

# Biotech Daily

Thursday March 26, 2009

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: GENERA UP 15%; PRANA DOWN 14%
- \* BENITEC, CSIRO CONTINUE CORE PATENT FIGHT WITH USPTO
- \* PRIMA GAINS 2nd EURO PATENT FOR CVAC OVARIAN CANCER THERAPY
- \* USCOM PRESENTS ITS CARDIAC MONITOR IN CHINA
- \* BONE MEETING BACKS ALL SHARE ISSUE RESOLUTIONS
- \* MESOBLAST REQUESTS 'CAPITAL RAISING TRADING HALT

## MARKET REPORT

The Australian stock market climbed 1.03 percent on Thursday March 26, 2009 with the S&P ASX 200 up 37.3 points to 3,646.6 points.

Sixteen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and seven were untraded.

Genera Biosystems was best, up five cents or 15.2 percent to 38 cents with 76,221 shares traded, followed by Genetic Technologies up 12.5 percent to 4.5 cents.

Alchemia and Avexa climbed more than 11 percent; Peplin was up 9.1 percent; Cytopia and Tyrian were up four percent or more; Cellestis was up three percent; Acrux, CSL, Optiscan and Starpharma rose two percent or more; Cochlear, Impedimed, Pharmaxis, Progen and Resmed were up more than one percent; with Arana and Sirtex up less than one percent.

Prana led the falls, down three cents or 14.3 percent to 18 cents with 106,000 shares traded, Viralytics down 8.1 percent to 3.4 cents.

Novogen lost 7.8 percent; Benitec and Chemgenex were down six percent or more; Biota and Living Cell fell more than four percent; with Universal Biosensors down 1.9 percent.

#### **BENITEC**

Benitec says the US Patent and Trademark Office has advised that its amendments, arguments and evidence "will not be entered on procedural grounds".

Benitec and the Commonwealth Scientific and Industrial Research Organisation are involved in a long-running debate with the US Patent and Trademark Office over the patent re-examination of the '099 Graham patent.

Last year, Benitec said the US examiner had "missed the point" but the company was "confident that its gene silencing intellectual property claims will be further secured through the re-examination of the '099 patent and these related patents or patent applications" (BD: Apr 21, 2008).

Benitec said at the time "the examiner has misinterpreted the science and the state of the art at the time Benitec's patent was filed". The company said the examiner had not accepted the company's arguments in respect of the Zamecnik and Szyf references.

"We believe the examiner has missed the point here as these references relate to ribozymes and oligonucleotides that differ from and don't have the elements of DNA directed RNAi," Benitec said last year.

In today's announcement Benitec said the US Patent and Trademark Office (USPTO) advisory action did not substantively address the extensive arguments presented in support of patentability, did not substantively address evidence in the form of a declaration from a technical expert and provided no explanation for why the proposed amendments would not place the application in condition for allowance.

"We believe this to be improper," Benitec said.

"We intend to seek recourse initially within the USPTO and will receive further advice on other available options before ultimately deciding whether to proceed with an appeal if necessary," the company said.

"Should we receive recourse within the USPTO, the re-examination process will continue taking into account our latest amendments, arguments and evidence," the company said. Representatives of Benitec and CSIRO met with the examiners in mid-February over the remaining re-examination issues.

A response was then lodged with the USPTO on February 26, 2009.

Benitec said it and the CSIRO were "fully committed to this patent and will take this matter to appeal with the USPTO board if necessary".

"If the matter proceeds to an oral hearing before the board of appeal, this would be expected towards the end of 2009 to early 2010 due to the backlog of appeals," the company said.

Benitec chief executive officer Sue MacLeman said her company and CSIRO "remain committed to the '099 Graham patent".

"Moreover, the '099 patent is only one member of a family and Benitec and CSIRO are also entitled to seek additional protection to the subject matter claimed in the '099 patent, subject to double-patenting laws, in pending US continuation applications," she said.

"These applications are not subject to all of the restrictions as apply to the '099 reexamination," Ms MacLeman said.

"Benitec and CSIRO are continuing to obtain specialist advice on how best to further develop the patent portfolio," Ms MacLeman said.

As per the August 2006 agreements, CSIRO had the right to request assignment of Benitec's co-ownership of the '099 patent and CSIRO has exercised this right. Benitec has therefore assigned its share of ownership of this US patent to CSIRO.

The assignment does not impact upon the commercial rights under the 2006 Agreements with CSIRO, with Benitec retaining its exclusive licence for human applications.

Benitec fell 0.2 cents or 6.9 percent to 2.7 cents.

#### **PRIMA BIOMED**

Prima says the European Patent Office has been granted a patent covering the administration of its ovarian cancer immunotherapy product CVac.

Prima said CVac was a therapy treatment for ovarian cancer administered post-surgery and post-chemotherapy to delay relapse and control metastases.

The patent is entitled 'Compositions for immunotherapy' and provides for the ex vivo application of conjugated vaccine to a patient's own dendritic cells.

Prima said the granted patent claims represented "significant value for the company because they create a potential pipeline of products, as they allow the use of any antigen to be conjugated to oxidised mannan fusion protein prior to administration to dendritic cells".

The company said the patent claims created additional value by extending the patent life to 2018, which provided a potential four more years of revenues for the current product under development.

Prima said the previously granted patent provides protection for the production of the CVac product will expire in 2014.

The patent will be validated in Austria, Belgium, Switzerland/Lichtenstein, Germany, Denmark, Spain, France, United Kingdom, Ireland, Italy, Luxembourg, The Netherlands and Sweden.

Prima said it was currently focused on the development of CVac to target the tumor specific antigen Mucin-1, an antigen highly expressed on the surface of ovarian cancer cells.

The company said there was a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate and no maintenance-based therapy products commercially available.

Prima said it was "making rapid progress towards commercializing CVac into the global multi-billion oncology pharmacy market".

Prima was up 0.8 cents or 66.7 percent to two cents with 20.6 million shares worth \$410,166 traded.

#### USCOM

Uscom has presented its ultra sonic cardiac output monitor's technology and science to a meeting in China.

The presentation entitled 'Circulation; measurement and management for all' by Uscom chairman and director of clinical s Rob Phillips was to the Critical Medicine Management Committee of the Traditional Chinese Medicine and Modern Medicine Institute in Tian Jin, followed by visits "to some of the elite medical centres in Beijing" Uscom said.

Uscom chief executive officer Paul Butler said there was "increasing interest in China in Uscom and our approach to management of circulation, particularly in children".

"This presentation supports our Chinese distributors, Pacific Medical Systems, and is expected to stimulate sales in the region," Mr Butler said.

Uscom said the presentation coincided with the publication in the Chinese Pediatric Emergency Medicine journal of research at the Beijing Children's Hospital "confirming the accuracy of Uscom in children".

The company said it had received an order for an additional 10 units from Spacelabs Healthcare for the international market.

Uscom was up two cents or 3.3 percent to 62 cents.

## **BONE MEDICAL**

All four resolutions put to Bone Medical's extraordinary general meeting were passed overwhelmingly.

The ratification of a previous share issue and approval of the issue of shares to the director related company Leif Helth Care were supported by more than 60.9 million proxy votes with just 3,750 proxy votes against.

The approval of share issues to Proxima Concepts and Proxima Laboratory and Research Services were supported by 13.2 million proxy votes with 3,750 proxy votes against and 47.7 million proxy votes abstaining.

Bone was untraded at 25 cents.

## **MESOBLAST**

Mesoblast has requested a trading halt pending an announcement "regarding a capital raising".

Trading will resume on March 30, 2009 or on an earlier announcement. Mesoblast last traded at 80 cents.