



# Biotech Daily

Wednesday March 9, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: HEARTWARE UP 5.5%; PRIMA DOWN 6%**
- \* **CAMBRIDGE, PHYLOGICA PARTNER IN PHENOMICA TARGET DISCOVERY**
- \* **EURO PATENT FOR ANTEO'S MIX&GO ANTIBODY GLUE**
- \* **HEALTHLINX DIFFICULT CASES SUPPORT ALGORITHM**
- \* **BIOMD AGREEMENT FOR IN VIVO, IN VITRO CARDIAC PATCH TRIALS**
- \* **JIANGSU AOSAIKANG TAKES 5% OF LIVING CELL FOR \$1.7m**
- \* **BIONICHE LOOKING FOR RETAIL INVESTORS**
- \* **PATRY'S PRODUCES COMMERCIAL YIELDS OF PAT-SC1 FOR CANCER**
- \* **NZ GONG FOR LIVING CELL FOUNDER PROF BOB ELLIOTT**
- \* **OBJ OPTIONS RAISE \$56k**
- \* **STIRLING REQUESTS 'PROGRESS' TRADING HALT**

## MARKET REPORT

The Australian stock market fell 0.84 percent on Wednesday March 9, 2011 with the S&P ASX 200 down 40.4 points to 4767.8 points.

Eight of the Biotech Daily Top 40 stocks were up, 14 fell, 14 traded unchanged and four were untraded.

Heartware was best, up 13 cents or 5.5 percent to \$2.50, with 1,150 shares traded.

Cellestis climbed five percent; Psivida and Virax were up more than three percent; with Chemgenex and Tissue Therapies up more than one percent.

Prima led the falls, down 1.5 cents or 6.25 percent to 22.5 cents, with 7.5 million shares traded, followed by Starpharma down five percent to \$1.045 with 514,473 shares traded.

Phosphagenics lost 4.2 percent; Benitec and Mesoblast were down more than three percent; Genetic Technologies and Pharmaxis shed more than two percent; with Acrux, Bioniche, Bionomics, Biota, Clinuvel, Nanosonics and Phylogica down one percent or more.

## PHYLOGICA

Phylogica will partner with University of Cambridge researchers in a spin-off company to pursue an application of its Phylomer peptides for discovery of disease-associated targets. Phylogica said the spin-off company, Phenomica, would combine its Phylomer libraries, of billions of naturally derived peptides, with technology from Cambridge to identify vulnerable points in a disease that could be the focus for new drug development.

The company said it had signed a memorandum of understanding with Cambridge Enterprise, the University's commercialization group and Phenomica would be based in Cambridge, maximizing access to state-of-the-art research facilities.

Phylogica said Phenomica would discover and validate new disease-associated targets and identify new avenues for therapeutic intervention.

The company said Phenomica had the potential to secure new revenue streams that would otherwise not be accessible to Phylogica without substantial investment in both capital and technical expertise.

Phylogica said it had begun discussions with prospective partners who are interested in the capabilities of the new Phylogica-Cambridge University venture.

Phylogica chief executive officer Dr Paul Watt said the formation of Phenomica followed extensive collaboration on target discovery and validation with the molecular therapeutics program directed by Prof Ashok Venkitaraman at the Hutchison Medical Research Council Research Centre.

"The researchers at Cambridge, in collaboration with Phylogica, reported that phenotypic screening of Phylomer libraries against biological pathways associated with the development of cancer, resulted in exceptional hit rates for modulating these pathways and hence a better understanding of the disease process and how to block it," Dr Watt said.

"Since then, intense work on the technology by the Cambridge-based team has established that this novel application of our libraries can be used more broadly as a tool to identify and validate disease-relevant biological targets for drug discovery," Dr Watt said.

Dr Watt said that Phenomica would provide access to the expanding field of phenotypic screening for target discovery without competing with or distracting from its core focus on drug discovery alliances.

Phylogica fell 0.1 cents or 1.4 percent to 7.2 cents.

## ANTEO DIAGNOSTICS

Anteo says the European Patent Office intends to grant the 'Generation of Surface Coating Diversity' patent for its Mix&Go technology.

Anteo said the process used to bind antibodies to more than 8,000 different types of surfaces could be copied in the European market and provided protection until 2023.

The company said additional screening exercises that could be initiated to identify new glues for a broad range of other industries and sectors would be covered under the patent.

Anteo said the patent had been granted in Australia and was being considered in other markets, while another family of patents had been filed to protect Mix&Go and further patents to protect more recent innovations were scheduled to be filed by July 2011.

Anteo managing director Dr Geoff Cumming said the patent "underpins the value of the intellectual property that led to the discovery of our Mix&Go technology".

"The Mix&Go technology can be applied to a broad number of sectors outside of healthcare and this presents significant future upside," Dr Cumming said.

Anteo was unchanged at 7.2 cents with 6.9 million shares traded.

## HEALTHLINX

Healthlinx has combined data from its two trials to show its Ovplex ovarian cancer diagnostic is superior to the standard CA-125 test alone.

The Ovplex test includes the CA-125 biomarker along with four other biomarkers: C-reactive protein, serum amyloid A, interleukin 6 and interleukin 8.

Healthlinx is also evaluating two further bio-markers, anterior gradient protein 2 (AGR2) and HTX010.

The company reported data from its first trial of 362 samples in November 2007, saying it had accuracy of 93 percent compared to CA-125's 70 to 80 percent accuracy and hoping for a target accuracy of 97 percent (BD: Feb 21, 2008; Aug 4, 2009).

Last month, Healthlinx published interim data on the first 485 samples from its 1150 sample trial currently underway saying the standard Ovplex test had 91.1 percent accuracy compared to CA-125 with 86.03 percent accuracy (BD: Feb 15, 2011).

Healthlinx said at the time that adding the AGR2 biomarker increased accuracy to 93.84 percent.

The company has not provided comparative sensitivity and specificity data.

Today, Healthlinx said that adding the more difficult to diagnose 127 benign patient cohort to the first trial's data showed approximately the same level of accuracy, 93.5 percent.

Healthlinx said the combined study of 489 samples from Australia and Singapore included 150 women with ovarian cancer, 127 women with benign gynaecological conditions and 212 normal control women.

Healthlinx said the first Ovplex biomarker trial included ovarian cancer cases (150) and control normal women (212) that were used to generate the first generation Ovplex algorithm.

The company said the second trial included a wider range of clinically relevant samples including women with benign gynaecological conditions.

Healthlinx said preliminary modeling studies to determine the impact of including this benign patient cohort into the existing Ovplex model showed that Ovplex correctly identified women with malignant ovarian cancer with greater than 93 percent accuracy.

The total number of misdiagnoses was only 32 or 6.5 percent of the 489 samples or a diagnostic efficiency of 93.5 percent, Healthlinx said.

The company said the analysis "further confirms the diagnostic efficiency [and] utility of the test in symptomatic women and suggests that significant improvements to the diagnostic capability of the Ovplex test will be possible to implement once all trial data is collected".

Healthlinx managing director Nick Gatsios said the company was continuing its data analysis and validation of the Ovplex test.

"What is extremely positive from these current data is the ability of Ovplex to correctly classify not only normal healthy women, but also women with benign conditions from women with malignant ovarian cancer," Mr Gatsios said.

"This is most significant and suggests that future improvements to the Ovplex test will only increase its clinical utility and benefit to women globally," Mr Gatsios said.

Healthlinx said that worldwide more than 240,000 new cases of ovarian cancer were diagnosed each year, while more than 130,000 women die from the disease.

The company said ovarian cancer was the most lethal of the reproductive tract cancers and 75 percent of women with ovarian cancer were not diagnosed until late stage disease.

Healthlinx said the chances of diagnosed women surviving five years was about 20 to 30 percent, but if the disease was diagnosed at an early stage, when it was contained within the ovary, the chance of surviving five years rose to 80 percent.

Healthlinx fell 0.3 cents or 4.8 percent to 5.9 cents.

## BIOMD

Biomd says it has signed a material transfer agreement with an unnamed company to allow the continuation of its tissue heart valve feasibility study (BD: Nov 1, 2010).

Biomd said a number of ready-for-sale tissue heart valves had arrived in Australia and the study would begin tomorrow, conducted jointly with its subsidiary Celxcel and the unnamed global tissue heart valve manufacturer.

The company said the next phase of the project involved two simultaneous studies, an in vivo tissue comparison study and an in vitro fatigue testing calcification model.

Biomd said the aim of the in vivo rat study was to compare the performance including biocompatibility and calcification potential of bovine pericardial tissue, treated with Biomd's Adapt anti-calcification process with the commercial tissue product provided by the tissue heart valve partner in a rat model.

The company said the study also hoped to determine the effect of the Adapt technology on the performance of the commercial heart valve tissue after treatment with the Adapt anti-calcification process.

Biomd said the explanted material would be subjected to histological examination to determine which cell types enter the implanted material and the calcium content of the materials would be determined, as well as the presence of host protein markers inside the explanted materials.

Biomd said the aim of the fatigue testing calcification model was to measure the calcification reduction potential of Adapt treated tissue heart valves when mounted in a pulse duplicator which was a dynamic and functional flow testing machine that mimics the opening and closing of a tissue heart valve.

The trial would measure the calcification reduction potential of the Adapt treated valves with the addition of Celxcel's sterilisation process and the valves would be continually monitored over 15 million cycles and then removed and evaluated for calcification.

Biomd said it expected the untreated commercial tissue heart valves to calcify over time, while the Adapt-treated commercial tissue heart valves should show a significant reduction in calcification while the addition of the sterilisation process should further reduce the calcification potential of the valves.

Last month, Biomd announced an off- market takeover of Allied Medical (BD: Feb 15, 2011).

Biomd fell 0.1 cents or 1.75 percent to 5.6 cents.

## LIVING CELL TECHNOLOGIES

Living Cell says it has received \$1.7 million from the Jiangsu Aosaikang Pharmaceutical Co for 14,334,080 placement shares or 4.7 percent of the company (BD: Jan 31, 2011).

Living Cell said that Jiangsu Aosaikang was a private research-based pharmaceutical company, based in Nanjing, China, established in 2005 and developed, produced and marketed pharmaceuticals and healthcare products, with more than 60 pharmaceutical products on the market.

Living Cell chief executive officer Dr Ross Macdonald said the company was "very pleased to welcome Jiangsu Aosaikang Pharmaceutical as a strategic investor".

Dr Macdonald said the funding would allow the company to progress development and clinical trials of Diabecell, for type 1 diabetes.

Living Cell said the two companies had agreed to negotiate a collaborative research agreement, including a right of first refusal to commercialize Diabecell in China and become the sole agency to treat patients once the product was registered in China.

Living Cell was unchanged at 9.5 cents.

## BIONICHE

Bioniche executives are on an Australian road-show to encourage new retail investors. The Canada-based Bioniche raised \$30 million primarily from institutions in Australia and Canada at the end of last year for its Urocidin phase III bladder cancer treatment.

Today, chairman and chief executive officer Graeme McRae told Biotech Daily that the company was pleased with the Australian institutional response but wanted to increase the retail investor profile of the company.

Mr McRae said Bioniche wanted to increase the liquidity of the Australian shares, along with retail investor interest in the company.

"We want to thank the investors, meet the new investors and find new investors among the general public," Mr McRae said.

Mr McRae said a phase III trial of Urocidin in 129 patients had been completed and the second 450-patient phase III trial was funded by Bioniche partner Endo Pharmaceuticals and had begun enrolments in centres in North America, Australia and India.

Mr McRae said the company had cash for a range of activities including improvements to facilities and its animal health arm.

Mr McRae said that Urocidin was originally developed in its animal health facilities and the company was examining further indications for the technology.

Mr McRae, along with Bioniche chief financial officer Brian Ford and communications vice-president Jennifer Shea are meeting investors in Sydney Melbourne Brisbane and New Zealand.

Bioniche fell two cents or 1.4 percent to \$1.38.

## PATRYS

Patrys says it has obtained commercial production yields for the natural human antibody PAT-SC1, facilitating a second human clinical trial for the treatment of cancer.

Prior to being acquired by Patrys, PAT-SC1 was evaluated for safety and efficacy in a human clinical trial involving gastric cancer patients (BD: Nov 5, 2011).

The company said the previous trial results were encouraging, as patients treated with PAT-SC1 experienced a significant survival benefit compared to a historical control set of patients that received similar treatment but for the PAT-SC1 antibody.

Patrys said Percivia, a US joint venture of Johnson & Johnson subsidiary Crucell NV with DSM Biologics achieved yields of 4 grams/litre, which exceeded the commonly cited industry standard for production of an antibody in phase I/II clinical trials of 1 gram/litre.

Patrys chief executive officer Dan Devine said the company would focus its efforts on how best to advance clinical development as an internal or partnered program.

The company said that several researchers from independent laboratories reported new data pointing to an expanded and critical role of PAT-SC1's target CD55.

Patrys said that cancer cells expressing CD55 were resistant to the antibody rituximab; inhibition of CD55 sensitized breast, prostate and leukaemia cancer cells to complement attack and could be useful as possible adjuvant to improve antibody-based cancer immunotherapy; expressions of CD55 in rectal tumor tissues significantly higher than in normal colorectal tissues and expression of CD55 correlated with tumor recurrence and metastasis; expression of CD55 significantly increased in human cervical cancer tissues; and inhibition of CD55 enhanced cell death and helped control cancer cell migration.

Patrys said that Percivia would optimize upstream processes for PAT-SC1, expected to be completed by July 2011, at which time PAT-SC1 would be ready for a clinical trial production program.

Patrys was unchanged at nine cents with 1.6 million shares traded.

### LIVING CELL TECHNOLOGIES

Living Cell Technologies says its founder and medical director Prof Robert Elliott has been awarded the prestigious Word Class New Zealand Award.

Living Cell said the Awards were for "outstanding individuals who have made major contributions to New Zealand's success on the world stage".

The company said the awards were sponsored by the New Zealand Trade and Enterprise and KEA, originally named for the Kiwi Expat Association, and dedicated to connecting New Zealand with the rest of the world.

Living Cell chief executive officer Dr Ross Macdonald said Prof Elliott was "a very deserving person for this award".

"He has dedicated his life to improving people's health and finding effective treatments for a range of diseases," Dr Macdonald said.

"While he gets most attention for work in diabetes, Bob is also leading the development of treatments for other illnesses, including Parkinson's disease," Dr Macdonald said.

### OBJ

OBJ says its non-renounceable rights issue raised \$55,748 through the issue of 111,496,835 options at 0.05 cents per option.

OBJ said the shortfall was 2,654,229 options worth \$1,327, they would not be placed and allowed to lapse.

OBJ fell 0.1 cents or 4.35 percent to 2.2 cents with 1.7 million shares traded.

### STIRLING PRODUCTS

Stirling has requested a trading halt pending an announcement "in relation to the commissioning of its pharmaceutical facility, completion of placement and funding arrangements as well as a report on progress".

Trading will resume on March 10, 2011 or on an earlier announcement.

Stirling last traded at 0.5 cents.