



# Biotech Daily

Friday June 3, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: BIONICHE UP 15.5%; USCOM DOWN 15%**
- \* **BPH'S CORTICAL DYNAMICS \$2m BRAIN ANAESTHESIA MONITOR IPO**
- \* **BIOMD EARLY LOOK SHOWS ADAPT HEART VALVE SUPERIOR**
- \* **BIONOMICS DETAILS KIDNEY CANCER PROGRAM**
- \* **HEALTHLINX OVPLEX OVARIAN CANCER TEST AUSTRALIAN PATENT**
- \* **NOVOGEN'S MARSHALL EDWARDS APPOINTS DR ROBERT MASS CMO**

## MARKET REPORT

The Australian stock market fell 0.38 percent on Friday June 3, 2011 with the S&P ASX 200 down 17.3 points to 4583.1 points.

Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and five were untraded. All three Big Caps were up.

Bioniche was the best, up 15 cents or 15.5 percent to \$1.12 with 10,517 shares traded, followed by Phylogica up 4.7 percent to 6.7 cents with 650,000 shares traded.

Acrux and Genetic Technologies rose more than two percent; with Alchemia, Cochlear, Starpharma and Universal Biosensors up one percent or more.

Uscom led the falls, down four cents or 15.4 percent to 22 cents, with 1,000 shares traded, followed by Antisense down 9.1 percent to one cent with 1.9 million shares traded.

Compumedics lost five percent; Virax fell 4.35 percent; Bionomics, Mesoblast, Optiscan, QRX and Sirtex were down more than three percent; Benitec and Heartware shed more than two percent; with Anteo, Living Cell and Tissue Therapies down one percent or more.

### CORTICAL DYNAMICS, BPH

Cortical Dynamics will raise up to \$4 million and list on the ASX to commercialize its Brain Anaesthesia Response Monitor developed at Melbourne's Swinburne University.

Cortical Dynamics is a 3.6 percent subsidiary of BPH Energy, formerly Biopharmica, which has interests in spin-out Molecular Discover Systems and the HLS5 tumor suppressor gene (BD: Nov 13, 24, 2009) and is associated with underwriter Grandbridge Securities. The Swinburne University-developed Brain Anaesthesia Response (BAR) Monitor was developed to detect the depth of anaesthesia in patients undergoing surgery, following reports of patients aware of their surgery and unable to communicate their level of pain and or consciousness (BD: Jul 23, 2010).

BPH and Grandbridge chairman David Breeze will be chairman and managing director, Grandbridge director Deborah Ambrosini an executive director, with the director of Swinburne's commercialization unit Dr Bruce Whan and Greg Gilbert also directors.

Cortical Dynamics said it would require the continued input of key researcher Swinburne's Dr David Liley to develop the product.

The initial public offer is for 10 million shares at 20 cents a share with one free attaching option per share exercisable at 20 cents up to June 30, 2012, with over-subscriptions of up to a further 10 million shares and options on the same terms.

The offer opens on June 10 and closes on July 22, 2011 with an expected listing on the ASX under the code CDZ on July 29, 2011.

Ms Ambrosini told Biotech Daily the BAR monitor would compete with the existing BIS Monitor which sold for \$11,000 to \$15,000.

The prospectus is at <http://www.corticaldynamics.com/application/doc/Prospectus.pdf>.

BPH was unchanged at 3.7 cents.

### BIOMD

Biomd says early examination of its Adapt bovine tissue heart valve has shown no calcification while two commercial samples had calcified.

Biomd said the study was being conducted by its subsidiary Celxcel and an unnamed tissue heart valve manufacturer.

The company said the feasibility study successfully completed its first major milestone last year (BD: Nov 1, 2010) and was continuing to the second phase of an in vivo tissue calcification comparison study and an in vitro fatigue testing calcification model.

Biomd said that explanted tissue samples from 30 rats, each with four implants, would be tested and subjected to histological examination at eight, 16 and 24 week intervals.

The company said the study began on March 22, 2011 and the eight week tissue samples from 10 animals were explanted.

Biomd said macroscopic and histological examination showed no calcification in the Adapt samples, but two commercial valve samples had mild to moderate calcification.

The company said the fatigue testing calcification model would measure the calcification reduction potential of Adapt-treated tissue heart valves when mounted in a pulse duplicator, a dynamic and functional flow testing machine that mimics the opening and closing of a tissue heart valve.

Biomd said the calcification reduction potential of the Adapt treated valves would be measured with the addition of Celxcel's sterilization process.

The company said the fatigue testing commenced on May 16, 2011, after a short delay in validating the test protocol and the valves would be continually monitored over 50 million cycles and then removed and evaluated for calcification.

Biomd was unchanged at 6.9 cents.

## BIONOMICS

Bionomics has detailed its phase I and II clinical trial program for BNC105 for patients with progressive metastatic renal cancer.

Bionomics announced the start of the phase II trial last year (BD: Jan 27, 2010).

Bionomics said the trial design would be presented in a poster entitled 'Phase I/II study of BNC105P in combination with everolimus or following renal cell carcinoma following prior tyrosine kinase inhibitors' to be presented at the American Society for Clinical Oncology meeting in Chicago on June 6, 2011, by principal investigator Dr Thomas E Hutson of the Baylor Sammons Cancer Center Texas.

The poster said the 24-patient phase I dose ranging trial would determine maximum tolerated dose and toxicities of the pro-drug from of BNC105 (BNC105P) in combination with everolimus (Afinitor) as well as response rates and pharmacokinetic profile.

The poster said the randomized phase II trial would enroll 134 patients to assess improvement in six-month progression-free survival with the addition of BNC105P to everolimus as well as determining progression-free survival with BNC105P alone in patients progressing on everolimus and evaluating adverse events and overall survival. Bionomics said it presented preclinical data supporting the trial in patients with renal cancer at the American Association for Cancer Research in April 2011 showing potent vascular disrupting effects of BNC105 in two mouse models of renal cancer, including a model in which the cancer spread to the lungs.

The company said BNC105 induced tumor blood vessel shutdown in both the primary tumor and the secondary lung cancer.

Bionomics said the tyrosine kinase inhibitor Sutent was used in first line renal cancer therapy and BNC105 was shown to be comparable to drug selling \$US1.1 billion in 2010.

The company said treatment options were limited in progressive metastatic renal cell cancer for patients who no longer respond to treatments such as Sutent.

Bionomics said the BNC105 trial was being conducted in patients who have failed tyrosine kinase inhibitor therapy and were also being treated with Afinitor, a mammalian target of rapamycin (mTOR) inhibitor.

Bionomics fell two cents or three percent to 64 cents with 1.9 million shares traded.

## HEALTHLINX

Healthlinx says it has been granted an Australian patent for its Ovplex technology entitled 'An assay to detect a gynecological condition'.

Healthlinx said that all of its claims had been deemed novel, inventive and having industrial application.

The company said it was the second jurisdiction after the United Kingdom in which it had been granted a patent for the company's lead product.

Healthlinx managing director Nick Gatsios said the Australian patent was further validation of the Ovplex panel's "first-in-class technology".

"This is the second jurisdiction in which the Ovplex patent has been granted," Mr Gatsios said. "We have applied to patent the Ovplex panel in all major jurisdictions and this news certainly makes us very confident of further good news."

Healthlinx said the Ovplex test examined a series of biomarkers from a blood sample deemed important in the diagnosis of ovarian cancer, including the current 'gold standard' biomarker CA125 and the granted patent covered the combination of proprietary biomarkers, as well as the methodology used for implementing the test in a typical clinical pathology environment.

Healthlinx was up half a cent or 11.1 percent to five cents with 1.2 million shares traded.

## NOVOGEN

Novogen says its 65 percent subsidiary Marshall Edwards has appointed former Genentech executive Dr Robert Mass as chief medical officer.

Novogen said Dr Mass had spend more than 10 years at Genentech, “where he played a leading role in the clinical development of blockbuster oncology drugs Herceptin , Tarceva and Avastin.

The company said Dr Mass had been a consultant for Marshall Edwards since October 2010.

Novogen said Dr Mass had more than 20 years experience as a medical oncologist in both clinical practice and clinical drug development and was most recently Genentech’s head of medical affairs for bio-oncology, a position created to strategically integrate and optimize the non-sponsored clinical programs within the company’s oncology portfolio.

The company said that prior to joining Genentech, Dr Mass practiced haematology and medical oncology from 1988 to 1998.

Novogen said Dr Mass held a bachelor’s degree in economics from Tufts University and a medical degree from Oregon Health & Science University.

Novogen said Marshall Edwards had granted Dr Mass options to purchase 177,620 shares of its common stock with an exercise price per share equal to the closing price of the company’s common stock on June 1, 2011 (\$US1.28).

The company said 25 percent of the options would vest one year from the date he commenced employment with the company, and the remaining 75 percent in equal monthly installments over the following 36 months.

Novogen was unchanged at 18.5 cents.