

# Biotech Daily

Wednesday November 9, 2011

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: ANTISENSE UP 22%; NEUREN DOWN 11%
- \* CSL RAISES \$1.5b TO RETIRE DEBT, BUY BACK SHARES
- \* PBAC DENIES PHARMAXIS BRONCHITOL SUBSIDY, AGAIN
- \* ACTINOGEN'S CANCER ACTINOMYCETES FOR CHEAP BIOFUEL; UP 150%
- \* BPH, CORTICAL DYNAMICS 3<sup>rd</sup> NZ PATENT FOR BAR MONITOR
- \* LOW-SHOW VOTES OPPOSE CLINUVEL DIRECTOR 'RIGHTS'

#### MARKET REPORT

The Australian stock market climbed 1.22 percent on Wednesday November 9, 2011 with the S&P ASX 200 up 52.3 points to 4,346.1 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and five were untraded.

Antisense was the best, up 0.2 cents or 22.2 percent to 1.1 cents with 10.5 million shares traded.

Genera climbed 6.9 percent; Cathrx was up five percent; Patrys was up four percent; Anteo, Clinuvel, Impedimed and Pharmaxis were up more than three percent; Phosphagenics, Prima and Universal Biosensors rose more than two percent; Cochlear was up 1.35 percent; with Biota, Circadian and CSL up by less than one percent.

Neuren led the falls, down 0.3 cents or 10.7 percent to 2.5 cents, with 18.3 million shares traded.

Allied Health and Benitec lost more than five percent; Psivida fell 4.65 percent; Phylogica was down 3.5 percent; Living Cell and Mesoblast shed more than two percent; QRX and Starpharma were down more than one percent; with Acrux and Sirtex down by less than one percent.

## **CSL**

CSL says it has raised \$1,524 million through a US\$750 million (\$A724 million) private US placement and the equivalent of about \$800 million in new lines of credit with its banks. CSL said the funds would be used to repay existing debt and fund the company's capital management plan, including the on-market share buy-back of up to \$900 million in shares as well as general corporate purposes.

The company said the lines of credit would be drawn down as required.

CSL said placement and lines of credit were foreshadowed in its full year results (BD: Aug 17, 2011).

CSL was up 15 cents or 0.5 percent to \$30.20 with 1.4 million shares traded.

## **PHARMAXIS**

Pharmaxis says the Pharmaceutical Benefits Advisory Committee has not recommended Bronchitol for cystic fibrosis for the Australian Pharmaceutical Benefits Scheme.

Pharmaxis said that the government's expert advisory body had given verbal advice of the decision made at the Pharmaceutical Benefits Advisory Committee's November meeting, the minutes of which will be published on the PBAC website next month and "on this occasion" not approved Bronchitol for Federal Government reimbursement.

Pharmaxis said it would meet the chair of Committee in early December to discuss the Committee's outstanding concerns.

Earlier this year the company's first submission to list Bronchitol for the treatment of cystic fibrosis was reviewed at the March meeting of the Pharmaceutical Benefits Advisory Committee and was not recommended for inclusion, due to what the Committee described as "uncertainties in where Bronchitol will fit in clinical practice and consequent difficulties in identifying the right comparator in one clinical setting that leads to uncertain cost effectiveness" (BD: Apr 21, 2011).

Pharmaxis chief executive officer Dr Alan Robertson said in April that "the majority of new drugs take at least two submissions before being recommended for PBS listing". In July the company submitted its re-application for the November PBAC meeting saying that if approved, Bronchitol would then be subject to consideration by the Pharmaceutical Benefits Pricing Authority and the Australian Government (BD: Jul 12, 2011).

Today Pharmaxis chief executive officer Dr Alan Robertson said the decision came "just weeks after a positive opinion on Bronchitol by European regulators and days after a positive additional reimbursement decision for Aridol in the US and highlights the fact that Australia is one of the most challenging reimbursement environments in the world".

"In response to issues raised by the PBAC during its previous review, Pharmaxis provided extensive additional data covering centres that serve more than half of all the Australian [cystic fibrosis] patients," Dr Robertson said.

"In addition, expert testimony was provided by the Thoracic Society of Australia on the role of Bronchitol in the management of cystic fibrosis," Dr Robertson said.

"We will continue to work with the PBAC to understand what further information it still requires in order to make Bronchitol available on a subsidized basis for Australians living with cystic fibrosis," Dr Robertson said.

Pharmaxis said that Bronchitol was an Australian discovered and developed product which was approved for marketing in Australia in February (BD: Feb 8, 2011) and recently received a positive opinion by a European regulatory committee, clearing the way for its marketing in 29 countries in Europe (BD: Oct 24, 2011).

Pharmaxis closed before the announcement up 4.5 cents or 3.4 percent at \$1.37 with 2.2 million shares traded.

#### **ACTINOGEN**

Actinogen says it has discovered actinomycetes that produce cellulase or cellulases as a by-product when breaking down newspaper, brown paper and glycerol.

Actinogen said it had been running a research program to develop the cheaper production of bio-fuel, which may make bio-fuel a cost-effective and environmentally friendly alternative energy option.

The company said cellulase was a key component in the production of bio-ethanol, but most cellulase production by a bio-cellulase producing system often uses an anaerobic environment and high temperatures in the producing system, which made biocellulase production costly.

Actinogen said it could produce cellulases from the activity of particular actinomycetes when the actinomycetes were exposed to brown paper, newspaper or glycerol and the cellulases produced in an aerobic environment did not require a high temperature system. The company said that production of cellulases by its actinomycetes did not require the use of foodstuffs and eliminated the need to use crops and food required by people in the production of bio-ethanol.

Actinogen said it planned to continue its research into producing cellulase from the break down of newspaper, brown paper and glycerol with an aim to produce cheaper bio-fuel for widespread use.

The company said the Commonwealth Scientific and Industrial Research Organisation had completed independent tests on Actinogen's method of producing cellulases and had confirmed that Actinogen could produce cellulases in volumes of up to 10 litres. Actinogen said it was ready to expand its research program to industrial based assessment and pilot scale development.

If successful, Actinogen said it hoped to be able to produce cellulases and bio-ethanol at a cheaper rate than the current commercial production.

In October, Actinogen won shareholder approval to acquire Celgenics to strengthen its cancer screening research and development programs (BD: Sep 26, Oct 4, 2011). Actinogen was up 2.7 cents or 150 percent to 4.5 cents.

## BPH ENERGY, CORTICAL DYNAMICS

BPH says its 3.6 percent investee company Cortical Dynamics has been granted a third New Zealand patent for its brain anaesthesia response (BAR) monitoring unit.

BPH said Cortical had patents awarded in Australia, New Zealand, Japan, the People's Republic of China and the US.

The company said the third New Zealand patent was entitled 'EEG Analysis System' (NZ patent number 573459) and was valid to June 6, 2027.

BPH and Cortical chairman David Breeze said the New Zealand patent grant was "a critical step in Cortical's business strategy as it provides protection for a method that is capable of providing clinically relevant information beyond just hypnotic state".

BPH said that Cortical Dynamics had applied for admission to the Australian Securities Exchange with the initial public offer to raise up to \$4 million closing date extended to January 31, 2012 (BD: Jun 3, Sep 26, 2011).

The company said the BAR monitoring system measured electroencephalogram brain electrical activity to indicate how deeply anaesthetised a patient was during an operation. BPH said the monitor was designed to assist anaesthetists and intensive care staff in ensuring patients do not wake up un-expectedly, as well as reducing the incidence of side effects associated with the anaesthetic.

BPH fell 0.1 cents or 2.9 percent to 3.3 cents.

## **CLINUVEL**

Five of seven resolutions at the Clinuvel annual general meeting were won against significant opposition, with director 'rights' the most controversial.

The closest vote was on the issue of 'performance rights' to director Elie Ishag which was won with 2,455,730 total votes (55.8%) in favor and 1,943,878 votes (44.2%) against. Performance rights for directors Stan McLiesh, Brenda Shanahan and Jack Wood were passed by a slightly wider margin.

Mr Wood was reelected a director with 3,433,253 proxy votes in favor and 87,572 proxy votes against, but Mr Ishag's reelection was opposed by 1,102,462 proxy votes (31.2%), with 2,425,586 proxy votes (68.8%) in favor.

The remuneration report was adopted with more than 3.3 million proxy votes in favor and 241,719 proxy votes against.

Clinuvel's most recent Appendix 3B share issue announcement said there were 30,394,206 shares on issue, meaning that the strongest opposition came from 6.4 percent of all shares on issue, sufficient to requisition extraordinary general meetings, and about 10 percent of all eligible votes were cast for the resolutions.

Clinuvel was up five cents or 3.4 percent to \$1.53.