



Biotech Daily

Friday November 28, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECHS EVEN: ANTISENSE UP 26%, UNIVERSAL BIO DOWN 10%**
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- * **BIODIEM RECEIVES 6th \$US1m FLU VACCINE MILESTONE PAYMENT**
- * **\$4m GERMAN BUILDING SUBSIDY FOR EASTLAND ASSOCIATE**
- * **BENITEC, CSIRO CONTINUE BATTLE WITH USPTO**
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- * **PHARMAUST WITHDRAWS PLACEMENT RESOLUTION**
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MARKET REPORT

The Australian stock market climbed 4.1 percent on Friday November 28, 2008 with the All Ordinaries up 144.5 points to 3,672.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and 12 were untraded.

Antisense was best, up 0.8 cents or 25.81 percent to 3.9 cents with 17,000 shares traded, followed by Cytopia up 1.5 cents or 10 percent to 16.5 cents.

Labtech and Pharmaxis climbed 9.09 percent; CSL and Novogen were up more than seven percent; Avexa and Polartech climbed five percent or more; Mesoblast was up 3.53 percent; Cochlear and Sirtex rose more than two percent; with Acrux, Progen and Resmed up more than one percent.

Universal Biosensors led the falls, down six cents or 10.17 percent to 53 cents with 85,400 shares traded, followed by Genetic Technologies down 10 percent to 4.5 cents.

Circadian and Clinuvel lost more than eight percent; Chemgenex was down 7.78 percent; Living Cell and Peplin were down 6.67 percent; Ventracor was down 3.7 percent; Bionomics and Biota shed more than two percent; with Arana and Cellestis down more than one percent.

[PRANA](#)

Prana has told its annual general meeting that it is pursuing a second indication of Huntington's disease for lead compound PBT2.

Prana has completed a phase IIa human clinical trial of PBT2 for Alzheimer's disease.

Prana said a commissioned report from independent US-based clinical researchers entitled 'The suitability and recommendations for the clinical development of PBT2 in Huntington's disease' concluded that PBT2 was a suitable candidate for investigation in clinical trials.

Prana said Huntington's disease was an inherited degenerative brain disease causing uncontrolled movements, loss of intellectual faculties and emotional disturbance.

The chairman of Prana's research and development advisory board Prof Jeffrey Cummings said the recommendation of the report was "a real plus for PBT2".

"There are currently no drugs available to patients which prevent or delay Huntington's disease," Prof Cummings said.

"PBT2 has the potential to affect the disease process and therefore to treat the disease," Prof Cummings said.

Prana said that both Huntington's and Alzheimer's diseases involved the toxic interaction of metals and specific protein aggregates in the brain that lead to nerve damage.

The company said its metal protein attenuating compound PBT2, exerted its activity by reducing the metal protein association, thereby reducing the damage to nerve tissue.

"Very importantly, PBT2 has a neuro-protective effect," the company said.

"On the basis of a relevant mechanism of action, supportive non-clinical proof-of-concept studies in Huntington's disease models, preliminary evidence of clinical safety and tolerability and promising clinical and biomarker outcomes in Alzheimer's patients, PBT2 is recommended to proceed to clinical trials in Huntington's disease research participants," the report concluded.

Prana said that PBT2 might be used to treat both Huntington's and Alzheimer's patients.

Prana's chief executive officer Geoffrey Kempler told Biotech Daily the company was "ready for the clinic" with PBT2 for Huntington's but had not set a time-frame.

He said in a notice to the ASX that Prana was ready for larger clinical trials of PBT2 for Alzheimers to advance the drug towards commercialization for that indication.

Earlier this year the company announced preliminary phase IIa trial results and that the primary endpoints of safety and tolerability were met (see Biotech Daily; July 30, 2008).

Prana said PBT2 showed improvement in executive function, an important aspect of cognitive performance and reduced levels of amyloid beta in the spinal fluid of patients.

Abeta is a key protein associated with Alzheimer's disease.

Prana said that publication of the results "attracted a great deal of attention from industry".

Mr Kempler said the company had "entered into confidentiality arrangements with several large pharmaceutical companies" and was in various stages of discussion in respect of the licencing of its lead compound PBT2.

Mr Kempler said Prana had therapeutic drug candidates from its Parkinson's disease program based on the understanding of the relationship between metals, particularly iron, and the metal induced oxidation of dopamine, believed to be involved in damage to the substantia nigra, the area of the brain affected in Parkinson's Disease.

"Already, a lead candidate drug, PBT427, has demonstrated positive effects in pre-clinical in vivo studies, protecting against damage to the substantia nigra," Mr Kempler said.

Prana said a recent cover story of Science-Business Exchange was dedicated to a description of Prana's work on Parkinson's disease.

Prana was unchanged at 30 cents.

BIODIEM

Biodiem says it has received a payment of \$US1m from Schering Plough subsidiary, Nobilon for its intranasal live attenuated influenza vaccine.

Biodiem said it had received \$US6 million of up to \$US8 million in development milestones with the remaining payments payable "over the next few years" prior to the commencement of sales of the influenza vaccine, for which royalties would be paid.

Biodiem has licenced most of the live attenuated influenza vaccine rights to Nobilon.

The company said the vaccine for seasonal indicators was expected to enter human clinical trials in the coming Northern Hemisphere influenza season.

Nobilon has received European registration for its Netherlands facility to begin manufacturing influenza vaccines in cell culture for clinical trials.

Biodiem said Nobilon had the responsibility for developing the influenza vaccine for registration in Europe at its cost.

The company said it retained the sales and marketing rights to North America, subject to an option Nobilon has to the rights, if no other partner is licensed by Biodiem two years after the commencement of phase III clinical trials.

Biodiem said the Japanese rights were to be shared between Biodiem and Nobilon.

Biodiem climbed half a cent or 6.67 percent to eight cents.

EASTLAND MEDICAL SYSTEMS

Eastland said the Federal State of Brandenburg will subsidize its German associated company HC Berlin Pharma SA AG for the construction of facilities.

The production facilities and laboratories are at the company's research and development location at Wissenschaftspark Golm in Potsdam.

Eastland said that after the establishment of a research laboratory, the first portion of the funds of €2 million (\$A3.9 million) will be applied to preproduction, research and quality assurance laboratories.

Eastland said its Artimist anti-malaria drug and other compounds would be bottled at Wissenschaftspark Potsdam-Golm.

Eastland said Artimist was "about to undergo the last clinical examination phase" and market admission was planned for 2009.

Eastland said it was confident that the production facilities necessary for delivering the required volumes to market during 2009 would be achieved positioning it to achieve significant positive revenues in 2009.

Eastland was unchanged at 11 cents.

BIOTA

Biota has appointed Richard Hill as a non executive director.

Biota said Mr Hill was "an experienced director of mid sized Australian public companies and brings extensive investment banking and legal skills to the board".

The company said Mr Hill was chairman of Sirtex Medical and Calliden Group and a director of Pelorus Property Group.

Biota said Mr Hill was a New York State attorney, a founding partner of Hill Young & Associates and formerly held senior executive positions in Hong Kong and New York with Wardley Holdings, a subsidiary of Hong Kong & Shanghai Banking Corporation.

Biota director Barbara Gibson retires on December 31, 2008 and chairman John Grant has said he intends to retire during 2009.

Biota fell one cent or 2.67 percent to 36.5 cents.

BENITEC, CSIRO

Benitec says that with the Commonwealth Scientific and Industrial Research Organisation it has requested a meeting with the US Patent and Trademark Office on core patents.

Benitec says that a 'final office action' from the USPTO on its '099 Graham patent saw the withdrawal of three "novelty rejections" which the company said was good, but one other novelty rejection has been maintained over the Szyf reference and the USPTO examiner has been asked to clarify the status of a second novelty rejection over the Fire reference. Benitec said there were also two "obviousness rejections", one essentially to claim 4 and its derivatives in the patent and one essentially to claim 5 and its derivatives.

The meeting with the USPTO examiner is scheduled for December 2008 and Benitec and CSIRO have the right to appeal the decision.

Benitec and CSIRO expect to file a written response in January 2009 and, if necessary, a notice of appeal in February 2009 and an appeal brief in April 2009.

Benitec said that in the meantime, the examiner would have the opportunity to amend or remove some or all of the remaining rejections "and this typically happens in such back and forth communications".

Benitec chief executive officer Sue MacLeman said that Benitec and the CSIRO were committed to the '099 Graham patent.

"Moreover, the '099 patent is only one member of a family," Ms MacLeman said.

"Benitec and CSIRO are also entitled to seek additional protection of the same subject matter claimed in the '099 patent, subject to double-patenting laws, in any of a number of US continuation applications," Ms MacLeman said.

"These applications are not subject to all of the restrictions that apply to the '099 re-examination," she said.

Ms MacLeman has previously said the Graham patent under re-examination was important, but the company had 98 patent applications and granted patents in the RNAi space (see Biotech Daily; April 21, 2008).

Benitec said in April "the examiner has misinterpreted the science and the state of the art at the time Benitec's patent was filed".

"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 at that time.

Benitec was untraded at three cents

PATRYS

A significant number of Patrys shareholders opposed the issue of options to directors at the company's annual general meeting.

The issue of 600,000 options to John Read was opposed by 13,279,785 proxy votes with 98,100,894 proxy votes in favor.

Mr Read was re-elected with 111,582,394 proxy votes in favor and 118,173 votes against. Director Dr Alan Robertson's 300,000 options were opposed by 12,907,794 proxy votes with 98,717,885 proxy votes in favor.

The 300,000 options for Michael Stork were opposed by 13,279,785 proxy votes with 67,032,054 proxy votes in favor.

Patrys's website says that Mr Stork is the managing director of FJ Stork, the parent entity for PNK Holdings, an original investor in Acceptys and Patrys.

The approval of the acquisition of Acceptys was opposed by 9,986,662 proxy votes, with 65,402,473 proxy votes in favor.

Patrys fell one cent or 10 percent to nine cents.

PHARMAUST

Pharmaust withdrew a resolution to approve the issue of up to 35,000,000 shares for a placement prior to its annual general meeting.

No one at Pharmaust was available to explain the resolution withdrawal.

Resolutions on the remuneration report and the re-election of directors Henry Gulev and Sam Wright were passed by more than 90 million proxy votes in favor to up to 4.8 million proxy votes against.

Pharmaust was unchanged at two cents.

ROCKEBY

Rockeby's annual general meeting faced strong opposition to all 18 resolutions.

The closest vote saw 112,907,271 proxy votes in favor of an increase in the voting power of Modern State International and Super Gateway Group with 71,650,970 proxy votes against.

All other resolutions were passed by similar margins and all were passed "on a show of hands".

Rockeby was unchanged at 0.1 cents.

FEDERAL GOVERNMENT

Industry Minister Senator Kim Carr has released the new guidelines for the Australian Government's re-invigorated Cooperative Research Centres program.

Senator Carr also launched the 11th selection round.

"The revitalization of the CRC program was an election commitment, which I am very pleased to say we have delivered after a comprehensive review of the program conducted by Prof Mary O'Kane," Senator Carr said.

"The re-instatement of public good as an assessment criterion and the inclusion of the humanities, arts and social sciences will broaden the base of the program," Senator Carr said.

"The revised objectives mean that CRCs will deliver significant economic, environmental and social benefits," he said. In 2008, the Australian Government will provide more than \$182 million to CRCs."

"Applications close on March 20, 2009 and I expect to announce the results of the selection process by the middle of next year," Senator Carr said.

"Information sessions will be conducted nationally and I urge participants to obtain a copy of the guidelines from the CRC Program website and to attend the information sessions (details attached)," Senator Carr said.