Biotech Daily

Friday October 25, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ALLIED HEALTH UP 30%, ATCOR DOWN 12%**

*** BIOTRON BIT-225 REDUCES G-3 HEP C IN HIV CO-INFECTED PATIENTS**

*** JAPAN APPROVES CYCLOPHARM TECHNEGASPLUS FOR CLINICAL USE**

*** TISSUE THERAPIES FILES FOR PIVOTAL US VITROGRO TRIAL**

*** ATCOR SPHYGMOCOR MEXICO APPROVAL NOT COMPLETE**

*** VIRAX RAISING $2.5m, PREPARING TO RESURFACE ON ASX**

*** MINDEROO (METAL) GROUP TAKES 18% OF ALLIED HEALTH**

*** WATERMARK, AUSTRALIAN LEADERS, BRAITLING BELOW 5% OF MAYNE**

*** KINETIC TAKES 6% OF OSPREY**

*** BELGRAVIA, GEOFFREY LORD INCREASES, DILUTED TO 9% OF IDT**

MARKET REPORT

The Australian stock market was up 0.25 percent on Friday October 25, 2013 with the S&P ASX 200 up 13.4 points to 5,386.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and two were untraded.

Allied Health was the best, up 3.5 cents or 30.4 percent to 15 cents with 46 million shares traded.

Benitec climbed 9.9 percent; Antisense and Reva were up more than eight percent; Living Cell was up 7.2 percent; Anteo, Optiscan and Psivida climbed five percent or more; Impedimed, Medical Developments and Starpharma rose more than two percent; GI Dynamics and Osprey were up more than one percent; with Acrux up 0.7 percent.

Atcor led the falls, down two cents or 11.8 percent to 15 cents with 2.7 million shares traded.

Circadian and Resmed lost more than eight percent, the latter despite posting record September quarter results; Phosphagenics fell 6.45 percent; Phylogica and QRX were down five percent or more; Avita fell 4.35 percent; Genetic Technologies and Patrys were down more than three percent; Bionomics, Ellex, Mesoblast, Tissue Therapies and Universal Biosensors were down more than one percent; with Cochlear, CSL and Sirtex down more than one percent.

BIOTRON

Biotron says that BIT-225 with interferon and ribavirin has reduced hepatitis C virus levels “below detectable” in six co-infected HIV and genotype 3 hepatitis C patients.

Biotron said that the 12-patient, phase II, open-label pilot study of BIT225 in patients co-infected with hepatitis C virus and HIV conducted at the Siriraj Hospital in Bangkok, Thailand, enrolled four patients with hepatitis C genotype 1a and eight patients with genotype 3, two of which discontinued.

The company said that all patients received interferon and ribavirin for seven days before commencing treatment with 300mg BIT225 twice daily, plus interferon and ribavirin for 28 days, followed by interferon and ribavirin for a total of 48 weeks.

Biotron said that all patients had undetectable levels of HIV at the time of enrolment into the study and continued to take anti-retroviral drugs throughout the study.

The company said that an interim analysis of virus levels in the treated patients indicated that all six genotype 3 subjects who completed 28 days of BIT225 therapy had undetectable levels of hepatitis C virus 12 weeks into the study.

Biotron said that the response to treatment at this time point was “generally a good indication of final outcome at 48 weeks”.

The company said that the detailed data would be presented in a late-breaking poster at the American Association for the Study of Liver Diseases conference in Washington DC, in early November.

Biotron managing director Dr Michelle Miller said that the genotype 3 data from this trial was “particularly encouraging”.

“The other new classes of direct-acting antiviral drugs in development are not very effective in these patients, with response rates as low as 37 percent after 12 weeks of treatment,” Dr Miller said.

“In contrast, we saw 100 percent response at 12 weeks, with only four weeks of treatment with BIT225,” Dr Miller said.

Biotron said it was the first trial of BIT225 in HIV and hepatitis C co-infected patients, who tended to more serious hepatitis C infection and had lower response rates to treatment with interferon and ribavirin than hepatitis C mono-infected patients.

“The added benefit of BIT225 in these hard-to-treat patients appears clear from the overall response rates,” Dr Miler said. “In addition, there was a marked improvement in the rate of virus eradication after commencing BIT225 treatment.”

Biotron said that the current approved treatment for co-infected patients was interferon and ribavirin but it was associated with a high rate of side effects and up to 50 percent of patients did not respond to treatment.

The company said that the lack of response was linked to a particular genetic form of the IL28B gene, in particular in patients infected with genotype 1.

Biotron said that two of the genotype 1-infected patients did not respond to treatment, which was “likely due to their specific IL28B genes which affected their ability to respond to [interferon and ribavirin]”.

The company said that the latest data of BIT225 activity against genotype 3 extended the drug’s data portfolio of anti-hepatitis C activity, with previous trials showing the drug had good activity against the hard-to- treat genotype 1 variant of the virus.

Biotron said that BIT225 targetted the HCV viral protein p7, which had crucial roles in virus replication and reproduction.

The company said that BIT225 was also in development for treatment of HIV, with demonstrated clinical efficacy against HIV in reservoir cells.

Biotron was up 0.1 cents or 1.1 percent to nine cents with 3.6 million shares traded.

CYCLOPHARM

Cyclopharm says Japan's Ministry of Health has approved its latest model of the Technegasplus Generator for clinical use.
Cyclopharm said that Japan was the dominant market for diagnostic radiopharmaceuticals in the Asia-Pacific region with more than 40 percent of the total market.
The company said that there were about 1,600 gamma cameras installed in about 1,120 nuclear medicine departments in Japan.
Cyclopharm said Technegas had been available in Japan since in the mid-1990s, but was predominantly used as a research tool with very little activity dedicated to clinical use.
Cyclopharm managing director James McBrayer said that "prior to registering the latest model of the Technegasplus generator we have been unable to effectively promote the clinical use of Technegas".
"Consequently, this approval will allow us to significantly expand the sales of Technegasplus into the Japanese market," Mr McBrayer said.
Cyclopharm said it expected meaningful revenues by July 2014.
Cyclopharm was untraded at 31 cents.

TISSUE THERAPIES

Tissue Therapies says it has lodged an application to conduct a pivotal trial of its Vitrogro wound treatment for venous ulcers with the US Food and Drug Administration.
Tissue Therapies said the trial would be performed over 12 months, pending funding, and was planned as a double-blinded, prospective, randomized control trial.
The company expected to begin Vitrogro sales 14 months after the trial was completed.
Tissue Therapies said that the submission was delayed by the recent US Government shutdown and the usual time for this type of application to be approved was 30 days but the backlog could cause this to be extended.
The company said that approval was expected by the end of 2013.
Tissue Therapies said it expected the trial to cost $10.2 million.
Tissue Therapies fell half a cent or 1.9 percent to 26 cents.

ATCOR MEDICAL

Atcor says that its Sphygmocor XCel has not been fully approved for sale in Mexico as stated last month (BD: Sep 4, 2013).
Atcor said it based its announcement on documentation provided by its Mexico distributor and registration certificate holder BCR Internacional and included a quote provided by BCR confirming the status.
The company said it had received a request from BCR for final, basic documentation to complete the registration file.
Atcor said it had conducted "an extensive investigation to verify what had previously been communicated … by BCR".
The company said that the review showed that while approval was in the final stages, it would not be completed until the documents were reviewed by the Mexican regulatory authority.
Atcor said the delay was not material and BCR believed full approval was imminent.
The company said that it took "responsibility for accurate and complete disclosure very seriously, and has implemented new procedures to ensure this type of error does not recur".
Atcor fell two cents or 11.8 percent to 15 cents with 2.7 million shares traded.

VIRAX HOLDINGS

Virax says it has had “significant interest in the capital raising and has received subscriptions well in excess of the proposed maximum $2,500,000”.
Virax chairman Dr Wayne Millen said the raising was “a reflection of the extremely buoyant biotechnology market in the United States”.
“Australia is following this trend with several significant transactions having recently occurred in this space,” Dr Millen said.
Virax said it was finalizing all outstanding compliance matters and when completed would seek re-admittance to the ASX official list.
In July, Virax, then in voluntary administration, announced a series of capital raisings to effect a deed of company arrangement with Otsana Capital “which embodied a proposal by Otsana for the reconstruction and recapitalization of the company” (BD: Jul 31, 2013).
The proposal included a 10-for-one consolidation; the issue of shares and proposed new directors Dr Millen, Dr Roland Toder and Dr Brendan de Kauwe.
Virax last traded at 0.9 cents.

ALLIED HEALTHCARE GROUP

Minderoo Group, formerly the Metal Group, says it increased its substantial holding in Allied Health from 176,571,070 shares (17.05%) to 222,438,937 shares (17.75%).
Minderoo, which is associated with Western Australian miner Andrew Forrest, said it acquired the 45,867,867 shares for $2,293,393 or 5.0 cents a share in the recent rights issue.
Allied Health climbed 3.5 cents or 30.4 percent to 15 cents with 46 million shares traded.

MAYNE PHARMA GROUP

Watermark Funds Management has ceased its substantial shareholding in Mayne Pharma by selling 710,000 shares for $491,963 or an average price of 69.3 cents a share.
The Sydney-based investment company’s previous notice in November 2012, said its 19,594,390 share holding was diluted in the major capital raising from 8.67 percent to 5.61 percent.
Watermark was further diluted in the completion of placements and a share plan.
The current holding of 18,884,390 shares is 3.35 percent of Mayne.
Last year, Watermark increased its holding in Mayne to 19,594,390 shares (8.67%) and a company executive told Biotech Daily that company was the manager of the Australian Leaders Fund, which said it became substantial in Mayne in August with Braitling Investments (BD: Aug 29, Oct 19, 2012).
Mayne fell half a cent or 0.7 percent to 70 cents.

OSPREY MEDICAL

The Melbourne-based Kinetic Investment Partners says it has become a substantial shareholder in Osprey with the acquisition of 7,143,309 shares (5.93%).
Kinetic said it acquired the shares in a large number of trades between April 2, 2012 and October 23, 2013, with the single largest acquisition 590,548 shares for $413,384 or 70 cents a share on October 23.
Kinetic is part of Challenger Financial Services, its principals are Jonathan Findlay, Richard Sharp and Anthony Porto and it holds 7.2 percent of Nanosonics.
Osprey was up one cent or 1.4 percent to 73 cents.

IDT AUSTRALIA

Belgravia Group has increased its holding in IDT from 5,646,499 shares to 6,831,907 shares but has been diluted from 13.14 percent to 9.04 percent.

The Belgravia substantial shareholder notice was signed by chairman Geoffrey Lord, who is also a director of IDT.

The notice said the change in voting percentage related to the recent $6 million placement and rights issue at 27 cents a share (BD: Sep 27, 2013).

IDT was untraded at 38 cents.