



Biotech Daily

Monday December 18, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: VOLPARA UP 8%; DIMERIX DOWN 8%**
- * **RESAPP: 'FURTHER ANALYSIS SHOWS ALGORITHM 90% ACCURATE'**
- * **BOTANIX PHASE Ib BTX1503 CANNABIDIOL ACNE TRIAL ENROLLED**
- * **AUSCANN JOINT VENTURE PLANTS 2nd CHILE MARIJUANA CROP**
- * **CRESO TO PAY KUNNA UP TO \$11m FOR COLOMBIA MARIJUANA**
- * **CHINA'S STEVEN MENG TAKES \$1.8m, 10% STAKE IN USCOM**
- * **INVESTORS MUTUAL TAKES 5% OF ELLEX**
- * **ACTIVE IMMUNITY, SPIRO SAKARIS SELL 19.75m IQ3 SHARES (19%)**
- * **BIOWORX, ANTHONY TSIGOUNIS TAKE 19% OF IQ3**
- * **PHARMAUST APPOINTS PROF BARBARA KITCHELL VET ADVISOR**

MARKET REPORT

The Australian stock market was up 0.7 percent on Monday December 18, 2017 with the ASX200 up 41.9 points to 6,038.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and three were untraded.

Volpara was the best on a trading update claiming revenue up 138 percent for the year to December 15, 2017, up 4.5 cents or 7.7 percent to 63 cents with 150,858 shares traded.

Genetic Signatures and Optiscan climbed more than five percent; Benitec, Impedimed, ITL, Medical Developments, Osprey, Polynovo and Resmed rose more than two percent; Clinuvel, Orthocell, Prana and Pro Medicus were up more than one percent; with CSL, Sirtex and Viralytics up by less than one percent.

Dimerix led the falls, down one cent or 7.7 percent to 12 cents with 42,719 shares traded.

LBT lost five percent; Reva fell four percent; Bionomics and Starpharma were down more than three percent; Mesoblast shed 2.1 percent; Admedus, Ellex, Neuren and Telix were down more than one percent; with Cochlear down 0.6 percent.

RESAPP HEALTH

Resapp says that further analysis of its Australia adult study of its mobile telephone application for respiratory illnesses diagnosis shows it is about 90 percent accurate. Resapp said the data showed accurate differential diagnosis of community-acquired pneumonia and acute asthma within an adult intended-use population, or those experiencing a broad range of respiratory illness, at 90 to 91 percent positive percent agreement and 88 percent negative percent agreement with clinical diagnosis.

The company said its diagnostic accurately identified chronic obstructive pulmonary disease and chronic asthma in adult patients at 87 to 89 percent sensitivity and 87 to 90 percent specificity compared to lung-function testing.

Resapp said the diagnostic correctly identified infective exacerbations in adult patients with chronic obstructive pulmonary disease with 91 percent positive percent agreement and 90 percent negative agreement.

In August, Resapp fell as much as 82.3 percent on news that its 1,245-patient US Smartcough-C trial failed to meet its endpoints (BD: Aug 9, 2017).

Resapp said at that time that “contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds [and] a high number of recordings were also found to contain a second person’s cough sounds or an unacceptable amount of background noise and interference”.

Last week, the company said it was preparing to start an updated version of the trial at the same US hospitals (BD: Dec 13, 2017).

In June, Resapp said that its 1,127 patient paediatric trial showed accuracy ranging from 70 percent to 97 percent. (BD: Jun 22, 2017).

Last year, Resapp says that interim data from 143 of 322 adult patients showed accuracy ranging from 83 percent to 100 percent (BD: Jun 21, 2016).

In October last year, the company said that further preliminary results from the adult study showed “high levels of sensitivity, specificity and accuracy on an expanded adult dataset” with the diagnostic’s algorithms achieving between 91 percent and 100 percent accuracy for distinguishing adult patients with chronic obstructive pulmonary disease, asthma or pneumonia from subjects with no discernible respiratory disease and the (then) new analysis showing “100 percent accuracy for distinguishing patients with an upper respiratory tract infection from the no respiratory disease group” (BD: Oct 3, 2016).

Resapp said the study of its cough sound-based algorithms was undertaken at the Perth, Western Australia-based Joondalup Health Campus and the Brisbane-based Wesley Hospital, with the data prepared by a team led by the University of Queensland’s Prof Udantha Abeyratne.

Today, the company said the results demonstrated accurate differential diagnosis of pneumonia and acute asthma in a real-world intended use population of adult patients with a board range of respiratory illnesses.

Resapp said the results were from 360 subjects with pneumonia and 251 subjects with other diseases including asthma and upper respiratory infections or those without any clinically discernible respiratory symptoms, while patients with a known chronic respiratory disease were excluded.

Resapp chief executive officer Dr Tony Keating said that “delivering accurate results within an adult intended use population is an excellent step forward, further demonstrating that Resapp’s algorithms can be applied effectively in a group of patients with a very broad range of respiratory illnesses”.

“We now have a strong foundation from which we can pursue pivotal adult clinical studies in support of regulatory submissions,” Dr Keating said.

Resapp was up two cents or 28.2 percent to 9.1 cents with 58.9 million shares traded.

BOTANIX PHARAMCEUTICALS

Botanix says its 20-patient, phase Ib study of its topical cannabidiol BTX1503 for acne has completed enrolment with results expected by April 2018 (BD: Aug 21, 2017).

In July Botanix said its 20-patient phase Ia study showed “excellent safety and tolerability of BTX1503” with little to no skin irritation and no severe adverse events when used as a single dose either once or twice on day-1 followed by a washout period, then starting on day-8, either once or twice daily for 14 days (BD: Jul 3, 2017).

Today, Botanix executive director Matt Callahan said he expected to have the data available early in the March quarter of 2018 “with a view to demonstrating that BTX 1503 can be the first new product to treat acne in more than 20 years”.

The company said that following completion of the study, it planned to file an investigational new drug application to the US Food and Drug Administration by July 2018 to conduct a multicentre phase II safety and efficacy study for BTX1503.

Botanix was up 0.1 cents or 1.7 percent to six cents with 1.5 million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says its Santiago, Chile-based joint venture Dayacann has begun planting its second marijuana crop, following the grant of its cultivation licence (BD: Nov 22, 2017).

Auscann previously said that Dayacann was a 50 percent each joint venture with Fundacion Daya.

The company said that the crop was being planted at Dayacann’s 30-hectare facility south of Santiago, with a maximum of 435 plants to be planted, providing a range of cannabis strains to be extracted and processed into trial cannabinoid formulations for the treatment of chronic and neuropathic pain.

Auscann said that once processed into pain formulations the product could progress to clinical trials and registration with the Chilean National Institute of Public Health and once registered, Chilean legislation permits medications to be exported.

The company said that the crop was expected to be harvested by July 2018.

Auscann managing-director Elaine Darby said that first Chile crop harvested 400kg of dried cannabis in April.

“We have since selected the highest yielding strains from that crop and are now cultivating our second crop using these strains,” Ms Darby said.

“From these strains, it is our intention to develop final dose-form medicines for the treatment of chronic and neuropathic pain that will be supplied into the significant Latin American market,” Ms Darby said.

Auscann was unchanged at 68 cents.

CRESO PHARMA

Creso says it will acquire Kunna Canada and its wholly-owned Colombian subsidiary, Kunna SAS for up to \$US7.15 million (\$A9.34 million) in shares.

Creso said that the shares would be at a deemed issue price of \$1.10 each, with a further up to \$US1 million in performance shares and a \$US250,000 exclusivity option payment.

The company said it would be “the only Australian-listed medicinal cannabis company with direct exposure to the Colombian market, which is expected to be exporting more than 40.5 tonnes of medicinal cannabis oil by 2019”.

Creso said it intended to seek shareholder approval for the issue of the consideration shares and the issue of the performance shares would be subject to regulatory approval.

Creso fell half a cent or 0.6 percent to 82.5 cents with 2.5 million shares traded.

USCOM

Uscom says that Steven Meng has subscribed for \$1,755,000 in shares at 13.5 cents a share in the current capital raising (BD: Dec 15, 2017).

Uscom said that Mr Meng was a senior pharmaceutical company executive and private investor with investments across multiple sectors and countries and held qualifications in economics, engineering management and business administration.

The company said that Mr Meng's investment would give him 10.3 percent of the company as a cornerstone investor.

Uscom said that Mr Meng had 10 years' experience as a government departmental head from 1987 to 1997, and had 20 years' experience in China pharmaceutical and medical devices, continuing as the executive manager of an unnamed Chinese pharmaceutical company and had previously overseen a network of more than 3,000 distributors to more than 10,000 Chinese hospitals.

The company said that access to Mr Meng's distribution network would "enhance its drive into China".

Uscom said the funds would be used to manufacture devices to fill outstanding orders and to build stock of the new BP+ blood pressure diagnostic, complete global regulatory for all devices, and add clinical support and sales staff.

Uscom executive chairman Prof Rob Phillips said that "China is the driver of the world economy and Mr Meng's unique experience in Chinese ... management and corporate strategy are a perfect fit for Uscom as we ramp up our expanded sales and marketing activities in China".

The company said the capital raising was facilitated by Beijing's Sinonew Capital Advisory and the \$1,755,000 was part of the raising which would close at the end of business today, December 18, 2017, with the results to be released to the market tomorrow.

Uscom was in a trading a halt and last traded at 15 cents.

ELLEX MEDICAL LASERS

Investors Mutual has become a substantial shareholder in Ellex with the acquisition of 7,450,000 shares or 5.21 percent.

The initial substantial shareholder notice said that the Sydney-based Investors Mutual acquired 11,407,120 shares for \$2,292,417 or 20 cents a share and the registered holder of the shares was RBC Global Services Australia.

The company said it bought the shares between August 4 and December 14, 2017 with the single largest purchase 976,402 shares for \$1,025,222 or \$1.05 a share.

Ellex fell one cent or 1.05 percent to 94 cents.

IQ3

Active Immunity and Oceana Horizons director Spiro Sakaris says he has ceased his substantial holding in IQ3, selling 19,750,000 shares at 20 cents each.

Earlier this month, IQ3 said that then director Mr Sakaris had resigned from the board effective, but would continue as an executive (BD: Dec 5, 2017).

IQ3 was unchanged at 20 cents.

IQ3

Bioworx Capital director Anthony Tsigounis says he bought 19,750,000 shares (19.00%) in IQ3 for 20 cents each on December 15, 2017.

PHARMAUST

Pharmaust says it has appointed US veterinary cancer specialist Prof Barbara Kitchell to its veterinary advisory board.

Pharmaust said that Prof Kitchell was the Veterinary Centres of America director of residency training and a staff oncologist at the Veterinary Care Animal Hospital and Referral Centre in New Mexico.

The company said that previously, Prof Kitchell was Michigan State University Centre for Comparative Oncology professor and director and held academic and clinical positions in comparative oncology at Stanford University, University of Illinois and the University of California, Davis.

Pharmaust said that Prof Kitchell had led more than 27 clinical studies and the author of more than 100 scientific publications, abstracts, proceedings, book chapters and handbooks on veterinary and comparative oncology.

The company said that Prof Kitchell held a Doctor of Veterinary Medicine from the West Lafayette, Indiana-based Purdue University, a Diplomate of the American College of Veterinary Internal Medicine -Oncology and a Doctorate of Philosophy from the University of California, Davis.

Pharmaust was up 0.6 cents or 11.8 percent to 5.7 cents with 2.8 million shares traded.