

Biotech Daily

Wednesday April 18, 2018

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: PSIVIDA UP 9%; AIRXPANDERS DOWN 10%
- * FEDERAL GOVERNMENT, MTP CONNECT \$10m FOR 11 GRANTS
- * APPLICATIONS OPEN FOR \$1m VICTORIA SECTOR GROWTH GRANTS
- * MESOBLAST APPROVED TO CONTINUE PHASE III HEART FAILURE TRIAL
- * OPTISCAN LOSES CHAIRMAN ALAN HOFFMAN
- * MGC COMPLETES \$5m PLACEMENT
- * NUHEARA RECEIVES \$1.2m FEDERAL R&D TAX INCENTIVE
- * PHARMAUST, ELANCO MONEPANTEL DOG CANCER AGREEMENT
- * ADALTA REDESIGNS AD-114 TO AD-214; TRIAL DELAYED 1 YEAR
- * ZELDA, CURTIN TO TEST MARIJUANA FOR DIABETIC DEMENTIA
- * CRESO, CLV TO LAUNCH MARIJUANA BEERS, TONICS
- * QUEENSLAND BAUXITE, MEDICAL CANNABIS HEMP SEED OIL CAPSULES
- * MAYNE PHARMA OPENS US MANUFACTURING FACILITY
- * INVION DIRECTOR DR MITCHELL GLASS SELLS 10m SHARES
- * AVITA RELEASES 3.5m ESCROW SHARES

MARKET REPORT

The Australian stock market was up 0.34 percent on Wednesday April 18, 2018 with the ASX200 up 19.9 points to 5,861.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and three were untraded.

Psivida was the best, up 15 cents or 9.1 percent to \$1.80 with 42,457 shares traded. Optiscan climbed 5.9 percent; Oncosil was up 3.7 percent; Clinuvel, Factor Therapeutics, Medical Developments and Starpharma rose more than two percent; Admedus, Cochlear, ITL and Neuren were up more than one percent; with Nanosonics, Opthea, Resmed, Sirtex and Viralytics up by less than one percent.

Airxpanders led the falls, down 1.5 cents or 10 percent to 13.5 cents with 1.4 million shares traded. Prana lost 6.5 percent; Dimerix fell 4.2 percent; Avita and LBT were down more than three percent; Actinogen, Impedimed, Mesoblast and Volpara shed more than two percent; Genetic Signatures, Osprey, Polynovo and Pro Medicus were down more than one percent; with Bionomics and CSL down by less than one percent.

FEDERAL GOVERNMENT, MTP CONNECT

The Minister for Health Greg Hunt and MTP Connect say that \$10 million will be provided to the first 11 recipients of the Biomedtech Horizons program.

The Federal Government-funded MTP Connect, or formally the Medical Technologies, Biotechnologies and Pharmaceuticals Industry Growth Centre, said the \$35 million program was part of the \$20 billion Medical Research Future Fund and aimed to move "ideas and breakthrough discoveries towards proof-of-concept and commercialization and stimulate collaboration across disciplines and between the research, industry and technology sectors to maximise entrepreneurship and idea potential".

MTP Connect said that the successful projects in the first round included a fully synthetic three-dimensional (3-D) printed spinal cage, a genome profiling platform to enable precision cancer medicine, a wireless brain-machine interface suitable for treating neurological disorders and micro-wearables for precision medicine.

MTP Connect chief executive officer Sue MacLeman said that the first investments were "set to fuel ongoing innovation in Australia, in line with MTP Connect's priorities for growth of the medical technology, biotechnology and pharmaceutical sector".

Ms MacLeman said the 11 projects addressed identified global trends including precision healthcare and the digital evolution, as well as forecasted areas of unmet clinical need, such as immunology, advanced prosthetics and infectious diseases including sepsis. MTP Connect said that projects to receive funding included:

A 3-D printed graft for wrist ligament surgical repair partnering Orthocell with Griffith University, the University of Western Australia and Queensland University of Technology; The University of Melbourne, Melbourne's St Vincent's Hospital, the University of Wollongong and Swinburne University of Technology's Biopen for in-situ bio-printing treatment for cartilage injuries;

Carina Biotech, Seattle Children's Research Institute, the University of Adelaide and the Women's and Children's Hospital Adelaide's chimeric antigen receptor t-cell (CAR-T) immunotherapies for solid cancers;

The Garvan Institute of Medical Research, Genome One and Illumina's "precision cancer medicine" through cost-effective genomic profiling of patient tumors";

The Bionics Institute, Hydrix, Taralye Early Intervention Centre, Plunkett Consulting Group and Australian Hearing's Eargenie personalized management of hearing impairment for infants:

Melbourne's Monash University, Alfred Health, MiniFAB and the Monash Vision Group's wireless brain-machine interface to bypass nerve and neural pathways damage to restore function to affected areas of the brain;

The Australian National University, Queensland Government, Johnson & Johnson Innovation, Australia National Fabrication Facility's Wearoptimo, or micro-wearables for personalized diagnostics across a range of diseases;

Anatomics' 3-D printing and the manufacture of Porestar craniomaxillofacial porous polyethylene implant material;

Biotech Resources, Monash University Centre for Biospectroscopy, the Alfred Hospital, Monash Health, for their Hydrix rapid diagnostic for the pathogens that caused sepsis; Towards Indee, the University of South Australia Future Industries Institute, Main Sequence Ventures, Defence Science Technologies Group, University of Sydney, Becton Dickinson's bedside gene therapies through the development of a micro-fluidic gene delivery device for immune cell modification and optimization; and Separately, Allegra said it would receive \$891,500 for its Sr-HT–gahnite spinal cage to

regenerate bone, with the University of Sydney, University of Wollongong, Boron Molecular and Sabre Medical under the Biomedtech Horizons program.

VICTORIA GOVERNMENT

The Victoria Government says that applications have opened for a new round of Sector Growth Program grants worth up to \$1 million each.

A Victoria Government media release said that the funding was for projects "that create jobs, and drive growth, productivity and competitiveness of local businesses".

The media release said that the eligibility requirements for the program had changed and applicants would need to show their trading history for two years, with a consortium required for Stream 2 projects, only.

The Government said that applicants "must address four assessment criteria, focusing on alignment with Future Industries sector strategies, economic benefits to the state, capacity to undertake project and value for money".

The media release said that the updated program guidelines were available at www.business.vic.gov.au/sectorgrowth and applications would close on June 13, 2018.

MESOBLAST

Mesoblast says a data management committee has approved the continuation of its phase III trial of stem cells for congestive heart failure "without modification".

Mesoblast said that the committee undertook a scheduled review of available data from 465 randomized patients in its 'Dream-HF trial of its MPC-150-IM mesenchymal precursor cells for class II/III patients with moderate-to-advanced chronic heart failure, including the primary and secondary endpoints of major adverse cardiac events and terminal cardiac events, and all safety data and "recommended continuation of the trial without modification".

The company said that enrolment was expected to be completed by the end of 2018. Mesoblast said that its 159-patient, phase IIb trial of MPC-150-IM for end-state heart failure patients with a left ventricular assist device (LVAD) had completed enrolment with 12-month data expected by October 2018.

The company said the trial was funded by the US National Institutes of Health and the Canadian Institute of Health Research.

Mesoblast said it was "actively pursuing a potential accelerated entry pathway for MPC-150-IM into the cardiovascular market" that might be provided by the US Food and Drug Administration regenerative medicine advanced therapy (RMAT) designation it received last year (BD: Dec 21, 2017).

Mesoblast fell 4.5 cents or 2.8 percent to \$1.555 with 760,555 shares traded.

OPTISCAN IMAGING

Optiscan says Alan Hoffman has resigned as chairman, effective from April 17, 2018. Optiscan said it thanked Mr Hoffman for his "valuable and significant contribution to the company during his tenure".

The company is due to hold a board spill extraordinary general meeting to remove directors which at that time included Mr Hoffman.

The notices of meeting and a website established by director Ian Mann, founder Peter Delaney and former chief executive officer Archie Fraser have said that six members of the senior management team had resigned and called for the current board, except Mr Mann, replaced, while a second requisition notice called for the removal of Mr Mann and the appointment of alternative directors (BD: Mar 28, 29, April 3, 4, 2018).

The extraordinary general meeting is due to be held on May 10, 2018.

Optiscan was up 0.4 cents or 5.9 percent to 7.2 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its placement at seven cents a share was oversubscribed and raised \$5 million, with funds going to the construction of its medical cannabis facility in Malta. MGC said that Bell Potter was the lead manager to placement, and would receive a five percent fee, payable on the funds raised under the placement.

The company said 10,000,000 unlisted options would be issued to the lead manager and corporate advisors who assisted with the capital raising, with an exercise price of 15 cents expiring on June 30, 2021.

MGC said the Government of Malta had awarded it a contract to build a 4,000 square metre medical cannabis production and cultivation facility (BD: Apr 11, 2018). MGC fell 0.8 cents or 9.3 percent to 7.8 cents with 7.9 million shares traded.

NUHEARA

Nuheara says it has received \$1,209,618 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nuheara said that the funds related to expenses in the year to June 30, 2017.

Nuheara was up 0.2 cents or 2.2 percent to 9.4 cents with 7.2 million shares traded.

PHARMAUST

Pharmaust says it has an option agreement with the US-based Eli Lilly subsidiary Elanco to develop monepantel as a treatment for cancer in dogs.

Pharmaust said Elanco would supply it with monepantel for clinical trials in dogs at commercial rates and Elanco would have the option to negotiate for a royalty-bearing commercial licence to use Pharmaust's intellectual property for cancer in animals.

The company said the option agreement would last for six months after receipt of the final report for the relevant canine trial.

Pharmaust chief executive officer Dr Richard Hopkins said the agreement helped to "build a relationship with a potential commercial partner".

Pharmaust was up 0.1 cents or two percent to 5.2 cents with 2.35 million shares traded.

ADALTA

Adalta says it has developed an improved form of its AD-114 for idiopathic pulmonary fibrosis treatment drug, re-named AD-214, delaying human trials by 12 months. Adalta said it intended to begin a phase I clinical trial for AD-214 by the end of 2019. The company said that the new drug showed a "significant improvement in half-life" that would result in less frequent dosing, as well as "enhanced activity" when compared to the previous drug.

Adalta said AD-214 was an Fc-Fusion protein that contained two AD-114 molecules to bind to human chemokine-type four receptor (CXCR4), as well as a traditional monoclonal antibody, to extend the duration the proteins would stay in the body.

Adalta chief executive officer Sam Cobb said "although the redesign of AD-114 into the new Fc-Fusion molecule AD-214 delays us from entering human clinical trials by around 12 months, Adalta believes the timeline associated with this new molecule is more than offset by its broader clinical utility in a wider range of fibrotic diseases outside of idiopathic pulmonary fibrosis".

Adalta was unchanged at 32.5 cents.

ZELDA THERAPEUTICS

Zelda says it has expanded its pre-clinical research program with Perth's Curtin University to include diabetes-related cognitive decline.

Zelda said the research with the Curtin Health Innovation Research Institute would study the effect of a cannabinoid-based therapeutic moderating the effects of cerebral capillary damage from diabetes.

The company said its research would be in "well-validated animal models of diabetic cognitive decline" that had been developed by Curtin University's research team led by Prof Ryu Takechi, over the next 12 to 18 months.

Zelda executive chairman Harry Karelis said the study had "the potential to demonstrate that daily dosing of certain cannabinoids can provide some type of long-term benefit to diabetes sufferers and moderate the effect of capillary damage, at least in validated animal models".

Zelda fell half a cent or 4.55 percent to 10.5 cents with 1.1 million shares traded.

CRESO PHARMA

Creso says joint venture CLV Frontier Brands will launch cannabis flavoured beers and tonics Europe and Canada in the Northern Hemisphere Summer.

Creso said that CLV was a joint venture with the London-based Baltic Beer Company and the Montreal-based LGC Capital to produce cannabis beers and tonics.

The company said that CLV's beers and tonics were marijuana flavored and scented due to the presence of cannabis terpenes, but did not contain any cannabinoids such as tetrahydrocannabinol (THC) or cannabidiol (CBD).

Creso fell 1.5 cents or 2.3 percent to 63.5 cents.

QUEENSLAND BAUXITE, MEDICAL CANNABIS

Queensland Bauxite says 55 percent subsidiary Medical Cannabis will release Australiangrown and processed hemp seed oil soft-gel capsules in Australia.

Queensland Bauxite said the capsules would be distributed by Medical Cannabis subsidiary Vitahemp to meet a "unique consumer demand" in the Australian market, as a plant-based alternative to fish oil capsules.

Queensland Bauxite was up 0.2 cents or 4.9 percent to 4.3 cents with 22.2 million shares traded.

MAYNE PHARMA

Mayne Pharma says it has formally opened its \$US80 million oral solid-dose commercial manufacturing facility in Greenville, North Carolina.

Mayne said the facility would quadruple its oral solid-dose manufacturing capacity in the US to more than one billion doses and introduce commercial scale, solvent-capable film coating and fluid-bed processing to modify how drugs were released after ingestion. The company said its previous facility would be repurposed to expand pre-commercial development, including more than 10 processing rooms and expanded laboratories. Mayne chief executive officer Scott Richards said that in the next few years the company expected to "introduce more than 20 products and double its manufacturing volumes in the Greenville site, driven by the pipeline of products under development, [and] the

Mayne fell two cents or 2.8 percent to 69.5 cents with 7.6 million shares traded.

transfer in house of several products currently manufacture by third parties".

INVION

Invion says that executive director Dr Mitchell Glass has sold 10,000,000 shares on-market, reducing from 18,706,932 shares to 8,706,932 shares.

Invion said the shares were sold on April 13, 16 and 17, 2018, and advised that Dr Glass retained 8,812,500 options, exercisable at 12 cents and by November 9, 2018.

The company said the sale of the shares was for "personal reasons related to taxation" and that Dr Glass had "no intention of selling further shares in the company in the immediate future".

Invion fell 0.7 cents or 21.2 percent to 2.6 cents with 71.5 million shares traded.

AVITA MEDICAL

Avita says 3,500,000 long-term incentive shares awarded to former chief executive officer Adam Kelliher will be released from voluntary escrow on May 2, 2018. Avita fell 0.2 cents or 3.4 percent to 5.7 cents.