

Biotech Daily

Monday January 22, 2018

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: COMPUMEDICS UP 6%; USCOM DOWN 19%
- * 'SAFETY, EFFICACY DATA' TAKE CYNATA TO 2nd GVHD COHORT
- * ICELAND APPROVES MEDICAL DEVELOPMENTS PENTHROX
- * MEDIBIO PARTNERS WITH STRIIV FOR MOBILE MENTAL HEALTH TEST
- * MGC MARIJUANA COSMETICS SALES DEAL WITH LONDON'S CULT BEAUTY
- * API TO DISTRIBUTE AUSCANN MEDICAL MARIJUANA
- * ESENSE \$766k SINGAPORE MARIJUANA TERPENE DEAL STARTS
- * MESOBLAST ISSUES 3.9m KENTGROVE SHARES, 1.5m ADVISOR OPTIONS
- * UNIVERSAL BIOSENSORS 2017 RECEIPTS UP 16% TO \$26m
- * COGSTATE H1 REVENUE DOWN 6% TO \$19m, RECEIPTS DOWN 28%
- * ESENSE TO RELEASE 4.5m ASX ESCROW SHARES
- * BTC SELLS BIOINTELECT TO HERZ FAMILY FOR \$700k
- * ZELDA TO TRADE ON US O-T-C MARKET
- * KAZIA TAKES 8% OF NOXOPHARM FOR NOX66 COLLABORATION
- * SG HISCOCK TAKES 6% OF NEUROTECH
- * OPTISCAN LOSES CEO ARCHIE FRASER
- * MEDIBIO APPOINTS PETER CARLISLE DIRECTOR

MARKET REPORT

The Australian stock market fell 0.23 percent on Monday January 22, 2018, with the ASX200 down 13.9 points to 5,991.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 12 traded unchanged and one was untraded.

Compumedics was the best, up 2.5 cents or 5.7 percent to 46.5 cents with 22,700 shares traded. LBT and Polynovo climbed more than five percent; Medical Developments, Nanosonics and Volpara rose more than two percent; with Admedus, Avita, CSL, Sirtex and Universal Biosensors up more than one percent.

Uscom led the falls, down five cents or 19.2 percent to 21 cents with 187,000 shares traded. Airxpanders lost 8.6 percent; Reva shed 7.6 percent; Prana fell five percent; Oncosil was down 3.45 percent; Actinogen, Ellex and Opthea shed more than two percent; with Genetic Signatures, ITL, Orthocell, Pharmaxis and Telix down by more than one percent.

CYNATA THERAPEUTICS

Cynata says it has "encouraging early safety and efficacy data" from its phase I trial of CYP-001 for graft-versus-host-disease and approval to dose the second cohort. Cynata says the independent data safety monitoring board recommended the trial of its Cymerus mesenchymal stem cells (MSCs) progress to the second eight-patients cohort. The company said that all eight patients in the first lower dose cohort demonstrated at least a partial response, with no treatment-related serious adverse events or safety concerns identified.

Cynata said that one of the eight patients in the first cohort died after developing pneumonia, which was a common finding in recipients of bone marrow transplants and similar procedures, but the death was not considered to be treatment-related.

The company said that the first cohort patients received one million CYP-001 cells per kilogram of body weight, to a maximum of 100 million cells per infusion.

Cynata said the second cohort would receive two infusions of CYP-001 at a dose of two million cells per kilogram of bodyweight, up to a maximum of 200 million cells per infusion. Cynata chief executive officer Dr Ross Macdonald said the company was "thrilled to report this encouraging early review of the phase I trial of CYP-001, which marks the first time that patients have been treated with an allogeneic, induced pluripotent stem cell-derived therapeutic [mesenchymal stem cell] product".

"The improvement in [graft versus host disease] grade observed in 100 percent of these gravely ill people is very promising, especially given the low dose administered," Dr Macdonald said.

"The positive [board] recommendation is an important milestone that enables us to begin enrolment in cohort B and advance toward our goal of completing the trial later this year," Dr Macdonald said.

Cynata said that patient enrolment into cohort B was open at seven sites in the UK and Australia.

Cynata was up five cents or 8.5 percent to 64 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its inhaled methoxyflurane analgesic Penthrox has been approved for sale in Iceland, the first of 22 expected European approvals.

In December, Medical Developments said the Medicine and Healthcare Products Regulatory Agency issued a final assessment with the support of all European country authorities noting the decentralised procedure had been completed (BD: Dec 12,2017). Today, the company said that the Icelandic Medicines Agency issued the marketing authorisation on January 16, 2018 making Penthrox available for sale effective immediately.

Medical Developments chief executive officer John Sharman said it was "great to see the first marketing authorisation come through so quickly".

"We expect the other 21 countries will issue marketing authorisations to approve the sale of Penthrox ... over the coming months," Mr Sharman said.

"It is a very proud moment to see Australia's first choice, front-line analgesic being used by doctors, hospitals and ambulances throughout Europe," Mr Sharman said.

"There are no other drugs like Penthrox," Mr Sharman said.

"The opportunities for Penthrox to treat patients with moderate to severe pain without the need to use dangerous opioids should drive our rapid expansion globally," Mr Sharman said.

Medical Developments rose 17 cents or 2.3 percent to \$7.52 with 138,476 shares traded.

MEDIBIO

Medibio says it has signed a partnership agreement with the Redwood City, Californiabased Striiv Inc to integrate its mental health tests into mobile tracking devices. Medibio said that Striiv had more than one million subscribers for its "smart watch" and personal tracking systems.

The company said that the Striiv wrist-wearable devices provided "the opportunity for Medibio's technology to be used for longer term patient monitoring and management". Medibio said that Striiv had collaborations with Unitedhealth Group, Qualcomm Life and Pfizer.

Medibio was unchanged at 30 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says its 51 percent European subsidiary has a sales and distribution agreement with London, UK-based online shop Cult Beauty.

MGC said that Cult Beauty would launch 15 of its cannabidiol cosmetic products and its Derma Plus skin care range from February 1, 2018.

The company said that revenues would be dependent on sales and the 6-month exclusive marketing campaign.

MGC was up half a cent or five percent to 10.5 cents with 31.1 million shares traded.

AUSCANN GROUP

Auscann says it has a "heads of agreement" with Australian Pharmaceutical Industries to distribute its cannabinoid medicines throughout Australia.

Auscann said the agreement would "help establish strong distribution channels for the supply of [its] medications to Australian patients", beginning with imported products from Canadian partner Canopy Growth Corp as it established its own local supply.

The company said it was working with Tasmanian Alkaloids to establish cultivation and manufacturing operations in Tasmania, with the first crop expected to be planted this year. Auscann managing director Elaine Darby said the distribution deal was "further evidence of the growing market and validity of what we're doing in Australia".

Auscann was up 2.5 cents or 1.6 percent to \$1.625 with 3.3 million shares traded.

ESENSE-LAB

Esense says it has approvals for its distribution agreement with Singapore's Advanced Technology Management Pte Ltd for its synthetic marijuana terpene products. Last year, Esense said that Advanced Technology specialized in cross-border business development, advising setting-up and managing business centres in Asia and had to purchase a minimum quantity of its products within the first 12 months valuing the one-year agreement between \$US540,000 and \$US600,000 (\$A689,511 to \$766,123) depending on the type of products purchased (BD: Oct 23, 2017).

Esense chief executive officer Haim Cohen said he was "very pleased that [Advanced Technology] had obtained the required approvals".

Esense fell two cents or 7.7 percent to 24 cents.

MESOBLAST

Mesoblast says it has issued 2,637,062 shares, 5,960,000 unquoted options and 1,500,000 incentive rights, primarily in relation to its Kentgrove facility.

In an Appendix 3B new issue announcement, Mesoblast said that the 5,960,000 options were issued under its employee share option plan, including 1,500,000 options to advisor Jonathan Symonds.

The company said 1,500,000 "incentive rights" would be issued to Melbourne's Kentgrove in accordance with the 2016 facility agreement with a further 2,000,000 "reserve shares" required under the facility as well as 381,150 shares for provision of the facility.

In 2016, Mesoblast said it had a \$60 million facility with Kentgrove over 18 months, with the option to increase it to \$120 million over 36 months (BD: Jul 1, 2016).

Mesoblast fell one cent or 0.7 percent to \$1.42 with 884,112 shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says receipts from customers for the year to December 31, 2017, was up 15.7 percent to \$25,959,000 compared to \$22,433,000 for the previous year. Universal Biosensors said that test strip fees from Johnson & Johnson for its Onetouch Verio blood glucose test was up 12 percent to \$19.99 million.

The company said that test strip fees from Siemens Health for the Xprecia Stride PT-INR blood coagulation test was \$4.07 million, compared to \$590,000 the previous year.

Universal Biosensors said it had \$26,260,000 in cash and cash equivalents at December 31, 2017 compared to \$20,402,000 the previous year.

Universal Biosensors was up half a cent or 1.85 percent to 27.5 cents.

COGSTATE

Cogstate says revenue for the six months to December 31, 2017, fell 6.1 percent to \$US15.5 million (\$A19.4 million), compared to \$20.67 million for the previous period. Cogstate said that it had changed its reporting to US dollars from July 1, 2017 "bringing reporting in line with the fundamentals of [its] business".

The company said that receipts from customers for the half year to December 31, 2017 amounted to \$US12,821,724 (\$A16,043,139) down 27.7 percent compared to

\$A22,192,663 for the six months to December 31, 2016 (BD: Feb 23, 2017).

Cogstate said it had \$US4,229,914 (\$A5,293,546) in cash and cash equivalents at December 31, 2017 compared to \$A11,212,073 the previous year.

Cogstate said that "strong sales for the half year reverses a disappointing sales result for the previous half year".

The company said that it "remains confident with the continued underlying growth trajectory of the clinical trials business" and that the six months to June 30, 2018 would outperform the six months to June 30, 2017.

Cogstate fell one cent or 1.1 percent to 93.5 cents.

ESENSE-LAB

Esense says it will release 4,500,000 shares from ASX escrow on February 7, 2018. According to the most recent Esense Appendix 3B new issue announcement it would then have 36,277,999 shares available for trading with a further 34,861,305 shares in escrow until January 30, 2019, seven shares not quoted on the ASX.

BTC HEALTH (FORMERLY BIOTECH CAPITAL)

BTC says it will sell its wholly-owned consulting business Biointelect Pty Ltd for \$700,000 to the Herz Family Trust, pending shareholder approval.

In 2016, the then Biotech Capital acquired Biointelect for 10,000,000 shares worth \$1.3 million (BD: Apr 4, 2016).

At today's closing price, those shares were worth \$2.1 million.

BTC said that the first few months of the current financial year "had proven more challenging for the Biointelect business than expected and that the anticipated return on the additional investment in people and new services had not been achieved".

The company said the sale agreement was between it and the Herz Family Trust, a related party of Biontelect founder and managing-director Jennifer Herz and Biointelect would be sold for \$700,000 in cash, subject to shareholder approval.

BTC said it expected a once-off impairment charge of about \$720,000 and a charge for a non-recoverable loan of \$280,000.

The company said the purchase would be funded through a separate agreement between Windarri Investments Pty Ltd as trustee for the Herz Family Trust and BTC executive chairman Dr Richard Treagus, with the Herz Family Trust selling 5,000,000 BTC shares to Dr Treagus at 20 cents a share.

BTC said that under the sale agreement Ms Herz would resign as a BTC director and 2,000,000 options granted to Ms Herz and Karl Herz would be cancelled.

Dr Treagus said the company was "disappointed that the investment in Biointelect has not delivered the anticipated outcomes and returns to the group".

"In reaching this divestment decision we believe that BTC Health and our shareholders will benefit from an even stronger focus on growing the in-licensing and product distribution elements of our business," Dr Treagus said.

BTC was unchanged at 21 cents.

ZELDA THERAPEUTICS

Zelda says its shares have been approved for trading on the US over-the-counter quality B (OTCQB) venture market under the code ZLDAF.

Zelda said that the dual-listing was non-dilutive to existing shareholders, with no capital being raised and no new shares issued.

The company said the listing provided "a new source of demand for Zelda shares from the US".

Zelda said that New York's Sichenzia Ross Ference Kesner LLP was its OTC markets sponsor and New York's Viriathus Capital LLC was the company's financial advisor. Zelda was unchanged at 11.5 cents with 1.8 million shares traded.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN), NOXOPHARM

Kazia says it has been issued 5,317,123 Noxopharm shares (8.63%) and 3,000,000 unlisted options under its NOX66 collaboration agreement (BD: Jan 21, 2018). Kazia said the shares would be held in voluntarily escrow until June 14, 2018 and the options would be exercisable at 80 cents each by January 18, 2020, but not prior to July 18, 2018.

The company said the securities had an estimated market value of \$6.5 million. Kazia was unchanged at 45 cents.

Noxopharm was up 3.5 cents or 3.6 percent to \$1.015.

NEUROTECH

Melbourne's SG Hiscock says it has increased its substantial holding in Neurotech from 5,464,482 shares (5.02%) to 6,760,403 shares (6.21%).

SG Hiscock said it bought 1,295,921 shares for \$289,303 or 22.3 cents a share between January 9 and 18, 2018.

Neurotech was up 1.5 cents or 7.7 percent to 21 cents.

OPTISCAN IMAGING

Optiscan says that "with regret we announce that [chief executive officer] Archie Fraser has resigned from the company, effective today".

Optiscan said that Mr Fraser joined the company "a little less than two years ago and in that time led the company to an increase in market capitalization from \$4 million to approximately \$45 million and leaves the company in a sound position both in terms of its balance sheet and the progress of its commercialization of the Optiscan technology" (BD: May 13, 2016).

The company said it had begun the process of recruitment of a suitably experienced and qualified chief executive officer to lead the company.

Optiscan was unchanged at 10 cents.

MEDIBIO

Medibio says it has appointed Peter Carlisle as a director.

Medibio said that Mr Carlisle was employed as marketing agency Octagon's managingdirector of "Olympics and action sports" and was in charge of "athlete brand-building through commercial, public relations and cause-related activities", had served on nonprofit boards and worked on programs for a variety of mental health issues.

The company said that Mr Carlisle had more than 20 years of experience in the sports marketing industry.

Medibio said that Mr Carlisle was previously an adjunct professor of sports law at the University of New Hampshire and Maine School of Law, and had been employed as a lawyer at Preti Flaherty.

The company said that Mr Carlisle held a Bachelor of Arts from the Lewiston, Mainebased Bates College and a Doctor of Juris from the University of Maine School of Law.