

# **Biotech Daily**

## Tuesday September 11, 2012

## Daily news on ASX-listed biotechnology companies

\* ASX, BIOTECH DOWN: PRANA UP 25%, IMPEDIMED DOWN 14%

- \* CSL POTENTIAL \$1.5b US 'FLU PANDEMIC PREPAREDNESS CONTRACT
- \* MEDICINES AUSTRALIA: R&D MORE THAN \$1b FOR 3<sup>rd</sup> YEAR
- \* ANU'S PROF CHRIS GOODNOW WINS \$80k GSK RESEARCH AWARD
- \* UQ'S DR FIONA SIMPSON WINS \$25k CANCER TRAILBLAZER PRIZE
- \* CALZADA, POLYNOVO TREAT 1<sup>st</sup> NOVOSORB FREE-FLAP PATIENT
- \* PHARMAXIS AGM FOR 230k DIRECTOR 'RIGHTS'

#### MARKET REPORT

The Australian stock market fell 0.18 percent on Tuesday September 11, 2012 with the S&P ASX 200 down 8.0 points to 4,325.8 points.

Seven of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and six were untraded.

Prana was the best, up 4.5 cents or 25 percent to 22.5 cents with 3.8 million shares traded, followed by Sunshine Heart up 23.5 percent to 4.2 cents with 3.7 million shares traded.

Both Neuren and Phylogica climbed 8.7 percent; Patrys was up five percent; Genetic Technologies was up 4.8 percent; Cochlear and CSL rose more than two percent; Heartware was up 1.2 percent; with Resmed up 0.3 percent.

Impedimed led the falls, down 2.5 cents or 14.3 percent to 15 cents with 335,020 shares traded, followed by Allied Health down 11.5 percent to 2.3 cents with 1.5 million shares traded.

Alchemia lost 7.5 percent; Living Cell fell four percent; Bionomics, Phosphagenics, Prima and Viralytics were down more than three percent; Ellex and Genera shed more than two percent; Acrux, Mesoblast, Reva and Starpharma were down more than one percent; with Biota, Pharmaxis, QRX and Sirtex down by less than one percent.

#### <u>CSL</u>

CSL Biotherapies has won a potential \$1,511,407,738 US Department of Health and Human Services contract for pre-pandemic and pandemic vaccine antigens and services. CSL's public affairs director Sharon McHale said the US stockpile contract amount was the maximum potential value should all options be exercised by the US Government requiring, among other things, an influenza pandemic to be declared within five years. Ms McHale said the value of the contract was likely to be significantly less than the potential value.

CSL said the US Government could request CSL Biotherapies to manufacture and store bulk antigen to be used against influenza strains with pandemic potential and it could be called on to develop working virus 'seeds' for other manufacturers and to formulate, fill and finish bulk stored antigen.

Ms McHale told Biotech Daily that a virus seed was "a live virus that has been adapted to be non-infectious and able to be grown in eggs".

CSL said the Biotherapies division was the only manufacturer of influenza vaccine in the Southern Hemisphere, able to produce more than 80 million doses of vaccine a year. The company said that CSL Biotherapies was "involved in every stage of influenza vaccine manufacture from the development of the seed viruses necessary to produce vaccine ... to final, packaged product in syringes, ready to be administered".

CSL said that during the 2009 H1N1 influenza pandemic, CSL Biotherapies was pivotal in producing vaccine early, initiating world-first clinical trials and providing pandemic vaccine for programs in Australia, New Zealand, the US, Germany, Singapore and Canada as well as the World Health Organisation.

CSL Biotherapies general manager Dr John Anderson said his division had a "history of developing and manufacturing vaccines, dating back to the 1918 Spanish 'Flu pandemic". CSL said it was Australia's only on-shore influenza vaccine manufacturer and was contracted by the Federal Government to manufacture vaccines in the event of an influenza pandemic.

"CSL takes its role in protecting Australia against influenza pandemic very seriously and we continually invest in our operations to remain pandemic ready," Dr Anderson said. "This puts us in a strong position to collaborate with governments globally to prepare for a

pandemic emergency," Dr Anderson said.

CSL said that funding for the contract was provided solely by the US Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority.

CSL was up 97 cents or 2.2 percent to \$44.85 with 1.7 million shares traded.

## MEDICINES AUSTRALIA

Medicines Australia says that the industry's research and development investment was more than \$1 billion for the third successive year.

Medicines Australia said the data was provided in the annual Australian Bureau of Statistics business expenditure report on research and development released today. The organization said the ABS data showed that the medicines industry attracted

\$1,036,000,000 in research and development investment in 2010-'11, the third largest by area of business expenditure, behind financial services and mining.

Medicines Australia chief executive Dr Brendan Shaw said the data highlighted the value of the Australian medicines industry to the national economy.

Dr Shaw said the Federal Government's research and development tax credit effectively reduced the cost of eligible research and development by up to 10 percent.

#### **GLAXOSMITHKLINE**

Glaxosmithkline says its \$80,000 research excellence award will go to the Australian National University's Prof Chris Goodnow for his work on autoimmune diseases. Glaxosmithkline said that the award, to be presented to Prof Goodnow tonight, was to further develop "his world-leading research on the cause of autoimmune diseases something still unknown in most people affected by these disorders".

The company said that Prof Goodnow was selected from more than 50 researchers. Glaxosmithkline said that Dr Goodnow's research would test a controversial theory, that autoimmune disorders were a form of benign cancer and had the potential to lead to more effective treatments and preventions for the millions of people with or at risk of these diseases.

"It's a high risk and high returns approach - testing a theory for autoimmune disease that's somewhat controversial," Prof Goodnow said.

"Some people really love it, but some people really hate it," Prof Goodnow said. "That's a good sign. No one finds it boring".

Glaxosmithkline said that in 30 years of research Prof Goodnow had improved the understanding of how the immune system decides what is a person's body and what is an invading microbe that should be attacked.

The company said that in patients with an autoimmune disorder, the immune system can't tell the difference between healthy body tissue and microbes.

Glaxosmithkline said that Prof Goodnow had identified genes and pathways involved in these decisions.

Prof Goodnow said the grant would enable his research team to use a new technology, Massively Parallel Sequencing, to test his hypothesis that autoimmune diseases were a form of benign lymphoma cancer.

"Without the grant from this award, the process to apply for funding to use the Massively Parallel Sequencing technology would potentially halt our research for years, delaying our understanding of autoimmune diseases and discovery of new treatments," Prof Goodnow said.

"We've based our hypothesis on lots of circumstantial evidence and now a path has opened that will allow us to see whether the genetic mutations that have recently been found to cause lymphoma also hasten the development of autoimmune disease," Prof Goodnow said.

"If we find this, it could open up opportunities in the future for treatments for autoimmune diseases, which may include using the new drugs developed for treating lymphoma cancers," Prof Goodnow said.

Prof Goodnow said that Prof Frank Macfarlane Burnet arrived at the same theory back in 1972.

Glaxosmithkline Australia medical director Dr Andrew Yeates acknowledged Prof Goodnow's work "as a reflection of the significant global contribution Australia makes to the advancement of health and medical research".

"We hope his achievements will inspire other researchers to continue their efforts to better understand human health and patient care," Dr Yeates said.

Glaxosmithkline said autoimmune diseases were some of the most complex, unfamiliar and devastating conditions affecting more than a million Australians, comprising more than 80 chronic and often disabling illnesses including type 1 diabetes, systemic lupus and rheumatoid arthritis and the prevalence was rising.

The company said Prof Goodnow knew the potential of his research as his mother suffered from systemic lupus and his father died from lymphoma.

#### THE UNIVERSITY OF QUEENSLAND

A University of Queensland and Diamantina Institute team led by Dr Fiona Simpson has won a \$25,000 to develop a diagnostic and drug candidate for squamous cell carcinoma. University of Queensland commercialization company Uniquest managing director David Henderson said Dr Simpson was among 14 finalists who competed for the prize pool of \$50,000 to further their research careers.

The University of Queensland's School of Chemical Engineering's Patrick Littlejohn won the \$25,000 student prize for a new method to recover valuable metals from mine waste. The media release said that the Trailblazer competition was run by Uniquest and sponsored by Davies Collison Cave, Fisher Adams Kelly, Griffith Hack, Campus Travel, NRG Solutions, Redback Conferencing and Dibbs Barker.

#### CALZADA, POLYNOVO

Calzada subsidiary Polynovo says it has treated the first of 10 patients in its Novosorb biodegradable temporizing matrix trial following major free-flap surgery.

Calzada said the team at the Royal Adelaide hospital on August 29, 2012, surgically created a full thickness wound at the donor site on the patient's thigh of about 180cm2 in area, from which a free-flap had been taken for use at another site.

The company said that a Novosorb biodegradable temporizing matrix (BTM) was implanted into the donor site, the first step in reconstruction.

Calzada said that early observations indicated that the matrix performance was consistent with the pre-clinical studies results, despite the magnitude of the surgery and that, to date, there had been no infection, good integration in the wound bed, new tissue in-growth, clinical appearance of neo-vascularisation and no wound contraction.

Calzada said the surgical team planned to delaminate the biodegradable temporizing matrix seal and apply a skin graft onto the integrated biodegradable temporizing matrix 'neo-dermis' following completion of new tissue in-growth.

The company said this was expected to happen within the next fortnight and that completeness, quality and rate of skin graft 'take' would be the next study outcomes. Calzada said that one more patient had been recruited into the vacuum assisted closure trial, bringing the total number of patients enrolled to 12 of the required 20, but one control patient had withdrawn "due to serious health issues unrelated to the trial". Calzada fell 0.1 cents or 2.1 percent to 4.7 cents.

#### PHARMAXIS

Pharmaxis shareholders will vote to issue chief executive officer Dr Alan Roberston and director Dr Simon Buckingham 230,000 'performance rights'.

Pharmaxis said the performance rights to acquire shares would be granted at no cost with no exercise price, with 200,000 rights for Dr Robertson and 30,000 rights for Dr Buckingham.

The company said shareholders would vote on the re-election of directors Dr Buckingham and Richard van den Broek.

The meeting will be held at the Sydney Harbour Marriott Hotel, 30 Pitt Street, Sydney on October 17, 2012 at 2.30pm (AEDT).

Pharmaxis fell one cent or 0.9 percent to \$1.10.

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