



Biotech Daily

Thursday May 17, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRESCIENT UP 9%; REVA DOWN 5%**
- * **FEDERAL FUND, ONEVENTURES \$2.6m FOR BIVACOR HEART PUMP**
- * **PARADIGM PPS KNEE OSTEOARTHRITIS TRIAL '80% RECRUITED'**
- * **ORTHOCELL TREATS 10th ORTHO-ATI ROTATOR CUFF PATIENT**
- * **CYCLOPHARM TECHNEGAS FOR ASTHMA, COPD TRIAL**
- * **PATRY'S: YALE, BETH ISRAEL PAT-DX1 BREAST CANCER MOUSE STUDY**
- * **ADMEDUS APPOINTS CARDIVA SPAIN, PORTUGAL DISTRIBUTOR**
- * **NOVITA: 'NDIS APPROVES TALI'**
- * **UP TO 25% OPPOSE REVA CEO DR REGINA GROVES STOCK**
- * **ADHERIUM RENAMES SMARTINHALER 'HAILIE'**
- * **FATIMA DICKEY, RICHARD BAYLES, LAGODA DOWN TO 10% IN CLINUVEL**
- * **FIL REDUCES TO 7.6% OF CLINUVEL**
- * **MEDADVISOR TO RELEASE 21m ESCROW SHARES**
- * **ANATARA EXECUTIVE CHAIRMAN DR MEL BRIDGES RETIRES**

MARKET REPORT

The Australian stock market fell 0.21 percent on Thursday May 17, 2018 with the ASX200 down 12.7 points to 6,094.3 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and two were untraded. All three Big Caps fell.

Prescient was the best, up one cent or 8.7 percent to 12.5 cents with 605,370 shares traded. Genetic Signatures climbed 4.3 percent; Clinuvel and Telix rose more than two percent; Admedus and Optiscan were up more than one percent; with Cyclopharm, Impedimed, Neuren and Viralytics up by less than one percent.

Reva led the falls, down 1.5 cents or 5.45 percent to 26 cents with 11,687 shares traded. Airxanders, Opthea and Pro Medicus fell more than four percent; Cynata, Immutep, LBT, Medical Developments, Osprey and Pharmaxis were down three percent or more; Cochlear, CSL, Ellex, Mesoblast and Starpharma were down more than one percent; with Bionomics, Nanosonics, Resmed, Sirtex and Volpara down by less than one percent.

FEDERAL GOVERNMENT, ONEVENTURES

The Federal Government says that through its Biomedical Translation Fund, Oneventures will invest \$2.6 million in Bivacor for its rotary artificial heart device.

A media release from Health Minister Greg Hunt and Innovation Minister Senator Michaelia Cash said the Fund and private investors would provide more than \$2.6 million to Oneventures for investment in the Houston, Texas and Brisbane-based Bivacor for the development of the external total artificial heart (TAH) controller in Australia.

The Government said the technology had “the potential to change the need for heart transplantation, transforming the outlook for people with heart disease worldwide”.

The media release said the fund consisted of equal parts Federal Government and industry funding and was managed by private sector fund managers directing investment to promising biomedical research.

Oneventures managing-partner Dr Paul Kelly told Biotech Daily that currently ventricular assist devices (VAD) were designed to support the left side of the heart, which was responsible for pumping blood to the body, but up to 30 percent of heart failure patients required support to the right ventricle to pump blood through the lungs to collect oxygen.

“This necessitates the complete removal of the diseased heart and implantation of a [total artificial heart] to assume the function of both sides of the heart, or alternatively, the implantation of a second VAD alongside the right heart to provide biventricular assistance,” Dr Kelly said.

“This latter approach, however, creates problems with regard to finding space to fit a second device within the chest cavity, as well as difficulties in controlling the devices to work together to balance left and right circulatory blood flow,” Dr Kelly said.

“Bivacor is a single compact device based on smaller rotary pump technology [and] it will fit inside the chest of most patients,” Dr Kelly said.

“Furthermore, its double-sided magnetically levitated disc is continuously moving to provide blood flow to the body and lungs,” Dr Kelly said.

“So the key is that the one device can support the function of both the right and left sides of the heart,” he said.

“It can therefore replace the total function of the heart in one device [and] moreover it includes technology that means the device can respond automatically to the changes demands of the patient’s physiology as would the normal heart,” Dr Kelly said.

The Government said that recent funding included \$1.5 million invested by Bioscience Managers in Avita Medical for improved skin regeneration, \$3.2 million invested by Brandon Capital Partners in Aravax Pty Ltd for peptide immunotherapy to treat peanut allergy and \$1 million invested by Brandon Capital in GI Therapies Pty Ltd to develop a device to treat a range of gastrointestinal motility disorders.

Mr Hunt said the investments benefited Australian companies and had the potential to improve the health and wellbeing of people across the country and around the world.

“These companies are modern day pioneers bringing hope to people everywhere suffering with diseases, disorders, allergies and injuries,” Mr Hunt said.

Senator Cash said the Fund assisted businesses “at their most critical point, where they have a great idea but lack the funds to develop and get that idea to market”.

“This tremendous work highlights the impact of innovation, from the generation of new products to making an economic impact, the creation of new jobs and on to helping create a stronger and healthier country,” Senator Cash said.

Bivacor is a private company.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its phase IIb trial of pentosan polysulfate sodium for knee osteoarthritis and bone marrow oedema lesions is more than 80 percent recruited.

According to the company's filing with the Australian New Zealand Clinical Trials Registry, the trial expects to recruit up to 100 patients.

Paradigm said the trial at six sites across Australia would evaluate pain levels in patients with knee osteoarthritis and sub-chondral bone marrow lesions and it expected to provide the results by the end of 2018 (BD: Oct 30, 2017).

Paradigm said that 260 osteoarthritis patients had been approved for treatment or had been treated by doctors with pentosan polysulfate sodium (PPS) through the Australian Therapeutic Goods Administration special access scheme "almost doubling of the number of patients from six weeks ago".

The company said it had also recruited more than 75 percent of the participants for its 24-patient, phase IIa clinical trial of PPS for Ross River virus and expected results from this trial by the end of the year (BD: Aug 9, 2017).

Paradigm climbed 4.5 cents or 9.6 percent to 51.5 cents.

ORTHOCELL

Orthocell says it has treated the tenth of 30 patients in its trial of its autologous tenocyte implantation (Ortho-ATI) for rotator cuff tendinopathy and shoulder tear.

Last year, the company said the study aimed to demonstrate the safety and feasibility of Ortho-ATI for shoulder rotator cuff tendinopathy and tear and would be performed in collaboration with Johnson & Johnson's DePuy Synthes Products, a collaboration facilitated by Johnson & Johnson Innovation (BD: Sep 5, 2017).

The company said that results from the first 10 patients, at 12 months after treatment with Ortho-ATI would be presented by chief investigator Dr Allan Wang at the combined meeting of the Australian Orthopaedic Association's Continuing Orthopaedic Education Conference and the Asia-Pacific Knee, Arthroscopy and Sports Medicine Society Congress in Sydney from May 31 to June 2, 2018.

Orthocell was unchanged at 35 cents.

CYCLOPHARM

Cyclopharm says its Technegas is the focus of a three-year, 100 patient study on asthma and chronic obstructive pulmonary disease.

Cyclopharm said study would use ventilation single photon emission computed tomography (VSPECT) imaging would use Technegas to measure asthma and COPD patient characteristics and treatment responses, and compare Technegas VSPECT imaging with other diagnostic techniques.

The company said the study headed by University of Sydney's Prof Greg King would be a collaboration with the Woolcock Institute for Medical Research, the University of Sydney and the Northern Sydney Local Health District.

Prof King said the outcomes of the study would "advance the understanding of treatment responses and make a strong case for Technegas VSPECT imaging to be used as an important tool in development of new asthma and COPD treatment regimes, disease characterisation in routine practice and to monitor the success and progress of treatment".

Cyclopharm was up half a cent or 0.5 percent to \$1.06.

[PATRYS](#)

Patrys says it will investigate the anti-tumor activity of PAT-DX1 on triple negative breast cancer with Yale University, and the Beth Israel Deaconess Medical Centre.

Patrys said the research and development collaboration with the New Haven, Connecticut Yale School of Medicine and the Boston-based and Harvard Medical School-affiliated Beth Israel Deaconess Medical Centre, followed a pilot study that showed anti-tumor activity in orthotopic, immune-competent mice (BD: Jan 29, 2018).

The company said that the program would be led by Yale's Dr James Hansen with the Boston hospital's Dr Gerburg Wulf and Dr Jaymin Patel and would investigate PAT-DX1 in the Beth Israel Deaconess mouse model of triple negative breast cancer.

Patrys said that Dr Hansen was "an expert in cell-penetrating antibodies and [the] inventor of [its] Deoxymab technology".

The company said that Dr Wulf had experience in the development and testing of new drug combinations to improve outcomes in triple negative breast cancer and Dr Patel's translational research on breast cancer spanned nanoparticle technology, genomic instability, DNA damage repair, tumor targeting and personalized medicine.

Patrys chief executive officer Dr James Campbell said that the "opportunity to build on the successful pilot study and to further investigate PAT-DX1 in an immune-competent mouse model of [triple negative breast cancer] is timely, following the successful completion of the PAT-DX1 orthotopic glioblastoma study completed at Yale University in March".

"Patrys' ... position in the field of DNA damage repair antibody therapeutics is increasingly being recognized, resulting in collaborations such as this one between the company, Yale University and the Beth Israel Deaconess Medical Center," Dr Campbell said.

Patrys was up 0.2 cents or 5.7 percent to 3.7 cents with 6.7 million shares traded.

[ADMEDUS](#)

Admedus says it has appointed the Madrid-based Cardiva to be the exclusive distributor of its Adapt tissue product range in Spain and Portugal.

Admedus said that under the agreement Cardiva would initially distribute its Cardiocel bovine cardiac patch and would begin distributing its Vascucel and Cardiocel 3D products later in the year.

Admedus chief operating officer David St Denis said the company was "thrilled to offer our clinically superior Adapt products to patients in Spain and Portugal, one of the five largest markets in Europe".

"With first orders due this month, we anticipate demand in this region to grow steadily as more surgeons are introduced to ... our Adapt technology," Mr St Denis said.

Admedus was up half a cent or 1.7 percent to 30 cents.

[NOVITA HEALTHCARE](#)

Novita says its wholly-owned subsidiary Tali Health has been approved for the Australian National Disability Insurance Scheme (NDIS).

Novita said the National Disability Insurance Agency had approved Tali as a registered provider of supports for the NDIS under the registration group "Comms & Info Equipment", which meant the Tali Train game based training program for autism, attention deficit hyperactivity disorder, Down's syndrome and non-specific intellectual disability could be used by participants in the NDIS in all states and territories except for Western Australia. Novita said that approval was pending for Tali Train in Western Australia.

Novita was up 0.3 cents or 9.7 percent to 3.4 cents with 1.2 million shares traded.

REVA MEDICAL

Reva's annual general meeting passed all resolutions but with 25 percent opposition to the issue of stock to chief executive officer Dr Regina Groves (BD: Apr 6, 2018). The strongest dissent was against the issue of 226,000 options over US shares equivalent to 2,260,000 Chess depository instruments (CDIs) and 114,000 US restricted shares equivalent to 1,140,000 CDIs to chief executive officer Dr Regina Groves, with 5,832,923 (25.31%) against the resolution and 17,209,894 (74.69%) votes in favor. Reva shareholders similarly opposed the issue of 25,000 options to director Brian Dovey and the advisory vote on the compensation of executive officers. Reva said the issue of 25,000 options over US shares to directors Dr Ross Breckenridge, Robert Stockman and Robert Thomas and the issue of 61,095 options for director Raymond Larkin and 86,917 options for director Dr Stephen Oesterle, passed easily, along with the re-election of directors Mr Thomas, Mr Larkin and Dr Oesterle, approval of a 10 percent placement capacity, the issue of securities under the company's equity incentive plan and the annual holding of an advisory vote on executive compensation. The company's most recent Appendix 3B said that Reva had 41,245,820 US shares on issue, meaning the opposition to Ms Groves' options and shares amounted to 14.14 percent of the company, sufficient to requisition extraordinary general meetings. Reva fell 1.5 cents or 5.45 percent to 26 cents.

ADHERIUM

Adherium says it has renamed its Smartinhaler device for asthma and chronic obstructive pulmonary disease "Hailie" in a global rebrand.

Adherium previously said that the Smartinhaler was a device that attached to prescription or over-the-counter inhalers with a mobile telephone application to record patient use and compliance, automatically transmitting the data to a smart telephone application, home monitoring hub, or personal computer and then to the company's internet cloud-based servers, where it could be accessed by the patient's health care professional or care giver (BD: Aug 27, 2015).

Today, Adherium said the Hailie rebrand would include the launch of a portal for healthcare professionals and clinicians that used Bluetooth wireless technology to provide data collection and reporting from Hailie sensors.

Adherium fell two cents or 15.4 percent to 11 cents.

CLINUVEL PHARMACEUTICALS

Lagoda Investment Manager, Fatima Dickey and Richard Bayles say they have reduced their holding in Clinuvel from 5,255,680 shares (11.01%) to 4,778,296 shares (10.01%). The New York-based Lagoda said it bought and sold shares on market between August 25, 2017 and May 15, 2018 at prices ranging from \$2.41 to \$13.35, which does not tally with Clinuvel's share price at the time.

Clinuvel was up 35 cents or 2.9 percent to \$12.50.

CLINUVEL PHARMACEUTICALS

FIL Limited, formerly Fidelity Investments, says it has reduced its substantial holding in Clinuvel from 4,109,676 shares (8.61%) to 3,625,982 shares (7.60%).

The Singapore-based FIL said that it sold 483,694 shares from April 27 to May 14, 2018 at prices between \$11.52 and \$13.10.

[MEDADVISOR](#)

Medadvisor says it will release 20,625,000 shares from voluntary escrow on Jun 1, 2018. According to the company's latest Appendix 3B, following the release of the shares, Medadvisor will have 885,127,760 shares available for trading, with a further 432,800,222 shares and 35,500,000 "performance" rights for chief executive officer Robert Read held in voluntary escrow, for a total of 1,353,427,982 shares on issue. Medadvisor fell 0.2 cents or 4.8 percent to four cents.

[ANATARA LIFESCIENCES](#)

Anatara says that executive chairman Dr Mel Bridges has retired with immediate effect. Anatara said that non-executive director Dr Jay Hetzel has been appointed interim chairman with executive director Dr Tracie Ramsdale appointed interim chief executive officer.

The company said that Iain Ross and Paul Grujic would continue as non-executive directors.

Anatara said that "with the planned change of focus toward developing the company's human pipeline in gastrointestinal health" a search had begun to augment the board with further expertise in this area.

Dr Hetzel said the company respected Dr Bridges decision "and want to thank him for his leadership of the company, culminating in the announcement earlier this week of the licence deal with Zoetis".

"It has been Mel's goal to secure a worldwide animal health development partner and he has passionately driven this initiative over the last three years," Dr Hetzel said.

"We sincerely wish him well and thank him for his immense contributions as a founder, chairman, CEO and substantial shareholder," Dr Hetzel said.

Dr Bridges said that "after 40 years of corporate history, this has been a challenging role with positive outcomes for shareholders and this is a suitable time for me to leave knowing that the company is in good hands with a corporate team that can take the company forward to the next level, focusing on human health," Dr Bridges said.

Dr Bridges was previously a chairman or director of Alchemia, Aquacarotene (now Leaf Energy, Benitec, Genera, Genetic Technologies, Incitive, Impedimed, Peptech (later Arana, now Teva Australia) and Tissue Therapies (now Factor Therapeutics), and continues as chairman of Oventus.

Anatara fell 21.5 cents or 18.5 percent to 94.5 cents with 1.6 million shares traded.