



# Biotech Daily

Friday May 23, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: PHOSPHAGENICS UP 12%, CELLMID DOWN 8%**
- \* **QUEENSLAND UNI, ORGANOVO PRINT KIDNEY TISSUE**
- \* **THAI COUP 'NO IMPACT ON BIOTRON TRIAL'**
- \* **EURO PATENT OFFICE UPHOLDS CHALLENGE TO BENITEC**
- \* **AGENIX RELEASES 11.5m ESCROW SHARES**
- \* **SIETSMA TAKES 7% OF PHYLOGICA**

## MARKET REPORT

The Australian stock market was up 0.24 percent on Friday May 23, 2014 with the S&P ASX 200 up 12.9 points to 5,492.8 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and one was untraded.

Phosphagenics was the best, up one cent or 12.2 percent to 9.2 cents with 1.5 million shares traded, followed by Universal Biosensors up two cents or 11.8 percent to 19 cents with 3.7 million shares traded.

Impedimed and Oncosil climbed five percent or more; Avita and Biotron were up more than four percent; IDT and Starpharma rose more than two percent; Acrux, Alchemia, Osprey and Nanosonics were up one percent or more; with CSL and Sirtex up by less than one percent.

Cellmid led the falls, down 0.2 cents or eight percent to 2.3 cents with 908,878 shares traded.

Analytica lost 7.7 percent; Neuren fell 5.3 percent; Admedus, Bionomics, Compumedics and Pharmaxis fell more than four percent; Antisense, GI Dynamics and Uscom lost more than three percent; Anteo, Patrys, Prana, Prima and Psivida shed more than two percent; Benitec, Clinuvel, Cochlear, Ellex and Medical Developments were down more than one percent; with Resmed down 0.4 percent.

## QUEENSLAND GOVERNMENT, UNIVERSITY OF QUEENSLAND

The Queensland Government says it has supported a University of Queensland collaboration to print kidney tissue in the US.

A media release from the Queensland Minister for Science and Innovation Ian Walker said that mini-kidney tissue would be printed by the San Diego, California-based three-dimensional bio-printing company Organovo following an agreement signed with the University of Queensland's commercialization company Uniquist.

The head of the University's Institute of Molecular Bioscience genomics of development and disease division Prof Melissa Little said that three-dimensional printing of fully functional mini-kidney tissue would enable better disease modelling and drug development.

"The mini-kidney tissue can be used to test the safety of new drugs," Prof Little said.

"The sad fact is that most new drugs fail during testing in humans and a big reason for that is that they turn out to be toxic to kidneys," Prof Little said.

"If we can test a drug for kidney toxicity before applying it to human trials, we'll save a lot of time, effort and money," Prof Little said.

The media release said that the goal of Prof Little's research was to produce artificial kidneys for humans.

"There's more work to get to this point but when we do it will save lives and cut the cost of treating the disease," Prof Little said.

Mr Walker said the collaboration "delivers on the Government's election promise to provide better front-line services to Queenslanders, especially in health".

In 2011, Organovo and the Melbourne-based Invetech won the Federal Government's Ausindustry Engineering Innovation Award for work on the world's first commercial three-dimensional bio-printer (BD: Nov 24, 2011).

"Prof Melissa Little and her team made a huge leap forward in stem cell technology last year by growing a tiny kidney in a laboratory dish," Mr Walker said.

"One in three Australians are at risk of developing chronic kidney disease so what Prof Little accomplished last year was a hugely important development," Mr Walker said.

"The agreement with Organovo, the world leaders in three-dimensional printing of human tissue, will optimize the cells created using Prof Little's technology in order to print kidney tissues from them using three-dimensional bio-printing," Mr Walker said.

"Mr Walker said the Queensland Government provided \$1 million to support Prof Little's research.

## BIOTRON

Biotron says the military coup in Thailand has not had an effect on its 60-patient phase II trial of BIT225 for hepatitis C.

Biotron said the trial was being undertaken at four Thai teaching hospitals in Bangkok, Chiang Mai and Khon Kaen.

The company said it was "closely monitoring the current situation in Thailand [and information received from the hospital trial sites indicates that no disruptions in operations are expected, and that recruitment and dosing will continue".

Biotron managing director Dr Michelle Miller said that the trial was expected to be fully-recruited in mid-2014 with results by the end of the year.

Biotron was up 0.4 cents or 4.4 percent to 9.5 cents.

## BENITEC BIOPHARMA

Benitec says the European Patent Office has upheld an opposition to one of the European 'Graham' patents directed to genetic constructs for RNA interference.

The patents relate to the work of Dr Michael Graham at the Commonwealth Scientific and Industrial Research Organisation and cover the use of expressed RNA interference in human therapeutic applications (BD: May 5, 2009; Jan 29, Sep 30, 2010; Feb 17, 2011). The main patent, US Patent 6,573,099, known as the Graham '099 patent, entitled 'Genetic Constructs for Delaying or Repressing the Expression of a Target Gene', was the subject of a long-running legal action defended by Benitec and the CSIRO in the US and was finalized in 2011 (BD: Mar 22, 2011).

Today, Benitec said that the European decision "does not have any relevance to other Graham patents in other jurisdictions, or the other patent families owned or licenced by Benitec".

Benitec said that it had executed a licencing agreement with one of the patent opponents, the Belgium-based Galapagos NV, for the use of that company's issued European patent 1 444 346 for human therapeutics and diagnostics, providing non-exclusive rights to use that patent for the further development of its DNA-directed RNA-interference (ddRNAi) pipeline in Europe.

Benitec said that CSIRO's European patent 1,555,317 in the 'Graham' family, licenced exclusively to Benitec for human therapeutics was granted on September 28, 2011 and was due to expire in 2019.

The company said that the opposition to the patent was filed in June 2012 by BASF and a party known as Strawman Limited, later identified as Galapagos NV.

Benitec said the European Patent Office decision was despite the initially favorable opinion from the panel issued prior to the hearing and the submissions presented at the hearing by CSIRO's legal counsel.

The company said that the decision was made on the preliminary ground that one claim feature was not clearly and unambiguously disclosed in this particular patent specification.

Benitec said that the novelty and inventiveness of the claims were not reviewed.

The company said that the decision was appealable and both Benitec and the CSIRO were considering the grounds on which they could appeal the decision.

Benitec chief executive officer Dr Peter French said that while the company was "obviously disappointed with this decision, we remain confident that it will have minimal impact on Benitec's commercial activities and [research and development] programs".

"We have a number of other pending European applications in the RNAi patent estate licensed from CSIRO, which we will continue to pursue," Dr French said.

"In addition we have several other granted patents and patent applications for Benitec's specific therapeutic indications and of course now the Galapagos patent for RNAi in Europe," Dr French said.

Benitec said that its other patents successfully met all of the patentability requirements for each of the countries where they were granted.

The company said that the corresponding US patent to the European patent that was the subject of the European decision underwent the very vigorous re-examination procedure in which all objections were overturned on appeal and the claims substantially reinstated. Benitec said that the Graham patent in Great Britain was also maintained against a revocation action.

The company said that the decision by the European Patent Office was "inconsistent with most of the rest of the world".

Benitec fell 1.5 cents or 1.3 percent to \$1.15.

### AGENIX

Agenix says that 11,516,035 shares were released from voluntary escrow on May 21, 2014.

Agenix chief financial officer Gary Taylor told Biotech Daily that following the release of the shares, his company would have 127,286,591 shares available for trading.

Agenix was untraded at 1.3 cents.

### PHYLOGICA

The Sydney-based Sietsma Holdings has increased its substantial shareholding in Phylogica from 62,000,000 shares (6.19%) to 73,000,000 shares (7.28%).

Sietsma became substantial earlier this week (BD: May 20, 2014).

Today's substantial shareholder notice signed by director David Sietsma said the company acquired 11,000,000 shares on market on May 19 and 20, 2014 for \$163,700 or an average price of 1.5 cents a share.

Phylogica was unchanged at 1.5 cents.