# Biotech Daily

Tuesday May 12, 2020

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: RESONANCE UP 17%; NEXT SCIENCE DOWN 8%**

*** INDUSTRY: 'FEDERAL JOBKEEPER FOR PRE-REVENUE COMPANIES'**

*** AAMRI: RESEARCH LOSING NON-GOVERNMENT FUNDING**

*** ORTHOCELL SUBMITS CELGRO FDA 510(k) APPLICATION**

*** PHARMAUST: MONEPANTEL 'SUCCESS' - 1 DOG TUMOR REDUCED**

*** SUDA ADDS DRUG SUPPLIER TO ZOLPIMIST TGA APPLICATION**

*** MEMPHASYS SHARE TRADING INCREASES IN GERMANY**

*** SIMAVITA EXTENDS $1.4m NOTES DATE TO DECEMBER**

*** THC ACQUIRES TETRA HEALTH FOR $3m IN CASH, EQUITY**

*** BOD RECEIVES UK SCRIPTS FROM PROJECT TWENTY21 PATIENTS**

*** PARADIGM DIRECTORS SELL 4.5m SHARES TO 'OFFSHORE INVESTORS'**

*** CLIME TAKES 7% OF MACH7**

*** MGC EXTENDS 'DISTRIBUTION AGREEMENT' SUSPENSION**

## MARKET REPORT

The Australian stock market fell 1.07 percent on Tuesday May 12, 2020, with the ASX200 down 58.2 points to 5,403.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and one was untraded.

Resonance was the best, up 2.5 cents or 16.7 percent to 17.5 cents, with 3.1 million shares traded. Cyclopharm climbed 10 percent; Starpharma was up 7.5 percent; Kazia rose 6.8 percent; Orthocell and Resmed were up more than five percent; Cynata and Immutep improved more than three percent; Amplia and Genetic Signatures rose more than two percent; CSL, Nanosonics, Pharmaxis and Volpara were up more than one percent; with Clinuvel up 0.3 percent.

Next Science led the falls, down 14 cents or 7.9 percent to $1.64, with 172,730 shares traded. Optiscan lost 6.25 percent; Alterity and Paradigm fell five percent or more; Antisense, Opthea, Prescient and Universal Biosensors retreated four percent or more; Kazia, Polynovo and Medical Developments were down more than three percent; Avita, Ellex, Impedimed and Telix shed more than two percent; with Cochlear, Neuren and Pro Medicus down by less than one percent.

## JOINT BIOTECHNOLOGY INDUSTRY STATEMENT

A “joint industry statement” calls on the Federal Government to extend its Jobkeeper program to biotechnology’s 65,000 jobs, primarily in pre-revenue companies.

The statement, co-signed by Ausbiotech, Australia’s National Digital Health Initiative, Medicines Australia, Medical Technology Association of Australia, Bio-Melbourne Network, Life Sciences Queensland said that “more than 85 percent of the sector need Jobkeeper to retain skills and talent” in health and medical start-ups.

“Despite this being the life sciences industry’s finest hour as it pivots to fast track Covid-19 vaccines, treatment and diagnostics and digital health solutions, the sector’s pre-revenues companies are calling for support to keep their highly-skilled 65,000 jobs,” the group said.

The industry groups said the Australian Taxation Office had “denied the industry’s application to expand the Jobkeeper payment eligibility criteria to include pre-revenue biotech and medtech companies working in Australia”.

The industry groups said that the health industry’s research and development, including clinical trials, was “a key contributor to Australia’s patient wellbeing and growth economy … [and they urged] the inclusion of pre-revenue life science companies in the Jobkeeper eligibility criteria”.

“These life science companies are at the heart of the essential research and development of vaccines, repurposed and emerging therapies, diagnostics, digital solutions, as well as test kits and ventilators to combat Covid-19,” the signatories said.

The industry groups said the Federal Government had acknowledged the unintended exclusion of other sectors and developed alternative tests.

The signatories said charities, including medial research institutes, could exclude government revenue from the Jobkeeper turnover test, enabling them to continue delivering services, and start-ups, including those in the technology sector who had high-growth, could use the alternative decline-in-turnover test that recognized that it might not be appropriate to compare current monthly or quarterly goods and services tax (GST) turnover with the same period a year ago.

The industry groups said that without Jobkeeper eligibility criteria being expanded to include pre-revenue life science companies, “they stand to lose up to a decade of substantial scientific and capital contributions”.

The signatories said that “many pre-revenue companies are under strain as their clinical trials are halted and delayed and venture capital markets dry up”.

The industry groups said life science companies often did not generate revenue for up to 15 years for therapeutics and seven years for medical devices and “therefore, they do not have revenue to show, nor revenue to reduce by 30 percent”, regardless of their need for cash and reliance on venture capital, which was drying up in the Covid-19 crisis.

The industry groups said that at the start of the year the sector and its “ecosystem” included more than 1,800 organizations and 240,000 employees, with start-ups and small and medium sized enterprizes accounting for 86 percent of the life sciences industry, employing more than 65,000 Australians in high-value jobs.

The signatories said the sector added more than $4 billion a year to Australia’s economy and was a world leader in developing new therapies to combat diseases.

The industry groups said that Jobkeeper’s intention was to retain staff and to support businesses to recommence quickly without needing to rehire when the downturn was over, and “omitting pre-revenue life science companies has the potential to knock over the entire industry”.

Access to Jobkeeper would enable staff to remain connected to the company and support businesses to recommence quickly without needing to rehire when the downturn was over, the industry groups said.

## AUSTRALIAN ASSOCIATION OF MEDICAL RESEARCH INSTITUTES

The Australian Association of Medical Research Institutes says a report by research organizations is concerned with falling non-government funding.

AAMRI said the report, titled 'Impact of the Pandemic on Australia's Research Workforce', was compiled with Australia chief scientist Dr Alan Finkel and is at:
https://www.science.org.au/sites/default/files/rrif-covid19-research-workforce.pdf

The Association said that the report "painted a troubling extended outlook for the research community".

AAMRI said that from March "we have been seeing a drop of about 30 percent on fundraising coming into institutes".

"Due to the understandable ban on face-to-face fundraising some institutes are currently losing 70 percent of their fundraising income," the Association said.

"Research grants in Australia do not pay for the full costs of conducting research, so fundraising is necessary even to cover basic research costs," AAMRI said.

"Institutes receive about half their funding from government revenue and the other half they make up with fundraising, philanthropy, commercialization, contract research and other income sources … [which is used] to pay researchers, research support staff salaries and the other indirect costs of research," the Association said.

AAMRI policy and operations director and contributing author Dr Peter Thomas said that the Australian medical research workforce "will be severely impacted for an extended period of time".

Dr Thomas said AAMRI had seeing a drop off in revenue streams at medical research institutes over the past few months, and if past downturns were a guide "it could take many years for these to bounce back to pre-coronavirus levels".

AAMRI president Prof Jonathan Carapetis said "we need to ensure strong support for the research sector so that we can deal with this and future pandemics".

"The report outlines a harsh truth, that it's not just about this pandemic and the effects right now, it's about how our future research capacity is at risk," Prof Carapetis said.

The report was produced by the Rapid Response Information Forum, a group of 35 research sector lead organisations, chaired by Dr Finkel with operations led by the Australian Academy of Science.

## ORTHOCELL

Orthocell says it has completed its US Food and Drug Administration 510(k) submission for its Celgro dental bone and soft tissue regeneration product.

Orthocell said 510(k) submission followed positive results from its 18-dog bone regeneration study which showed that Celgro was effective in facilitating bone regeneration when used with bone substitute and a dental implant (BD: Mar 11, 2020).

The company said the submission was alongside an Australian regulatory submission for dental bone and soft tissue regeneration applications and it had planned submissions in the US, Europe and Australia for Celgro for the repair of crushed or severed nerves and augmentation of tendon repair.

Orthocell managing-director Paul Anderson said the submission was "a significant milestone for Orthocell as we drive our innovative regenerative medicine products into the US, the largest global healthcare market".

"We are in a strong position to gain US approval and are actively progressing our US market launch strategy," Mr Anderson said.

Orthocell was up two cents or 5.5 percent to 38.5 cents with 2.2 million shares traded.

## PHARMAUST

Pharmaust says monepantel for naïve B cell lymphoma in dogs is successful, with one of seven dogs having a 60 percent reduction in tumor size after treatment.

Pharmaust said the trial was on hold while an interim report was finalized for the supplier of monepantel, the Greenfield, Indiana-based Elanco US, as part of a data sharing agreement between the companies (BD: Apr 18, 2018; Jan 29, 2019).

The company said that seven dogs were enrolled, six dogs completed 14 days of the at-home monepantel tablet treatment, administered by their owners.

Pharmaust said that after 14 days one dog had a partial response with “a greater than 60 percent reduction in total tumor burden and with one lymph node tumor regressing completely”, four dogs had stable disease, one dog had progressive disease, and one dog had a partial response but showed elevated liver enzymes and discontinued treatment.

Pharmaust said that the four remaining dogs completed the 28-day treatment schedule, “with all four pet dogs achieving stable measured lymph nodes”.

“A new lesion, however, became apparent in two of these dogs and some elevated liver enzyme values not resulting in clinical illness were also noted,” the company said.

Pharmaust said the outcome compared favorably with the original liquid monepantel formula reported in December 2017, where six of seven dogs achieved stable disease and progressive disease was seen in one dog (BD: Dec 13, 2017).

The company said the high dose levels caused loss of appetite and weight loss in some dogs, with some owners having difficulties in administering tablets, and reducing the dose was expected to result in better outcomes in terms of efficacy, safety and dosing pets.

The principal investigator and University of Melbourne oncology lecturer Dr Claire Cannon said monepantel appeared to show anti-cancer activity in dogs with lymphoma and believed that “controlled phase III trials are now warranted to investigate the efficacy and safety of lower dose monepantel”.

“The phase II trial results suggest that monepantel, perhaps in combination with standard of care lymphoma therapy, may represent a future prospect for treatment of dogs with this disease,” Dr Cannon said.

Pharmaust chief scientific officer Dr Richard Mollard said that “having the monepantel tablets achieve a 60 percent reduction in tumor burden in one dog, with one lymph node returning to normal, is a terrific and unexpected outcome”.

Pharmaust was up one cent or 10 percent to 11 cents with 36.6 million shares traded.

## SUDA PHARMACEUTICALS

Suda says it has added a drug manufacturer and supplier to its Australia Therapeutic Goods Administration application for Zolpimist for insomnia.

Last year, Suda said its TGA application for Zolpimist, or zolpidem tartrate oral spray, had passed its preliminary assessment and the TGA would complete a full evaluation, including potential approval of Zolpimist, within 255 days (BD: Apr 4, 2019).

Today, the company said that it had amended the submission to include a supplemental active pharmaceutical ingredient supplier and manufacturer, which would reduce the costs of raw material and finished product.

Suda said it was required to provide data supporting the quality of Zolpimist when it was produced using the active ingredient supplied by the unnamed manufacturer.

The company said the additional data had been submitted and the TGA review decision was expected by the end of 2020.

Suda was up 0.4 cents or 8.7 percent to five cents.

## MEMPHASYS

Memphasys says there has been an increase in the trading of its shares on German stock exchanges.

Memphasys said it was listed on the Frankfurt Stock Exchange, the Berlin-based Tradegate Exchange, and the Berlin, Munich and Stuttgart Stock Exchanges.

Memphasys executive chair Alison Coutts said that in the past few months, the company had “noticed an increase in demand of Memphasys shares in the German-speaking region through a secondary listing at the open market of the Frankfurt Stock Exchange”.

“The listing on the additional exchanges was driven by local investor demand, which has increased in recent weeks,” Ms Coutts said.

The company said its Felix device, which quickly separated sperm from semen samples in human in-vitro fertilization procedures, was in the pre-commercialization phase and expected the first sales “in late 2020”.

Memphasys fell 0.2 cents or 2.9 percent to 6.6 cents.

## SIMAVITA

Simavita says the holders of convertible notes worth $1.4 million have agreed to extend the maturity date by nine months to December 21, 2019.

Simavita was unchanged at 2.2 cents.

## THC (THE HYDROPONICS CO) GLOBAL

THC says it has acquired medical marijuana access provider Tetra Health for $2.5 million in shares and $500,000 in cash, to be paid over six months.

THC said Tetra connected Australian patients and medical practitioners to prescribers of medical marijuana medicines and had a network of more than 600 referring physicians, 30 prescribing physicians, more than 10,000 prospective patients and more than 1,100 active patients.

The company said the acquisition allowed it to increase accessibility and reduce costs of medical marijuana by cutting out intermediary mark-ups and handling costs.

THC said that followed the settlement of the acquisition, Tetra and THC would pursue opportunities, including expanding its partnerships with private hospitals and medical centres in Australia and the potential to launch in new regions including New Zealand.

The company said it had retained all Tetra staff to ensure the continuity of Tetra’s services and Tetra would continue to operate autonomously.

THC was up three cents or 10 percent to 33 cents.

## BOD AUSTRALIA

Bod says it has received Medicabilis prescriptions from patients in Project Twenty21, a European medical marijuana registry with 20,000 patients.

Bod said it would sell Medicabilis for GBP150 ($A286) a unit and expected to supply it to a minimum of 1,000 patients suffering from conditions including chronic pain, multiple sclerosis, post-traumatic stress disorder, Tourette’s syndrome, anxiety disorders and issues arising from substance abuse.

The company said it would be registered with the project until the end of 2021, with the potential continue into 2022 “due to current conditions”.

Bod was up 3.5 cents or 12.1 percent to 32.5 cents.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says directors have sold 4,431,569 shares to offshore institutional investors to repay director loans and diversify the register.
Paradigm said managing-director Paul Rennie sold 92,108 shares, chair Graeme Kaufman sold 184,216 shares and director John Gaffney sold 115,695 shares to fund the repayment of an employee share plan loan from May 2015, which was due to be repaid by May 29, 2020.
The company said that the repayment of the loans would increase its net cash position of $106 million by $840,000.
Mr Kaufman said the company appreciated “the support of these offshore institutions for helping facilitate this transaction as our share register continues to globalize”.
Paradigm said Mr Rennie also sold 4,039,460 shares to fund a personal residential property, a loan, tax liabilities and to “balance his investment portfolio”.
In a substantial shareholder notice, Mr Rennie said his holding in the company had decreased from 23,640,790 shares, or 11.95 percent, to 19,509,222 shares or 8.68 percent.
Mr Rennie said that on May 8, 2020 he sold 4,131,568 shares for $9,502,606 or $2.30 a share.
The company said Mr Rennie had agreed to escrow the balance of his holding until December 31, 2022.
Paradigm fell 13 cents or five percent to $2.48 with 5.6 million shares traded.

## MACH7 TECHNOLOGIES

Clime Investment Management says it has increased its substantial shareholding in Mach7 from 11,656,143 shares (6.38%) to 13,621,458 shares (7.45%).
The Sydney-based Clime said that between March 13 and May 7, 2020 it bought and sold shares at prices ranging from 41 to 60 cents a share.
Mach 7 fell half a cent or 0.85 percent to 58 cents.

## MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested an extension to the voluntary suspension following a trading halt “in relation to a distribution agreement” (BD: May 7, 11, 2020).
In March and April, MGC requested seven extensions to a voluntary suspension following a trading halt requested on March 19, 2020 for what is said was a Covid-19-related joint venture (BD: Mar 19, 23, 24, 25, 26, 27, 31; Apr 2, 3, 2020).
MGC was eventually suspended by the ASX and emerged saying the trading halt and suspension had nothing to do with Covid-19, before making a further announcement that the joint venture with Swiss company Micelle Technology AG was to repurpose malaria compound Artemic for Covid-19 (BD: Apr 15, 17, 2020).
Today, MGC said it expected the suspension to last until May 18, 2020.
MGC last traded at 2.6 cents.