Biotech Daily

Monday August 20, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ALLIED HEALTH UP 17%, CIRCADIAN DOWN 6%**

*** QRX SAYS MORE EXISTING MOXDUO DATA COULD CONVINCE US FDA**

*** USCOM RAISES $696k, HOPES FOR MORE**

*** EASTLAND COMPLETES ARTIMIST TRIAL DOSING**

*** FISHER FUNDS TAKE 5% OF NANOSONICS**

*** CHAIRMAN ANGUS HOLT'S GRALAW DOUBLES TO 10% OF OPTISCAN**

*** BIOTA EAST COAST SHAREHOLDER BRIEFINGS**

MARKET REPORT

The Australian stock market slipped 0.13 percent on Monday August 20, 2012 with the S&P ASX 200 down 5.8 points to 4,364.3 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and six were untraded. All three Big Caps were up.

Allied Health was the best, up 0.3 cents or 16.7 percent to 2.1 cents with 1.9 million shares traded, followed by Bionomics up 12.7 percent to 31 cents with 705,700 shares traded.

Neuren, Pharmaxis and Phylogica climbed more than four percent; Nanosonics and Phosphagenics were up more than three percent; Cochlear, CSL and Optiscan rose more than two percent; Anteo, Mesoblast, QRX, Resmed and Viralytics were up more than one percent; with Alchemia, Acrux and Sirtex up by less than one percent.

Circadian led the falls, down 2.5 cents or 6.3 percent to 37 cents with 42,543 shares traded.

Antisense, Cellmid and Sunshine Heart all lost 5.6 percent; Patrys fell 4.35 percent; Uscom was down 3.3 percent; Impedimed and Tissue Therapies shed more than two percent; Reva was down 1.8 percent; with Clinuvel and Starpharma down by less than one percent.

QRXPHARMA

QRX says the US Food and Drug Administration has requested more data for its Moxduo new drug application including further analysis of trials already completed.

QRX said that the FDA requested more information from its Study 022 which was not part of the package originally sent with the application.

The FDA formally accepted the application in November 2011 and the headline data from the study, showing mixed results when equi-analgesic doses were compared, was published in June 2011 (BD: Jun 14, 29; Nov 8, 2011).

QRX said that Study 022 evaluated oxygen desaturation levels in patients receiving Moxduo compared to those on morphine or oxycodone alone at equi-analgesic doses.

QRX said it was surprised to receive a complete response letter from the FDA rejecting its Moxduo application as the company said it believed it only had to show equivalence to the existing component parts, morphine and oxycodone (BD: Jun 27, 2012).

The company has maintained that the two-to-three ratio of morphine and oxycodone in Moxduo provided either increased analgesia with comparable side-effects or equal analgesia with reduced side-effects, especially nausea, vomiting and respiratory depression, when compared to the component drugs.

The equi-analgesic dose study provided mixed results when Moxduo (12mg morphine and 8mg oxycodone) was compared to either 24mg morphine or 16mg oxycodone alone (BD: Jun 14, 2012).

Moxduo was significantly superior to oxycodone on a measure of blood oxygen saturation as well as occurrence of nausea and vomiting.

While the company said there was trend in favor of Moxduo over morphine on oxygen saturation, it was not significant and that morphine and Moxduo had comparable rates of moderate to severe vomiting.

Today, QRX chief executive officer Dr John Holaday said the FDA confirmed the earlier combination rule study, Study 008, “satisfied efficacy requirements and there were no unexpected or problematic safety issues in any of the studies submitted as part of the Moxduo [application].

“Additionally, at the FDA’s invitation, we agreed to submit more extensive information on Study 022 and believe the results of this study provide further safety data to support approval of Moxduo,” Dr Holaday said.

QRX said that the analysis of Study 022 was completed after the Moxduo filing in August 2011, although early safety data was included in the 120-day update filed last December.

The company said that additional efficacy and safety information from this study was of significant interest to the FDA and it was preparing an additional data package for review and was considering “further strategies to optimally manage the regulatory process”.

The company said that the review of additional data and subsequent re-filing of the application could result in a positive decision from the FDA by mid-2013.

QRX was up one cent or 1.4 percent to 71 cents.

USCOM

Uscom has raised $696,000 through the placement of 5.8 million shares at 12 cents each.

Uscom executive chairman Rob Phillips told Biotech Daily that he had raised the funds without the support of a broker, manager or adviser and hoped to raise further funds by August 24, 2012.

Mr Phillips said that along with a Federal Government research and development tax credit the company would have funds for nine to 12 months of operations.

Uscom fell half a cent or 3.3 percent to 14.5 cents.

EASTLAND MEDICAL SYSTEMS

Eastland says its trial of sublingual Artimist for paediatric malaria has completed recruitment and dosing.

Eastland said the 150-patient, phase III, randomized, open-label, controlled, multi-centre, trial compared Artimist (sublingual artemether) to intravenous quinine in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications."

The company said patients would be monitored for 28 days, when pharmacodynamics studies, biochemistry and parasitology and other data evaluations would be completed.

Eastland said that the results would be forwarded to bio-statisticians for analysis and a medical writer for compilation into the final clinical report, expected by the end of 2012.

The company said that the manufacturing program in Canada was on time and budget and an article in The Lancet examining trends in malaria mortality showed that malaria in 2010 was the cause of death for 1.2 million individuals, including 714,000 deaths in children younger than five years and 524,000 in individuals aged five years or older, almost twice the number that the World Health Organisation had estimated.

Eastland was up 0.2 cents or 9.1 percent to 2.4 cents with two million shares traded.

NANOSONICS

Fisher Funds Management and associates have become substantial shareholders in Nanosonics with the acquisition of 13,350,565 shares or 5.12 percent.

The initial substantial shareholder notice said Fisher Funds most recent acquisitions between May 4 and August 17, 2012 totalled 1,839,340 shares for $953,066 or an average price of 51.8 cents.

Nanosonics was up 1.5 cents or 3.1 percent to 50 cents.

OPTISCAN

Gralaw Pty Ltd has increased its substantial share-holding in Optiscan from 6,689,000 shares (5.16%) to 13,883,729 shares (9.54%).

The Gralaw substantial shareholder said that executive chairman Angus Holt had a direct interest and an indirect interest in the shares as a director of Gralaw, Carlisle Lavelle Pty Ltd and the Kwnauro Pty Ltd self-managed superannuation fund.

Optiscan was up 0.2 cents or 2.35 percent to 8.7 cents.

BIOTA HOLDINGS

Biota says chief executive officer Peter Cook and chief financial officer Damian Lismore will hold briefings for shareholders and other interested parties next week.

Biota said the briefings on finances, programs and proposed US listing would begin at 11am and run for about one hour at The Marra Conference Room, Level 2, The Grace Hotel, 77 York Street Sydney on August 28; RBS Morgans, Level 29, 123 Eagle Street, Brisbane on August 29; and Room 1, Lower Ground Floor, Rialto Hotel, 495 Collins Street, Melbourne on August 30, 2102.

Biota was unchanged at 67.5 cents.