



Biotech Daily

Thursday June 15, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: AVITA UP 10.5%, PSIVIDA DOWN 15%**
- * **US APPROVES MAYNE DOXYCYCLINE HYCLATE**
- * **CANADA ACCEPTS MEDICAL DEVELOPMENTS PENTHROX FILE, \$250k**
- * **BIOTRON OKAY TO DOUBLE BIT225 DOSE IN HIV TRIAL**
- * **ATOMO RAISES \$1.4m**
- * **PROTEOMICS TELLS ASX: 'RESULTS WITHHELD FOR CONFERENCE'**
- * **ZELDA, KNOP PARTNER FOR MEDICAL MARIJUANA MANUFACTURE**
- * **AUSCANN GIVES M-D ELAINE DARBY 55% PAY RISE TO \$310k**
- * **PARADIGM REQUESTS 'RHINITIS TRIAL STATUS' TRADING HALT**
- * **MICHAEL POWELL, JOLIMONT TAKE 7% OF SIMAVITA**
- * **ROBERT HUTCHISON, MARY-ANN MCKENZIE TAKE 6% OF SIMAVITA**
- * **CRYOSITE APPOINTS CFO MARK BYRNE INTERIM CEO**
- * **AUSCANN: DR DANIAL SCHECTER CMA, DAVID PRYCE ALT-DIRECTOR**
- * **BIO-MELBOURNE BREAKFASTS ON CHINA**

MARKET REPORT

The Australian stock market fell 1.21 percent on Thursday June 15, 2017 with the ASX200 down 70.7 points to 5,763.2 points. Nine of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Avita was the best, up 0.8 cents or 10.5 percent to 8.4 cents with 246,760 shares traded. Prana climbed 6.4 percent; both Atcor and Polynovo improved 5.6 percent; Pharmaxis, Pro Medicus and Sirtex rose two percent or more; with Bionomics and Reva up more than one percent.

Psivida led the falls, down 44 cents or 14.7 percent to \$2.56 with 4,552 shares traded. Dimerix lost 12.5 percent; Neuren was down 11.3 percent; Universal Biosensors fell 6.25 percent; Acrux shed 4.1 percent; Cellmid, Factor Therapeutics, Nanosonics, Opthea and Osprey were down more than three percent; Airxpanders shed 2.1 percent; CSL, ITL and Viralytics were down more than one percent; with Cochlear, Ellex, Impedimed, Medical Developments, Mesoblast, Resmed and Starpharma down by less than one percent.

MAYNE PHARMA GROUP

Mayne Pharma says it has US approval for its 75mg and 150mg generic doxycycline hyclate immediate release tablets.

Mayne said that the US Food and Drug Administration approved its abbreviated new drug application and it has begun the commercial launch of the generic version of Acticlate tetracycline antibacterial tablets for infections, including adjunctive therapy in severe acne. The company said that US sales of Acticlate amounted to about \$US250 million in the 12 months to April 2017.

Mayne chief executive officer Scott Richards said the approval “exemplifies Mayne Pharma’s commitment to bringing first-to-market generic products to the marketplace”. The company said that it was its fourth first-to-market generic launch since June 2016. Mayne said it had 18 drug applications pending at the FDA.

Mayne was up one cent or 0.96 percent to \$1.05 with 16.4 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Health Canada has accepted the regulatory dossier for its inhaled analgesic Pentrox, triggering a \$C250,000 (\$A247,786) milestone.

Medical Developments said the milestone would be paid by Canada distribution partner Purdue Pharma.

Medical Developments chief executive officer John Sharman said the acceptance was “another positive step towards globalizing Pentrox”.

Medical Developments fell four cents or 0.7 percent to \$5.35.

BIOTRON

Biotron says it has approval to increase the dose of BIT225 to 200mg in its phase II HIV-1 trial with combination antiretroviral therapy.

Biotron said that the first cohort of nine patients was fully recruited and being treated and the independent data and safety monitoring committee approved the increase from 100mg BIT225 daily to 200mg for the second cohort of 27 patients.

The company said that the Thailand-based multi-centre, randomized, placebo-controlled, double-blind study enrolled treatment naïve HIV-1 patients who would receive either combination antiretroviral therapy with BIT224 daily for 12 weeks or combination antiretroviral therapy with placebo (BD: Feb 13, 2017).

Biotron said that the trial was designed to show that BIT225 could improve combination antiretroviral therapy by demonstrating a faster decline in viral loads compared to combination antiretroviral therapy alone, and/or through the lowering of immune activation, or the lessening of the effect of having HIV-1 continually “smouldering” in the reservoirs or background of a patient.

The company said that a mouse study showed that the addition of BIT225 to combination antiretroviral therapy “resulted in significantly faster clearance of HIV-1 as well as delayed viral rebound, confirming the hypothesis that BIT225 attacks a different source of virus than current anti-HIV-1 drugs”.

“If these improvements are confirmed by the current BIT225 phase II HIV-1 clinical trial, the data will imply that BIT225 is targeting a different source of virus than that currently treated with [combination antiretroviral therapy] standard drugs and that the drug may have a key role in eradication or cure of HIV-1,” Biotron said.

The company said it expected preliminary headline data by October 2017.

Biotron fell 0.2 cents or 10 percent to 1.8 cents with 1.3 million shares traded.

ATOMO DIAGNOSTICS

Atomo says it has raised \$1.42 million from current shareholders to support its rapid HIV test business expansion.

Atomo said that the shareholders included the New York-based Global Health Investment Fund, Grand Challenges Canada, property developer Lang Walker, former Macquarie Bank head Allan Moss along with founders and staff.

The company said it was accelerating marketing of its single-use, rapid in-vitro diagnostic blood test technology through licencing and partnership deals.

Atomo is a public unlisted company.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has told the ASX that it completed internal data analysis of the Promarkerd test for kidney disease on June 1, but withheld it for presentation at a conference.

An ASX 'aware' query cited a 25 percent jump in share price from 16 cents on June 8 to 20 cents on June 9, 2017.

Proteomics said that it had previously disclosed an expected timeline for the results, noted the 'Code of Best Practice for Reporting by Life Science Companies (Second Edition)' and said that "disclosure of results before peer review to independently prove the findings is premature and without publication key opinion leaders are less likely to consider the results for the company's studies credible".

The company said the data was to be presented on June 10 at the American Diabetes Association meeting, coinciding with the Queen's Birthday public holiday in Australia. Proteomics said it "considered its continuous disclosure obligations and in particular, timing of release of the results to the ASX" and concluded that as the results were being presented at a conference in the US over the long weekend in Australia, they would be released once it confirmed they had been published by the Association, prior to the market open on June 13, 2017 and requested the trading halt on June 9, 2017.

Last week, Proteomics last traded before the trading halt up four cents or 25 percent to 20 cents with 37,300 shares traded (BD: Jun 9, 2017).

On Tuesday, Proteomics said the 792-patient validation study showed the Promarkerd blood test could "predict the onset of diabetic kidney disease better than any current measure", with its shares closing up two cents to 22 cents (BD: Jun 13, 2017).

Today, Proteomics fell two cents or 10 percent to 18 cents.

ZELDA THERAPEUTICS

Zelda says it has a medical marijuana manufacturing and distribution agreement with the Quilpué Chile-based Knop Laboratorios SA, which has 70 pharmacies throughout Chile. Zelda said that the agreement was "an important part of Zelda's Chilean activities and locks in a high quality supply of Zelda's formulated medicinal-cannabis medicines initially for its planned clinical trials and subsequently a secure, scalable and [good manufacturing practice] grade source of commercial quantities following product registration".

Zelda said that Chile's legal framework recognized the importance of medical cannabis, allowing its production under regulatory controls for the treatment of medical conditions and provided a cost-effective location for Zelda to conduct clinical trials.

The company said that the Knop agreement would "potentially allow the mass production of Zelda's medicines for the treatment of eczema, insomnia and autism, providing a natural alternative to many patients who suffer from these conditions".

Zelda was up 0.3 cents or 4.05 percent to 7.7 cents with 31.6 million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says managing director Elaine Darby will have a 55 percent pay rise to a base salary of \$310,000 a year “to bring her remuneration into line with market rates”.

According to the Auscann prospectus filed to the ASX on February 1, 2017, Ms Darby was to receive \$100,000 for the 12 months to June 30, 2017, rising to \$200,000 for the 12 months to June 30, 2018.

Today, the company said Ms Darby’s base salary would be \$310,000 a year plus 9.5 percent superannuation, with a short term incentive of up to 25 percent of the base salary including superannuation, or up to \$84,862.50, based on key performance indicators, payable in cash at June 30, 2018, as well as a cash bonus of \$50,000 payable at June 30, 2017 in recognition of her performance in the year to June 30, 2017.

Auscann fell 0.5 cents or 1.4 percent to 35 cents with one million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested a trading halt to “review the status of its current clinical trial in allergic rhinitis”.

Trading will resume on June 19, 2017 or on an earlier announcement.

Paradigm last traded at 70 cents.

SIMAVITA

Michael Powell says he has increased his substantial shareholding in Simavita from 15,912,265 Chess depository instruments (5.51%) to 22,912,265 CDIs (7.39%).

The Melbourne-based Mr Powell said the shares were held by Jolimont Lodge acting for the Powell Family superannuation fund and between June 20, 2013 and May 8, 2017 and the group bought the 7,000,000 new shares for four cents each.

In May, Simavita said it raised \$1,500,000 in a placement and \$848,109 in a rights issue at four cents a share (BD: May 3, 8, 25, 2017).

Simavita was unchanged at four cents.

SIMAVITA

Robert Hutchison says he has become a substantial shareholder in Simavita with 17,025,354 Chess depository instruments or 5.54 percent.

The Melbourne-based Mr Hutchison said the shares were held by him and Mary McKenzie and the Inspiration superannuation fund.

Mr Hutchison said that 2,025,354 CDIs were acquired on June 30, 2013 for \$2,129,259 or \$1.05 per CDI.

Mr Hutchison said that 5,000,000 shares were bought on May 19 and 29, 2017 for \$200,000 or four cents a share, and a further 10,000,000 CDIs acquired but with no consideration stated.

CRYOSITE

Cryosite says chief financial officer Mark Byrne has been appointed interim chief executive officer, replacing Andrew Shine from June 30, 2017.

Cryosite said that it would begin a search for a new chief executive officer and Mr Shine’s 359,663 performance rights would lapse on his departure.

Cryosite was untraded at 18 cents.

[AUSCANN GROUP HOLDINGS](#)

Auscann says it has appointed Dr Danial Schechter as its chief medical advisor and director Bruce Linton has appointed David Pryce as his alternate director.

Auscann said that Mr Pryce was currently Canopy Growth Corp head of market expansion and government relations, with Canopy “the largest cannabinoid medicine producer in North America”.

Auscann said that prior to Canopy, Mr Pryce worked for Blackberry and D2L, founded the Dewhurst Group, and was an advisor to the Governments of Canada and Ontario.

The company said Mr Pryce held a Bachelor of Arts from Ontario’s University of Guelph and a Master of Business Administration degree from Ontario’s Wilfrid Laurier University. Auscann said that Dr Schechter had worked “extensively within the field having founded the largest referral-only clinic in Canada that [specialized] in cannabinoid medicine”.

The company did not cite Dr Schechter’s qualifications, but his LinkedIn page said he was a “hospitalist” at the Barrie, Ontario-based Royal Victoria Hospital and was previously a physician at Chigamik Community Health Centre following two years as a resident at Toronto’s Mount Sinai Hospital and a resident at the University of Toronto.

The LinkedIn page said that Dr Schechter previously was at the Université de Montréal, but did not specify the qualification.

[BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says its June 30, 2017 Bio-Breakfast is entitled ‘Strategies for China: Managing Risk to Build Opportunity’.

The Network said that the Bio-Breakfast would be of interest to companies considering expanding into China.

The industry organization said that speakers would include Australian Trade and Investment Commission senior China advisor Liu Bing, the Walter and Eliza Hall Institute’s Prof David Huang who leads the research team responsible for the development of cancer drug Venetoclax and also acts as head of WEHI’s strategic alliances in Asia

The Network said that the Melbourne-based Swisse vitamin company head of government relations for China Isaac Huang would also speak at the breakfast.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that “changes in demographics and shifts in consumer preferences are giving rise to new market opportunities in China for Melbourne-based companies”.

“The strong consumer health focus and a growing internet retail market is creating new distribution channels and shifts in approaches to partnering for health products,” Dr Evans said.

The Network said that MAI Capital investment director Tom Ellis would join the speakers for the panel discussion.

The industry organization said that Mai Capital specialized in supporting companies to access the necessary resources for expansion into China.

The Bio-Breakfast will be held at the Australian Centre for the Moving Image in Federation Square in Melbourne on June 30, 2017, with registration from 7.15am, for a 7.30am breakfast followed by presentations and discussion from 8am until 9am.

To register go to: <https://tinyurl.com/biomelbchina>.