



Biotech Daily

Monday March 14, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PRANA UP 10%, PSIVIDA DOWN 5%**
- * **UK NHS 2-YEAR USCOM BP+ SUPPLY CONTRACT**
- * **RECCE-327 ANTIBIOTIC ACTIVE AGAINST 7 CANCERS IN-VITRO**
- * **ATCOR RECEIVES \$462k FEDERAL R&D TAX REFUND**
- * **RESAPP TO TAKE 'DE NOVO' FDA ROUTE, PIVOTAL TRIAL**
- * **AUSTRALIAN ETHICAL TAKES MORE ELLEX PROFIT TO 10%**
- * **JCP TAKES 8% OF NANOSONICS**
- * **GI DYNAMICS REQUESTS ENDO TRIAL TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.37 percent on Monday March 14, 2016 with the ASX200 up 19.1 points to 5,185.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and four were untraded.

Prana was the best, up 0.7 cents or 10.3 percent to 7.5 cents with 16,000 shares traded.

Acrux and Avita climbed more than four percent; Admedus was up 3.8 percent; Living Cell, Pro Medicus and Tissue Therapies rose more than two percent; with Impedimed, Medical Developments, Mesoblast and Osprey up more than one percent.

Psivida led the falls, down 21 cents or 5.2 percent to \$3.85 with 500 shares traded.

Actinogen, Cellmid, Compumedics and Prima fell four percent or more; Anteo and Oncosil were down more than three percent; Cochlear, Nanosonics and Opthea shed more than two percent; Ellex, Orthocell Polynovo, Sirtex, Universal Biosensors and Viralytics were down more than one percent; with Resmed down 0.25 percent.

USCOM

Uscom says the UK National Health service has awarded distributor, Medimax Global a two year contract to supply the BP+ central blood pressure diagnostics.

Uscom said the contract to supply the NHS from June 1, 2016, included a further two-year option.

The company said that following a review of central blood pressure devices, contracts were awarded for the Uscom BP+ and the Welch Allyn 7100BP.

Uscom said that central blood pressure and pulse wave analysis was "the new frontier in [blood pressure] monitoring".

The company said that its Uscom BP+ was validated in children from one year to 18 years of age at the Great Ormond Street Hospital for Children, with results presented last month at the US Society for Critical Care Medicine in Orlando, Florida, showing that the BP+ non-invasively provided equivalent results to cardiac catheters in children.

"This proof of effectiveness sets the BP+ device apart from its competitors and confirms the integrity of the science underlying the device and confirms its application in critical care and as a guide for advanced treatment of hypertension," Uscom said.

The company said the BP+ was used as a physiologic monitor on the International Space Station and its inclusion as the preferred technology in an international hypertension drug trial currently being run by an unnamed European pharmaceutical company.

Uscom executive chairman Prof Rob Phillips said the contract would facilitate sales into more than 1000 UK hospital trusts and into general practitioner practices and was "the foundation for the European marketing of the BP+".

Uscom was untraded at 16.5 cents.

RECCE

Recce says that its Recce-327 antibiotic has demonstrated in-vitro anti-cancer activity against seven human cancer cell lines of cancers

Recce said that the anti-biotic was trialled on cell lines for leukaemia, stomach, intestine, breast, prostate and kidney cancer and melanoma conducted by an independent US laboratory.

The company said it had lodged a provisional patent application to protect its rights over the information from the findings.

Recce said that concentrations of the antibiotic did not cause toxicity in normal human epithelial cells or Vero cells derived from African green monkey kidney epithelial cells.

The company said that "at any time, this finding would be considered to be of great potential medical importance and even more so in this case, because antibiotic activity and anti-cancer activity are found in the same product".

Recce said that inflammation from prolonged bacterial activity was increasingly being associated with the propensity for cancer.

The company said that infection by *Helicobacter pylori* bacteria was "strongly associated with inflammation and the subsequent development of cancer in the stomach and duodenum of the upper intestines of humans".

Recce executive chairman Dr Graham Melrose said that "exciting as this finding is, it is cautioned that much work remains to confirm any relevance of these findings to the possibility of developing a commercial medical product".

"This development is part of Recce's current priority assessment of the range of potential markets which may be accessible through its patented polymer technology," Dr Melrose said.

Recce was up four cents or 16.7 percent to 28 cents.

ATCOR MEDICAL

Atcor says it has received \$461,916 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Atcor chief financial officer Peter Manley told Biotech Daily that the payment related to research and development expenditure in the year to June 30, 2015.

Atcor was unchanged at 18 cents.

RESAPP HEALTH

Resapp says that it will pursue a "direct de novo premarket submission" in the US for its respiratory disease diagnostic, initially for paediatric use.

Resapp said that during a pre-submission meeting with the US Food and Drug Administration it received targeted feedback regarding the proposed US regulatory pathway, clinical study protocols, planned non-clinical evaluations and data requirements for its mobile telephone software application, the Resappdx.

The company said that a submission for adult use would be prepared in parallel to be submitted shortly after the paediatric submission.

Resapp said that the de novo pathway was designed for innovative medical devices, with no predicate device, where controls provided a reasonable assurance of safety and effectiveness.

The company said that the de novo process led to a class I or class II classification and had a 120-day review cycle, compared to a 90-day review period for a 510(k) application for equivalence to an existing device or diagnostic.

Resapp said that it would perform pivotal clinical studies at one or more US hospitals to provide a key portion of the clinical data required to support both paediatric and adult submissions, with the balance of the required data to be gathered from pivotal studies at previously established Australian sites.

Resapp chief executive officer Dr Tony Keating said that the pre-submission meeting "was very productive and we were encouraged by the high level of engagement exhibited by the FDA team".

"We have obtained the clarity required to optimise our clinical and regulatory pathway and we are on track to reach our announced regulatory milestones," Dr Keating said.

Resapp fell one cent or 3.7 percent to 26 cents with 23.3 million shares traded.

ELLEX MEDICAL LASERS

Australian Ethical Smaller Companies Trust says it has again reduced its holding in Ellex from 12,005,022 shares (11.15%) to 10,798,902 shares (10.03%).

Australian Ethical became substantial in Ellex in 2013, acquiring 8,794,563 shares or 9.01 percent with 5,000,000 shares believed to be acquired in a capital raising at 26 cents a share (BD: Oct 3, 2013).

In October 2013, Australian Ethical increased its holding to 10.06 percent with the acquisition of 1,033,834 shares at 29.7 cents a share and in 2014 increased again to 13,151,270 shares or 12.2 percent at 30 cents a share (BD: Nov 1, 2013).

The investment group first reduced its holding on January 11, 2016, from 13,151,270 shares (12.21%) to 12,005,022 shares (11.15%), but failed to disclose the value of the 1,146,248 shares (BD: Jan 25, 2016), but Ellex was trading about 75 cents at that time.

Today, Australian Ethical said it sold 1,206,120 shares between January 11 and March 9, 2016 but the transaction values did not accord with recent prices.

Ellex fell 1.5 cents or 1.9 percent to 77.5 cents.

[NANOSONICS](#)

The Melbourne-based JCP Investment Partners says it has increased its substantial holding in Nanosonics from 20,820,304 shares (7.34%) to 23,775,753 shares (8.38%). JCP said that it bought the shares between February 24 and March 10, 2016 with the single largest purchase 1,250,000 shares for \$2,696,305 or \$2.16 a share. Nanosonics fell five cents or 2.4 percent to \$2.04 with 498,586 shares traded.

[GI DYNAMICS](#)

GI Dynamics has requested a trading halt “pending the release of an announcement regarding [its] Endo trial”.

Trading will resume on March 16, 2016 or on an earlier announcement.

GI Dynamics last traded at two cents.