Biotech Daily

Friday October 22, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CHEMGENEX UP 16%; PSIVIDA DOWN 5%**

*** CEPHALON TAKES (POTENTIAL) 30% OF CHEMGENEX ON ROAD TO FDA**

*** PHARMAXIS COMBINED CYSTIC FIBROSIS PHASE III DATA 'SIGNIFICANT'**

*** VICTORIAN GOVERNMENT SPECIFIES $3.3m OF $55m ACTION PLAN**

*** GSK PAYS BIOTA $2.1m RELENZA ROYALTY**

*** SELECT VACCINES UNDERWRITTEN RIGHTS ISSUE RAISES $1.2m**

*** AQUACAROTENE VOTES ON MEL BRIDGES, NAME CHANGE, BACKDOOR**

*** VIRAX VOTES ON DIRECTORS' SHARES IN LIEU OF PAY**

*** ACORN TAKES 5% OF PHARMAXIS**

*** ARTEMIS, ROTHSCHILD FAMILY CEASE SUBSTANTIAL IN BENITEC**

*** AUSBIOTECH: DR MARK SHACKLETON WINS $1m PFIZER FELLOWSHIP**

*** AUSBIOTECH APPOINTS MEERA VERMA, PAUL WALTON DIRECTORS**

MARKET REPORT

The Australian stock market climbed 0.55 percent on Friday October 22, 2010 with the S&P ASX 200 up 25.3 points to 4648.2 points.

Ten of the Biotech Daily Top 40 were up, 17 fell, seven traded unchanged and six were untraded. All three Big Caps were up.

Chemgenex was best, up seven cents or 16.1 percent to 50.5 cents with 1.6 million shares traded, followed by Cathrx up 8.3 percent to 26 cents with 50,000 shares traded. Viralytics climbed 6.25 percent; Heartware was up 5.3 percent; Acrux, Cochlear, Genera, QRX and Resmed rose more than two percent; with Bionomics and Tissue Therapies up more than one percent.

Psivida led the falls, down 32 cents or 5.35 percent to $5.66 with 9,662 shares traded, followed by Clinuvel down 5.3 percent to 18 cents with 450,621 shares traded. Cellmid, Circadian, Novogen, Phosphagenics and Starpharma fell four percent or more; with Benitec, Phylogica, Sirtex and Universal Biosensors down two percent or more.

CHEMGENEX

The Pennsylvania-based Cephalon has an option on 19.9 percent of Chemgenex from existing investors, with an additional 10 percent through a $15 million convertible note.

Last year Cephalon acquired Arana for about $329 million (BD: Feb 29, 2009).

Today, Chemgenex said Cephalon had agreed to a $15 million convertible note at 50 cents a share, a premium of 13 percent to the volume weighted average price of Chemgenex shares for the month to October 15, 2010 with interest of 10 percent a year.

Chemgenex said $10 million would be drawn down immediately to fund operations, including collection and analysis of patient data for its new drug application to the US Food and Drug Administration for Omapro (omacetaxine mepesuccinate) for chronic myelogenous leukemia patients who have failed two or more tyrosine kinase inhibitor.

Chemgenex chief executive officer Dr Greg Collier told Biotech Daily that the draw down of the remaining $5 million was dependent on shareholder approval.

Cephalon also has option agreements with Stragen International and Merck Santé SAS to acquire up to 19.9 percent of Chemgenex shares they own at 70 cents a share.

Cepahlon can exercise the option at any time before the later of March 31, 2011 and one week after the completion of the data collection and analysis.

Chemgenex said Cephalon had “indicated no present intention to exercise the options” as its decision would depend on the progress of the data collection and analysis and Cephalon’s assessment of Chemgenex’s prospects following completion of that process.

Chemgenex said the options effectively gave Cephalon an immediate 19.9 percent relevant interest under the Corporations Act, even thought they may not be exercised.

Dr Collier said that Stragen and Merck Santé held about 22 percent of the company and would retain an interest of about three percent if the option was exercised.

Dr Collier said Alta Partners held 15 percent of the company and GBS held eight percent.

Should Cephalon make an offer at some time in the future and both Alta and GBS accept, it would have about 53 percent of the company.

Dr Collier said Stragen acquired its 37 million shares in exchange for Chemgenex acquiring the intellectual property relating to Omapro.

Dr Collier said Cephalon had been building its business through acquisitions and had made “a real push in the haematology and oncology space”.

“This is right in their sweet spot,” Dr Collier said.

Chemgenex said it would seek shareholder approval to allow Cephalon to increase its relevant interest in Chemgenex beyond 20 percent by conversion of the convertible notes as soon as practicable and in any event prior to December 31, 2010.

Chemgenex said Alta, Stragen, Merck and GBS held a combined 44.4 of the company and indicated they would support the convertible note issue and intended to vote in favor of a resolution that would allow the immediate conversion of the notes.

If shareholder approval was obtained, the notes would be converted by early in 2011.

In a media release, Dr Collier said the company was “delighted that Cephalon has indicated its interest in Chemgenex and omacetaxine by becoming a substantial investor”.

If shareholder approval is not obtained by December 31, 2010, Cephalon may redeem the first $10 million tranche of notes and would not be obliged to subscribe for the second $5 million tranche of notes.

If shareholder approval was obtained by December 31, 2010, no interest would be payable on the notes and if the patient data collection and analysis process was completed by March 31, 2011, the charge would be released and no interest would be payable. Cephalon would be entitled to redeem the notes if the patient data collection and analysis process was not completed in accordance with agreed milestones.

Chemgenex was up 7.0 cents or 16.1 percent to 50.5 cents with 1.6 million shares traded.

PHARMAXIS

Pharmaxis says combined data from 643 patients in its two phase III trials of Bronchitol for cystic fibrosis has shown statistical significance for its primary endpoint.

Pharmaxis said the combined results were presented for the first time at the North American Cystic Fibrosis Conference underway in Baltimore, Maryland and more results from the second trial were released to supplement those reported on June 22, 2010.

Pharmaxis said that over 26 weeks, patients treated with Bronchitol (inhaled mannitol) had an average 7.3 percent improvement in lung function compared to baseline ($p<0.001$) and a highly significant improvement compared to patients in the control group ($p<0.001$).

Pharmaxis chief financial officer David McGarvey told Biotech Daily that the $p<0.001$ significance figure for the primary endpoint of improvement compared to patients in the control group compared to the first trial's $p<0.001$ and the second trial's $p=0.059$.

Missing the primary endpoint in the second trial triggered a fall in Pharmaxis share price to as low as $1.66 (BD: June 22, 23, 2010).

Pharmaxis said that in the sub-group of patients who were also on rhDNase (Pulmozyme), patients taking Bronchitol showed a 5.3 percent improvement from baseline ($p<0.001$), that was again superior to the control group ($p=0.020$).

In patients not on rhDNase, those taking Bronchitol showed a 9.44 percent improvement from baseline ($p<0.001$), that was also superior to the control group ($p=0.009$).

The company said that the overall rate per annum reduction in exacerbations for patients on Bronchitol versus those on control was 25 percent and the number of patients experiencing an exacerbation was 29 percent lower for those taking Bronchitol, but these were not statistically significant.

Pharmaxis said the result was achieved in a well-treated patient population who overall had a very low rate of exacerbations in the study.

Pharmaxis chief executive officer Dr Alan Robertson said the comprehensive analysis of the pooled results "provides an important insight into the overall benefits Bronchitol can provide to patients who are receiving current best standard of care".

"The number of exacerbations in the two studies was fairly low, reflecting the aggressive treatment with antibiotics that is now common practice in the clinic," Dr Robertson said.

"Despite this, Bronchitol produced a clinically relevant reduction in exacerbations in patients completing the study," Dr Robertson said.

"Together with recent data showing sustained benefit in lung function out beyond 18 months this pooled data suggests that Bronchitol might slow disease progression," Dr Robertson said.

Pharmaxis said other results from CF302 presented at the conference underlined both the good safety profile of Bronchitol and patient adherence.

Overall adverse events on Bronchitol were similar to those on control with seven percent of patients on Bronchitol withdrawing due to adverse events compared to four percent of patients on control, with no increase in the numbers of bacteria present in the lungs.

The most commonly reported adverse event related to treatment was cough occurring in six percent of the Bronchitol group and 3.3 percent of the control group.

The principal investigator, the University of Washington's Prof Moira Aitken said she was "excited by the results of the Bronchitol phase III clinical program".

Prof Aitken said the results suggest Bronchitol would have a significant impact on cystic fibrosis patient well-being.

Pharmaxis said a marketing application was under review by the European Medicines Agency and it expected to have discussions with the US Food and Drug Administration by December 31, 2010.

Pharmaxis was up one cent or 0.35 percent to $2.85.

VICTORIAN GOVERNMENT

Victoria's Innovation Minister Gavin Jennings says Medicines Development has been engaged to provide specialist drug development expertise to companies developing new pharmaceutical products.

Mr Jennings said the $1.3 million practical drug development program would see five project managers trained in clinical strategy and placed within biotechnology companies to lead and manage drug development programs.

"The long-term goal of the program is to enhance the development of new pharmaceutical products, add value to intellectual property, lead to more effective translation of research and increase the sector's attractiveness to investors," Mr Jennings said

Mr Jennings said the Victorian Government's $55 million action plan identified skills as an essential component for building the capability and competitiveness of the biotech sector.

"Initiatives under the action plan will address findings of the recently released Biotechnology Industry Skills Review, carried out by the Allen Consulting Group, which provides a comprehensive analysis of the specific skills, training and workforce needs of the Victorian biotechnology sector," Mr Jennings said.

Mr Jennings said Medicines Development was one of a number of partners contracted by the Government to deliver commercialization services under the Victorian Government's $8 million smart small and medium sized enterprises innovation commercialization program.

For further information go to www.medicinesdevelopment.com.

Science and Technology International Partnering Program

Mr Jennings said a $1 million program would help small technology companies develop international partnerships.

Mr Jennings said the Science and Technology International Partnering Program (STIPP) would provide grants to companies to attend recognized overseas conferences, trade events and meetings with regulatory authorities.

Details about the program are available at www.biotechnology.vic.gov.au/STIPP.

Victoria-California Stem Cell Alliance

Mr Jennings said a $2.2 million project by Victorian and Californian researchers would assess whether stem cell therapies could be used to combat diseases such as multiple sclerosis and type 1 diabetes and help organ transplant recipients.

Mr Jennings said the Victorian Government had contributed $575,505 to the project, the fifth to be funded through the $28 million Victoria-California Stem Cell Alliance which was established in 2008 under the Biotechnology Strategic Development Plan.

Competitive Business Fund

Mr Jennings said Victoria was providing $410,000 to help three companies improve their competitiveness, save money on production costs and create local jobs.

Mr Jennings said Universal Biosensors, Glaxosmithkline and SGE Analytical Science would be funded through the Government's $11.4 million Competitive Business Fund.

A Government media release said the $410,000 fund would provide $250,000 to Universal Biosensors to expand its Rowville manufacturing site to develop more point of care diagnostic tests for the global market; $60,000 to Glaxosmithkline Australia to support the first pilot trial of membrane contactor technology to reduce the manufacturing and environmental disposal costs of medicinal alkaloids, saving up to $1 million a year; and $100,000 to assist SGE Analytical Science to apply a new diamond-like coating technology to a range of products.

BIOTA

Biota expects to receive a royalty payment of $2.1 million from Glaxosmithkline for $29.6 million sales of Relenza in the three months to September 30, 2010.
The payment compares to a royalty payment of $900,000 for $12.8 million sales of Relenza in the three months to June 30, 2010 and a royalty payment of $24.1 million for the three months to September 30, 2009.
Biota fell 1.5 cents or 1.6 percent to 92.5 cents with 1.2 million shares traded.

SELECT VACCINES

Select Vaccines says its fully-underwritten rights issue has raised $790,708 from the issue of 395,353,920 shares at 0.2 cents a share.
Select hoped to raise up to $1,174,612 through the issue of up to 587,306,038 shares and said it had placed the shortfall shares through Patersons Securities.
Select was unchanged at half a cent with 1.5 million shares traded.

AQUACAROTENE

Aquacarotene shareholders will vote on the election of biotechnology entrepreneur Mel Bridges as a director in what is effectively a backdoor listing.
Aquacarotene (ASX: AQL) said that along with Mr Bridges, shareholders would vote to elect Kenneth Lionel Richards and Hubert Michael Glencross Finney and change the company's name to Leaf Energy and adopt a new constitution.
Mr Bridges told Biotech Daily that the company was effectively the back-door listing of a spin-out from the Queensland University of Technology to produce a commercial plant protein for clinical research, for stem cell and tissue culture applications.
The meeting will also vote on the issue of 200,000 options for chief executive officer David Hudson.
The meeting will be held at the Tattersalls Club, 215 Queen Street, Brisbane on November 22, 2010 at 4.30pm (AEST).
Aquacarotene was untraded at 17 cents.

VIRAX

Virax shareholders will vote on the issue of shares to directors in lieu of payment along with the ratification of a prior share issue.
The resolutions propose issuing shares to the value of $40,875 to Michael Humphris as deferred remuneration for the six months to June 30, 2010 along with shares to Ian Pyman ($29,975), Dr Albert Ting ($29,975) and Tim Cooper ($19,983) as well as 1,062,500 options to Mr Cooper.
Virax shareholders will also vote on the election of Mr Humphris and Mr Cooper and the ratification of the prior issue of 616,936 shares to Alpha Securities.
The meeting will be held at the Quest Beaumont Hotel, 7 Studley Park Road, Kew, Melbourne on November 19, 2010 at 2.45pm (AEDT).
Virax was untraded at 2.6 cents.

PHARMAXIS

Acorn Capital says it has become a substantial shareholder in Pharmaxis with the acquisition of 11,385,872 shares or 5.04 percent of the company.
Acorn said it acquired 11,385,872 shares between September 24, 2003 and October 21, 2010 for $7,682,792 or an average price of 67.5 cents share.
Pharmaxis was up one cent or 0.35 percent to $2.85.

BENITEC

Artemis Trustees and members of the Rothschild family as beneficiaries of the Whale Trust have ceased their substantial holding in Benitec.
The group gave its address as St Peter Port, Guernsey, a Channel Islands tax haven, and said they sold 2,430,400 shares for $91,506 or an average price of 3.7 cents a share.
Benitec fell 0.1 cents or 2.5 percent to 3.9 cents.

AUSBIOTECH, PFIZER

Ausbiotech says Dr Mark Shackleton won the $1 million Pfizer senior research fellowship for research into 'Identifying determinants of human melanoma progression'.
The five year fellowship was presented by the chair of the selection committee, Prof John Funder.
Ausbiotech said Dr Shackleton was a medical oncologist and the head of the melanoma research laboratory at Melbourne's Peter MacCallum Cancer Centre.
The industry organization said Dr Mark Shackleton's research project aimed to better understand the mechanisms through which melanomas progress in patients, with a view to identifying new and more effective therapies against the disease.

AUSBIOTECH

Ausbiotech has appointed Hospira's head of Adelaide operations Dr Meera Verma and CSL's head of corporate development Dr Paul Walton as directors, effective today.
Dr Verma joined Bresa in 1987, rising to Bresagen's chief operating officer in 2000, was appointed executive director in 2004 and was appointed to her present position when Bresagen was acquired by Hospira in 2006.
Dr Verma is a member of the Therapeutic Goods Committee of the TGA.
Dr Walton is responsible for CSL's corporate strategy and opportunities for corporate growth including mergers and acquisitions.
Prior to joining CSL, Dr Walton held research and management roles at Genentech in San Francisco, Diagnostic Systems in Houston, Gropep in Adelaide and the the Commonwealth Scientific and Industrial Research Organisation.
Ausbiotech's board also comprises chair Dr Debroah Rathjen, chief executive officer Dr Anna Lavelle, Dr Peter Isdale, Geraldine Farrell and Dr Stewart Washer.
Michael Gilbert and Dr Greg Roger have retired from the board.