



Biotech Daily

Friday September 11, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: PHYLOGICA UP 16%; ANTISENSE DOWN 8%**
- * **CSL'S LOW-DOSE 'FLU VACCINE SHOWS 'ROBUST IMMUNE RESPONSE'**
- * **CSL VOTES ON \$17m FREE SHARES TO DR BRIAN MCNAMEE, TONY CIPA**
- * **HEALTHLINX, MATER COLLABORATE IN OVARIAN CANCER STUDY**
- * **BIOPHARMICA TO RAISE \$20m TO INVEST \$7m IN OIL & GAS COMPANY**
- * **PHARMAXIS AGM TO RATIFY 20m SHARE PLACEMENT, ELECT DIRECTOR**
- * **HUNTER HALL INCREASES TO 27% OF FLUOROTECHNICS**
- * **BIONOMICS DETAILS \$2.2m SHARE PLAN**
- * **IMPEDIMED REAPPOINTS STEPHEN DENARO COMPANY SECRETARY**
- * **STIRLING APPOINTS NEIL COVEY DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.55 percent on Friday September 11, 2009 with the S&P ASX 200 up 25.3 points to 4596.1 points.

Nineteen of the Biotech Daily Top 40 stocks were up, five fell, 13 traded unchanged and three were untraded.

Phylogica was best for the second day in a row, climbing 1.6 cents or 16.2 percent to 11.5 cents with 815,027 shares traded, followed by Sunshine Heart up 13.5 percent to 5.9 cents and Bionomics up 10 percent to 27.5 cents.

Psivida climbed 9.5 percent; Genera was up 7.4 percent; Living Cell rose 6.1 percent; Compumedics was up 5.3 percent; Alchemia, Chemgenex, Tyrian and Universal Biosensors were up more than four percent; Sirtex was up 3.7 percent; Acrux, Benitec and Cellestis rose more than two percent; with Heartware, Nanosonics and Peplin up more than one percent.

Antisense led the falls, down 0.4 cents or eight percent to 4.6 cents with 480,000 shares traded. Labtech and Optiscan both lost more than six percent; Tissue Therapies shed 2.22 percent; with Mesoblast and Resmed down by less than one percent.

CSL

CSL says early data from the first study of its candidate pandemic H1N1 vaccine showed “a robust immune response in healthy adults after a single unadjuvanted 15mcg dose”. CSL said the preliminary data, published in the New England Journal of Medicine, showed that more than 95 percent of participants receiving the single 15mcg dose of the vaccine achieved antibody levels that correlated with the prevention of influenza infection. The article entitled ‘Response after One Dose of a Monovalent Influenza A (H1N1) 2009 Vaccine - Preliminary Report’ concluded that “a single 15-mcg dose of 2009 H1N1 vaccine was immunogenic in adults, with mild-to-moderate vaccine-associated reactions”.

The article is available at <http://content.nejm.org/cgi/content/full/NEJMoa0907413>.

CSL said the study also showed that the vaccine had a tolerability profile consistent with seasonal influenza vaccines.

CSL said that in the single-centre observer-blind study, 240 healthy adults aged 18 to 64 years were randomized into two dose groups: the standard dose of 15mcg of vaccine used for a single strain in the trivalent seasonal influenza vaccine and a 30mcg dose.

Each participant received an initial vaccination followed by a second vaccination three weeks later and blood samples were taken three weeks after each dose.

CSL said that preliminary data after the first vaccination demonstrated that post-vaccination antibody titres of 1:40 or greater were achieved in 96.7 percent of patients receiving the 15mcg dose and in 93.3 percent of participants receiving the 30mcg dose.

This immune response remains consistently strong irrespective of age.

CSL chief scientific officer Dr Andrew Cuthbertson told Biotech Daily that the difference between the doses was not statistically significant and the company would proceed with the lower dose.

CSL said no deaths, serious adverse events or adverse events of special interest were reported.

The company said the most commonly reported solicited adverse events were injection site tenderness, headache and injection site pain.

Dr Cuthbertson said in the media release that the preliminary data obtained showed “a promising result which gives us confidence that a vaccination program can be successfully carried out in adults using a single standard dose of the H1N1 vaccine”.

“CSL currently has other studies underway that are examining the vaccine in children and older adults,” Dr Cuthbertson said.

“The results of our initial study provide critical information given that vaccine yields have been much lower than expected around the world,” he said.

“Knowledge of the likely effective dose will enable the available vaccine to go further,” Dr Cuthbertson said.

“CSL can also offer reassurance that no safety signals have been noted so far in any of our current studies,” Dr Cuthbertson said.

“We will, of course, continue to monitor safety through the clinical study process and with post-marketing surveillance,” he said.

CSL said it had “worked quickly to make the preliminary dose response and safety data available to public health and regulatory authorities around the world in order to inform policy decisions about how immunization programs against pandemic H1N1 2009 influenza should be implemented”.

CSL was up 16 cents or 0.47 percent to \$34.21 with 4.3 million shares traded.

CSL

CSL's annual meeting will vote on the issue of 500,000 performance rights worth about \$17.1 million to executive directors, Dr Brian McNamee and Antoni Cipa.

In 2006, CSL shareholders approved the award of 500,000 performance rights – then worth about \$24.5 million – to chief executive officer Dr McNamee and chief financial officer Mr Cipa (BD: Sep 15, 2006).

At that time CSL shares were trading at \$49, but climbed to \$100 taking the value of a full performance rights allocation to about \$50 million, before the three-way share split.

CSL's 2009 notice of meeting said the rights "represent the right to subscribe for or acquire one share for either nil consideration (in the case of rights) or an exercise price based on the market price of the company's shares at or about the time of the offer (in the case of options)".

The notice of meeting said that since the 2006 approval, Dr McNamee had been awarded 45,660 rights and 152,520 options and that Mr Cipa had been awarded 18,900 rights and 63,420 options.

In the most recent director's interest statement of March 23, 2009, Dr McNamee reported the acquisition of 210,000 performance rights taking his total holding to 835,669 shares, 325,080 performance rights and 311,280 performance options.

The most recent change of director's interest statement for Mr Cipa, dated October 28, 2008, said that he acquired 9,720 performance rights and 33,720 performance options exercisable at \$37.91 each; and held 25,777 shares, 186,060 performance rights and 121,560 performance options.

At the time of publication, Biotech Daily was unable to establish whether the \$37.91 exercise price was uniform for all the performance options.

CSL's 2006 annual report said that following shareholder approval in October 2003, Dr McNamee received 147,500 performance rights and Mr Cipa received 70,000 performance rights. In each case the acquisition price and exercise price was nil.

The meeting will also vote on the election of directors Prof John Shine, Antoni Cipa and Maurice Renshaw and the renewal of partial takeover provisions.

The company has also proposed shareholders renew its "partial takeover provision". The provision, known as rule 147 in the company's constitution, prohibits the registration of a transfer of shares resulting from a proportional takeover bid unless shareholders in a general meeting approve the bid.

CSL said a proportional takeover bid would involve a bidder conducting an off-market takeover bid for a specified proportion of the shares held by each shareholder.

It is a requirement of the Corporations Act that proportional takeover bid approval rules apply for a maximum period of three years unless renewed. It was last renewed in October 2006.

"At the date of this notice, no director is aware of any proposal by any person to acquire, or to increase the extent of, a substantial interest in the company," CSL said.

CSL's annual general meeting will be held on October 14, 2009 at the Function Centre, National Tennis Centre, Batman Avenue, Melbourne at 10am (AEST).

FLUOROTECHNICS

Hunter Hall Investments has increased its substantial shareholding in Fluorotechnics from 6,250,000 shares (24.12%) to 8,100,000 shares (26.71%).

The 1,850,000 shares were bought for \$518,000 or 28 cents a share in the recent placement and rights issue (BD: Sep 9, 2009).

Fluorotechnics was untraded at 43.5 cents.

HEALTHLINX

Healthlinx says it will collaborate with Queensland's Mater Health Services in a second study of its early stage ovarian cancer diagnostic, Ovplex.

The company said the trial with the health services group originally known as the Sisters of Mercy Hospital aimed to demonstrate ovarian cancer accuracy for Ovplex to a 97 percent or greater diagnostic efficiency.

Healthlinx said the clinical work at the Mater would use 200 blood samples collected retrospectively for the study planned for later this year.

The company said it would measure the performance of Ovplex against CA125 alone, the existing gold-standard test, in a clinical environment.

The company said the study would be run by gynecological oncologist Prof Lewis Perrin, and pathologists Prof Jane Armes and Prof Deon Venter.

Healthlinx said the trial was subject to ethics committee approval at the Mater Health Services expected by the end of 2009.

The company said the samples collected at the Mater would be one of a number of sites in Australia, Asia, and the United Kingdom that would contribute to a 1,155 patient study to determine sensitivity and specificity for Ovplex when compared to CA125 alone.

Healthlinx said it would screen the samples using the company's original five biomarker panel as well as two novel biomarkers HTX005 and HTX010.

A biomarker is a specific biochemical in the body that measures disease or the effects of treatment.

The company said a preliminary analyses on the novel markers suggested they might increase the diagnostic efficiency to greater than 97 percent.

Healthlinx said that if the larger study was successful the company "could become the clear market leader within the area of ovarian cancer diagnostics".

Healthlinx was unchanged at 7.5 cents.

BIOPHARMICA

Biopharmica hopes to raise \$20 million of which \$7 million will be a passive investment in Perth oil and gas company Advent Energy, with the balance for its biotechnology projects. Biopharmica says it "has been offered an exclusive option to invest in Advent Energy".

Biopharmica said it could acquire 9.7 percent to 19.4 percent of Advent's share capital at 50c a share which was consistent with the Talbot Group Holdings investment, subject to shareholder approval at the annual general meeting to be held on November 11, 2009.

Biopharmica said it intended to place \$20 million worth of its shares to sophisticated and institutional investors, also subject to shareholder approval.

The company said Advent was an unlisted oil and gas exploration company based in Perth, Western Australia and had secured a \$7 million conditional funding agreement with Talbot Group Holdings.

Biopharmica said it would "continue to maintain its interest" in Molecular Discovery Systems, Cortical Dynamics, Diagnostic Array Systems and the surface enhanced raman spectroscopy (SERS) nanoprobe project, with biotechnology projects its majority investments.

Biopharmica said the investment in Advent was "passive" and it would "not be involved in any of the decisions affecting the ongoing operations of the projects of Advent".

The company said the expansion of corporate activities "presents [Biopharmica] shareholders with the capacity to reduce investment risk in their shareholding whilst retaining their interest in the core activities and investments".

Biopharmica was up 3.5 cents or 29.2 percent to 15.5 cents with 1.8 million shares traded.

PHARMAXIS

Pharmaxis shareholders will vote on the issue of 20 million placement shares along with the issue of stock to directors.

Pharmaxis said the annual general meeting would consider the issue of 20 million placement shares at \$2.35 a share and the renewal of the company's constitution for a further three years.

The meeting will also vote on the re-election of Richard van den Broek as a non-executive director of the company.

Pharmaxis said the meeting would consider the issue of 30,000 restricted shares to Mr van den Broek and the granting of 200,000 employee options to chief executive officer Dr Alan Robertson.

The meeting will be held at the Intercontinental Hotel, corner of Phillip and Bridge Streets, Sydney on October 21, 2009 at 2.30pm.

Pharmaxis was unchanged at \$2.45.

BIONOMICS

Bionomics has released the details of its \$2.2 million share purchase plan announced earlier this week (BD: Sep 8, 2009).

The company said the record date would be September 14, 2009, the plan opens on September 16, 2009 and closes on October 12, 2009.

Bionomics was up 2.5 cents or 10 percent to 27.5 cents.

IMPEDIMED

Impedimed has reappointed Stephen Denaro as company secretary replacing Phil Auckland who has resigned as chief financial officer and company secretary.

Impedimed said Mr Denaro has acted as company secretary for Impedimed before and was company secretary for other medical device and biotechnology companies.

The company said it was continuing its search for a San Diego California-based chief financial officer.

Impedimed was unchanged at 59 cents.

STIRLING PRODUCTS

Stirling says it has appointed Neil Covey as a non-executive director.

Stirling said Mr Covey had senior positions in sales, marketing and business development with Astra and Knoll Pharmaceuticals and was head of sales and marketing for Bayer, Australia.

The company said Mr Covey would replace Alpha Securities director George Karantzias who had resigned "to focus on his own expanding business commitments".

Stirling was unchanged at 1.2 cents.