

# Biotech Daily

Monday February 19, 2018

## Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: COMPUMEDICS UP 12%; OPTHEA DOWN 5%
- \* VOLPARA UK BREAST CANCER RISK SCREENING PROGRAM
- \* SOMNOMED H1 REVENUE UP 33% TO \$32m, LOSS UP 593%; HALT
- \* ADALTA: 'AD-114 HAS PROMISE FOR LUNG FIBROSIS IN MICE'
- \* IMUGENE ARGININE MODULATOR 'ANTI-TUMOR ACTIVITY IN MICE'
- \* LABCON BLUECHIIP TRACKING ENABLED CRYOGENIC VIALS ON SHOW
- \* MEDICAL DEVELOPMENTS PENTHROX: ESTONIA OK, AUSTRIA ORDER
- \* KAZIA RECEIVES \$4m R&D TAX INCENTIVE
- \* SOUTH AUSTRALIA \$4m 'LOW COST' LBT LOAN
- \* CRESO COMPLETES MERNOVA MEDICAL MARIJUANA ACQUISITION
- \* CANN RENEWS MARIJUANA GROWING, PRODUCTION LICENCES
- \* DIMERIX REQUESTS 'SHORTFALL PLACEMENT, CAPITAL RAISING' HALT
- \* JASON CONROY REPLACES MMJ CEO ANDREAS GEDEON

#### MARKET REPORT

The Australian stock market was up 0.64 percent on Monday February 19, 2018 with the ASX200 up 37.6 points to 5,941.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and four were untraded.

Compumedics was the best, up 4.5 cents or 12 percent to 42 cents with 130,270 shares traded. Mesoblast climbed 9.2 percent; Prana was up 6.9 percent; Genetic Signatures and LBT improved more than five percent; Uscom was up four percent; Acrux and Impedimed were up more than three percent; Actinogen, Airxpanders and Optiscan rose more than two percent; Bionomics, Cochlear, CSL, Ellex, Nanosonics and Osprey were up one percent or more; with Pro Medicus and Sirtex up by less than one percent.

Opthea led the falls, down three cents or 5.2 percent to 55 cents with 23,564 shares traded. Immutep fell 4.35 percent; Clinuvel and Medical Developments were down more than three percent; Admedus, Benitec, Neuren and Telix shed two percent or more; Pharmaxis and Starpharma were down more than one percent; with Resmed down 0.08 percent.

#### **VOLPARA HEALTH TECHNOLOGIES**

Volpara says its breast cancer density risk and risk-based screening software will be trialled on 8,000 women in a UK National Health Service program.

Volpara said its Volpara Density software, which measured breast density as well as its risk-based breast cancer screening, would be implemented in Greater Manchester, East Cheshire and East Lancashire regions as part of the Manchester University NHS Foundation Trust 'Predicting Risk of Cancer at Screening' program.

The company said that the grant to Manchester University was entitled 'Providing breast cancer risk information as part of national breast cancer screening program: building an evidence base on benefits and harms to inform a decision to implement'.

Volpara said the trial would run for two years at six sites, with 8,000 consenting women receiving breast cancer risk information based on risk assessment that incorporated mammographic density as estimated by the Volpara Density software.

Volpara said the trial was the second stage of the Predicting Risk of Cancer at Screening (Procas) study, which aimed to enhance the NHS Breast Screening Programme by including breast cancer risk prediction for women when they attended routine breast screening.

The company said the trial would include an initial consultation period with the Manchester University Trust and that an agreement addressed data governance and system design before trial implementation.

Volpara said it was selected by the UK's National Health Service following the Procas 1 study, which recruited participants over 66 months from the Greater Manchester breast screening program.

Volpara chief executive officer Dr Ralph Highnam said the trial would "change the way breast screening is approached in the UK and globally, and [would] ensure women better understand their risk and [that] high-risk patients are offered appropriate screening options".

"To be selected as the tool of choice for measurement of breast density is an important validation of our work and competitive advantage," Dr Highnam said.

"Following the data consultation and trial implementation, it is hoped that breast density measurement, using Volpara Density software, will be adopted as routine across the NHS Breast Screening Programme," said Dr Highnam.

Volpara was unchanged at 76 cents.

#### SOMNOMED

Somnomed says revenue for the six months to December 31, 2017, was up 32.5 percent to \$31,619,569, with net loss after tax up 593.1 percent to \$5,620,376 loss.

Somnomed said the acquired Renew Sleep Services drove its North American revenue growth of 48 percent which was expected to continue increasing but sales and marketing expenses increased from \$5,763,978 to \$11,449,279.

The company said diluted loss per share increased 814.2 percent from 1.13 cents per share for the six months to December 31, 2016 to 10.33 cents per share for the six months to December 31, 2017, with net tangible asset backing per share down 26.7 percent to 29.37 cents.

Somnomed said that cash and equivalents was \$7,578,486 at December 31, 2017 compared to \$16,712,880 at December 31, 2016.

Somnomed requested a trading halt, for a proposed one-for-17 rights offer at \$3.00 a share to raise \$10.4 million, until February 21, 2018 and last traded at \$3.03.

#### **ADALTA**

Adalta says AD-114 selectively targets and binds to the chemokine receptor CXCR4, which is expressed at higher levels in patients with lung fibrosis.

Adalta said that the mouse research, published in Nature Scientific Reports found that AD-114 was a potential treatment for idiopathic pulmonary fibrosis or lung fibrosis.

The company said that AD-114 was its lead I-body, which it previously said was named from the intermediate group of immunoglobulin or immunoglobulin-like domains, and had been selected for fibrosis (BD: Jul 7, 2016).

The research article, entitled 'Anti-fibrotic Effects of CXCR4- Targeting I-body AD-114 in Preclinical Models of Pulmonary Fibrosis', was co-authored by Adalta chief scientific officer Dr Mick Foley and senior scientist Dr Kate Griffith and was available at: <a href="https://www.nature.com/articles/s41598-018-20811-5">https://www.nature.com/articles/s41598-018-20811-5</a>.

The article concluded that "in a murine bleomycin model of pulmonary fibrosis, AD-114 reduced the accumulation of fibrocytes ... in fibrotic murine lungs and ameliorated the degree of lung injury".

"Collectively, these studies demonstrate that AD-114 holds promise as a new biological therapeutic for the treatment of [idiopathic pulmonary fibrosis]," the article concluded. Adalta said the paper showed the ability of AD-114 to selectively target and bind to the chemokine receptor CXCR4, which was believed to play a role in the recruitment of fibrotic cells to the lung, and thought to contribute to the progression of idiopathic pulmonary fibrosis.

The company said that the research showed that AD-114 slowed the migration of diseased fibroblasts, but had no effect on healthy cells and reduced the over-production of collagen, a protein contributing to the disease pathology of fibrosis.

Adalta chief executive officer Sam Cobb said the data demonstrated the therapeutic potential of the I-body for lung fibrosis and its promise as a therapeutic option. Adalta fell 1.5 cents or 4.7 percent to 30.5 cents.

#### **IMUGENE**

Imugene says its arginine modulator has shown anti-tumor activity in 12 different cancer mouse models with significant activity for melanoma.

Imugene said that depletion of arginine, "an amino acid critical for the activation, growth and survival of the body's own cancer fighting cells" had been observed in a number of cancers, and researchers believed increasing its availability could help restore the tumor-killing activity of cancer fighting cells.

The company said that its arginine modulator program stemmed from a 2016 agreement with Melbourne's Baker Heart and Diabetes Institute to develop and commercialize its modulators for oncology (BD: Dec 13, 16, 2016).

Imugene said it submitted a joint National Health and Medical Research Council grant application with the Baker Institute this year that would investigate developing new and improved immunotherapy drug candidates to enhance the anti-tumor actions of immune T-cells with the lead application focused on melanoma.

Baker Institute director principal research fellow Prof David Kaye said the collaboration was "supporting an exciting and novel therapeutic approach to treat cancers with a strong potential for improving patient outcomes".

Imugene chief executive officer Leslie Chong said the collaboration aimed "to yield important composition of matter intellectual property and with improved anti-tumor activity".

Imagene was up 0.2 cents or 9.5 percent to 2.3 cents with 63.4 million shares traded.

#### **BLUECHIIP**

Bluechiip says that Labcon North America is manufacturing a range of cryogenic vials incorporating its tracking technology and is the first to put them on public display. Bluechiip said that Labcon's Coldpoint Bluechiip Enabled cryogenic vial range was displayed at the Society of Laboratory Automation Systems show in San Diego, California, earlier this month, along with cryogenic boxes which store up to 100 vials, a Bluechiip multi-vial reader and software.

The company said it was the first time an original equipment manufacturer partner had Bluechiip-enabled products in production and on display.

Bluechiip managing-director Andrew McLellan said the company was "scaling production to meet demand and have already supplied Labcon with tens of thousands of Bluechiip tags following their purchase order in December last year" (BD" Dec 5, 2017).

"Three batches have been delivered to date for manufacture into Labcon's Coldpoint Bluechiip-enabled cryovials, with orders in hand to dramatically increase volumes delivered each month over the coming year," Mr McLellan said.

Labcon president Jim Happ said that the Bluechiip-enabled Coldpoint cryogenic vial range was "a significant pillar in our product line and one which overcomes the issues currently experienced by the biological storage market".

"Having a product which can identify samples in the coldest conditions, with details able to be read through frost, dramatically improves productivity and quality for our customers," Mr Happ said.

Bluechiip was up 0.9 cents or 16.7 percent to 6.3 cents.

#### MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Estonia has approved its Penthrox methoxyflurane inhaled analgesic and it has its first Penthrox order for a launch in Austria.

Medical Developments said that the Republic of Estonia Agency of Medicines issued the marketing authorization on February 13, 2018 taking the total number of approvals over the last four weeks to six.

Medical Developments chief executive officer John Sharman said he expected the remaining 16 European Union countries to issue Penthrox marketing authorizations in the coming months."

The company said that Austria approved Penthrox on January 29, 2018.

Mr Sharman said the announcement of the first Austrian order was "to demonstrate sales in the first of the 22 EU members states".

"Whilst we expect to receive orders from other countries during [2018], we consider these to be in the ordinary course of business and therefore we do not necessarily intend to announce individual country orders as they are received," Mr Sharman said.

Medical Developments fell 24 cents or 3.2 percent to \$7.24.

#### KAZIA THERAPEUTICS

Kazia says it has received \$3,973,052 from the Australian Taxation Office under the R&D Tax Incentive Program, for the financial year ending June 30, 2017.

Kazia chief executive officer Dr James Garner said "the R&D tax rebate is an important, non-dilutive source of funding for the company".

"The amount is fully in line with our expectations, and will be devoted to progressing our two key clinical programs," Dr Garner said.

Kazia was up 0.5 cents or 0.9 percent to 57.5 cents.

#### LBT INNOVATIONS, THE GOVERNMENT OF SOUTH AUSTRALIA

LBT says it has a \$4 million low cost loan from the South Australian Government, as part of a jobs and innovation initiative.

LBT said the funding was designed to help extend its platform technology by recruiting 16 full time Adelaide-based staff over the next two years.

The company said drawdowns would be of \$1 million on signing the documents and, subject to operational milestones, a further \$1.5 million by December 2018 and \$1.5 million by December 2019.

LBT said the interest rate was the "South Australian Government cost of funds plus a 2.0 percent margin, set on the date of first drawdown".

LBT chief financial officer Ray Ridge told Biotech Daily that he believed the South Australian Government interest rate to be between 2.7 percent and 3.0 percent, making to loan rate 5.0 percent or lower.

No one from the South Australian Government was available to confirm the rate, at the time of publication.

The company said until the last drawdown, expected to be December 31, 2019, there would be no repayments of principal or interest, with interest "accrued and capitalized", effectively a compound interest rate.

LBT said that on the last drawdown, the loan would become a three-year fixed principal and interest term loan, with repayments to be made quarterly until repayment, which was expected in December 2022.

South Australia Premier Jay Weatherill said LBT's automated plate assessment system (Apas) Independence instrument "will help deliver the State Government's plan to increase global exports of locally made hi-tech systems".

LBT chief executive officer Brent Barnes said the State Government funding "comes at a critical time for us as an early revenue company where future product development is necessary to retain our leading edge position".

South Australia has a State election on Saturday March 17, 2018.

LBT was up one cent or 5.4 percent to 19.5 cents.

#### **CRESO PHARMA**

Creso says it has completed the acquisition of medical marijuana producer Mernova Medicinal for \$C200,000 (\$A201,312) and 8,300,000 Creso Canada shares.

Last year, Creso said it would buy the Nova Scotia, Canada-based Mernova Medicinal for \$C10.1 million (\$A10.1 million) in cash and equity (BD: Jul 27, 2017).

Today, Creso said that following tax advice it completed the acquisition of Mernova through two new Canadian subsidiaries, Creso Canada and Creso Canada Corporate.

The company said that the Creso Canada shares would be exchangeable for Creso shares on the satisfaction of milestones.

Creso said the deal was its "formal entry into Canada and means it is the only Australian cannabis company with direct exposure to the world's largest legal medical cannabis market".

The first marijuana company to list on the ASX, MMJ Phytotech, said it had operations in Canada and Switzerland (BD: Jan 22, Mar 24, 2015; Aug 3, 2016).

Today, Creso said that its strategy was to establish a Canadian presence and pursue "opportunities in the medicinal cannabis space, with added exposure to the huge recreational cannabis market once this is legalized, with legalization expected in mid-2018.

Creso fell seven cents or 7.45 percent to 87 cents with 1.1 million shares traded.

#### **CANN GROUP**

Cann says it has been granted two new licences by the Federal Office of Drug Control for the cultivation and production of cannabis for research and medicinal purposes.

Cann said that after the 12-month expiry of earlier licences it was required to reapply for the Cannabis Research Licence and Medicinal Cannabis Licence.

The company said that corresponding permits had been issued including for cultivation relating to research activity, for the maintenance and use of mother plants and for cultivation and product for supply for therapeutic purposes.

Cann said the licences would allow it to continue its research and work with partners including La Trobe University, Aurora Cannabis, Agriculture Victoria, the Commonwealth Scientific and Industrial Research Organisation and Anandia Labs.

Cann chief executive officer Peter Crock said the licences provided "the security to continue to pursue our business plan aggressively, including cannabis cultivation for both domestic demand as well as export opportunities".

Cann fell five cents or 1.5 percent to \$3.20 with 367,444 shares traded.

#### **DIMERIX**

Dimerix has requested a trading halt pending an "announcement of completion of the rights issue shortfall placement and an additional capital raising" (BD: Jan 24, 2018). Trading will resume on February 21, 2018 or on an earlier announcement. Dimerix last traded at 13.5 cents.

### MMJ PHYTOTECH

MMJ says it has appointed Jason Conroy as chief executive officer, replacing Andreas Gedeon, effective from February 26, 2018, starting on \$300,000 a year.

MMJ said Mr Conroy was an executive and corporate financier with more than 20 years' experience most recently as chief executive officer of Duet Group.

According to Mr Conroy's Linkedin page he holds a Bachelor of Commerce from Western Sydney University and a Master of Business Administration from the University of New England.

The company said Mr Gedeon would retire as chief executive office to devote attention to its Canada based subsidiary Harvest One Cannabis.

MMJ chairman Peter Wall thanked Mr Gedeon "for his tireless work and commitment towards establishing MMJ as a leading Australian-based cannabis business".

Mr Wall said that Mr Gedeon would remain available to provide industry advice and assist Mr Conroy in the leadership transition.

MMJ fell 2.5 cents or 5.15 percent to 46 cents with 1.7 million shares traded.