Biotech Daily

Wednesday June 22, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: TISSUE THERAPIES UP 10%, PRANA DOWN 8%**

*** FDA ESCALATES CSL DEVIATIONS TO 'WARNING LETTER'**

*** HEALTHLINX 3.25-3.5c SHARE PLAN**

*** FLUOROTECHNICS PROSPECTING FOR MINING BUSINESS**

*** M&G GROUP INCREASES TO 8% OF MESOBLAST**

*** ORBIS TAKES 19% OF PHARMAXIS**

*** HELICON LOSES GRAEME BODEN FOR SOLAGRAN'S JUSTYN STEDWELL**

*** STIRLING TO SELL 80% OF TELEMEDCARE FOR $3m**

MARKET REPORT

The Australian stock market was up 0.54 percent on Wednesday June 22, 2011 with the S&P ASX 200 up 24.4 points to 4,532.6 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Tissue Therapies was the best, up five cents or 10.1 percent to 54.5 cents with 558,622 shares traded, followed by Cellmid up 0.2 cents or 9.1 percent to 2.4 cents with one million shares traded.

Patrys climbed 8.6 percent; Optiscan was up 7.4 percent; Virax was up five percent; Cathrx and Sunshine Heart were up four percent or more; Bionomics and Mesoblast were up more than three percent; Nanosonics and Starpharma rose more than two percent; with Phylogica, Psivida and QRX up more than one percent.

Prana led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 17,705 shares traded.

Genera and Genetic Technologies fell five percent or more; Circadian, Impedimed and Phosphagenics were down more than three percent; Living Cell and Viralytics shed more than two percent; with Cochlear, Heartware and Resmed down more than one percent.

CSL

The US Food and Drug Administration has issued CSL a 'Warning Letter' relating to its production of biological vaccine Afluria and monovalent influenza bulks.

The letter from the director of the Office of Compliance and Biologics Quality Center for Biologics Evaluation and Research Mary A Malarkey to CSL's chief executive officer Dr Brian McNamee cited an FDA inspection of CSL Biotherapies in Parkville Victoria between March 21 and March 31, 2011.

CSL was previously the subject of an FDA 'Untitled Letter' relating to an inspection between April 19 and 28, 2010 in which investigators "documented deviations from current good manufacturing practice (CGMP) requirements in the manufacture of licensed biological vaccine products and monovalent influenza bulks" including Afluria and Influenza A (H1N1) Monovalent vaccine and cited US regulations from which it alleged CSL had deviated (BD: June 30, 2010).

The June 15, 2011 FDA letter gave CSL 15 days to comply or explain why it needed more time: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm259888.htm.

The letter said that in March 2011, FDA investigators documented deviations from current good manufacturing practice requirements in the manufacture of Afluria and monovalent influenza bulks and cited requirements under the US Federal Food, Drug and Cosmetic Act and the US Code of Federal Regulations.

The FDA said that after the inspection, it issued a Form FDA 483, Inspectional Observations, "which described a number of significant objectionable conditions relating to your facility's compliance with CGMP".

Significant deviations included, but were not limited to, a failure "to thoroughly investigate any unexplained discrepancy, or the failure of a batch or any of its components to meet any of its specifications and failed to extend the investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy".

The FDA said the April 2010 investigation initiated to determine a root cause for adverse events for fever and convulsions in children "is inadequate in that there was no documentation of the adverse event investigation".

The FDA said documentation was required for actual or potential problems which may affect the quality and reliability of products, processes or quality systems.

"There was a limited analysis of the … process to determine why there was a substantial increase in adverse event reports of fever and convulsions in the 2010 Southern Hemisphere influenza season in comparison to previous seasons," the FDA said.

There was no analysis of all critical parameters and critical processing steps to try to determine differences in the 2010 lots associated with adverse event reports compared to lots from previous seasons.

The FDA said the April 2010 failure investigation was "inadequate" for several reasons and also "failed to establish and follow written production and process controls for the execution of various production and process control functions".

"Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include license suspension and/or revocation," the FDA said.

CSL Biotherapies executive vice-president Dr Jeff Davies said the technical team was "preparing more substantive details about our corrective actions to meet the FDA's requirements".

A CSL spokeswoman told Biotech Daily that the FDA warning related to "the way we document and manage processes and investigations" and not the physical establishment in Parkville.

CSL fell 16 cents or 0.5 percent to $32.10 with 2.3 million shares traded.

HEALTHLINX

Healthlinx hopes to raise an undisclosed sum through the issue of shares between 3.25 cents and 3.5 cents.
Healthlinx did not say how much it hoped to raise or the maximum number of shares that could be issued.
The company said the price would be the lower of 3.5 cents or a 12.5 percent discount to the five-day volume weighted average price prior to the date of issue of the plan shares, but not discounted below 3.25 cents.
Healthlinx said shareholders eligible at the record date of June 14, 2011 would be able to apply for parcels of shares up to $15,000.
The company said the share plan would open on June 22 and close on July 13, 2011.
Healthlinx said the funds would assist: in the collection of the remaining 680 samples required for the ongoing multi-centre Ovplex study; the 220-patient South Korean regulatory approval study; the roll out of Ovplex in Europe, Israel and other Asian jurisdictions; and the company's intellectual property portfolio.
Healthlinx said its directors intended to participate in the share plan.
Healthlinx fell 0.8 cents or 21.05 percent to three cents.

FLUOROTECHNICS

Fluorotechnics says it has reviewed "multiple acquisition opportunities" and will focus on the resources sector.
The company said it had not agreed terms with any acquisition target.
Fluorotechnics said that if it did acquire a resources company, it would be required to seek shareholder approval comply with the ASX Listing Rules relating to changes of activities.
In 2008, Fluorotechnics raised $8 million of the hoped for $12 million in a $1 a share initial public offer to ramp-up production of its protein detection and analysis equipment and list on the ASX (BD: Sep 4, 2008).
Fluorotechnics was spun-out of Macquarie University by chief executive officer Prof Duncan Veal in 2002, acquired German-based Elektrophorese-Technik and the San Francisco based The Gel Company.
Fluorotechnics said at that time that it produced and sold high value consumables for protein research and had 200 customers of which "98 percent" were outside Australia, evenly split between Europe and the US.
The company planned to bring 20 new products to the market in the next three years.
Fluorotechnics board was originally chaired by co-founder Rick Taylor a tax partner for more than 20 years and leader of Deloitte's private equity team and boasted the former chief executive officer of the Coles Group John Fletcher, who was one of the first investors in the company in 2002 and joined the board in March 2008, along with former GE Healthcare global strategic marketing director, Gunter Thesseling.
Fluorotechnics was unchanged at two cents with 1.9 million shares traded.

PHARMAXIS

Orbis Investment Management has increased its substantial shareholding in Pharmaxis from 40,729,893 shares (17.84%) to 43,816,936 shares (19.19%).
An Orbis executive told Biotech daily the shares were purchase for "about $1.00" each.
Pharmaxis was unchanged at $1.00.

MESOBLAST

M&G Investment Funds have increased their substantial holding in Mesoblast from 19,712,296 shares (7.04%) to 22,494,385 shares (8.04%).
Mesoblast was up 27 cents or 3.3 percent to $8.40.

HELICON GROUP

Helicon says Graeme Boden has resigned as company secretary, effective from June 22, 2011 and will be replaced by Solagran's Justyn Stedwell.
Mr Boden continues as the company secretary for Phylogica.
Helicon said Mr Stedwell was the company secretary for several publicly listed companies and completed a Bachelor of Business and Commerce at Monash University and held a Graduate Diploma in Applied Corporate Governance with Chartered Secretaries Australia and a Graduate Diploma of Accounting from Deakin University.
Helicon was up 0.1 cents or 4.55 percent to 2.3 cents with 3.3 million shares traded.

STIRLING PRODUCTS

Stirling says it has exchanged a conditional purchase offer term sheet with Spain's Grupo Neat of Spain for the sale of 80 percent of Telemedcare for $3,000,000.
Stirling said the term sheet provided for time to be of the essence, was subject to due diligence, that the sale be clear of all encumbrances and present a balance sheet free of debt, promissory notes and other liabilities.
Last year, Stirling said it acquired a 65 percent controlling interest in Telemedcare for $511,302 over 12 months as settlement of the company's trade creditors (BD: Aug 3, 2010). Stirling said at that time that it would provide $3 million in working capital over 18 months and allow for the repayment of shareholder loans of $3.66 million from future Telemedcare profits.
Stirling fell 0.1 cents or 33.3 percent to 0.2 cents with 5.8 million shares traded.