Biotech Daily

Monday May 4, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP; CYTOPIA, PEPLIN UP 12.5%, BIOTA DOWN 15%**

*** PHARMAXIS BRONCHITOL 'IMPROVES CYSTIC FIBROSIS LUNG FUNCTION'**

*** AVEXA IN HIV OPTION DEAL WITH J&J'S TIBOTEC**

*** GIACONDA RAISES $250k**

*** BIOTA SAYS GSK INCREASING RELENZA PRODUCTION**

*** PEPLIN PLEADS SCHULTZ TO ASX 22% PRICE QUERY**

*** BIOPHARMICA REQUESTS COLLABORATION DEAL TRADING HALT**

*** DR JAMES CAMPBELL REPLACES CHEMGENEX CFO RICK MERRIGAN**

*** OBJ DIRECTOR JEFFREY EDWARDS SELLS 1.5m OF 55.5m SHARES**

MARKET REPORT

The Australian stock market climbed 3.01 percent on Monday May 4, 2009 with the S&P ASX 200 up 113.4 points to 3,883.0 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, three traded unchanged and eight were untraded.

Cytopia and Peplin were best, both up 12.5 percent to 13.5 cents and 72 cents, respectively, followed by Benitec up 11.11 percent to three cents.

Living Cell and Chemgenex climbed 8.33 percent, the latter with 6.4 million shares traded, of which 5,856,171 shares were sold in a single trade, believed to be Queensland Investment Corporation exiting the company; Sirtex was up five percent; Circadian climbed 4.76 percent; Acrux, Genera and Universal Biosensors were up more than three percent; Psivida rose 2.6 percent; with Alchemia, Impedimed and Progen up more than one percent.

Biota led the falls, down 21 cents or 15.2 percent to $1.17 with 6.2 million shares traded, followed by Antisense down 11.9 percent to 3.7 cents.

Cathrx and Tyrian lost more than eight percent; Phosphagenics fell 5.9 percent; Avexa, Bionomics, Nanosonics, Novogen and Polartechnics fell more than four percent; with Mesoblast, Resmed and Tissue Therapies down more than two percent.

PHARMAXIS

Pharmaxis says its phase III trial of Bronchitol for cystic fibrosis “comfortably met” the endpoint of improving lung function.

Pharmaxis said the study was “one of the largest clinical trials conducted in cystic fibrosis” and the primary endpoint was assessed by measuring a change in forced expiratory volume over one second (FEV1) when 400mg of Bronchitol was administered twice a day for six months.

“The clinical trial comfortably met this endpoint,” Pharmaxis said. “Patients treated with Bronchitol had a statistically significant improvement in lung function from baseline of 6.6 percent (p=0.001 versus placebo).

Lung function improved at week six and was sustained through to week 26.

Pharmaxis said the key secondary endpoint of the trial was to assess whether Bronchitol further improved lung function in patients already being treated with the most commonly used cystic fibrosis therapeutic, dornase alfa or Pulmozyme.

For patients being treated with concurrent dornase alfa, FEV1 improved after six months by 5.2 percent from baseline (p=0.002 versus placebo).

Over the six month treatment period, there was significant lung function improvement for both those patients being treated with Bronchitol and dornase alfa (p=0.008 versus placebo) and those being treated with Bronchitol alone (p=0.015 versus placebo).

Pharmaxis said consistent loss of lung function was the leading cause of death for people with cystic fibrosis and this deterioration averaged one to two percent a year.

Pharmaxis chief executive officer Dr Alan Robertson said the company was “delighted that Bronchitol performed so well in this important long term study and we now know that it can change the therapeutic landscape for many of the 75,000 people with this disease”.

“In a trial which recruited a wide range of patients with varying disease severity, Bronchitol showed significant health benefits,” Dr Robertson said.

“As the first dry powder formulation to publish positive results in cystic fibrosis it promises convenience for patients who have complex daily schedules dominated by difficult treatment regimens,” Dr Robertson said.

The company said that 324 subjects were randomized in the trial with an average age of 23 years.

The mean lung function on entry to the trial was 62 percent of the predicted normal FEV1, and 55 percent of subjects were using dornase alfa.

Bronchitol was well-tolerated overall and had a favorable safety profile.

At screening, only seven percent of recruited subjects were unable to tolerate Bronchitol and were not entered into the study.

There was no difference in adverse events or serious adverse events between the treatment groups. The most common adverse event was cough, which was mild to moderate in most cases and similar between the treatment arms.

The double blind, placebo controlled trial was conducted in 40 centres in the United Kingdom, Ireland, Australia and New Zealand.

Pharmaxis said it would move to file a marketing application later this year.

The first scientific presentation of the results will be made at the June European Cystic Fibrosis Society meeting in France. In addition a more detailed account of the results of the trial is planned to be presented at the North American Cystic Fibrosis conference in Minneapolis in October.

Bronchitol has orphan drug designation and development fast track status from the US Food and Drug Administration and Orphan Drug Designation from the European Medicines Agency.

Pharmaxis was in a trading halt until the announcement and was untraded at $2.28.

AVEXA

Avexa has signed a six-month, exclusive option agreement with Johnson & Johnson subsidiary Tibotec Pharmaceuticals for its HIV integrase program.

Avexa chief executive officer Dr Julian Chick told Biotech Daily that his company's lead drug apricitabine was not an HIV integrase inhibitor and was not the subject of the collaboration with Tibotec.

In a media release to the ASX, Avexa said the option agreement provided an exclusivity period for the two companies to formalize a collaborative research and licence agreement while Tibotec continued to review the Avexa HIV-1 integrase inhibitor drug program portfolio.

Dr Chick said his company was "excited and very encouraged by the results of the preliminary evaluation of HIV-1 integrase inhibitors that Avexa and Tibotec have undertaken to date".

"One of the major benefits of working with Tibotec is the breadth of experience and resources in the anti-HIV drug field that they bring to bear which may enable us to significantly accelerate our programs,"

Avexa said that over the past five months the two companies had been working collaboratively to evaluate compounds from Avexa's HIV integrase program.

If they enter into a research collaboration and license agreement, Tibotec and Avexa will continue to collaborate, harnessing the medicinal chemistry and the in-vitro resources of both companies to support and accelerate the Avexa HIV integrase program.

Treatment of HIV infected patients with the only currently approved anti-HIV integrase drug results in the selection of viruses that are resistant to that drug.

Avexa's lead anti-integrase compounds are able to inhibit these integrase inhibitor-resistant HIV because they interact with the HIV-integrase in a different way to the marketed drug.

"Tibotec has considerable HIV drug development experience and of course this would benefit our programs in their development," Dr Chick said.

Avexa climbed to 13 cents before closing down half a cent or 4.35 percent at 11 cents with 6.2 million shares traded.

GIACONDA

Giaconda says it has obtained a $250,000 funding facility through Sydney Capital Partners.

Giaconda said the facility was secured and would provide the company with sufficient funding for its operations to progress its discussions with third parties for licencing and product development.

The company said the funders would be granted a right to invest an amount equal to the facility limit into shares in the company at a price which is calculated in part by the price of future capital raisings and the share price performance of the company.

Giaconda said Sydney Capital Partners would also act as one of the company's key advisers in future fund raising and business strategy execution.

Giaconda was untraded at 8.1 cents.

BIOTA, GLAXOSMITHKLINE

Glaxosmithkline says it is increasing production of Biota's Relenza to support the response of governments and health authorities to the influenza A (H1N1) strain.

In a Glaxosmithkline media release republished by Biota the company said it would increase Relenza production levels to produce 50-60 million treatment packs a year and expected to achieve the output of five million treatment packs a month within the next 12 to 14 weeks.

Biota chief financial officer Damian Lismore told Biotech Daily that if Glaxosmithkline sold that number of courses, Biota would earn $100 million in royalties.

Mr Lismore said the company had earned a total of $59 million in Glaxosmithkline royalties over the past two years.

Glaxosmithkline also said it had put in place measures to manage existing stocks of Relenza.

The company said it had developed "a number of potential interventions which it believes may be of value in efforts to reduce the impact and spread of this new influenza virus" including the antiviral Relenza (zanamivir) and significant vaccine capability and technology, including the use of novel adjuvants.

Glaxosmithkline said that to ensure continuity of supply and manufacture of all its critical medicines and vaccines, it had "invoked its own internal pandemic preparedness plan".

The company said that since 2003, Relenza had been supplied to 26 governments for the purposes of pandemic stockpiling and on average the product constituted 13 percent of these stockpiles.

Prior to the recent outbreak, the last significant order for Relenza was for 10.6 million treatment packs, which was delivered to the UK Government in April 2009.

Glaxosmithkline said that In relation to the influenza A (H1N1) strain, the World Health Organisation reported that the viruses obtained from the recent human cases were sensitive to oseltamivir and zanamivir but resistant to amantadine and remantadine and the company had contacted governments to ascertain demand for Relenza, including those countries most affected by the virus, such as Mexico and the US.

The company said that at April 23, 2009 it had fulfilled all orders from commercial and public purchasers for Relenza and had six million treatment packs of Relenza stock.

Glaxosmithkline said it had "prioritized orders to governments" and was working with them to determine the best mechanisms for distribution of Relenza either through public or commercial routes.

The company said that to further expand production volumes, it was "in active discussions with several other companies to increase manufacturing capacity of the product" and was exploring alternative delivery systems for Relenza, beyond the currently approved Diskhaler device.

The company said it planned to discuss these alternatives with regulatory authorities with the objective of agreeing a potentially expedited pathway to approval and availability.

Glaxosmithkline said that in China, it was working with Simcere Pharmaceuticals as a further option to raise production levels of Relenza.

The company said it had granted a voluntary licence to Simcere in 2006 to manufacture and sell products containing zanamivir, in China and a number of other countries, including all 50 of the world's least developed countries.

Glaxosmithkline said it planned to directly allocate a proportion of new stock to least developed countries either directly or through multilateral agencies and would engage in voluntary licence discussions with any companies willing to manufacture and supply a zanamivir product for use in developing countries.

Biota fell 21 cents or 15.22 percent to $1.17 with 6.2 million shares traded.

PEPLIN

Peplin has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 60 cents on April 30, 2009 to 73 cents, a 21.7 percent increase, on May 4, 2009.
Peplin was up eight cents or 12.5 percent to 72 cents.

BIOPHARMICA

Biopharmica has requested a trading halt pending an announcement "regarding the HLS5 collaborative research and technology farm-in agreement".
Trading will resume on May 6, 2009 or on an earlier announcement.
Biopharmica last traded at 3.9 cents.

CHEMGENEX

Chemgenex's chief financial officer and company secretary Rick Merrigan has retired and will be replaced by chief operating officer Dr James Campbell.
Chemgenex said the change was effective from today.
The company said Dr Campbell had more than 20 years experience in scientific research, research management, management consulting and venture capital and has been with Chemgenex since September 2002.
Chemgenex was up 3.5 cents or 8.33 percent to 45.5 cents with 6.4 million shares traded, of which 5,856,171 shares were sold in a single trade, believed to be Queensland Investment Corporation exiting the company.

OBJ LTD

OBJ director Jeffrey Edwards has indirectly sold 1,500,000 shares for $9,000.
Mr Edwards holds 54,008,500 OBJ shares (8.19%).
OBJ fell 0.2 cents or 28.6 cents to 0.5 cents with 2.1 million shares traded.