



# Biotech Daily

Tuesday May 20, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: COMPUMEDICS UP 10%, ONCOSIL DOWN 9%**
- \* **COMPUMEDICS SELLS \$295k DOPPLER BOX X TO BRAZIL**
- \* **RESONANCE FERRISCAN DEAL WITH FLORIDA HOSPITAL**
- \* **ANALYTICA COMPLETES \$3m RAISING**
- \* **CORRECTION: AGENIX**
- \* **QRX SLIDES CRITICISE MOXDUO TRIAL DESIGN**
- \* **FISHER FUNDS REDUCE TO 6% OF UNIVERSAL BIOSENSORS**
- \* **FIL TAKES 7% OF CLINUVEL**
- \* **SIETSMA TAKES 6% OF PHYLOGICA**
- \* **AVITA APPOINTS LOU PANACCIO CHAIRMAN**

## MARKET REPORT

The Australian stock market was up 0.21 percent on Tuesday May 20, 2014 with the S&P ASX 200 up 11.4 points to 5,420.4 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and four were untraded.

Compumedics was the best, up one cent or 10 percent to 11 cents with 29,000 shares traded.

Benitec and Prima climbed more than six percent; Admedus and Psivida were up more than four percent; Circadian, Clinuvel and Neuren rose more than two percent; Mesoblast was up 1.3 percent; with Medical Developments and Resmed up by less than one percent.

Oncosil led the falls, down one cent or 9.1 percent to 10 cents with 703,685 shares traded.

Atcor and Universal Biosensors lost more than eight percent; Acrux and Phosphagenics fell more than six percent; Biotron, Pharmaxis and Prana were down more than five percent; Analytica, Cellmid and Optiscan fell four percent or more; Impedimed shed 2.4 percent; Alchemia and Sirtex were down more than one percent; with CSL, Nanosonics, Osprey and Starpharma down by less than one percent.

## COMPUMEDICS

Compumedics says its German division has secured a EUR200,000 (\$A294,551) deal to supply its Doppler-Box X technology to 10 stroke centers across Brazil.

Compumedics said that the Doppler Box was its main trans-cranial Doppler device used to monitor blood flow through the brain using ultrasound to look for blockages in the brain following a stroke, to assist medical staff identify where the blockage was and determine how to remove it.

Compumedics' executive chairman Dr David Burton said his company's German division "continues to expand its presence in global markets and winning this deal provides an excellent opportunity for Compumedics to build our presence in Brazil and Latin America". Compumedics Germany managing director Christoph Witte said the contract was "an important achievement".

"It follows the EUR400K agreement that we secured in Brazil in 2012 and confirms our strong position in the country as well as our winning strategy for the Latin American market," Mr Witte said.

Compumedics was up one cent or 10 percent to 11 cents.

## RESONANCE HEALTH

Resonance says it has signed a Ferriscan contract with a university hospital in Florida, which has a high population of patients with sickle cell disease, many with iron overload.

Resonance said that since the beginning of 2104 it has signed contracts with new customers in South Carolina, Germany, the UK, Tunisia and Australia, with 21 new radiology facilities set up for Ferriscan imaging.

The company said the expansion was the result of new contracts with hospitals, the expanding use of Ferriscan in clinical trials of iron overload and the establishment of additional Ferriscan facilities participating in programs funded by third party pharmaceutical companies to assist patients on iron chelation therapy.

Resonance said it had an established network to introduce the Hepafat-Scan product and had positive feedback from a number of clinicians who see value in the role of Hepafat-Scan in the management of their patients.

The company said that its immediate focus was on clinical trials for drugs under development to address fatty liver disease.

Resonance said it expected the immediate use of Hepafat-Scan will be in a clinical trial in Australia and then the US.

Resonance was unchanged at 4.9 cents.

## ANALYTICA

Analytica says it has completed its \$3 million capital raising with applications for \$831,060 in shares in its underwritten one-for-15, \$1.2 million entitlement offer at 2.4 cents a share.

Analytica said the shortfall of \$368,940 would be placed by underwriter Patersons Securities of which \$250,000 would be taken up by priority sub-underwriter and company chairman Dr Michael Monsour.

Last month, the company raised \$1.8 million in a placement (BD: Apr 22, 2014).

Analytica fell 0.2 cents or 4.65 percent to 4.1 cents with 11.4 million shares traded.

## AGENIX

Last night's edition carried a headline wrongly identifying "Conkate" as the buyer of Agenix AGX-1009 hepatitis B China.

The company is Cinkate Pharmaceutical Intermediates Co.

The sub-editor has influenza and no Relenza. He's suffering enough so no punitive action will be taken in this circumstance.

Agenix was unchanged at 1.4 cents.

## QRX PHARMA

QRX has released a 48-slide presentation entitled 'Moxduo Status Overview May 2014' which focuses on its previous regulatory approach and oxygen desaturation.

Last month, the US Food and Drug Administration Anesthetic and Analgesic Drug Products Advisory Committee voted 14 to nil against approval of QRX's Moxduo dual opioid, the third knock-back for the company (BD: Aug 28, Nov 26, 2013; Apr 23, 2014).

Yesterday, QRX said that time to first oxygen desaturation was markedly in favor of its Moxduo dual opioid combination of 12mg morphine and 8mg oxycodone than equi-analgesic doses of 24mg morphine or 16mg oxycodone.

The presentation said that much of the problem with the FDA advisory committee was in its "post-hoc analysis" and said the analysis did not allow for "p" significance values.

In 2011 when it announced the results of its phase III comparison trial, QRX said that Moxduo had a mixed superior safety profile to equi-analgesic doses of either morphine or oxycodone alone (BD: Jun 14, 2011).

QRX said at that time that Moxduo was superior to oxycodone for blood oxygen desaturation but not significantly so for morphine.

QRX said Moxduo was significantly superior to oxycodone for moderate to severe vomiting but was comparable for morphine for vomiting.

QRX said in 2011 that respiratory depression as measured by oxygen desaturation was less severe and of shorter duration in patients receiving Moxduo compared to those receiving either 24mg morphine or 16mg oxycodone alone.

QRX said blood oxygen was measures through pulse oximetry (SpO2) and oxygen desaturation SpO2 of less than 90 percent over time was used to assess the severity and duration of respiratory impairment indicating that Moxduo has a significantly better safety profile than oxycodone ( $p < 0.02$ ).

The company said morphine and Moxduo had comparable rates of moderate to severe vomiting and that the overall incidence of nausea trended lower in the Moxduo treated subjects than oxycodone and morphine, but the differences were not significant.

Yesterday's presentation said that the company could need up to \$US53 million (\$A57 million) to run two new phase III trials which would take about two years to be completed and receive an FDA Prescription Drug User Fee Act date.

QRX said that it proposed to begin trials in patients at higher risk of opioid induced respiratory depression namely older patients, heavier patients and smokers.

The company said that among "lessons learned" were that it "expected too much from FDA management" and "ongoing protestations regarding FDA rules [and] processes can be unhelpful".

QRX said that the Study 022 was not designed for desaturation as its primary endpoint and did not meet strict statistical criteria.

In 2011, QRX said the Study 022 primary endpoint was respiratory depression as measured by oxygen desaturation.

QRX fell 0.6 cents or 6.4 percent to 8.8 cents.

### UNIVERSAL BIOSENSORS

New Zealand's Fisher Funds says it has reduced its substantial shareholder in Universal Biosensors from 13,010,390 shares (7.45%) to 11,014,077 shares (6.27%).

Fisher Funds said that from it acquired shares from August 22, until September 24, 2013 and sold shares between May 13 and May 19, 2014, the day of the largest sales of 874,097 shares for \$146,261 or 16.7 cents a share.

In its previous substantial shareholder notice Fisher Funds acquired 3,066,457 shares for \$2,356,049 or an average price of 76.8 cents a share (BD: Jun 26, 2013).

Universal Biosensors fell 1.5 cents or 8.3 percent to 16.5 cents with 1.6 million shares traded.

### CLINUVEL

The Singapore-based FIL Limited, formerly Fidelity Investments, says it has become a substantial shareholder in Clinuvel with 2,788,449 shares (6.58%).

FIL said it acquired 2,752,710 shares on May 16, 2014 with most bought for \$1.66 a share.

Clinuvel was up three cents or 2.1 percent to \$1.45.

### PHYLOGICA

The Sydney-based Sietsma Holdings says it has become a substantial shareholder in Phylogica with the acquisition of 62,000,000 shares (6.19%).

Sietsma said it acquired the shares between January and May 2014 for \$1,235,000 or an average price of two cents a share.

Phylogica fell 0.1 cents or 6.7 percent to 1.4 cents with 11.7 million shares traded.

### AVITA MEDICAL

Avita says it will appoint Lou Panaccio as its chairman, replacing interim chairman Ian Macpherson, effective from July 1, 2014.

An assistant to Mr Macpherson said he would continue as a director of Avita.

Avita said that Mr Panaccio had more than 30 years executive leadership experience in healthcare services and life sciences, including approximately 15 years board-level experience.

The company said that Mr Panaccio would oversee the further development and accelerated commercialization of the Recell technology

Avita said that Mr Panaccio was currently a director of Sonic Healthcare and executive chairman of Genera Biosystems as well as the executive chairman of Health Networks Australia Group, a director of Yarra Community Housing and a director of Inner East Community Health Service.

The company said that Mr Panaccio was formerly the chief executive officer and an executive director of Melbourne Pathology for 10 years to 2001.

Avita was unchanged at 11 cents.