

Biotech Daily

Thursday November 15, 2018

Daily news on ASX-listed biotechnology companies

- * ASX FLAT, BIOTECH DOWN: AIRXPANDERS UP 20%; OSPREY DOWN 10%
- * PHARMAXIS: LOXL2 DRUG 'SAFE, 85% ENZYME INHIBITION'
- * FEDERAL \$4m FOR AUTISM RESEARCH
- * PROF GEORGINA LONG, PROF RICHARD SCOLYER WIN GSK \$80k
- * PARADIGM RECEIVES \$2.3m FEDERAL R&D TAX INCENTIVE
- * SUDA RECEIVES \$745k FEDERAL R&D TAX INCENTIVE
- * US PATENT FOR DORSAVI BODY ORIENTATION TECHNOLOGY
- * CYNATA SURVIVES 24.55% REMUNERATION DISSENT
- * SUDA SURVIVES 22% REMUNERATION DISSENT
- * RESAPP 18% PLACEMENT FACILITY DISSENT AT AGM
- * MGC STARTS UK LEGAL PROCEEDINGS AGAINST VARM COSMO
- * BVF, MARK LAMPERT TAKE PROFIT TO 16% OF OPTHEA

* DIMERIX LOSES KATHY HARRISON

MARKET REPORT

The Australian stock market edged up 0.06 percent on Thursday November 15, 2018 with the ASX200 up 3.2 points to 5,736.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and five were untraded.

Airxpanders was the best, up 0.6 cents or 20 percent to 3.6 cents, with 16.2 million shares traded. Avita climbed 6.6 percent; Imugene improved 4.8 percent; Benitec was up 3.3 percent; Volpara rose 2.5 percent; Impedimed, Opthea and Pharmaxis were up more than one percent; with Cochlear, CSL, Mesoblast, Neuren and Polynovo up by less than one percent.

Osprey led the falls, down 1.5 cents or 10.0 percent to 13.5 cents with 844,705 shares traded. Actinogen lost 8.7 percent; Immutep was down 7.5 percent; Telix fell 5.7 percent; Optiscan and Paradigm were down more than three percent; Clinuvel, Ellex, Reva, Starpharma and Universal Biosensors shed more than two percent; Compumedics, LBT, Nanosonics and Pro Medicus were down one percent or more; with Cynata, Medical Developments and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis says a phase I trial has shown that its second lysyl oxidase-like 2 inhibitor for fibrotic diseases is safe with "85 percent inhibition" of the enzyme.

Pharmaxis said the double-blind, placebo-controlled study of the lysyl oxidase-like 2 (LOXL2) inhibitor compounds were targeting diseases including non-alcoholic steatohepatitis and idiopathic pulmonary fibrosis.

Last month, Pharmaxis said the first of its LOXL2 inhibitor compounds was safe and showed "a large and highly meaningful inhibition" of the enzyme (BD: Oct 11, 2018). Today, the company said the first stage was a single, ascending-dose study conducted in 48 healthy volunteers in six groups ranging from 5mg to 200mg or placebo.

Pharmaxis said the 24-participant second stage of the study had three groups receiving a daily dose of 50mg, 100mg, 200mg or placebo for 14 days and found the second LOXL2 inhibitor compound demonstrated "significant target engagement" of the enzyme in blood serum and displayed "more than 85 percent inhibition of the LOXL2 enzyme" over 24 hours from a 100mg daily dose.

Pharmaxis chief executive officer Gary Phillips said "several large [pharmaceutical] companies are interested in the Pharmaxis program where both of our LOXL2 inhibitors have now successfully completed phase I studies and demonstrated a best-in-class profile with 24-hour inhibition of the target enzyme from a single daily dose".

Mr Phillips said the "compounds directly inhibit the activity of the raised levels of LOXL2 seen in diseased tissue from [non-alcoholic steatohepatitis and idiopathic pulmonary fibrosis] animal models".

Mr Phillips said the company expected to report results from its three-month toxicity studies for both compounds by January 2019.

Pharmaxis was up half a cent or 1.9 percent to 26.5 cents.

FEDERAL GOVERNMENT

Federal Health Minister Greg Hunt says the Federal Government will provide \$3,939,367 for research into the diagnosis, treatment and care of autism.

A media release from Mr Hunt's office the National Health and Medical Research Council had funded five projects in Queensland, Victoria and New South Wales.

Mr Hunt said the Brisbane-based Queensland Institute for Medical Research Berghofer Medical Research Institute's Prof Sarah Medland would receive \$1,523,438 for the project 'Examining the impact of changes to diagnostic criteria on Autism Spectrum and Attention Deficit Hyperactivity Disorders'.

The media release said that the Melbourne-based Florey Institute's Prof Anthony Hannan would receive \$571,890 for the project 'What Causes Attention Deficits in Autism Spectrum Disorder' and the Florey's Dr Jess Nithianantharajah would receive \$735,723 for 'Mapping learning-dependent remodelling of synapse balance across the brain'.

The Federal government said the Melbourne-based La Trobe University's Prof Cheryl Dissanayake would receive \$473,475 for 'School-age Outcomes of Children with Autism Spectrum Disorder and Parental Wellbeing: Investigations on the contribution of Methodof-Referral and Age-of-Diagnosis' and the University of Sydney's Dr Michael Bowen would receive \$634,841 for 'Characterising and exploiting [delta] subunit-containing GABA-A receptors as novel targets for treating social disorders'.

Mr Hunt said the projects "bring together the best people in their field to produce highquality research to ensure that we continue to transform lives".

"Every breakthrough brings us closer to an answer to autism, which makes every piece of research that much more important," Mr Hunt said.

RESEARCH AUSTRALIA, GLAXOSMITHKLINE

Research Australia says Prof Georgia Long and Prof Richard Scolyer have won the \$80,000 Glaxosmithkline Research Excellence award for their work on melanoma. Research Australia said the funds would be used by Prof Long and Prof Scolyer's research team at the Sydney-based Melanoma Institute Australia to focus on the personalization of immunotherapies.

Prof Long said that "immuno-oncology is the penicillin moment for cancer therapy". "We've discovered how to leverage the relationship melanoma has with the immune system to allow a patient's immune system to kill the cancer cells," Prof Long said.

"We are moving towards melanoma no longer being a possible death sentence, but rather a treatable, chronic condition," Prof Long said.

Research Australia said that research by Prof Long and Prof Scolyer had "tripled the life expectancy for some advanced melanoma patients and transformed how the cancer is diagnosed and managed worldwide".

Prof Scolyer said there was a "critical need to better understand why some melanomas develop so we can improve prevention and treatment".

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has received \$2,318,717 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Paradigm said the rebate related to research and development activities for the year to June 30, 2018.

Paradigm fell 3.5 cents or 3.9 percent to 86 cents.

SUDA PHARMACEUTICALS

Suda says it has received \$745,245 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Suda said the rebate related to research and development expenditure for the year to June 30, 2018.

Suda chief executive officer Stephen Carter said the Research and Development Tax Incentive provided "a valuable benefit to companies such as Suda, so that we can invest more in developing our pipeline of novel oral sprays".

Suda was unchanged at 0.7 cents with 28.3 million shares traded.

DORSAVI

Dorva says the US Patent and Trademark Office has granted a patent for the algorithms and sensors for its body orientation technology.

Dorsavi said the patent, titled 'Apparatus and method for classifying orientation of a body of a mammal', protected its intellectual property until December 19, 2033.

The company said the patent protected its body orientation algorithms and sensors which were "able to detect whether a person is sitting, standing, lying down or performing dynamic activities" that were used in its body orientation technology for clinical and workplace settings.

Dorsavi said it had granted patents covering its intellectual property in Australia and China (BD: May 4, 2017).

Dorsavi was unchanged at 6.8 cents.

CYNATA THERAPEUTICS

Cynata has narrowly avoided a first strike on its remuneration report with 24.55 percent of votes opposed, but all resolutions at the annual general meeting were carried. Cynata said that 11,995,395 votes (24.55%) opposed to the company's remuneration report with 36,868,662 votes (75.45%) in favor

The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.

The company said the 10 percent placement facility faced similar opposition with 22.81 percent of votes opposed and 77.19 percent of votes in favor, but director Dr Stewart Washer was re-elected easily with 4.95 percent opposed and 95.05 percent in favor. Cynata's most recent Appendix 3B share issue announcement said there were 100,758,624 shares on issue, meaning that the strongest opposition vote of 12,168,105 votes against the 10 percent placement facility represented 12.08 percent of all shares on issue, sufficient to requisition extraordinary general meetings.

Cynata fell half a cent or 0.5 percent to \$1.065.

SUDA PHARMACEUTICALS

Suda has narrowly avoided a remuneration report first strike with 21.6 percent of votes opposed, but all resolutions at the annual general meeting were carried.

Suda said that 166,366,170 votes (21.6%) opposed the company's remuneration report with 603,195,676 votes (78.4%) in favor, of which 352,087,621 votes were in favor and 251,108,055 votes were at the proxy's discretion.

The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.

The company said that the re-election of chairman Stephen Carter faced slightly less dissent with the ratification of a prior share issue and the re-election of director David Phillips passed easily.

Suda's 2018 annual report said there were 1,224,141,804 shares on issue, meaning that the vote against the remuneration report represented 13.6 percent of all shares on issue, sufficient to requisition extraordinary general meetings.

RESAPP HEALTH

Resapp says that up to 18.3 percent of annual general meeting votes opposed the 10 percent placement facility, but a doubling of directors' remuneration passed easily. Resapp said that 35,406,133 votes (18.26%) opposed the 10 percent placement facility with 158,479,286 shares (81.74%) in support.

Resapp said all other resolutions passed easily, with 11,121,471 votes (6.01%) against increasing the total remuneration for directors from \$200,000 a year to \$400,000 a year, 9,317,817 votes (5.11%) against the remuneration report, and 8,475,875 votes (6.71%) against the ratification of the \$7,500,000 September placement (BD: Sep 19, 2018). The company said that directors Chris Ntoumenopoulos and David Buzza were re-elected with less than five percent dissent.

The company's most recent Appendix 3B share issue announcement said there were 693,130,512 shares on issue, meaning the vote against the placement facility was 5.1 percent of all shares on issue, sufficient to requisition extraordinary general meetings. Resapp was up half a cent or 4.55 percent to 11.5 cents with 2.4 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has begun legal proceedings in the UK against South Korean cosmetics manufacturer Varm Cosmo for its failure to meet marijuana cosmetic supply obligations. Last year, the MGC share price climbed 100 percent to 7.6 cents after news that Varm Cosmo had signed a \$40 million a year binding agreement to buy marijuana-based cosmetics from Ljubljana, Slovenia-based subsidiary MGC Derma (BD: Oct 20, 2017). In October last year, MGC said it expected the first \$1 million payment of an \$8 million binding agreement from Varm Cosmo in November 2017 (BD: Oct 30, 2017).

In January 2018, MGC told the ASX it had not received the \$1 million payment expected in November and that the delay in the receipt of the \$1 million payment had been caused by "operational and logistics factors, including damage in transit to some of the bulk sample containers" (BD: Jan 21, 2018).

In September, MGC said it had issued "a formal contract default notice" to Varm Cosmo for its failure to meet obligations agreed last year (BD: Sep 25, 2018).

Today, the company said it had commenced formal legal proceedings against Varm Cosmo in the UK and sought a minimum of EUR625,00 (\$A972,313) for "contract restitution at the time of default, plus damages suffered by MGC Derma in connection with Varm Cosmo's failure to comply with its obligations under the agreement including loss of contract revenue".

MGC said it would "vigorously pursue" the legal action against Varm Cosmo.

MGC fell 0.4 cents or 9.3 percent to 3.9 cents with 15.7 million shares traded.

<u>OPTHEA</u>

BVF Partners and Mark Lampert say they have reduced their holding in Opthea from 39,305,918 shares (17.65%) to 37,705,918 shares (16.39%).

The San Francisco, California-based BVF Partners, Biotechnology Value Fund and Mr Lampert said they sold 1,600,000 shares on November 13, 2018 for \$926,344 or 57.9 cents a share.

Last week, BVF and Mr Lampert said they acquired the 6,817,134 shares through the exercise of listed 27 cents options (BD: Nov 9, 2018).

Opthea was up one cent or 1.75 percent to 58 cents.

<u>DIMERIX</u>

Dimerix says that founding general-manager Kathy Harrison has left the company, effective from November 9, 2018.

Dimerix chairman Dr James Williams told Biotech Daily that Ms Harrison was the general manger when Dimerix listed on the ASX and was most recently chief executive officer before stepping back to her role as chief operating officer with the appointment of Dr Nina Webster as chief executive officer (BD: Nov 7, 2016; Apr 30, Aug 27, 2018).

"We wish Kathy all the best for her future," Mr Williams said.

Dimerix was unchanged at 9.5 cents.