Biotech Daily

Thursday July 12, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CELLMID UP 14%, AVITA DOWN 10%**

*** RESONANCE APPLIES FOR FDA CLEARANCE FOR LIVER FAT TEST**

*** COGSTATE EXPECTS UP TO $12m REVENUE, $2.7m PROFIT**

*** RICHARD CARREON STARTS AS IMPEDIMED CEO**

*** BIOXYNE SENDS DATA PACK TO POTENTIAL SUITORS**

*** CITIGROUP CEASES IN PATRYS**

*** CONSEGNA REQUESTS LICENCING TRADING HALT**

*** GENESIS APPOINTS CATHERINE YAN DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.7 percent on Thursday July 12, 2012 with the S&P ASX 200 down 28.5 points to 4,068.0 points.

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

Cellmid was the best, up 0.2 cents or 14.3 percent to 1.6 cents with 888,770 shares traded.

Viralytics climbed 5.4 percent; Neuren and Genetic Technologies were up more than four percent; CSL was up 2.2 percent; Bionomics, Impedimed, Mesoblast, Resmed and Starpharma were up more than one percent; with Reva up 0.9 percent.

Avita led the falls, down two cents or 10.3 percent to 17.5 cents with 353,747 shares traded, with Sunshine Heart, following the Nasdaq retreat from three days of increases, down half a cent or 10 percent to 4.5 cents with 4.9 million shares traded.

Universal Biosensors lost 6.7 percent; Allied Health and Benitec fell five percent or more; Antisense and Tissue Therapies fell four percent or more; Living Cell was down 3.7 percent; Pharmaxis and QRX shed more than two percent; Anteo, Biota and Cochlear were down more than one percent; with Acrux, Clinuvel and Nanosonics down by less than one percent.

RESONANCE HEALTH

Resonance Health says it has applied for US regulatory approval of its Hepafat Scan through a US Food and Drug Administration 510(k) pre-market submission.
The FDA website said that a 510(k) pre-market submission was to demonstrate that the device to be marketed was “at least as safe and effective, that is, substantially equivalent, to a legally marketed device”.
Resonance said the Hepafat Scan was a software technology for the non-invasive quantitative measurement of fat in the liver using magnetic resonance imaging.
The company said that a clinical study had been completed involving 60 patients with liver disease comparing the Hepafat Scan to the gold standard liver biopsy assessment of liver fat (BD: May 23, 2011, Apr 5, 2012).
Resonance managing director Liza Dunne told Biotech Daily that the full results from the 60-patient trial were being prepared prior to submission to a peer-reviewed journal.
Resonance said that the area under the receiver operating characteristic (AUROC) curve was used to assess the diagnostic performance of Hepafat Scan.
The company said that results were very good with an AUROC of 0.96 or higher in all categories of assessment and a high degree of sensitivity and specificity at all clinically relevant liver fat thresholds.
Resonance said that as the rate of obesity and the associated health care costs continued to increase, the Hepafat Scan would provide an important tool to assist medical practitioners in the clinical diagnosis of fatty liver and in decisions on patient management.
The company said that the Hepafat Scan also provided a non-invasive alternative to a liver biopsy in clinical trials for therapies to address fatty liver disease, where repeat measurements were required throughout the clinical studies.
Resonance said it hoped to receive a response from the FDA by the end of 2012.
The company said that the Hepafat Scan provided a non-invasive alternative for diagnosing fatty liver disease.
This company said the 510(k) submission was “an exciting transition for the company from research and development to the commercialization of Hepafat Scan”.
Resonance said it was also nearing completion of a study aimed at developing a magnetic resonance imaging-based test for liver fibrosis.
The company said it was awaiting the final results from an external laboratory to complete the assessment of the liver fibrosis tests.
Resonance was up one cent or 8.3 percent to 1.3 cents.

COGSTATE

Cogstate says its unaudited revenue for the year June 30, 2012 is expected to be $11.5 million to $12.0 million with net profit after tax expected to be $2.2 million to $2.7 million.
The company said that cash at June 30, 2012 was $4.66 million with trade debtors of $1.98 million.
Cogstate was untraded at 29 cents.

IMPEDIMED

Impedimed says that Richard Carreon has taken up his appointment as chief executive officer on July 10, 2012, based in San Diego.
Impedimed said that Greg Brown would continue to serve as an executive director.
Impedimed was up half a cent to 1.9 percent to 26.5 cents.

BIOXYNE

Bioxyne says it is sending the results of its phase IIb trial of HI-164OV for chronic obstructive pulmonary disease exacerbations to more than 50 companies

Bioxyne said that although the study showed no statistical difference in the treated versus untreated group (BD: Jun 28, 2012), a subset of 35 active patients compared to 56 placebo patients under that age of 65 years "demonstrated statistically significant differences in several main areas of interest".

The company said that as a result of the signals from the under 65 years group it had committed to embarking on a commercialization process for HI-164OV.

Bioxyne said that a slide deck and information package had been developed which provides non-confidential information about the HI-164OV asset, which would be sent "to a targeted list of over 50 companies that have been identified as potentially having an interest in the respiratory or vaccine technology space".

The company said that initial discussions and feedback might take up to six weeks, after which time it expected to have a clearer indication of any potential interest in further commercial discussions.

Bioxyne said that if it was successful with the commercialization discussions, the average time for a deal to be completed was about 12 months.

Bioxyne fell 0.2 cents or 4.8 percent to four cents.

PATRYS

Citigroup Global Markets says it has ceased its substantial shareholding in Patrys.

On Monday, Citigroup said it had increased its substantial share-holding in Patrys from 29,729,971 shares (8.176%) to 41,618,349 shares (11.446%) (BD: Jul 9, 2012).

The Citigroup substantial shareholder notice described the London and Sydney-based company as a prime broker for the holders of the shares, but gave no details about the price paid for the 11,888,378 shares.

Patrys was unchanged at two cents.

CONSEGNA GROUP

Consegna has requested a trading halt pending "a proposed worldwide licencing agreement for Breatheassist and an equity subscription agreement".

Trading will resume on July 16, 2012 or on an earlier announcement.

Consegna last traded at 2.5 cents.

GENESIS RESEARCH AND DEVELOPMENT CORP

Genesis says it has appointed NZ Dairy Processing (HK) financial controller Catherine Yan as a director.

Genesis said that Ms Yan was a member of the Australian Society of Certified Public Accountants and of the Hong Kong Institute of Certified Public Accountants.

Genesis was untraded at three cents.