



Biotech Daily

Tuesday May 22, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: MESOBLAST UP 5%; OPTISCAN DOWN 9%**
- * **ORTHOCELL CLAIMS 1st UK, EU CELGRO DENTAL SALES, USE**
- * **OVENTUS: 'STATISTICALLY SIGNIFICANT APNOEA IMPROVEMENT'**
- * **DORSAVI SIGNS 2-YEAR DEAL WITH INSURER AIG**
- * **ADMEDUS AORTIC VALVE REPLACEMENT SHEEP TRIALS**
- * **VICTORIA, J&J \$300,000 QUICKFIRE DEVICE CHALLENGE**
- * **SIRTEX REQUESTS 'CDH BID DEVELOPMENTS' TRADING HALT**
- * **SIENNA RECEIVES \$632k FEDERAL R&D TAX INCENTIVE**
- * **RHS VOTES 99.97% FOR PERKINELMER ACQUISITION**
- * **AIRXPANDERS 43% OPPOSE 1.3m DIRECTOR OPTIONS**
- * **MINDEROO (METAL) GROUP BELOW 5% OF ADMEDUS**
- * **ZELDA APPOINTS PHARMAUST CEO DR RICHARD HOPKINS M-D ON \$250k**
- * **RHYTHM: GLENN GILBERT COO, DR JOANNE BOAG COMMERCIAL G-M**

MARKET REPORT

The Australian stock market fell 0.7 percent on Tuesday May 22, 2018 with the ASX200 down 42.6 points to 6,041.9 points. Six of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and 15 were untraded. All three Big Caps fell.

Mesoblast was the best, up seven cents or 4.7 percent to \$1.55 with 2.15 million shares traded. Opthea climbed 4.3 percent; Orthocell rose 1.4 percent; with Ellex, Pro Medicus and Starpharma up by less than one percent.

Optiscan led the falls, down 0.6 cents or 8.7 percent to 6.3 cents with 20,000 shares traded. Airxpanders fell four percent; Osprey and Prescient lost more than three percent; Benitec, Clinuvel, Cyclopharm, Cynata, Factor Therapeutics, Impedimed and Uscom shed more than two percent; Bionomics, Cochlear, Nanosonics, Neuren and Volpara were down more than one percent; with CSL, Polynovo, Resmed, Sirtex, Telix and Viralytics down by less than one percent.

ORTHOCELL

Orthocell says its Celgro collagen scaffold for dental bone and soft tissue repair has been sold and used for the first time in the European Union.

In 2017 Orthocell said that Celgro had been granted Conformité Européenne (CE) mark for dental bone and soft tissue procedures (BD: Nov 9, 2017).

Today, Orthocell managing-director Paul Anderson said the commercialization of Celgro for bone and soft tissue repair in the EU was “a key focus”.

Mr Anderson said the first product use and sale in the UK was “an important milestone”.

Orthocell said that European manager Kevin Edwards would expand distribution networks of Celgro and increase product adoption and sales through education and promotional initiatives.

The company said it was finalizing further commercial partner agreements for product distribution in the UK.

Orthocell was up half a cent or 1.4 percent to 36 cents.

OVENTUS MEDICAL

Oventus says a 32-patient sleep apnoea trial of its airway showed a statistically significant 57 percent improvement in shallow breathing events ($p < 0.0001$).

Oventus said that the patients' apnoea hypopnoea index (AHI), or the rate of shallow breathing or abnormally low respiratory rate reduced from 23.9 to 10.2 events per hour.

The company said the Brisbane OVEN-003 trial was a randomized, controlled trial examining the treatment outcomes of oral appliance therapy with and without the Oventus airway technology, which comprised an adjustable mouth-guard appliance with an airway. Oventus said that “a strong response” was found across the group of 32 patients suffering from obstructive sleep apnoea wearing a jaw or mandibular advancement oral appliance incorporating the Oventus airway technology.

The company said the study found that the number of patients that responded to treatment increased by 40 percent for non-responders to traditional jaw advancement therapy, with a responder defined as a minimum 50 percent improvement in AHI.

Oventus said that patients who did not respond well to jaw advancement alone, who then used the same device incorporating the Oventus airway technology, achieved a statistically significant 20 percent improvement in AHI ($p = 0.05$).

The company said that a large number of responding patients in the study had nasal restrictions and further data analysis at the patient subgroup level was ongoing.

Oventus founder and clinical director Dr Chris Hart said the results “consistently demonstrate treatment incorporating Oventus airway technology is more efficacious than traditional mandibular advancement therapy alone”.

“We also now have further clinical evidence that our airway technology is able to improve clinical outcomes for patients that have previously failed to respond to traditional oral appliance therapy,” Dr Hart said.

“Nasal obstruction is very common in obstructive sleep apnoea sufferers ... [and] is an issue which impacts more than 50 percent of patients,” Dr Hart said.

“The airway technology embedded in our O2Vent appliance range recognizes that these patients will be unable to breathe through their noses and therefore delivers air through the mouth to the back of the throat,” Dr Hart said.

“It effectively operates like a second nose, helping mild to moderate [obstructive sleep apnoea] patients to sleep better without the need for conventional sleep apnoea treatments,” Dr Hart said.

Oventus fell two cents or 5.6 percent to 34 cents.

DORSAVI

Dorsavi says it has signed a two-year “master pilot agreement” for risk assessment with New York’s American International Group affiliate AIG PC Global Services Inc.

Dorsavi said it would provide professional services to AIG for its wearable movement sensor technology for assessments of their clients’ manual handling activities.

The company said it would train AIG risk consultants to use its technology and provide analytics and recommendations for the assessments so AIG could to develop interventions for its clients.

Dorsavi said its technology would be used in the US, UK, Hong Kong and Singapore and potentially other countries.

The company said that AIG had been granted exclusive rights to purchase Visafe equipment and perform their own Visafe assessments in the insurance and broker markets for a period of six months.

Dorsavi said the program allowed AIG to assess the potential of a broader roll-out and application of Dorsavi’s technologies and products.

Dorsavi chief executive officer Dr Andrew Ronchi said the company was “looking forward to a long and rewarding partnership with AIG”.

“It is fantastic to be working with a global insurance group of AIG’s reach and stature across a number of markets,” Dr Ronchi said.

Dorsavi was unchanged at 16 cents.

ADMEDUS

Admedus says it will begin trials of its transcatheter aortic valve replacement in sheep at an unnamed European reference laboratory.

Admedus said that the study, titled ‘Experimental assessment of the Admedus valve - ovine model of aortic valve replacement’ would begin in July to examine the safety and feasibility of its three-dimensional (3D), single-piece, moulded valve.

The company said that after an initial trial period of about three months, the study would test the valves in calves, with the experiments expected to be completed by early 2019.

Admedus said the transcatheter aortic valve replacement (TAVR) device had benefits for patients and physicians “through novel engineering and leveraging the ... capabilities of its clinically-superior Adapt tissue”.

The company said that multiple patent applications had been filed in the US, a key durability test had been completed and staff appointed.

Admedus chief executive officer Wayne Paterson said the company’s “unique ability to create shaped collagen tissue has opened the door to unprecedented levels of opportunity as we investigate potential new products and applications,” Mr Paterson said.

“The 3D valve recently passed a critical viability test ... completing more than 200 million simulated cycles which has allowed us to progress to animal trials,” Mr Paterson said.

“The European reference lab conducting the study is regarded as one of the best in the world and has significant experience performing valve experiments for leading companies in the med tech industry,” Mr Paterson said.

“Admedus isn’t just looking to create a new TAVR product,” Mr Paterson said. “Our aim is to set a new benchmark in cardio-vascular science and technology.”

“We are looking to completely revolutionize the space with innovations in both the tissue [and] valve science and engineering up and down the catheter,” Mr Paterson said.

Admedus said the global transcatheter aortic valve replacement market was worth about \$US3 billion and was projected to reach \$US5 billion by 2020.

Admedus was unchanged at 30 cents.

VICTORIA GOVERNMENT, JOHNSON & JOHNSON

Johnson & Johnson says that applications for its \$300,000 Victoria Johnson & Johnson Quickfire Challenge: 'Driving Device Innovation' close on June 22, 2018.

Earlier this year, Victoria Innovation Minister Philip Dalidakis formally launched the Victoria Johnson & Johnson Device Quickfire Challenge and Victoria Health Minister Jill Hennessy said that three finalists would share a cash prize of \$300,000 as well as receive mentoring and support from Johnson & Johnson (BD: Feb 15, Mar 27, 2018).

A media release at that time said the Victoria Quickfire Challenge aimed "to help kick-off the search for new medical device innovation".

For information and to apply, go to: <https://jllabs.jnjinnovation.com/quickfire-challenges>.

SIRTEX MEDICAL

Sirtex has requested a trading halt "pending the release of an announcement on material developments in the proposal from CDH".

At publication at 6pm Sirtex published a binding offer from CDH. Details tomorrow.

Earlier this month, Sirtex said it had received an unsolicited proposal from China's CDH Investments to buy it for \$33.60 a share, valuing it at \$1.87 billion, but the Sirtex board backed the Varian bid (BD: May 4, 2018).

In January, California's Varian Medical Systems offered \$28 a share to buy the company, valuing it at \$1.56 billion (BD: Jan 30, 31, 2018).

On May 4, Sirtex said the offer was non-binding, indicative and conditional and CDH was an alternative asset fund manager with more than \$US20 billion under management.

The company said it had no engagement with CDH until it received the proposal and had called a Court-approved shareholder meeting to approve the Varian offer for Monday, May 7, 2018, which was adjourned to a time and date to be determined.

Trading will resume on May 24, 2018 or on an earlier announcement.

Sirtex last traded down one cent or 0.03 percent to \$29.83.

SIENNA CANCER DIAGNOSTICS

Sienna says it has received \$631,691 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Sienna said the rebate related to research and development expenditure for the year to June 30, 2017.

Sienna was unchanged at 9.9 cents.

RHS (FORMERLY REPRODUCTIVE HEALTH SCIENCE)

RHS says its shareholders have overwhelmingly approved the scheme of arrangement for Perkinelmer to acquire the company.

In February, RHS said the Waltham, Massachusetts Perkinelmer Inc would acquire it for \$25,177,735 or 28 cents a share (BD: Feb 26, 2018).

RHS has been attempting to commercialize its Embryocollect pre-implantation genetic screening test for in-vitro fertilization.

Today, the company said that a poll of percent of shareholders resulted in 73,033,448 votes (99.97%) in favour and 25,316 votes (0.03%) against, its application to the Federal Court of Australia for approval of the scheme was scheduled for May 29, 2018 and if approved, the scheme was expected to be implemented on June 14, 2018.

RHS was unchanged at 27.5 cents.

AIRXPANDERS

The Airxpanders annual general meeting passed all resolutions but faced up to 42.9 percent opposition to the issue to directors of 1,257,555 Chess depository instruments. Earlier this month, Airxpanders proposed that directors Barry Cheskin, Dennis Condon, Elizabeth Hammack, Gregory Lichtwardt and Zita Peach, who all received options at last year's annual general meeting, would each be granted options over 83,837 US shares, equivalent to 251,511 CDIs, exercisable at the price on the date of the grant, vesting in monthly instalments over 12 months from the date of the grant and expiring after 10 years, as well as vote to approve the 10 percent placement facility and re-elect director Barry Cheskin (BD: May 1, 2018).

Last year, Airxpanders shareholders granted chief executive officer Scott Dodson and five directors options over the equivalent of 1,349,250 CDIs, but with up to 31.5 percent opposition (BD: May 23, 2017).

Today, the company said the strongest opposition vote was to the grant of options to Mr Cheskin with 40,377,378 votes (57.1%) in favor and 30,325,587 votes (42.9%) against. Airxpanders said that the resolutions to grant options to Mr Condon, Ms Hammack, Mr Lichtwardt and Ms Peach were supported by more than 55 million votes and opposed by more than 15 million votes.

The company said that Mr Cheskin was re-elected with 56,223,904 votes (78.77%) with 15,155,761 votes (21.23%) withheld.

Each US share is equivalent to three Airxpanders' CDIs.

The company's most recent Appendix 3B new issue announcement said that Airxpanders had the equivalent to 287,830,224 CDIs on issue, meaning the votes against Mr Cheskin's options amounted to 10.5 percent of the company, sufficient to requisition extraordinary general meetings under the Australian Corporations Act.

Airxpanders is a Delaware US-incorporated company and its amended and restated certificate of incorporation said that "only the chairman of our board of directors, chief executive officer or a majority of our board of directors may call special meetings of our stockholders".

Airxpanders fell 0.4 cents or four percent to 9.5 cents.

ADMEDUS

The Perth Western Australia-based Minderoo Group says it has reduced its holding in Admedus from 14,815,000 shares (6.54%) to below the five percent substantial level. Minderoo, formerly the Metal Group, and associated with Western Australian miner Andrew Forrest, said that in 2016 it was diluted in a \$10 million placement and \$5.7 million rights issue (BD: Jul 29, Sep 1, 2016).

In 2011, the public unlisted Allied Medical, with Mr Forrest as the major shareholder, merged with Biomed to form Allied Healthcare Group, which was later renamed Admedus (BD: Feb 15, Jun 29, 2011; Nov 21, 2013).

In 2015, Minderoo said it sold 18,027,958 pre-consolidation shares for \$1,498,687 or an average price of 8.3 cents a share, or 83 cents post-consolidation (BD: Apr 28, Oct 14, 2015).

Today, Minderoo said that between May 2 and 17, 2018 it sold 1,204,255 shares for \$376,050 or 31.2 cents a share and was further diluted in a \$6 million placement at 30 cents a share (BD: May 10, 2018).

Biotech Daily calculates that Minderoo continues to hold 13,610,745 shares or 4.9955 percent of Admedus.

ZELDA THERAPEUTICS, PHARMAUST

Zelda says it has appointed Pharmaust chief executive officer Dr Richard Hopkins as its managing-director, commencing on July 1, 2018, starting on \$250,000 a year.

Zelda said that Dr Hopkins was “an experienced bio-pharmaceutical executive” with more than 11 years in corporate leadership roles with public biotechnology companies, with “an established track record in drug development of novel cancer therapies and has strong experience with corporate strategy, business development and intellectual property matters”.

The company said that prior to Pharmaust, Dr Hopkins was Phylogica’s managing-director, a company he co-founded in 2001 where he had been chief scientific officer and chief operating officer.

Zelda said that Dr Hopkins was an author on more than 25 peer-reviewed publications and was an inventor on 17 patents and patent applications.

Dr Hopkins LinkedIn page said that he held a Bachelor of Science from the University of Western Australia and a held a Doctor of Philosophy from Perth’s Murdoch University.

The company said that executive director Dr Stewart Washer would revert to a non-executive director.

Zelda said Dr Hopkins’ \$250,000 salary included superannuation and he would be issued with 25 million options, subject to shareholder approval at three months, 15 months and 27 months, exercisable at prices from 15 cents to 50 cents within three years of issue.

Pharmaust said that Dr Hopkins would leave the company on May 25, 2018.

Pharmaust executive chairman Dr Roger Aston said the board thanked Dr Hopkins “for his time and achievements ... and wishes him the best for his future”.

The company said it was “well-advanced in talks with a leading candidate” for chief executive officer and Dr Aston would assume the role of acting chief executive officer.

Zelda was up half a cent or 4.55 percent to 11.5 cents.

Pharmaust fell 0.2 cents or 4.1 percent to 4.7 cents with 1.98 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has appointing Glenn Gilbert as chief operating officer and Dr Joanne Boag as commercial general-manager.

Rhythm said Mr Gilbert was an executive with eight years at Medical Developments, most recently as head of sales and marketing with oversight of product commercialization, with experience in mergers, acquisitions and intellectual property.

The company said that Mr Gilbert previously held leadership roles at CSL’s biotherapeutics arm, Seqirus.

Rhythm said that Mr Gilbert held a Bachelor of Science from Melbourne’s Monash University and a Master of Business Administration from Geelong’s Deakin University.

The company said Dr Boag had 14 years’ experience in the health and medical research fields, including 10 years in commercializing technologies, most recently at research institutes to improve and develop programs and commercialize early-stage technologies.

Rhythm said that Dr Boag was a registered Australian patent and trade mark attorney, with more than five years in private practice and held a Doctor of Philosophy from the University of Western Australia.

Rhythm fell half a cent or 2.9 percent to 17 cents.