biocurate said the agreement would provide both parties "potential co-investment opportunities in early stage research into new drugs and therapeutics".

Uniseed chief executive officer Peter Devine said the collaboration with Biocurate would "ensure early stage drug and therapeutic projects are appropriately funded and managed and given the best chance of success through the collective input and experience of the Uniseed and Biocurate teams".

Biocurate chief executive officer Dr Glenn Begley said the Uniseed team "bring invaluable industry experience that will be instrumental in our continued efforts to accelerate the development of new drugs that have the greatest commercial potential".

#### SPEEDX PTY LTD

Sydney's Speedx says it has an agreement with Roche to expand access to its infectious disease and antibiotic resistance tests and technology.

Speedx did not disclose the value of the agreement with the Basel, Switzerland-based Roche or any financial terms.

In 2016, The company said it had Conformité Européenne (CE) mark for its in-vitro diagnostic for three herpes viruses (BD: Jul 4, 2016).

In 2018, the company said it had CE mark for a gonorrhea test (BD: Dec 10, 2018). Today, Speedx chief executive officer Colin Denver said the agreement was "a significant inflection point for our company and will enable more patients and clinicians around the world to access key diagnostic tools for the management of antibiotic resistance". Speedx is a private company.

#### **DIMERIX**

Dimerix says it has completed dosing of the 10 patients in its phase IIa trial of DMX-200 for focal segmental glomerulosclerosis (FSGS).

Last year, Dimerix said that patients in the double-blind, randomized, placebo-controlled, cross-over design trial would receive 16 weeks of DMX-200 and 16 weeks of a placebo, with a six-week washout period (BD: Jul 10, 2019).

Today, the company said focal segmental glomerulosclerosis was an inflammatory disease that attacked the kidney's filtering units, which caused tissue scarring and led to permanent kidney damage and kidney failure.

Dimerix the trial aimed to evaluate the safety and preliminary signs of efficacy of DMX-200 in patients receiving the angiotensin receptor blocker irbesartan.

The company said no serious adverse events had been reported to date and it expected data by the end of July 2020.

Dimerix said it had a separate phase II trial of DMX-200 for diabetic kidney disease, with the final patient scheduled to receive the last dose in July 2020.

Dimerix was up 2.5 cents or six percent to 44 cents with 1.5 million shares traded.

#### STARPHARMA

Starpharma says dendrimer-enhanced product (DEP) lutetium shows "statistically significant anti-cancer activity" in a mouse model of human prostate cancer.

Starpharma said the 30-mouse study, conducted at the University of Queensland's Centre for Advanced Imaging compared two doses of its DEP-lutetium to vehicle injecting the mice with either 15 megabecquerel (MBq) of DEP lutetium on day one, nine MBq on day-one and day-15 or vehicle on days one and 15, in three groups of 10 mice.

Starpharma said DEP-lutetium combined radioisotope lutetium-177 and its DEP platform and was well tolerated in both dose regimens, with minimal weight loss and recovery with subsequent weight gain.

The company said that in a single dose of 15 MBq, it achieved a significant anti-tumor activity (p < 0.0001) on day one, tumor regression of more than 55 percent on day 36 and 100 percent survival over 70 days.

Starpharma chief executive officer Dr Jackie Fairley said that radio-therapeutics was "a rapidly growing and increasingly important area of cancer therapy and represent an exciting extension of the DEP platform".

"The impressive efficacy and survival benefit of DEP-lutetium illustrates the versatility of Starpharma's DEP platform ... [and] DEP-lutetium is one of several promising DEP radio-therapeutic candidates in development." Dr Fairley said.

Starpharma said that radio-pharmaceuticals was "a rapidly developing area of cancer treatment and diagnosis ... estimated to grow to \$US12 billion to \$US15 billion by 2030. Starpharma was up 9.5 cents or nine percent to \$1.155 with 1.3 million shares traded.

#### ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says it has implanted its 25-millimetre Duravr transcatheter aortic heart valve into three of nine pigs as part of a feasibility aortic valve replacement study.

Anteris said the study, conducted in Minneapolis and scheduled to be completed by December 31, 2020, aimed to confirm Duravr valve deployment, fixation and to provide insight into the valve's haemodynamic function.

Last month, the company said a second patient had been implanted at Belgium's University Hospitals Leuven as part of its first-in-human surgical aortic valve replacement (SAVR) study (BD: Mar 27, May 11, 2020).

Today, Anteris said the feasibility study would allow it to make refinements to the frame and delivery system for the Duravr valve for a planned US Food and Drug Administration submission for a human clinical trial in 2021.

Anteris chief executive officer Wayne Paterson said the study "provides encouraging data and, importantly, will inform our development program and product design fine tuning". Anteris fell 24 cents or 4.55 percent to \$5.03.

#### PRESCIENT THERAPEUTICS

Prescient says the US Patent and Trademark Office has allowed two patents for its PTX-200 candidate for leukaemia and breast cancer.

Prescient said the patents, both titled 'Compositions of triciribine and epidermal growth factor receptor inhibitor compounds or salts thereof and methods of use thereof' would protect its intellectual property until 2025.

The company said PTX-200 inhibited the tumor survival pathway, known as protein kinase B (Akt), which played a key role in the development of many cancers.

Prescient was up 0.2 cents or 3.6 percent to 5.7 cents with 1.4 million shares traded.

#### ZELIRA THERAPEUTICS

Zelira says it will partner with Melbourne's Levin Growing Pty Ltd to develop a marijuanabased treatment for retired athletes with chronic pain.

Zelira said retired athletes were more likely to suffer from chronic pain and associated conditions such as depression and anxiety due to injuries and physical exertion over long periods of time.

The company said it would design and coordinate a trial funded by Levin to assess safety and efficacy and then licence the marijuana formulation to Levin to support the trial. Zelira said it would hold marketing rights for North and South America and Levin would hold rights in all other countries, with profits shared equally between the companies. Zelira fell 0.1 cents or 1.7 percent to 5.7 cents.

#### ZELIRA THERAPEUTICS

Zelira says its extraordinary general meeting will vote to increase its pool of directors' fees 150 percent from \$300,000 to \$750,000.

Earlier this month, Zelira said its US chief executive officer and managing director Dr Oludare Odumosu would receive a base salary of \$US150,000 (\$A217,361) and 25,000,000 unlisted options, subject to shareholder approval (BD: Jun 4, 2020).

Today, the company said it would vote to issue 25,000,000 options to Dr Odumosu and 1,000,000 shares to managing-director Dr Richard Hopkins.

Zelira said it would also vote to adopt its US employee share option plan and to ratify the placement of 91,855,182 shares.

The meeting will be held at Blackwall Legal Boardroom, Level 26, 1 40 St Georges Terrace Perth, Western Australia on July 21, 2020 at 9am (AWST).

#### **RHINOMED**

Rhinomed says the Australian Foreign Investment Review Board has approved Whitney George to underwrite its \$6.5 million renounceable rights issue.

Last month, Rhinomed said it expected a fully-underwritten, one-for-two rights offer at 7.7 cents a share to raise \$6.5 million, underwritten by the Carlsbad, California-based Whitney George, subject to review board approval (BD: May 11, 2020).

In his most recent substantial shareholder notice, Mr George said he held 49,291,543 shares or 29.13 percent of Rhinomed (BD: Mar 16, 2020).

Rhinomed was up 0.7 cents or 9.3 percent to 8.2 cents.

#### RACE ONCOLOGY

Race says it has agreed with founder and former chief executive officer Dr Peter Molloy to repay an \$800,000 limited recourse loan through a share buy-back.

Last month, Race said that Dr Molloy had resigned, it would him in lieu of notice and he had until May 27, 2020 to repay the loan (BD: May 20, 2020).

Today, the company said it would buy-back 2,222,222 loan shares at 36 cents a share, the five-day volume weighted average price to May 18, 2020.

Race said the buy-back would be subject to shareholder approval and it expected to implement the buy-back in late July to early August 2020.

The company said that on completion, it would lift the holding lock on the remaining 1,777,778 loan shares held by Dr Molloy.

Race fell three cents or 6.25 percent to 45 cents.

#### **GI DYNAMICS**

GI Dynamics says it has further extended the maturity date of its \$US5,000,000 (\$A6,595,767) Crystal Amber Fund convertible note from June 15 to June 29, 2020. Last month, GI Dynamics said Crystal Amber extended the maturity from May 1 to May 15 and then to June 15, 2020, and said that if funding was not secured it "would need to cease operations" and delist from the ASX (BD: Jun 15, 2017; May 4, 18, 2020). GI Dynamics fell 0.2 cents or 28.6 percent to 0.5 cents with 7.8 million shares traded.

#### **IMMURON**

Authentics Australia says it has ceased to be a substantial shareholder in Immuron. In 2017, the Melbourne's Authentics said it held 10,249,998 shares or 10.11 percent of the company, with shares held by it and Kenneth and Catherin Biddick (BD: May 5, 2017). Immuron was up 1.5 cents or 4.8 percent to 33 cents with 8.5 million shares traded.

### **VISIONEERING TECHNOLOGIES**

Regal Funds Management it has increased its substantial shareholding in Visioneering and been diluted from 52,956,789 shares (11.37%) to 83,960,912 shares (10.11%). The Sydney-based Regal Funds said that on June 3, 2020 it bought 37,368,515 shares for 1.4 cents a share and between May 29 and June 12, 2020 it sold 6,364,392 shares for between 1.4 and 1.9 cents a share.

In April, Visioneering said it raised \$5 million at 1.4 cents (BD: Apr 29, 2020). Visioneering fell 0.1 cents or 6.7 percent to 1.4 cents with 1.5 million shares traded.

## **CSL**

CSL says chief financial officer David Lamont has resigned effective from October 30, 2020 to pursue a career opportunity with another company.

CSL said Mr Lamont joined the company as chief financial officer in January 2016. CSL was up \$3.15 or 1.1 percent to \$287.16 with 909,588 shares traded.

#### **BIO-MELBOURNE NETWORK**

Bio-Melbourne Network says it has appointed Jeff Malone as its chief executive officer, effective from July 13, 2020.

Bio-Melbourne said that Mr Malone had experience in research and development, product design and development, market analysis and business development, including in advanced manufacturing and medical technologies.

The Network said that Mr Malone had more than 30 years' experience in operations management in Australia, the US, China, Indonesia and South America and had been involved in developing and mentoring entrepreneurs through contact with universities, accelerators and incubators and government-led research organizations.

Bio-Melbourne said that Mr Malone held a Bachelor of Electrical Engineering from Missouri's St Louis University.

#### **BIO-MELBOURNE NETWORK**

The Bio-Melbourne Network says it will discuss 'Developing an Australian Novel Vaccine: The UQ, CEPI, CSL Coronavirus Vaccine Development Project'.

Bio-Melbourne said that the development of a Covid-19 vaccine was "an extraordinary project in extraordinary times".

"Work that would normally take years has been accelerated into weeks and months, and planning that would typically take place sequentially is occurring simultaneously," the Network said.

The Bio-Melbourne Network said the Bio-Forum would question "How has this work occurred with such unprecedented speed, and what are the risks involved in completing steps of a vaccine development pathway in parallel?"

The Network said that the panel included World Health Organisation Collaborating Centre for Reference and Research on Influenza director Prof Subbarao, University of Queensland head of chemistry and molecular biosciences Prof Paul Young, CSL Behring head of process engineering Dr David Glover and Seqirus Global clinical program director Dr Frank Albano.

Bio-Melbourne said the University of Queensland partnered with the Coalition for Epidemic Preparedness Innovations (CEPI) in January 2019, to develop a "molecular clamp" vaccine platform and in January 2020 expanded the deal to develop the platform to produce a vaccine candidate against Covid-19, joining with CSL to progress the vaccine candidate to the clinic.

The Network said the Bio-Forum would be held online on Friday June 26, 2020, starting at 10:30am until 11:50am.

To register go to: <a href="https://bit.ly/3e9faOv">https://bit.ly/3e9faOv</a>.