

Biotech Daily

Monday October 8, 2018

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH EVEN: MEDICAL DEVELOPMENTS UP 12%;
 GENETIC SIGNATURES DOWN 10%
- * VICTORIA GOVERNMENT \$300k FOR BALLARAT R&D COLLABORATION
- * MEDICAL DEVELOPMENTS, DAIICHI SANKYO FOR PENTHROX IN CHINA
- * PATRYS \$50k FEDERAL GRANT FOR YALE BREAST CANCER STUDIES
- * VOLPARA PLEADS SCHULTZ. ANALYST REPORT TO ASX 27% QUERY
- * ANALYTICA APPOINTS UNNAMED PERICOACH MANUFACTURER FOR US
- * CRESO APPLIES FOR CANADA MARIJUANA LICENCE; \$2.7m LOAN
- * AUSBIL REDUCES TO 6.4% OF BIONOMICS
- * FIL BELOW 5% IN STARPHARMA
- * RESONANCE AGM FOR 21.5m 'EMPLOYEE' OPTIONS
- * IMUGENE LESLIE CHONG PAY RISE, OPTIONS; PAUL HOPPER OPTIONS

MARKET REPORT

The Australian stock market fell 1.38 percent on Monday October 8, 2018 with the ASX200 down 85.2 points to 6,100.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and four were untraded. All three Big Caps fell.

Medical Developments was the best, up 60 cents or 12.2 percent to \$5.50 with 255,177 shares traded. Compumedics, Ellex and Volpara climbed three percent or more; Airxpanders, Bionomics and ITL rose more than two percent; Mesoblast, Osprey and Polynovo were up more than one percent; with Cynata and Starpharma up by less than one percent.

Genetic Signatures led the falls, down 6.5 cents or 9.6 percent to 61 cents, with 165,090 shares traded. Paradigm and Prescient lost more than seven percent; Opthea fell 4.55 percent; Immutep was down 3.9 percent; Benitec, Dimerix, Oncosil, Orthocell and Pro Medicus shed more than two percent; Clinuvel, CSL, Nanosonics and Telix were down more than one percent; with Cochlear and Resmed down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it will provide \$300,300 for the Ballarat Innovation and Research Collaboration in Health (BIRCH) project.

A media release form Victoria's Minister for Regional Development Jaala Pulford said the project would be based at the St John of God Hospital and be a collaboration with Ballarat Health Services, Federation University and the four other universities operating in Ballarat, the Australian Catholic University, Deakin University, Notre Dame University and the University of Melbourne.

The media release said it would be "the first-time collaboration has occurred between two major hospitals and universities for health research in Ballarat".

The State Government said the Collaboration "aspires to have 300 researchers within a decade and [more than] 1,000 researchers working and living in the region within the next 20 years".

The Government said the Collaboration would "attract medical practitioners to the region and make it easier for medical graduates to settle in Ballarat and contribute to meeting Ballarat's future health and education workforce needs".

The media release said that the City of Ballarat and the Central Highlands Regional Partnership identified the Ballarat Innovation and Research Collaboration in Health as a key project "to create job opportunities for science, medical, allied health and nursing graduates and students".

Victoria Health Minister Jill Hennessy said that Ballarat had "some amazing medical research already taking place, and this project will bring this excellence together to achieve more and put Ballarat researchers in the spotlight".

The Government said it had invested \$461.6 million to rebuild and redevelop Ballarat Base Hospital and had increased operational funding by 10.2 percent over the last year, and the project was supported by its Regional Skills Fund.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has an exclusive distribution and licence agreement with Tokyo's Daiichi Sankyo Co for Penthrox in China, Thailand and Vietnam.

Medical Developments said that Daiichi Sankyo would pay up to \$US32.5 million (\$45.8 million), including \$US15 million (\$21.1 million) upfront and milestone payments based on sales of the inhaled methoxyflurane analgesic.

The company said it and Daiichi Sankyo would contract Japan clinical and regulatory service provider EPS International Holdings to have Penthrox approved in China. Medical Developments said it would fund the approval process to \$US10 million and would own the intellectual property generated from the program.

The company said it would own the drug import licence once Penthrox was approved. Medical Developments chief executive officer John Sharman said the company was "delighted to partner with Daiichi Sankyo, one of Japan's biggest pharmaceutical companies".

"Acute pain in trauma and minor surgical procedures is undertreated in the Chinese healthcare system," Mr Sharman said.

"Penthrox, with its fact acting, non-addictive, non-opioid characteristics will be an important tool for pain management in the Chinese, Vietnamese and Thai markets," Mr Sharman said.

Medical Developments was up 60 cents or 12.2 percent to \$5.50 with 255,177 shares traded.

PATRYS

Patrys says it has won a \$50,000 Federal Government grant for research with Yale University for proof-of-concept studies of PAT-DX1 for imaging breast cancer in rodents. Patrys said the Australian Academy of Technology and Engineering Global Connections Bridging Grant would be used for Yale University positron emission tomography (PET) scanning of rodent models.

The company said that the research would be led by the Newhaven, Connecticut-based Yale's Dr Bernadette Marquez Nostra and Dr Jiangbing Zhou would test PAT-DX1 as a PET imaging agent to detect metastatic triple negative breast cancer in animal models. The company said the work would couple its PAT-DX1 with zirconium-89 as an imaging companion to therapy based on PAT-DX1.

Patrys chief executive officer Dr James Campbell said the Yale laboratories previously showed that PAT-DX1 conjugated to nanoparticles "localizes at both primary tumors and metastases".

"This collaboration will enable us to track the distribution of PAT-DX1 in the body by linking it with a radionuclide and imaging the radio-labelled PAT-DX1 using PET to detect cancer cells," Dr Campbell said.

Patrys was unchanged at 3.8 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose 26.7 percent from 90 cents on October 1 to \$1.14 on October 5, 2018 and noted a significant increase in trading volume.

"We believe that the most likely reason for the share price/volume increase is a Buy alert from an analyst on the website Livewiremarkets.com," Volpara said.

Volpara was up 3.5 cents or three percent to \$1.215 with 1.2 million shares traded.

ANALYTICA

Analytica says it has a manufacturing agreement with an unnamed Australian contract manufacturer following withdrawal of US registration by its previous manufacturer. In March, Analytica said it would select a new US manufacturer for its Pericoach Pericoach intra-vaginal pelvic floor exercise training system for women with stress urinary incontinence after the previous manufacturer withdrew US Food and Drug Administration registration (BD: Mar 23, 2018).

The company said at that time that the Pericoach system was a class II medical device in the US which required a US quality system regulation compliant manufacturing facility. The company said it suspended supply of Pericoach in the US, until a new FDA-compliant manufacturer was registered but the decision did not affect supply outside the US. Today, Analytica said it had spent "several months" negotiating the agreement and the systems with the new manufacturer would provide flexibility in product and process changes and the supply chain.

The company said the new manufacturer was ISO13485 certified and US Quality System Regulation compliant, with experience in taking medical devices from concept to mass manufacture.

Analytica said it expected to re-register its establishments with the FDA and resume Pericoach supply by the end of 2018.

Analytica was unchanged at 0.6 cents.

CRESO PHARMA

Creso says Health Canada has accepted its subsidiary Mernova Medicinal's application for a cultivation licence.

Creso said that the application was "a major milestone" and if granted Mernova would hold "one of few licenses issued to local companies in Nova Scotia".

The company said terms had been agreed for a \$2.7 million construction loan from L1 Capital Global Opportunities Master Fund and the Canadian Special Opportunity Fund. Creso said the loan had a drawdown price of 90 percent of the face value and it would receive \$2.42 million to finalize the construction of Mernova's cannabis growing facility. The company said the loan had a 10.0 percent per annum interest rate, until June 28, 2019 and secured over the Mernova's assets.

Creso said it would pay 3.0 percent of any draw-down amount and issue the lenders 3,900,000 CPHO listed options, exercisable at 80 cents each by August 21, 2020.

The company said the lenders had the right to provide up to \$1 million in additional funds until March 21, 2019 and until June 28, 2019 Creso could redeem the outstanding amount on the loan for an additional fee 5.0 percent.

Creso said that if it raised capital while there was an outstanding amount under the loan, the lenders could require it to apply the funds raised to redeem the loan.

The company said it would repay the loan in cash in three instalments starting on February 10, 2019, with the first two instalments comprising 25 each of the face value plus interest, with the final instalment for the remaining outstanding value and interest.

Creso said that when the Health Canada licence was granted, Mernova would plant its first crop in the 2,200 square metre (24,000 square foot), indoor growing facility in Windsor, Nova Scotia, expected by the end of 2018.

The company said that when Mernova had grown two crops it would apply for a sale licence, the final stage to produce commercial cannabis crops, with first revenues expected by April, 2019.

Creso chief executive officer Dr Miri Halperin Wernli said the company was "close to achieving one of its major strategic objectives, to supply consistent, high-quality medicinal cannabis products to its global markets".

Dr Halperin Wernli said the facility had been constructed to good manufacturing practice standards "making it superior to other cultivation facilities ... [and] designed to produce three to four ton of dry cannabis annually".

Creso fell one cent or 1.8 percent to 54.5 cents.

BIONOMICS

Ausbil Investment Manager says it has reduced its substantial shareholding in Bionomics from 39,115,389 shares (8.108%) to 30,768,312 shares (6.372%).

The substantial shareholder notice said that the Sydney-based Ausbil bought and sold shares between March 6 and October 3, 2018, selling 12,851,643 shares for \$2,406,629 or 18.7 cents a share on October 2 and 3, 2018.

On October 2, the Bionomics share price fell up to 69.0 percent to 15.5 cents on the news that its 193-patient, phase II trial of anti-anxiety drug BNC210 in adults with post-traumatic stress disorder failed to meet its primary endpoint (BD: Oct 2, 2018).

In March, Ausbil increased its holding with the single largest acquisition 3,435,646 shares for \$1,335,092 or 38.86 cents a share (BD: Mar 6, 2018).

Ausbil said it was an investment manager for a number of institutional investors which were generally superannuation funds.

Bionomics was up half a cent or 2.6 percent to 19.5 cents with 3.0 million shares traded.

STARPHARMA

FIL Limited says it has reduced its substantial holding in Starpharma from 21,789,977 shares (5.88%) to below the five percent substantial level.

The Bermuda-based FIL said it sold 3,291,851 shares between September 12 and October 3, 2018 at prices ranging from \$1.46 to \$1.56 a share.

Biotech Daily calculates that FIL retains 18,498,126 shares or 4.98 percent of Starpharma. Starpharma was up one cent or 0.6 percent to \$1.59.

RESONANCE HEALTH

Resonance says shareholders will vote at the annual general meeting to ratify the prior issue of 21,500,000 options to unnamed "employees".

Resonance said that 21,000,000 employee options were issued in an Appendix 3B announcement on March 9, 2018, but did not disclose the recipients, with a further 500,000 employee options issued on September 13, 2018.

In March, the company said that the options were exercisable in tranches at 3.0 cents, 5.0 cents, 7.5 cents and 10.0 cents, by March 9, 2021, with the 500,000 options exercisable in two equal tranches at 5.0 cents and 7.5 cents by September 13, 2021.

Today, the company said the meeting would vote on the remuneration report, the reelection of chairman Dr Martin Blake and director Mitchell Wells and the 10 percent placement capacity.

Last year, prior to the meeting Resonance withdrew resolutions to adopt the option plan, issue 7,000,000 options to Dr Blake and directors Dr Travis Baroni and Simon Panton. At the meeting, both Mr Panton and Mr Baroni faced 24.0 percent opposition to their reelection with those votes amounting to 7.7 percent of the company, sufficient to requisition extraordinary general meetings. (BD: Nov 23, 2017).

The meeting will be held at the University of Western Australia Water Sports Complex, Hackett Drive, Crawley on November 8, 2018 at 10am (AWST).

Resonance was up 0.1 cents or 4.2 percent to 2.5 cents.

IMUGENE

Imugene says chief executive officer Leslie Chong will receive a 16.7 percent pay rise and 50,000,000 options with executive chairman Paul Hopper receiving 25,000,000 options. Imugene said that Ms Chong's base salary will increase to \$350,000 a year, her first pay rise since 2016, and she would be granted 50,000,000 options as a long-term incentive "vesting against defined performance criteria" with 10,000,000 options exercisable at four cents by June 30, 2021; 20,000,000 options exercisable at 4.2 cents by June 30, 2021; and 20,000,000 options exercisable at 4.5 cents by June 30, 2021 (BD: Nov 21, 2016). The company said that executive chairman Paul Hopper would continue on \$137,400 a year following a reduction from \$US200,000 in 2016, with a non-recurring cash short term incentive up-to \$25,000 including superannuation or excluding GST (where applicable) pending milestones, along with long term incentives of 25,000,000 options vesting over 24 months with 5,000,000 options exercisable at four cents by June 30, 2021; 10,000,000 options exercisable at 4.2 cents by June 30, 2021; and 10,000,000 options exercisable at 4.5 cents by June 30, 2021.

Imagene was unchanged at 2.2 cents with 3.5 million shares traded.

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