



Biotech Daily

Wednesday July 21, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PRESCIENT UP 12%; OPTISCAN DOWN 7%**
- * **BCAL CLIMBS 10% ON \$10m IPO FOR BREAST CANCER SCREENING**
- * **IMMUTEP 'OVER-SUBSCRIBED' PLAN RAISES \$7.2m; TOTAL \$67.2m**
- * **TOTAL BRAIN \$6.5m PLACEMENT, RIGHTS OFFER**
- * **AMPLIA: 'AMP945 SAFE, WELL-TOLERATED, APPROPRIATE FOR FAK'**
- * **ECOFIBRE RECEIPTS DOWN 24% TO \$23m**
- * **MICRO-X NEW GENERATOR: 'HALF THE PRICE, 4 TIMES THE POWER'**
- * **HYDRIX TAKES GUARDIAN CARDIAC ARREST DEVICE TO TGA**
- * **ARGENICA'S PROF BRUNO MELONI WINS \$290k GRANT FOR RAT STUDY**
- * **MGC TELLS ASX: 'JUNE 23 SLOVENIAN PATENT MATERIAL AT JULY 15'**
- * **BARD1 REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **AUSTRALIAN ETHICAL TAKES 7.55% OF MACH7**
- * **MILANO TOPCO, HMS INCREASE, DILUTED TO 11.7% OF MEDADVISOR**
- * **HANNO CAPPON REPLACES BOD DIRECTOR PATRICE MALARD**
- * **STEMCELL UNITED APPOINTS FRANCESCO CANNAVO DIRECTOR**

MARKET REPORT

The Australian stock market recovered 0.78 percent on Wednesday July 21, 2021, with the ASX200 up 56.5 points to 7,308.7 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and one was untraded. All Big Caps rose.

Prescient was the best, up 2.5 cents or 12.2 percent to 23 cents, with 6.9 million shares traded. Imugene climbed 7.9 percent; Alterity was up 5.9 percent; LBT improved 4.55 percent; Avita and Nova were up more than three percent; Amplia, Cyclopharm, Dimerix, Opthea, Orthocell, Paradigm, Patrys and Pharmaxis rose more than two percent; Clinuvel, Cochlear, CSL, Kazia, Neuren and Resmed were up more than one percent; with Genetic Signatures, Mesoblast, Proteomics and Volpara up by less than one percent.

Optiscan led the falls, down 1.5 cents or 6.8 percent to 20.5 cents, with 610,270 shares traded. Impedimed fell 4.8 percent; Antisense, Compumedics, Pro Medicus and Telix shed more than two percent; Cynata, Next Science, Polynovo and Universal Biosensors were down one percent or more; with Nanosonics and Starpharma down less than one percent.

BCAL DIAGNOSTICS

BCal was up as much as 10 percent to 27.5 cents on the ASX, following its \$10 million initial public offer at 25 cents a share to develop its blood test for breast cancer.

BCal, or breast cancer associated lipids, said its core technology evolved from Australian and US research, which showed that breast cancer patient samples contained significantly different lipid profiles from those of both healthy volunteers and lung cancer patients.

The company said it was aiming for Australian approval for the finger-prick blood test to complement mammography, increasing the sensitivity of breast cancer detection.

BCal said the test could assist breast cancer screening, including women who self-exclude for religious or other reasons, noting that mammograms could be painful.

The company said that following a domestic launch of the test it would “seek further clinical data both to support broader uses of the technology domestically and consider appropriate pathways to markets in other jurisdictions”.

BCal said Genesiscare would conduct the clinical research for regulatory approvals across several jurisdictions and commercialization.

BCal executive chair Jayne Shaw said the goal was to bring the test to the market “at which time we will evaluate the technology and its application in other cancers”.

The company’s non-executive directors were Dr Marilyn Sleigh, Ron Phillips, Jonathan Trollip and Mark Burrows with product development adviser Dr Jane Ryan, chief financial officer and company secretary Guy Robertson, chief scientist Dr Amani Batarseh and Alison Cook (formerly Alison Mew) as the regulatory and commercialization manager

BCal said the offer valued it at \$51.7 million, with PAC Partners the sole lead manager.

BCal opened up two percent at 25.5 cents and closed unchanged at 25 cents with 7.6 million shares traded.

IMMUTEP

Immutep says its share plan has raised \$7,175,720, more than the hoped-for \$5 million, taking the total raised with the June placement to \$67,175,720 (BD: June 21, 2021).

Immutep said the board exercised its discretion to increase the size of the plan to accept the full number of applications received from eligible shareholders.

The company said the funds raised would be used to support its ongoing and planned immuno-oncology clinical development programs, its pre-clinical program in autoimmune disease and for general working capital purposes.

Immutep was unchanged at 50 cents with 1.9 million shares traded.

TOTAL BRAIN

Total Brain says it has commitments to raise \$6.5 million in a \$2.5 million placement and a fully-underwritten, one-for-seven rights offer for \$4 million at 26 cents a share.

Total Brain said the offer price was a 10.3 percent discount to last closing price of 29 cents and the funds would be used to improve the IBM partnership, build and launch a direct-to-customer business with Hamptons Life, increase the clinical business and

corporate pipeline and partially settle shareholder loans with managing-director Louis Gagnon, directors David Torrible and David Daglio and chief operating officer Matt Mund.

The company said it would issue one option for every two new shares, exercisable at 36 cents within 12 months from issue; the record date for the rights offer was July 26, it would open on July 29 and close on August 12, 2021.

Total Brain said that following the capital raising it would have \$7.3 million in cash.

Total Brain fell one cent or 3.45 percent to 28 cents.

AMPLIA THERAPEUTICS

Amplia says its 56-patient, phase I study of oral AMP945 shows it is safe and well-tolerated with plasma concentrations above that required to inhibit focal adhesion kinase. Amplia said the results confirmed preliminary analyses and showed that AMP945 was “safe and well tolerated at all doses tested, supporting its progression into later stages of clinical development in both cancer and fibrosis”.

The company said the randomized, double-blind, placebo-controlled study of single and repeat doses, up to 125mg and 100mg respectively, of oral AMP945 in healthy adult volunteers was conducted at the Nucleus Network in Melbourne.

Amplia said the primary endpoints focused on safety and tolerability, assessed by evaluating the nature, incidence and severity of adverse events, withdrawals, physical examinations, vital signs, electro-cardiograms and safety laboratory test results including assessment of biochemical and haematological markers, with secondary endpoints assessing pharmacokinetics.

The company said one cohort was given AMP945 before and after food, with AMP945 “well tolerated at all doses given and there were no withdrawals or serious adverse events recorded in the trial” and no evidence of any food effect on the absorption of AMP945. Amplia said that adverse events were generally mild or moderate and were distributed evenly across participants assigned to AMP945 or placebo, with mild headache the most frequently observed adverse event and the majority of safety findings were considered as either not related or unlikely to be related to AMP945.

The company said that events considered possibly related to AMP945 included one incidence of diarrhoea, two incidences of headache, one taste disorder and one hot flush, but there were no clinically significant changes in vital signs, clinical or laboratory parameters associated with AMP945, and no adverse safety signals or dose-related trends were detected in any of the parameters measured.

Amplia said that plasma half-life was about 20 hours indicating that AMP945 was both orally bioavailable and could be administered once daily.

The company said that plasma levels exceeded concentrations required to inhibit the intended target focal adhesion kinase with maximum plasma levels achieved after about two to four hours post dose.

Amplia said studies were ongoing to measure the inhibitory activity of AMP945 on focal adhesion kinase in biopsies and to assess the plasma metabolite profiles of AMP945.

Amplia managing-director Dr John Lambert said the phase I trial “delivered exactly what we wanted: AMP945 has been shown to have a safety and tolerability profile suitable for progressing it into phase II trials in both pancreatic cancer and pulmonary fibrosis”.

“We are now planning those trials and expect to start the phase II trial in pancreatic cancer around the end of 2021,” Dr Lambert said.

Dr Lambert said the completion of the trial was “yet another significant milestone”.

Amplia was up cent or 2.4 percent to 21.5 cents with 1.3 million shares traded.

ECOFIBRE

Ecofibre says receipts from customers for the year to June 30, 2021 fell 24.05 percent to \$32,866,000 compared to the previous corresponding period.

Ecofibre said that receipts from customers for its marijuana-based pharmacy and material products for the three months to June 30, 2021 were up 9.1 percent to \$7,936,000.

Ecofibre chief executive officer Eric Wang said the US businesses were “beginning to return to normal as Covid-related issues appear to be abating”.

Ecofibre was up six cents or 8.1 percent to 80 cents.

MICRO-X

Micro-X says its first test of a new x-ray tube and high voltage generator delivering four times the x-ray energy of the current products.

Micro-X said the new systems would power the second generation of its Mobile DR range of bedside imaging products and provided a modular high-voltage platform for all future products, along with “major cost savings from in-house generator manufacture”.

The company said the second-generation Rover would take it beyond the requirements of intensive care units and open wards into “the more specialized and demanding environment of trauma imaging in emergency departments and operating rooms”.

Micro-X said that developing high voltage power supplies was “a critical competitive advantage” and removing the supply chain associated with importing generators became a priority during the logistics challenges of 2020 associated with the Covid-19 pandemic.

The company said the generator was the largest cost component and the new generator would cost less than half of the imported unit, with a four-fold increase in performance.

Micro-X managing-director Peter Rowland said it was the company’s “first venture into a high voltage electronics design program and so was not without risk”.

“We set out to create a platform technology in a design which could be used across all our products [and] once again, our technical team has done a fantastic job in providing us with a world-leading design for this sub-system which boosts our competitive advantage with a much higher power density than anything else available”.

Mr Rowland said the company would launch the unit as the Rover Mark II at the Radiological Society of North America’s meeting in Chicago at the end of November.

Micro-X was up cent or 3.2 percent to 32 cents with 1.2 million shares traded.

HYDRIX

Hydrix says it has applied to have the Angel Medical Guardian cardiac arrest warning device included on the Australian Register of Therapeutic Goods.

Hydrix said it made the application to the Australian Therapeutic Goods Administration following the US Food and Drug Administration pre-market approval for the device and its new upgraded battery, with TGA approval expected “by early 2022” (BD: Jun 28, 2021).

Hydrix general-manager Paul Kelly said that each milestone took the company a step closer to commercializing “the world’s only implantable heart attack alert system”.

Hydrix said it was working with Australia’s Medical Services Advisory Committee for listing the procedure on the Medical Benefits Schedule, to provide a physician fee and the Prostheses List Advisory Committee to enable private health insurance reimbursement.

Hydrix was up 1.5 cents or 9.1 percent to 18 cents.

ARGENICA THERAPEUTICS

Argenica says that chief scientific officer Prof Bruno Meloni and his team at the Perron Institute have secured a \$290,000 cash grant for an ARG-007 rat study for stroke.

Argenica said the grant from MSWA, formerly the Multiple Sclerosis Society of Western Australia, would fund the defining the ideal dose of ARG-007 for neuroprotective response effectiveness when administered alone, or with clot dissolving drugs.

The company said it previously confirmed that ARG-007 was neuroprotective after permanent middle cerebral artery occlusion stroke in rats at 300nmol/kg and the new study would confirm the most effective dose of ARG-007 for a phase I trial, as well as confirm its effectiveness when used during thrombolysis treatment.

Argenica was up half a cent or 2.6 percent to 20 cents.

[MGC \(MEDICAL GRADE CANNABIS\) PHARMACEUTICALS](#)

MGC has told the ASX that it filed a June 23 Slovenian patent application announcement as 'market sensitive' after the market closed on July 15, 2021.

Last week, MGC said it had applied to the Slovenian Intellectual Property Office for a patent covering its "self-nano-emulsifying drug delivery system" for marijuana molecules, but did not include the title or the expected duration of the patent in the announcement (BD: Jul 16, 2021).

The London-based managing-director Roby Zomer told Biotech Daily by email on July 16 that the patent was titled 'Cannabinoids-Ionic complex self-nanoemulsifying concentrate and method for preparation thereof' and after publication a further email said it would protect the company's intellectual property until June 2041.

Today, the ASX said that although the announcement was made on July 15 the patent had a priority date of June 30 and asked whether the company considered the announcement contained "information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities".

The ASX cited Section 7.10 of Guidance Note 8 on "ramping".

The ASX said: "Ramping announcements come in many forms, including the release of a 'business update' or something similar, which will typically be worded in an exuberant fashion but which on closer examination contains little in the way of substance that has not already been disclosed to the market or ...an announcement that has no substance but seeks to ride on the back of strong market sentiment in a particular sector".

The ASX said that when it detects "what it suspects to be a ramping announcement, it will give careful consideration to suspending the entity's securities from trading and issuing a query letter to the entity asking the entity: if it marked the announcement as market sensitive when it was lodged ... to identify what information in the announcement the entity considered was market sensitive and why".

The ASX did not ask a direct question relating ramping.

In its reply, MGC said that the formal acceptance was sent from the Slovenian Ministry of Economic Development and Technology to its Slovenian lawyer on June 30, 2021, who sent it to the UK subsidiary, which at the time of the response to the ASX had not been received "and we suspect that this is due to COVID-19 related logistics delays in Europe". The company said that the Slovenian lawyer also sent the letter to patent co-applicant Graft Polymer UK's Slovenian office.

MGC said it waited "for receipt of the original letter to action, but decided to the commence the process of drafting the ASX announcement based on the copy provided by Graft Polymer, in case of extended mail delays".

The company said the announcement was drafted with Graft Polymer UK followed by technical and legal review before providing the board a draft copy on Wednesday July 14.

MGC said that with directors in Australia, the UK and Europe the announcement was released to the ASX "late in the day on July 15".

The company said the patent announcement was material and it was complying with the ASX Listing rules.

MGC was up 0.1 cents or 2.5 percent to 4.1 cents with 6.8 million shares traded.

[BARD1 LIFE SCIENCES](#)

Bard1 has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on July 23, 2021 or on an earlier announcement.

Bard1 last traded at \$1.80.

[MACH7 TECHNOLOGIES](#)

Australian Ethical Investment says it has increased its substantial shareholding in Mach7 from 15,141,322 (6.45%) to 17,855,057 shares (7.55%).

The Sydney-based Australian Ethical said that between November 6, 2020 and July 19, 2021 it bought and sold shares with the single largest purchase 1,500,000 shares for \$1,487,450 or an average of 99.16 cents a share.

Mach7 was up 6.5 cents or 7.2 percent to 97 cents with 1.5 million shares traded.

[MEDADVISOR](#)

Health Management Systems says it has increased and been diluted in Medadvisor from equivalent to 31,428,571 shares (12.8%) to 43,999,999 shares (11.66%).

The New York-based Milano Topco said that from April 1, 2021 it had control of HMS Holdings, which controlled Health Management Systems and it adjusted the number of shares following the seven-to-one consolidation (BD: Nov 20, 2019).

Today, Milano Topco said it acquired 12,571,428 shares in a \$3.2 million rights offer at 38 cents a share in November 2020 and was diluted in a \$5.25 million placement at 30 cents a share in May (BD: Dec 4, 2020; May 6, 2021).

Medadvisor was up half a cent or 1.7 percent to 30.5 cents.

[BOD AUSTRALIA](#)

Bodsays Hanno Cappon will replace Patrice Malard as a non-executive director, representing Hong Kong's New H2 and Health and Happiness Group.

Bod said that Mr Cappon was the Health and Happiness chief technology officer and had a background in chemistry, life sciences, nutrition and health innovation and developing new consumer and healthcare products for commercialization.

The company said Mr Cappon previously worked for Bayer Consumer Health in Switzerland and Danone Nutricia in the Netherlands.

Bod was up half a cent or 1.5 percent to 34 cents.

[STEMCELL UNITED](#)

Stemcell United says it has appointed executive and capital markets advisor Francesco Cannavo as a non-executive director.

Stemcell said that Mr Cannavo was "an experienced public company director with ... business and investment experience", formerly a director of Lifespot Health, currently a director of Western Mines Group and the founder of Melbourne corporate advisory firm Golden Venture Capital.

Stemcell was up 0.1 cents or 5.3 percent to two cents with 15.1 million shares traded.