



Biotech Daily

Wednesday June 24, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ALTERITY UP 20%; IMPEDIMED, RESONANCE DOWN 6%**
- * **PFIZER \$720m FOR CLINICAL-STAGE BIOTECHS**
- * **FEDERAL \$36m FOR RARE DISEASE PROJECTS**
- * **RHINOMED UNDERWRITTEN RIGHTS RAISE \$6.5m**
- * **AROA 2-DAY \$45m IPO FOR ENDOFORM SOFT TISSUE REGENERATION**
- * **MAYNE: US FDA ACCEPTS E4/DRSP CONTRACEPTIVE NDA**
- * **G MEDICAL: 1st ITALIAN PRIZMA ORDER**
- * **BOTANIX RESUMES BTX1801 RECRUITMENT**
- * **ALTHEA: DRUG SCIENCE REFERRAL FOR UK MARIJUANA**
- * **CRESO UPS CANADA MEDICAL, PARTY MARIJUANA PRODUCTION**
- * **'FREEMAN ROAD', DR TI WAN NG TAKE 5% OF HERAMED**
- * **PARADIGM LOSES CHAIR GRAEME KAUFMAN**
- * **SIMON GRAY TO REPLACE ELLEX CO SEC KIMBERLEY MENZIES**

MARKET REPORT

The Australian stock market was up 0.19 percent on Wednesday June 24, 2020, with the ASX200 up 11.3 points to 5,965.7 points. Twenty of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and one was untraded. All three Big Caps were up.

Alterity (Prana) was the best, up 0.3 cents or 20 percent to 1.8 cents, with 150,000 shares traded. Next Science climbed 12.25 percent; Amplia was up 8.3 percent; Paradigm and Prescient were up more than seven percent; Genetic Signatures, Universal Biosensors and Volpara improved five percent or more; Nanosonics and Oncosil climbed more than four percent; Medical Developments, Mesoblast and Opthea rose two percent or more; Antisense, Clinuvel, Cochlear, CSL, Ellex, Pro Medicus and Resmed were up more than one percent; with Cynata, Polynovo and Starpharma up by less than one percent.

Impedimed and Resonance led the falls, both down 5.9 percent to 6.4 cents and 16 cents, respectively, with 1.3 million shares and 466,491 shares traded, respectively. Compumedics and Proteomics lost more than five percent; Actinogen fell four percent; Avita, Kazia and Neuren shed two percent or more; with Dimerix, Orthocell and Telix down by less than one percent.

PFIZER INC

The New York-based Pfizer Inc says its Breakthrough Growth Initiative will invest up to \$US500 million (\$A720.1 million) in biotechnology companies for clinical programs. Pfizer said the funds would “help provide funding and access to Pfizer’s scientific expertise to ensure continuity of the biotechnology companies’ most promising clinical development programs”.

Pfizer chief business officer John Young said there had “never been a more important moment to pursue new collaborations in our industry”.

“The Pfizer Breakthrough Growth Initiative seeks to do just this by injecting crucial capital into biotechnology companies that share our commitment to delivering transformative therapies for patients,” Mr Young said.

Pfizer said the Initiative would “focus on making non-controlling equity investments in clinical-stage public companies, with a primary focus on companies with small- to medium-sized market capitalizations across a range of therapeutic categories that are consistent with Pfizer’s core areas of focus”.

The company cited the main areas of focus as: internal medicine, inflammation and immunology, oncology, rare disease and vaccines.

Pfizer said that partner companies might have “the opportunity to access Pfizer’s significant expertise and resources in research, clinical development and manufacturing”.

In a subsequent email, Pfizer told Biotech Daily that it had received “hundreds of inquiries about this initiative” and to expedite assessment companies should provide: a non-confidential slide deck with a company overview, clinical pipeline and pre-clinical assets; if a public company, the ticker symbol, exchange listing, and current market capitalization; if a private company, current investors, capital raised to date, and most recent series raised by date and value; amount of equity investment being sought; other potential partnering needs including development, manufacturing, commercial, and geographic; closest Pfizer therapeutic category, that internal medicine, inflammation and immunology, oncology, rare disease and vaccines.

The company said that biotechnology companies interested in learning more should contact: pbqi@pfizer.com.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$35.9 million to fund 17 research projects for rare cancers, rare diseases and unmet medical needs.

A media release from Federal Health Minister Greg Hunt said the Government aimed to increase clinical trial activity to drive ideas and discoveries to improve quality of life and survival rates.

The Government said it would provide \$3,480,677 for the University of Melbourne for a trial of non-invasive ventilation for motor neuron disease; \$3,418,152 for the University of Queensland for a phase III trial of sildenafil, marketed as Viagra, to avert the risk of contraction-induced hypoxia in labour; \$3,328,736 for the University of New South Wales for a phase I/II dose escalation trial, combining azacytidine and defactinib for high-risk myelodysplastic syndrome; \$2,572,403 to the University of Queensland for metformin therapy to ease decline in kidney function in polycystic kidney disease; and \$2,459,666 for the University of Queensland to treat mitochondrial dysfunction with a form of anaplerosis.

The media release said it would provide \$2,387,925 to the University of Melbourne to evaluate fibroblastic activation protein inhibitors as a radiopharmaceutical targeting cancer-associated fibroblast to diagnose and treat cancer of an unknown primary.

The Government said the funding was through the Medical Research Future Fund.

RHINOMED

Rhinomed says it has raised \$6,514,439 through a renounceable rights issue at 7.7 cents a share.

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).

Last week, the company said the Australian Foreign Investment Review Board had approved Whitney George to underwrite the rights issue (BD: Jun 17, 2020).

Today, Rhinomed said it had entitlement applications for \$3,909,429 and the shortfall of \$2,605,010 would be placed with Whitney George as the underwriter.

Rhinomed was up 0.2 cents or 2.7 percent to 7.7 cents.

AROA BIOSURGERY

Aroa says it hopes to raise up to \$45 million through a capital raising and sell-down at 75 cents a share to list on the ASX for its Endoform soft tissue regeneration products.

The Auckland, New Zealand-based Aroa said the offer included a \$30 million fully underwritten capital raising and a \$15 million sell-down from existing investors.

The company said it had five commercial products based on Endoform, which was derived from sheep stomach, which acted as a scaffold to grow new tissue lost or damaged through disease or injury, eventually replaced by the patient's own tissue.

Aroa said the five products included Endoform Natural, a tissue matrix for stalled chronic wounds, Endoform Antimicrobial, an antimicrobial tissue matrix for stalled chronic wounds, Myriad, a biological graft for dermal and implantable soft tissue reconstruction, Ovitex, a reinforced biological scaffold for abdominal wall reconstruction for hernia and Ovitex PRS, a reinforced biological scaffold for plastic and reconstructive surgery.

The company said revenue of \$NZ22 million (\$A20.5 million) for the 12 months to March 31, 2020, came from direct sales of its five commercial products, from its Appulse joint-venture with Hydrofera LLC and distribution partner, the Pennsylvania-based Tela Bio Inc.

Aroa said its Endoform had been used in more than four million procedures to date, it had regulatory clearance in more than 37 countries, had sales with more than 600 US hospitals and had 10 patents and 25 pending patent applications.

The company said it also had a pipeline of additional products in development, based on the Endoform technology, including Symphony, a skin substitute for closing wounds for severely impaired healing and a single-use negative pressure wound therapy.

Aroa said it currently had 240,074,950 shares on issue and a \$30 million capital raising and \$15 million sell-down by existing investors would value the company at \$225 million.

The company said that proceeds from the offer would be used to invest in sales and marketing, to increase manufacturing capacity to meet anticipated demand and facilitate product development, to cover operating costs and to repay borrowings.

Aroa said the offer would open on July 1 with minimum investments of \$7,500 and would close on July 3, 2020.

The company said its board comprised chairman James McLean, managing director Brian Ward with directors Steven Engle, Philip McCaw, John Pinion and John Diddams.

Aroa said the management team included chief executive officer and founder Mr Ward, chief financial officer James Agnew, head of operations Simone Von Fircks, head of technology Barnaby May and head of commercial operations Brad Adams.

The company said Bell Potter Securities and Wilsons would be joint lead managers to the offer and it expected to list on the ASX on July 30, 2020 under the ASX code ARX.

Aroa is a public unlisted company.

MAYNE PHARMA GROUP

Mayne says the US Food and Drug Administration has accepted its new drug application for its estetrol and drospirenone combination contraceptive E4/DRSP.

Mayne said it expected the FDA to complete its review by June 30, 2021.

In May, the company said it had a supply agreement with Mithra Pharmaceuticals to distribute E4/DRSP in Australia and expected to file the product with the Australian Therapeutic Goods Administration in 2020 for a potential launch by December 31, 2021 (BD: May 29, 2020).

Last year, Mayne said it had a 20-year deal with Mithra to commercialize E4/DRSP in the US and in April 2020 said it had submitted a new drug application to the US Food and Drug Administration (BD: Oct 2, 2019, Apr 16, 2020).

Mayne was up two cents or 5.4 percent to 39 cents with 15.4 million shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical says Milan's Meditel srl has ordered 1,000 Prizma mobile telephone vital signs devices, the company's first Italian purchase order.

In April, G Medical said it had a 12-month agreement with Meditel to promote, sell and distribute its Prizma device and extended holter in Italy (BD: Apr 6, 2020).

Today, the company said the first batch of devices had been delivered from Israel and Meditel was equipped to process consumer sales.

G Medical was unchanged at 4.8 cents with 5.4 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it will resume recruitment of its phase IIa study of synthetic cannabinoid BTX1801 as an antimicrobial, following a pause caused by the Covid-19 pandemic.

Botanix said it had scheduled a US Food and Drug Administration end of phase II meeting for BTX1503 for acne for July 2020.

In April, Botanix said it would suspend its dermatology program and focus on antimicrobial targets following the failure of both BTX1204 for eczema and BTX1503 for acne to meet their primary endpoints (BD: Oct 23, 2019; Mar 25, Apr 16, 2020).

Today, the company said it expected to complete recruitment of its BTX1801 study by October 2020 and the trial would be conducted wholly in Western Australia.

Botanix said its BTX1702 study for rosacea was on hold until restrictions eased in Australia and New Zealand, but preparations were underway to ensure enrolment could occur once restrictions were lifted.

Botanix chairman Vince Ippolito said that "as Covid-19 restrictions continue to ease, Botanix is well positioned to relaunch its antimicrobial and dermatology clinical work".

Botanix fell 0.1 cents or 2.3 percent to 4.2 cents with 9.3 million shares traded.

ALTHEA GROUP

Althea says it has a patient referral agreement with Drug Science and the UK Care Quality Commission has approved five new My Access Clinics locations in the UK.

Althea said Drug Science would refer patients to My Access Clinics to be assessed for inclusion and treatment in the Project Twenty21 UK trial of medical marijuana, which aimed to enrol 20,000 patients by 2021, and it had approval for additional clinics in London, Birmingham, Leeds, Liverpool and Manchester.

Althea was up 0.3 cents or 20 percent to 1.8 cents.

[CRESO PHARMA](#)

Creso says its Halifax, Nova Scotia-based subsidiary Mernova Medical is increasing marijuana production to meet medical and recreational market demand in Canada. Creso said operational improvements at its Nova Scotia production facility had improved marijuana quality and it was in initial discussions with recreational customers in Canada. Creso was unchanged at 4.1 cents with 10.6 million shares traded.

[HERAMED](#)

Freeman Road Pty Ltd, for The Avenue account, says it has become a substantial holder Heramed with 6,912,365 shares or 5.33 percent.

The substantial shareholder notice, signed by director Dr Ti Wan Ng of 168 St George's Terrace, Perth, Western Australia, said Freeman Road bought 3,333,333 shares for \$300,000 or 9.0 cents a share on June 15, 2020.

In May, Heramed said it would work with Perth's Freeman Road Pty Ltd on pilot and clinical studies of its Herabeat and Heracare for telehealth and remote pregnancy monitoring (BD: May 20,2020).

In 2018, Freeman Road said in a substantial shareholder notice signed by director Tee Yen Ng of the same address, said it held 6.28 percent of Resapp (BD: Sep 28, 2018). Heramed was up 0.4 cents or 4.6 percent to 9.1 cents.

[PARADIGM BIOPHARMACEUTICALS](#)

Paradigm says chairman Graeme Kaufman has resigned for personal and family reasons. Paradigm said that chief executive officer Paul Rennie would replace Mr Kaufman on an interim basis.

Paradigm said Mr Kaufman joined the board prior to its initial public offering and ASX listing and had contributed to its development and success.

"Graeme has overseen the development of Paradigm since IPO and I would like to personally thank Graeme for his contribution to Paradigm," Mr Rennie said.

Prior to Paradigm, Mr Kaufman was chairman of IDT, Cellmid and Bionomics and was previously CSL's chief financial officer.

Paradigm was up 25 cents or 7.1 percent to \$3.79 with 1.8 million shares traded.

[ELLEX MEDICAL LASERS](#)

Ellex says Simon Gray has been appointed joint company secretary and will replace company secretary Kimberley Menzies, effective from June 30, 2020.

Ellex said that Mr Gray had more than 35 years' experience as an accountant and 20 years as a partner with accounting firm Grant Thornton.

The company said that Mr Gray was currently a director and company secretary of Havilah Resources and company secretary and chief financial officer of Vintage Energy and a director of several unlisted companies.

Ellex said that Mr Gray was currently a director of the Flinders Medical Research Foundation and the South Australia Medical Research Foundation.

Ellex was up one cent or 1.7 percent to 60 cents.