

Biotech Daily

Monday October 14, 2019

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: COMPUMEDICS UP 11.5%; ANTISENSE DOWN 8.5%
- * ADMEDUS: 'UP-TO \$36m ADAPT LEMAITRE DISTRIBUTION DEAL'
- * CORRECTION: RECCE PHARMACEUTICALS
- * VICTORIA BOOSTS EPILEPSY MARIJUANA; ENDS IDT, CANN DEALS
- * CELLMID RAISES \$1.5m; SHARE PLAN FOR \$500k MORE
- * ANATARA BROMELAIN GARP EFFECTIVE FOR IBD, IBS, IN MICE
- * CELLMID. AUSTRALIAN SHOPPING NETWORK EVOLIS AGREEMENT
- * TELIX INTEGRATES GE HEALTHCARE GALLIUM WITH TLX591-CDX
- * MEDADVISOR 3-YEAR CHEMIST WAREHOUSE DEAL
- * POLYNOVO 50% DIRECTOR FEE POOL HIKE TO \$600kAGM
- * PAINCHEK \$840k MD, DIRECTORS PERFORMANCE RIGHTS AGM
- * SUDA 40m CHAIR PAUL HOPPER OPTIONS, 25-TO-1 CONSOLIDATION
- * BARD1 100% DIRECTOR FEE POOL HIKE TO \$400k AGM
- * MERCHANT TAKES 11.5% OF AUSCANN; CANOPY CEASES
- * 'ODD FELLOWS' BELOW 5% IN RHINOMED
- * PHARMAUST APPOINTS COLIN LA GALIA EPICHEM CEO; DR KEENAN DIRECTOR
- * IMAGION SCIENTIFIC ADVISORY BOARD

MARKET REPORT

The Australian stock market was up 0.54 percent on Monday October 14, 2019, with the ASX200 up 35.8 points to 6,642.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and three were untraded.

Compumedics was the best, up seven cents or 11.5 percent to 68 cents, with 141,497 shares traded. Oncosil climbed 10.5 percent; Uscom was up 9.1 percent; Orthocell rose 7.9 percent; Patrys and Telix improved more than four percent; Mesoblast was up 3.3 percent; Ellex, Neuren, Paradigm and Universal Biosensors rose more than two percent; Medical Developments, Nanosonics and Pro Medicus were up more than one percent; with Cochlear up 0.7 percent.

Antisense led the falls, down 0.8 cents or 8.5 percent to 8.6 cents, with 4.9 million shares traded. Both Actinogen and Pharmaxis fell five percent; Dimerix lost 4.55 percent; Impedimed was down three percent; Cynata, Next Science and Polynovo shed more than two percent; Clinuvel, Kazia and Proteomics were down one percent or more; with Avita, CSL, Genetic Signatures and Resmed down by less than one percent.

ADMEDUS

Admedus says it has sold the distribution rights of its Adapt tissue technologies Cardiocel and Vascucel to Lemaitre Vascular for up to \$36.2 million.

Admedus said the Burlington, Massachusetts-based Lemaitre Vascular would pay \$22.8 million upfront, with deferred payments of \$1 million in 12 months and 36 months.

The company said it retained manufacturing rights for Cardiocel and Vascucel for three years and retained all Adapt intellectual property rights.

Admedus said it could receive a further \$11.4 million on the achievement of regulatory approvals, extended shelf life for the Cardiocel and Vascucel, revenue above \$22.4 million in the first 12 months, revenue above \$33.5 million in the second 12 months, and the completion of reporting procedures.

The company said it would continue manufacturing the products for Lemaitre at its Perthbased facility at a "20 percent margin over cost".

In April, Admedus requested a trading halt "pending an announcement regarding the ... [Coridon] immunotherapies sale transaction" and later responded to an ASX query, announcing the termination of the Vaccine business sale (BD: Apr 15, 17, 23, 2019). The company requested a suspension for a recapitalization plan, which was followed by

multiple extensions (BD: May 7, 21; Jun 4; Jul 1, Aug 5, Sep 2, 30, 2019). Earlier this year, Admedus sold its hospital infusion business to BTC Health for \$6.3 million (BD: May 31, 2019).

Today, the company said it retained ownership on all intellectual property for the underlying Adapt technology platform, including its transcatheter aortic valve replacement device and single-piece, three-dimensional aortic valve.

Admedus chief executive officer Wayne Paterson said "the transaction provides a significant injection of non-dilutive capital and streamlines operations with cost reductions from a reduced headcount and operating expenses".

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"Admedus plans its first-in-human studies for its single-piece, 3-D aortic valve in 2020," Mr Paterson said.

Admedus was up 0.8 cents or 13.3 percent to 6.8 cents with 9.6 million shares traded.

CORRECTION: RECCE PHARMACEUTICALS

Friday's edition incorrectly reported that Recce listed on the ASX in 2016, having raised \$45 million by issuing 25 million shares at 20 cents apiece.

The digital error was caused by the Friday sub-editor's digits typing the '\$' symbol at the same time as slipping the 'shift' key, prior to typing the '5'.

In fact, Recce raised \$5 million by issuing 25 million shares at 20 cents apiece.

The sub-editor has been sent back to typing school to be taught that accuracy is more important than speed.

We apologise unreservedly to Recce Pharmaceuticals for the missing \$40 million, and have bought a Tattslotto ticket with the numbers 18, 5, 3, 16, 1, 13, 20 and 10. Biotech Daily's petty cash jar doesn't extend beyond 8-series tickets.

Recce fell one cent or 3.6 percent to 26.5 cents.

VICTORIA GOVERNMENT, CANN GROUP IDT AUSTRALIA

The Victoria Government says it will supply medical marijuana to 90 epileptic children and end its existing contracts with Cann Group and IDT.

A media release from Health Minister Jenny Mikakos published on Sunday October 13, said the compassionate access scheme would be increased from 60 to 90 places, with 10 children with intractable epilepsy added this year and a further 20 next year.

The media release said that medical marijuana could be "a life-changing treatment for many children when other medication has failed".

"The compassionate access scheme uses Canadian pharmaceutical grade cannabidiol, after the Commonwealth followed Victoria's lead and allowed its import, overturning its own previous ban on the importation of medicinal cannabis," the State Government said. "With an emerging medicinal cannabis market taking hold in Victoria thanks to the Labor Government's leadership, Ms Mikakos also announced today that the Labor Government will no longer produce its pioneering cannabidiol product developed from cannabis it has grown," the media release said.

A spokesperson for the Minister for Health told Biotech Daily that "Victoria imports medicinal cannabis for the sickest children who are part of the compassionate access scheme, and that will continue to be the case".

"There is no charge whatsoever for families with children in this scheme," the spokesperson said.

"It is funded entirely by the Andrews Labor Government," the spokesperson said. "The 12kg of purified crystallized cannabidiol manufactured by the Government will be provided for use in health and medical research and clinical trials, which are essential for encouraging the Commonwealth to include medicinal cannabis on the pharmaceutical benefits scheme, making it affordable for all Australians who need it," the media release said.

The State Government said that the Department of Health and Human Services would open an expression of interest for medical researchers to apply to access the cannabidiol. In a media release to the ASX, IDT said the development agreement with the State Government of Victoria for the development of good manufacturing practice cannabidiol active pharmaceutical ingredient "will not be extended past its natural conclusion; being IDT's completion of the third process validation batch of [cannabidiol], scheduled for early in 2020.

IDT said it had worked with the Victoria Government "during the last two years to develop a fully validated GMP process for the manufacture of pharmaceutical grade cannabidiol". The company said that it retained the know-how and intellectual property that it has developed with respect to the manufacture of pharmaceutical grade cannabidiol. "As a direct result of this project, Australia is set to have a much needed locally manufactured source of pharmaceutical grade cannabidiol," IDT said. "IDT is now looking ahead to the activities required to commercialize a range of cannabidiol products for local as well as international markets," the company said. In August, Cann said that following the 2018 maiden revenue of \$616,000 from the sale of medical marijuana for the Victoria Government paediatric epilepsy trial it had received \$2,347,668 from the Victoria Government for the supply of Melbourne grown marijuana for the 12 months to June 30, 2019 (BD: Aug 23, 2018; Aug 27, 2019). Today, Cann chief executive officer Peter Crock told Biotech Daily that the company "continues to have a strong relationship with IDT and we hope to replace imported products as soon as possible to supply Victorian and Australian patients.

Cann was up four cents or 2.9 percent to \$1.415.

IDT was unchanged at 17.5 cents.

CELLMID

Cellmid says it has raised \$1.5 million in a placement of shares at 20 cents each, and plans to raise a further \$500,000 in a share plan.

Cellmid said that 41 percent of the 7,500,000 new shares would be issued to chief executive officer Maria Halasz and director Dennis Eck if approved by shareholders at the annual general meeting.

The company said that the funds would be used for its consumer health business. "including inventory and working capital for the newly signed distribution agreements for the Evolis anti-aging hair care products in Germany and China". Cellmid was unchanged at 22.5 cents.

ANATARA LIFESCIENCES

Anatara says its pineapple, bromelain-based diarrhoea treatment has shown statistically significant efficacy in mice.

Anatara said that the product it called gastro-intestinal re-programming or Garp was a "dietary supplement designed to restore and maintain a healthy human gut and microbiome" and was being developed to target inflammatory bowel disease (IBD), including ulcerative colitis and Crohn's disease, and irritable bowel syndrome (IBS). The company said that "pharmaceutical treatments have high failure rates and severe side-effects, leading to over 50 percent of IBS and IBD patients trying complementary and alternative medicines in the hope of effectively managing their chronic bowel condition ... [and] patients are willing to spend significant amounts of money on these therapies". Anatara said the treatment approach with IBD was "to suppress the inflammation with the goal of inducing and maintaining remission, while in the case of IBS, gastroenterologists primarily treat the symptoms of abdominal pain, bloating and alternating constipation and diarrhoea ... [and] these therapeutic approaches have high treatment failure rates". The company said that Garp addressed "the dysbiosis of the microbiome by inhibiting the attachment and invasion of pro-inflammatory bacteria, obtained from IBD and IBS patients, into healthy gut cells [in mice] by more than 95 percent (p = 0.002)". The company said the product "reduced gut inflammation by 85 percent by significantly

reducing the production of pro-inflammatory proteins (p < 0.001)".

Anatara said that daily treatment with Garp "demonstrated a therapeutic benefit by significantly reducing the key disease indicators of colitis in mice ... [and] compared to a placebo control, Garp reduced the combined disease characteristics of colon inflammation and disrupted bowel habits by 2.5-fold (p = 0.012).

The company said that the product promoted mucosal healing by increasing mucin genes by a factor of five to seven-fold (MUC2 and MUC6, p < 0.001) and both genes had been shown to be significantly reduced in both IBD and IBS patients.

Anatara said that through increasing the genes, it expected that the proteins which produced gut protecting and healing mucins would also increase, which in turn might promote mucosal healing.

The company said it expected to begin human clinical study activities in late 2019, with a view to partnering in the second half of calendar 2020.

Anatara chief executive officer Steven Lydeamore said the completion of the pre-clinical program "provided strong scientific proof that the Garp dietary supplement has the potential to be game changing".

"This is a major milestone for Anatara's Garp development program bringing us closer to partnering," Mr Lydeamore said.

Anatara was up 3.5 cents or 17.5 percent to 23.5 cents.

CELLMID

Cellmid says it will sell its Evolis anti-aging haircare products through the Australian Shopping Network "from the last week of October 2019".

Cellmid said the contract with the Channel 7 and Australian Shopping Network system was through its subsidiary Advangen International and the network would be the only antiaging hair brand offered on the channel the time.

The company said that television shopping was "currently the most significant revenue source for Cellmid".

TELIX PHARMACEUTICALS

Telix says GE Healthcare's cyclotron-based 68-galium production data has been included in its regulatory package for TLX591-CDx for imaging prostate cancer.

In June, Telix said it had an agreement with GE Healthcare to validate GE's 68-gallium produced on the positron emission tomography (PET) trace cyclotron with its 68-gallium-prostate specific membrane antigen (PSMA) preparation kit TLX591-CDx, marketed as Illumet, and include the data in Telix's product dossier.

The company said the data had been validated and presented to US and European regulators.

Telix chief executive officer Dr Christian Behrenbruch said that the company was aware of more than 20 cyclotron-based gallium projects underway in the US "with the express objective of meeting the potential market demand for [68-gallium]".

"The commitment by manufacturers to cyclotron-based production of gallium by manufacturers such as GE Healthcare ... is an important augmentation of the existing supply chain that will improve accessibility of this commercially important isotope," Dr Behrenbruch said.

Telix was up six cents or 4.3 percent to \$1.455 with 1.1 million shares traded.

MEDADVISOR

Medadvisor says it has a three-year deal with Chemist Warehouse for its Plusone medication management software, which it expects will generate up to \$5 million. Medadvisor said it would receive payments for 'software as a service' licence fees and patient messaging fees.

The company said it would provide Chemist Warehouse customers with health programs to promote health literacy and improved medication adherence.

Medadvisor was unchanged at 5.3 cents with 4.5 million shares traded.

POLYNOVO

Polynovo says shareholders will vote to increase the \$400,000 pool for directors fees by 50 percent, or \$200,000, to \$600,000 a year at its annual general meeting.

Polynovo said that the proposed \$600,000 limit if approved would "be divided between non-executive directors" at the board's discretion.

The company said shareholders would also vote to approve the remuneration report, the re-election of directors David William and Leon Hoare, and the renewal of the employee share option plan.

The meeting will be held at the Ernst & Young Office, Level 23, 8 Exhibition Street, Melbourne on November 15, 2019 at 1pm (AEDT).

Polynovo fell six cents or 2.3 percent to \$2.50 with 4.3 million shares traded.

PAINCHEK

Painchek says shareholders will vote to grant \$840,000 performance rights to managing director Philip Daffas and directors Ross Harricks, Adam Davey and John Murray. Painchek said its annual general meeting would vote to grant Mr Daffas \$600,000 of performance rights in equal tranches over three years, subject to the company share price reaching a compounded annual increase of 15 percent, with half vesting two years after the grant date and the other half vesting three years after the grant date.

The company said it proposed to issue chairman Mr Murray \$120,000 of performance rights and directors Mr Harricks and Mr Davey \$60,000 of performance rights each and vesting over three years, but did not disclose vesting conditions.

The company said shareholders would vote to increase the total directors' remuneration pool by 60 percent from \$250,000 to \$400,000 a year.

Painchek said shareholders would also vote to adopt the remuneration report, re-elect director Mr Davey, approve a 10 percent placement capacity, ratify shares and amend the terms and conditions of the 2016 options.

The meeting will be held at the Country Women's Association of Western Australia Board Room, 1176 Hay Street, West Perth on November 20, 2019 at 2pm (AWST).

Painchek fell half a cent or 1.5 percent to 32.5 cents with 2.8 million shares traded.

SUDA PHARMACEUTICALS

Suda says shareholders will vote in the issue of 40,000,000 inventive options to non-executive chairman Paul Hopper and a 25-to-one share consolidation plan. Suda said it proposed to issue Mr Hopper the options as a long-term incentive for remaining with the company, with 13,000,000 vesting once approved and exercisable at 145 percent of the market value, 13,000,000 vesting 12 months from the grant date exercisable at 155 percent of the market value, and the remaining 14,000,000 vesting after 24 months exercisable at 165 percent of the market value.

The company said the meeting would vote to approve a 25-to-one consolidation, reducing the amount of company shares from 3,556,371,635 to about 142,254,865 shares. Suda said shareholders would also vote to adopt the remuneration report, re-elect directors Mr Hopper, David Phillips and David Simmonds, ratify the prior issue of shares with attaching options, and approve a 10 percent placement capacity.

The meeting will be held at the Perth Convention and Exhibition Centre, 21 Mounts Bay Road, Perth, on November 12, 2019 at 10.30(AWST).

Suda was unchanged at 0.3 cents with 58.8 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says shareholders will vote to double the \$200,000 total pool of non-executive director fees to \$400,000 a year at its annual general meeting.

Bard1 said it would propose the \$400,000 limit to "accommodate an increase in the number of non-executive directors ... and allow for future increases".

The company said shareholders would also vote to adopt the remuneration report, modify the constitution, re-elect chairman Peter Gunzburg, and directors Robert (Max) Johnston and Philip Powell, ratify placements, approve a 10 percent placement capacity, and approve the incentive option plan.

The meeting will be held at the Ernst & Young Office, Level 23, 8 Exhibition Street, Melbourne on November 14, 2019 at 3:30pm (AEDT).

Bard1 was unchanged at 4.5 cents with 16.6 million shares traded.

AUSCANN GROUP HOLDINGS

Merchant Funds says it has become a substantial shareholder in Auscann with 36,237,639 shares (11.43%), acquired from Canopy Growth Corp. The Perth-based Merchant Funds said it bought the shares through an off-market transaction on October 11, 2019 for \$5,435,645 or 15 cents a share. Separately, Auscann said that Canopy Growth has sold all of 42,087,639 shares (13.2%), with "the majority of the holding (11.43%) acquired by Merchant Funds Management. Auscann fell 1.5 cents or 4.6 percent to 31 cents with 1.96 million shares traded.

RHINOMED

IOOF Holdings says it has ceased its substantial shareholding in Rhinomed, having acquired 9,090,910 shares, or 5.373 percent of the company, last week (BD: Oct 8, 2019). The Melbourne-based IOOF, formerly the Independent Order of Odd Fellows, with Sydney subsidiary Perennial Value Management, did not disclose how many shares it had sold. Rhinomed fell half a cent or 1.85 percent to 26.5 cents.

PHARMAUST

Pharmaust says Colin La Galia will replace Dr Martine Keenan as the chief executive officer of its subsidiary Epichem, who continues as a director and head of drug discovery. Pharmaust said Mr La Galia had more than 20 years' experience in drugs, devices and diagnostics and was previously employed at Abbott Rapid Diagnostics, Alere, Origin Healthcare, Hollywood Fertility Centre, Glaxosmithkline and Merck Sharpe and Dohme. Pharmaust was up half a cent or four percent to 13 cents.

IMAGION BIOSYSTEMS

Imagion says it has established a scientific advisory board to be chaired by Dr John Hazel, with members Prof Andrew Scott, Prof Lisa Horvath, Prof Robert Ivkov and Dr Paul Grint. Imagion said Dr Hazel was the chair of imaging physics at the University of Texas MD Anderson Cancer Centre, and was previously a director of Imagion.

The company said Prof Scott was a director of molecular imaging and therapy at Austin Health and a laboratory head at Melbourne's Olivia Newton-John Research Institute. Imagion said Prof Horvath was the medical oncology director at Sydney's Chris O'Brien Lifehouse.

The company said Prof Ivkov was a radiation oncology professor at the Baltimore, Maryland-based Johns Hopkins University School of Medicine.

Imagion said Dr Grint had more than 20 years' experience in biologic and small molecule research and development and was formerly Ampliphi Bioscience's chief executive officer. Imagion chief executive officer Bob Proulx said the scientific advisory board came at "a crucial time for [Imagion], with the first-in-human study just on the horizon". Imagion was up 0.3 cents or 8.3 percent to 3.9 cents.