



Biotech Daily

Wednesday December 11, 2013

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ANTEO UP 7%; PHARMAXIS DOWN 16%**
- * **MOST PATIENTS ENROL IN PRANA PBT2 ALZHEIMER'S EXTENSION TRIAL**
- * **CORRECTION: ANTISENSE**
- * **CELLMID RAISES \$2m**
- * **FDA SETS MAY 2014 QRX PDUFA DATE**
- * **AVEXA: 'ALABAMA COAL REVENUE FOR ATC BY OCTOBER 2014'**
- * **AVITA LOSES CHAIR DALTON GOODING, CEO DR BILL DOLPHIN**

MARKET REPORT

The Australian stock market fell 0.8 percent on Wednesday December 11, 2013 with the S&P ASX 200 down 39.4 points to 5,104.2 points.

Seven of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and six were untraded. All three Big Caps fell.

Anteo was the best, up one cent or 6.9 percent to 15.5 cents with 4.7 million shares traded.

Yesterday's best, Pharmaxis, led the falls, down two cents or 16 percent to 10.5 cents with 3.6 million shares traded.

Due to circumstance beyond our control a detailed market report was not available tonight.

PRANA BIOTECHNOLOGY

Prana says that 33 of the 40 patients who completed dosing in its phase II imaging trial of PBT2 for Alzheimer's disease have enrolled in the open-label extension trial.

On Monday, Prana said that treatment had been completed in the phase II 'Imagine' trial with 40 of the 42 enrolled patients completing treatment (BD: Dec 9, 2013).

Today, the company said that 33 patients had chosen to continue into the extension trial, which was approved by Melbourne's Austin Health Human Research Ethics Committee in July (BD: Jul 3, 2013).

Prana said that all extension patients would receive a once daily dose of 250mg of PBT2. The company said that the Austin approval followed a full review of the potential benefit to patients and safety data collected during the trial.

Prana said that all patients in the phase II trial were given the opportunity to participate in the extension trial, which required consent to receive PBT2 for 12 months following the end of the Imagine trial, as well as undergoing further brain scans, blood tests and cognitive testing.

The company said that the independent data safety monitoring board had reviewed the available safety data from the extension trial and recommended the study proceed without change to the original protocol.

Prana fell 3.5 cents or 5.1 percent to 65.5 cents.

ANTISENSE THERAPEUTICS

Last night's market report headline incorrectly said Antisense fell by 12 percent.

Yesterday the company lost one cent or 5.9 percent to 16 cents with 122,550 shares traded.

The mistake was made by the sub-editor who showed no sense and has been summarily dismissed.

Biotech Daily apologizes for the mistake unreservedly.

Antisense was unchanged at 16 cents.

CELLMID

Cellmid says it has raised \$2 million through the placement of 66,666,666 shares at three cents a share to sophisticated and professional investors.

Cellmid said the placement price was a 14.2 percent discount to the 10-day volume weighted average price prior to the offer.

The company said that the funds were for to begin investigational new drug-enabling studies and preparation for a therapeutic antibody program to become clinical trial ready.

Cellmid fell 0.2 cents or 6.1 percent to 3.1 cents with 5.1 million shares traded.

QRX PHARMA

QRX says that the US Food and Drug Administration has set May 25, 2014 as the new Prescription Drug User Fee Act (PDUFA) date its dual opioid Moxduo application.

QRX said it had refiled its new drug application for the immediate release Moxduo and the FDA would schedule an advisory committee meeting prior to the PDUFA date and assuming approval the company planned to launch Moxduo in the US after June 2014.

QRX chief executive officer Dr John Holaday said that "as May 25, 2014 falls on a Sunday the FDA will most likely issue the action letter on the preceding Friday being May 23".

QRX fell two cents or 3.2 percent to 61 cents.

AVEXA

Avexa says it expects Alabama coal mine revenues to fund its apricitabine for HIV program by October 2014.

Last year, Avexa announced it would invest \$US10 million in the coal mine and hold 25.5 percent of the coal mine with 17 percent Avexa shareholder Jonathan Lim holding a separate 25.5 percent of the mine (BD: Nov 5, 2012).

A 2012 annual general meeting resolution to approve the coal mining proposal passed with 53.5 percent of the vote in favor and 46.5 percent against (BD: Dec 14, 2013).

Today the company said it had executed the documents formalizing its 30 percent capital investment in the North Pratt coal project and its investment was reduced to \$US8 million (\$A8.76 million) from the previous \$US10 million.

Avexa chairman Iain Kirkwood said that the mine was “a good solid investment”.

The company said work was underway at the North Pratt, Alabama coal mine site and revenue expected by October 2014 would “fund the final clinical development of apricitabine, our late stage drug candidate for drug-resistant-HIV, prior to seeking marketing approval”.

Avexa was unchanged at 1.5 cents.

AVITA MEDICAL

Avita says that chief executive officer Dr William Dolphin will leave the company and chairman Dalton Gooding will step down but remain a director, effective immediately.

Avita said that chief operating officer and chief financial officer Timothy Rooney would be interim chief executive officer until June 30, 2014, on a gross remuneration of \$US250,000 a year with a bonus entitlement of up to 35 percent of salary.

The company said that Dr Dolphin would provide consultancy services until June 30, 2014 to ensure a smooth transition.

Avita said that Ian Macpherson had been appointed interim chairman and Dr Dolphin had served the company during a pivotal time when significant clinical trials had been established and crucial relationships formed with key industry stakeholders”.

Avita said Mr Rooney joined the company in October 2012 and had more than 25 years’ experience in financial and operational roles.

The company said that Mr Rooney had a Bachelor of Science in business administration from California State University, Northridge.

Avita said that an executive recruitment firm had been engaged to identify suitable candidates.

The company said that it had begun a review of its remuneration policy following feedback from shareholders that change was needed.

Avita fell 0.3 cents or 3.2 percent to nine cents.