Biotech Daily

Thursday August 14, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: ACRUX, NEUREN UP 6%, LIVING CELL DOWN 12%**

*** POLARTECHNICS DEMAND DOUBLES; RESULTS IMPROVE; US INTEREST**

*** ACRUX MANUFACTURING ALLIANCE WITH ORION**

*** BIOTRON EXPANDS HEPATITIS C PHASE II TRIAL**

*** PROGEN RENEWS PHASE I PG11047 ANTI-CANCER TRIALS**

*** PEPLIN COMPLETES PHASE II ACTINIC KERATOSIS ENROLMENT**

*** CSL RAISES $1.75b TO BUY TALECRIS**

*** SOLAGRAN TO RETAIN RUSSIANS; DIRECTORS LOSE 21m SHARES**

*** CIRCADIAN TAKES VEGENICS; DR JONATHAN SKIPPER ON BOARD**

*** SAFETY MEDICAL SELLS 285k SYRINGES TO DIABETES SCHEME**

*** FMR, FIDELITY INCREASES TO 8% OF HEARTWARE**

MARKET REPORT

The Australian stock market climbed 0.9 percent on Thursday August 14, 2008 with the All Ordinaries up 43.1 points to 5,039.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and eight were untraded.

Acrux and Neuren were best, both up 6.25 percent to $1.275 and 8.5 cents respectively, followed by Viralytics up six percent to 5.3 cents.

Progen climbed 5.43 percent; Mesoblast was up 3.2 percent; Circadian and Psivida rose more than two percent; with Alchemia, Cellestis, Genetic Technologies and Phosphagenics up more than one percent.

Living Cell led the falls again, down three cents or 12 percent to 22 cents on small volumes followed by Polartechnics down eight percent and Arana down 7.96 percent.

Bionomics and Proteome fell more than five percent; Pharmaxis lost 4.1 percent; Chemgenex, CSL and Heartware shed more than three percent; with Clinuvel, Cochlear and Resmed down more than one percent.

POLARTECHNICS

Polartechnics says China's demand for its Truscreen cervical cancer test has outstripped supply, the test is more accurate than previously stated and there is increased interest in the US for the product.

In a quarterly shareholder update the company said there had been a three month delay to the production ramp-up of the Truscreen test's single use sensors.

Chinese production of the sensors began in March 2008, with production increasing according to plan until quality issues arose.

"We have now identified the causes of the quality issues, which included unacceptable variations in the lens component during plastic injection moulding in China and dust contamination of the lens during transport and handling to and from the US for specialized coatings," Polartechnics said.

"We have revised our processing procedures accordingly. We anticipate that production will slowly ramp up and we are only three months behind our original plan," the company said.

"This process is not unusual when taking a product from test manufacturing to full commercial production," Polartechnics said.

Polartechnics managing director Ben Dillon told Biotech Daily that the company had backorders to fill but there had been "a doubling of the market opportunity in China", following the acquisition of the distributor by an unnamed "major Chinese technology conglomerate".

Mr Dillon said a total of 160 Truscreen console sets had been sold, of which 90 were in China.

Typically each hospital would have one console originally expected to run an average of 2,000 tests a year.

"The average in China is 5,000 tests per annum per machine," Mr Dillon said.

Due to the increase in expected demand the company was considering the commissioning of a second manufacturing plant outside China.

The Polartechnics shareholder update said sales were 94 percent of forecast units in the six months to June 30, 2008.

"Once we have achieved a user base of 600 to 800 Truscreen consoles the associated SUS sales will take us to breakeven cash flow," Polartechnics said. "This should be achieved within the near term dependent of course, on our SUS production build-up."

Mr Dillon said the Chinese commitment to 200 consoles had doubled.

He said the additional results coming from experienced operators of the system showed sensitivity had increased from 70 percent to 80 percent compared to the PAP smear test's average of 54 percent sensitivity.

"Recent published abstracts from trials of Truscreen in Poland and China have confirmed the superior performance of Truscreen at, or better than the initial [Conformitée Européenne] CE product registration trials," Polartechnics said.

"This continues to reinforce Truscreen as the only proven real-time point-of-care screening test for cervical cancer," the company said.

Mr Dillon said he had been travelling extensively and there was significant interest in the test from "key opinion leaders and medical practitioners in the US".

"Consequently we are involved in discussions regarding the entry of Truscreen into the US market.

"Support has been offered from a number of parties to assist with the US Food and Drug Administration product registration process, which is expected to take up to two years to complete," Mr Dillon said.

Polartechnics fell one cent or eight percent to 11.5 cents.

ACRUX

Acrux says it has entered into a commercial manufacturing alliance with European pharmaceutical company Orion Corporation.
Acrux said Orion developed, manufactured and marketed pharmaceuticals, active pharmaceutical ingredients and diagnostic tests for global markets.
The company said Orion would manufacture testosterone metered dose lotion (MD lotion) and transdermal spray products (MDTS) such as Evamist (Ellavie outside the US), on a commercial scale, at its facility in Finland.
Acrux said it would supply product to licencees in all territories, targeting a global market of $900 million growing at 20 percent a year with Orion as the exclusive commercial manufacturer of its testosterone MD lotion.
Acrux said with the start of testosterone MD lotion phase III trials the company expected to file marketing applications in the US and Europe by the end of 2009, with Orion as the authorized manufacturer with the capacity to manufacture Acrux's MDTS products for globally release.
Acrux said the alliance involves an investment by both companies in additional infrastructure at the Orion facility and formed part of Acrux's existing budget for the Testosterone MD-Lotion phase III program.
Acrux chief executive officer Dr Richard Treagus said the agreement secured supply for both the testosterone metered dose lotion and transdermal spray products which "represents a crucial element in our overall commercialization strategy".
"We are very pleased to be strongly aligned with a company having both the capabilities and scale of Orion," Mr Treagus said.
Acrux said Orion had a reported market capitalization of EUR1.8 billion ($A3.1 billion), a reported turnover of EUR683 million with an operating profit of EUR192 million in 2007.
Acrux climbed 7.5 cents or 6.25 percent to $1.275.

BIOTRON

Biotron says its phase Ib/IIa clinical trial of BIT225 in hepatitis C virus infected patients will include a second trial site in Brisbane.
Biotron said the trial would run at the original Sydney site and Brisbane during the second half of 2008.
The company said the trial was a placebo-controlled, randomized study of the safety, pharmacokinetics and antiviral activity of BIT225 in patients with hepatitis C virus infection.
Biotron said the primary objective was to assess the safety and tolerability of BIT225, given twice daily, for 14 consecutive days.
The secondary objective was to assess the pharmacokinetics of BIT225 as well as to assess the antiviral efficacy of BIT225 in these patients.
Eighteen patients would be randomly assigned to receive one of two dose levels of BIT225 or placebo.
Biotron said BIT225 was an orally-administered, antiviral compound for treatment of hepatitis C virus infections and represented a first-in-class drug for treatment of hepatitis C virus, targeting the p7 protein of hepatitis C virus.
Biotron said BIT225 had demonstrated good antiviral activity in surrogate models of hepatitis C virus infection, and had been shown to be highly synergistic with current leading therapies for this disease.
Biotron expected the trial would be completed by the end of 2008.
Biotron was untraded at 16 cents.

PROGEN

Progen says it has begun enrolment for a phase I trial of its polyamine analogue PG11047 in combination with other drugs for patients with advanced cancer.
Progen said it would also continue with an existing phase I mono-therapy trial of PG11047.
The company said both phase I trials had begun but was suspended by Cellgate before Progen acquired the business.
Progen said polyamines were a class of chemical involved in regulation of cell growth and were overproduced in many cancers.
PG11047 was believed to restore polyamine reduction to natural levels.
Progen said the monotherapy study was designed to establish the safety and tolerability of PG11047 as a single agent while the second trial would explore the potential of PG11047 in combination with a range of other marketed anti-cancer drugs including Taxotere, Gemzar, Avastin, Tarceva, cisplatin, Sutent and 5-flurouracil and was designed to assess the agent's maximum tolerated dose in these combinations.
Progen said this approach would provide a range of clinical data to inform the further clinical development of PG11047.
The company said it was recruiting at 10 US sites, with 2 more expected to join.
Progen climbed 3.5 cents or 5.43 percent to 68 cents.

PEPLIN

Peplin says 240 patients are enrolled for its phase IIb clinical trial in actinic (solar) keratosis a common skin condition that can develop into skin cancer.
Peplin said the PEP005-015 US and Australian multi-center, randomized, double-blind, vehicle-controlled clinical trial would evaluate the safety and efficacy of each of three concentrations (0.005%, 0.010% or 0.015%) and two treatment regimens (once a day for two or three consecutive days) of PEP005 (ingenol mebutate) gel in patients with actinic keratosis lesions on the head, comprising face and scalp.
Peplin chief executive officer Michael Aldridge said that enrolment of patients into the trial was faster than Peplin expected which "advances the timeline of pending milestones for this program and underscores the unsatisfied medical need which our product addresses".
Peplin said the primary efficacy endpoint for this clinical trial being the complete clearance rate of actinic keratosis lesions and the secondary endpoint would be the partial clearance rate of actinic keratosis lesions.
Peplin said it would evaluate efficacy on the 57th day after treatment.
The phase IIb trial would support the design of a subsequent phase III trial, planned for 2009, pending successful meetings with the US Food and Drug Administration.
Peplin was unchanged at 37.5 cents.

CSL

CSL says it has completed the institutional component of the equity raising for the acquisition of Talecris Biotherapeutics (see Biotech Daily; August 13, 2008).
CSL said the offer closed early and oversubscribed at a final price of $36.75 per share.
The company said 47.5 million ordinary shares would be issued through this institutional placement, worth $1.75 billion, or 8.6 percent of CSL's currently issued share capital, to be allotted and issued on August 20, 2008.
The placement was arranged and underwritten by Merrill Lynch.
CSL fell $1.35 or 3.46 percent to $37.65.

SOLAGRAN

Solagran says it has an agreement to retain its key Russian scientists and administrators following the loss of 42 percent of the company's shares to the Opes Prime collapse.
Shares held by Solagran chairman Dr Vagif Soultanov and directors Denis Kilroy and Charles Pellegrino as well as the Russian scientists and others were placed in Solamind Pty Ltd.
Solamind gave its shares to Opes Prime Stockbroking and when that company collapsed, the ANZ Bank acquired 56,129,515 ordinary shares or 42.6 percent of ordinary shares along with 10,132,865 contributing or partly paid shares or 21.0 percent of that issue.
Solagran said in a release to the ASX that "Solamind has advised the company that it has reserved all of its legal rights to claim damages from ANZ".
The director's interest statement said Dr Soultanov lost 9,048,927 ordinary shares and 50,000 contributing shares through Solamind, but retained 3,238,883 ordinary shares and 1,682,151 contributing shares.
Mr Kilroy lost 7,807,177 ordinary shares and 50,000 contributing shares through Solamind, but retained 1,920,175 ordinary shares and 4,758,786 contributing shares.
Mr Pellegrino apparently lost 3,916,361 ordinary shares and 3,562,090 contributing shares through Solamind and retained 40,000 ordinary shares and 1,682,151 contributing shares.
Solagran fell four cents or 8.7 percent to 42 cents.

CIRCADIAN

Circadian says the takeover of Vegenics has been completed and Dr Jonathan Skipper has been appointed to the Circadian board.
Circadian said the acquisition gave it complete ownership of Vegenics' product pipeline and intellectual property portfolio covering key targets for the treatment of diseases associated with angiogenesis (see Biotech Daily; July 15, 2008) .
Circadian said Vegenics' patent estate and rights cover vascular endothelial growth factor proteins C and D (VEGF-C, VEGF-D) that help regulate the growth of new blood vessels or angiogenesis.
The company said blocking these proteins around tumors may inhibit the growth of existing tumors and prevent the spread of new cancer cells.
Circadian chief executive officer Robert Klupacs said the takeover was "a key step in Circadian's strategy to focus on Vegenics as our core business and to become a prominent international biologics drug development company in the anti-angiogenic space."
Circadian said it had appointed the executive director for intellectual property and licencing at the Ludwig Institute for Cancer Research Dr Jonathan Skipper as a director of the company.
Dr Skipper has been in charge of the Institute's international operations to commercialize its technologies.
Circadian's chairperson, Dominique Fisher said Dr Skipper "brings to the company scientific expertise in cancer biology and exposure to the international pharmaceutical licensing arena. He has completed a number of licensing deals with large pharmaceutical companies which will be of significant benefit to our long-term partnering strategy."
"He also brings a deep understanding of the VEGF intellectual property owned by Vegenics much of which was originally developed by scientists from LICR and the University of Helsinki," Ms Fisher said.
Circadian climbed two cents or 2.41 percent to 85 cents.

SAFETY MEDICAL

Safety Medical says it has sold 285,000 Securetouch retractable syringes into the National Diabetes Services Scheme (NDSS) since March 2008

Safety Medical said it was the only Australian company supplying the scheme.

The company said that it had been supplying the Securetouch syringe since March 2008 and its Insulin Pen Needles and Standard Syringes to the scheme from July 2008.

The company said that promotional material began appearing in nationwide diabetes issues and newsletters in late June and with more than 70 million syringes and pen needles supplied through the NDSS last financial year, there was a "significant scope" for Safety Medical to generate substantial revenues.

Safety Medical said feedback about the products from both diabetes educators and diabetes patients had been "excellent".

Safety Medical fell 0.1 cent or 1.25 percent to 7.9 cents.

HEARTWARE

The US based FMR Corp and Fidelity Investments have increased their substantial shareholding in Heartware from 22,636,983 shares (7.29%) to 25,807,667 (8.32%).

Heartware fell two cents or 3.23 percent to 60 cents.