



# Biotech Daily

Wednesday June 11, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECHS DOWN: MESOBLAST UP 18%, PSIVIDA DOWN 15.5%**
- \* **CIRCADIAN MORPHS INTO VEGF CANCER DRUG COMPANY**
- \* **HALCYGEN ANTI-FUNGAL DRUG MAY HAVE ANTI-TUMOR ACTION**
- \* **ETHICS APPROVAL FOR CLINUVEL PHASE II TRIAL**
- \* **OPTISCAN RAMPS SALES FORCE FOR RESEARCH MICROSCOPE**
- \* **GENERA FALLS IN FIRST DAY TRADE**
- \* **SUNSHINE HEART RAISES \$5.4m**
- \* **HEARTWARE CANCELS SHARE PLAN**
- \* **NEIL BALVANES GIVES \$500k FOR CHILDREN'S CANCER RESEARCH**
- \* **WILSON HTM TAKES 10% OF UNIVERSAL BIOSENSORS**
- \* **ANZ DECREASES TO 11% OF OPES PRIME'S BIOPROSPECT**
- \* **BIOLAYER APPOINTS SHANE HARTWIG COMPANY SECRETARY**

## MARKET REPORT

The Australian stock market edged up 0.3 percent on Wednesday June 11, 2008 with the All Ordinaries up 17.6 points to 5,561.9 points. Eight of the Biotech Daily Top 40 stocks were up, 19 fell, nine were unchanged and four were untraded.

Mesoblast was best, up 17.5 cents or 17.95 percent to \$1.15 cents on moderate volumes, followed by Universal Biosensors up 7.89 percent to 82 cents.

Prana climbed five percent to 42 cents; Antisense and Portland were up more than three percent; Chemgenex rose 2.55 percent; with Clinuvel up 1.43 percent.

Psivida led the falls, down 1.7 cents or 15.45 percent to 9.3 cents, followed by Agenix down 10.96 percent to 6.5 cents and Novogen down 10.71 percent to \$1.25.

Phylogica lost 9.09 percent; Peplin, Polartechnics and Tissue Therapies were all down 7.14 percent; Living Cell and Pharmaxis fell more than six percent; Avexa and Cytopia were down more than more than five percent; Cellestis, Circadian and Starpharma fell more than four percent; Benitec, Cochlear and Proteome were down more than three percent; with Biota down 2.65 percent.

## CIRCADIAN

Circadian says it has assembled a team of highly-qualified people to assist its change into a cancer drug company.

Circadian managing director Robert Klupacs told Biotech Daily the company was “moving from a biotechnology company incubator to a drug development company based around VEGF technologies”.

Circadian said it had “a particularly strong cash position” with \$46 million in consolidated cash as well as \$12.5 million in shares in listed companies which would enable the development of its vascular endothelial growth factor (VEGF) technology portfolio and provide strength in negotiating licence arrangements.

The company said it had established a product development review group, whose members hold or held senior positions with large pharmaceutical or biotechnology companies.

Circadian said Dr Errol Malta, Dr George Morstyn, Dr Russell Howard and Carlo Montagner brought “extensive experience in international drug development to Circadian in toxicology, clinical development, oncology and antibody experience”.

Circadian said its drug development strategy was based on the exploitation of its VEGF-C, VEGF-D and VEGFR-3 technologies of its subsidiary company Vegenics which is 67 percent owned by Circadian, with the remainder held by the Ludwig Institute and the University of Helsinki's Licentia.

Circadian said the multi-billion dollar anti-cancer drug Avastin was a humanized antibody against VEGF-A (an anti-angiogenic therapy) sold by Genentech and Hoffman-La Roche. Used in combination with chemotherapy, Avastin starves tumors of oxygen and nutrients and slows tumor growth by inhibiting one part of the VEGF receptor pathway (VEGFR-2).

Circadian said targeted VEGF-C and VEGF-D had the potential to block another key receptor in that pathway (VEGFR-3) and either alone or in combination with a VEGF-A inhibitor such as Avastin may provide more effective anti-cancer treatments.

The chairman of Circadian's review group, Dr Malta, worked with the US-based Amgen for more than 10 years including eight years as product development team leader.

Dr George Morstyn was senior vice-president and head of development at Amgen, a member of the executive committee and responsible for global preclinical and clinical development as well as regulatory affairs.

Dr Russell Howard is chief executive officer of Maxygen, a company working on human therapeutics with programs in protein pharmaceuticals.

Dr Howard also served as the president and scientific director of Affymax Research Institute, an institute employing combinatorial chemistry and high throughput target screening to discover drug leads.

Carlo Montagner is Abraxis Bioscience's president of oncology for Asia. He is a former global head of Schering AG Berlex Labs US oncology business unit.

Circadian's Mr Klupacs said the team comprised “highly experienced Australian expats and former expats, who have gained enormous drug development experience overseas, share our belief in the potential of our technology and the vision for Circadian to become a prominent international biologics company”.

Circadian said there was a breadth of product development opportunity using the VEGF technology including the development of several antibody and protein products for the treatment of certain cancers, eye disease and other niche disease indications.

The company said the objective was to generate value by undertaking pre-clinical and early human clinical development and partnering further development of major therapeutic indications while retaining the rights to selected niche and orphan indications.

Circadian fell four cents or 4.08 percent to 94 cents.

## HALCYGEN

Halcygen says itraconazole is a “potent inhibitor of the proliferation of endothelial cells” the key cells involved in tumor angiogenesis and related growth of tumors.

Itraconazole is the active ingredient in Halcygen’s lead drug SUBA-itraconazole.

The company said the finding emerged from collaborative research with New Zealand’s University of Otago to investigate the anti-tumor activities of SUBA-itraconazole.

Halcygen said research at the Johns Hopkins School of Medicine published last year in the American Chemical Society’s ‘Chemical Biology’ demonstrated that itraconazole had the ability to inhibit the growth of tumor vasculature (anti-angiogenesis).

The process of angiogenesis is important for wound healing and tissue growth, but, it is also important in the transition to malignancy and growth of tumors through inducing new blood vessels (angiogenesis) to provide nutrients and oxygen essential for tumor growth.

The company said researchers had been searching for a drug to inhibit or prevent tumor-related angiogenesis as a potential treatment for cancer.

Halcygen said the completion of initial work at Otago paved the way to evaluating SUBA-itraconazole in inhibiting tumor growth following oral administration.

Halcygen’s SUBA-itraconazole formulation was licenced from Hospira to treat fungal infections, but Halcygen may pursue other clinical applications of SUBA-itraconazole.

The company said clinical studies had demonstrated that its formulation had significantly improved bioavailability or absorption by the gastrointestinal track compared with the market leader, Johnson & Johnson’s Sporanox, “hence providing the opportunity for launching a lower dose form of the drug”.

Halcygen is preparing for a program of pivotal registration trials to register SUBA-itraconazole as an anti-fungal agent.

Halcygen was untraded at 33 cents.

## CLINUVEL

Clinuvel has ethics approval for phase II trials of its photo-protective drug, CUV1647, for solar urticaria.

Solar urticaria is one of five ultra-violet and light-related indications identified by Clinuvel to test CUV1647 and will be the fourth indication to start clinical trials.

Clinuvel said the common factor was melanin compromised skin and treatment with CUV1647 was preventative rather than therapeutic.

The company said solar urticaria is a skin disorder affecting less than one percent of the population. Sufferers may develop a burning redness on the skin from limited exposure to sunlight with more prolonged exposure resulting in the development of wheals or red, raised areas on the skin, which can be accompanied by headache, nausea, breathing difficulty or fainting. The symptoms usually develop soon after sun exposure and last anywhere from 30 minutes to 24 hours.

The phase II solar urticaria trial will be at Hope Hospital in Manchester, UK.

Clinuvel was seeking approval from the relevant medical ethics committees at trial sites in Vienna and Düsseldorf.

The phase II trial will be an open label trial of a single 16mg implant of CUV1647 administered subcutaneously of up to 10 subjects, aged between 18-70 years.

The trial will begin by September 30, 2008 subject to recruiting and is expected to be completed in nine months.

Clinuvel’s chief executive officer Dr Philippe Wolgen said that although, solar urticaria concerned a small group of patients, the disease was “very severe for those affected”.

Clinuvel was up half a cent or 1.43 percent to 35.5 cents.

## OPTISCAN

Optiscan has established a global sales and distribution network for its Five-1 endo-microscope for preclinical research.

Optiscan said the Five-1 was a development from its original endomicroscope with minor changes to tailor the instrument for the research market and in particular suitability for pre-clinical animal trials.

Optiscan said it had opened a US sales office in San Diego and would operate through its US subsidiary, Optiscan Inc.

Optiscan Inc has appointed Neil Shirley as US national sales manager and said he had "a strong background in sales and marketing of digital imaging systems for laboratory pre-clinical applications".

To accelerate sales in Australasia, Optiscan has appointed Steve Hunter as its regional sales manager.

The company said Mr Hunter had "a wealth of sales experience in the research and imaging markets, including many years within the Olympus microscopy division".

Optiscan has also appointed and trained distributors for the Five-1 in Europe, Japan, China, Taiwan, India, South Korean and Malaysia.

Optiscan said the Five-1 (fluorescence in vivo endomicroscopy) allowed hand-held confocal microscopy of in vivo tissue imaging at cellular level in real time.

The company said the Five-1 was "particularly suitable for a range of pre-clinical applications in the important areas of stem cell research, tissue regeneration and development of cancer therapies".

Optiscan has sold the microscope to leading research institutes in Australia, the US, Singapore and Europe.

Optiscan business development manager Dr John Allen said researchers could see what was happening "in real time".

"They can see blood vessels, cell structure and other tissue detail that allows them to draw meaningful conclusions from what they see," Dr Allen said.

"This tool provides them with so much more information than was available through traditional means," he said.

Dr Allen said there had been "several research papers published using the Five-1 as the key tool for investigation" the two most prestigious recent publications being in the Gastroenterology Journal and in the Journal of Hepatology.

He said one article received front page exposure in Gastroenterology "where for the very first time the 'gaps in the gut lining' that result from the dislodgement of surface cells in the intestinal lining were imaged in vivo".

"This was only possible because of the very high sub-cellular resolution that the compact Five-1 probe provides," Dr Allen said.

Optiscan was unchanged at 22.5 cents.

## GENERA BIOSYSTEMS

Genera Biosystems opened at 45.5 cents, down 4.5 cents or nine percent from its 50 cents initial public offering.

In early trade it fell as low as 30 cents or 40 percent below IPO.

Genera has been spun-out from the Walter and Eliza Hall Institute and raised \$5 million to develop women's health diagnostic tests (see Biotech Daily April 30, 2008).

Genera closed down half a cent or one percent at 45 cents with 1.3 million shares traded.

## SUNSHINE HEART

Sunshine Heart shareholders have subscribed for 55,017,092 new shares equivalent to \$3.851 million and representing 71 percent of the issue.

Sunshine Heart said the shortfall of 22,776,366 new shares worth \$1.594 million would be issued to the underwriters.

Sunshine Heart's chief executive Don Rohrbaugh said the support of shareholders in difficult market conditions was "very encouraging" and the funds would strengthen the company's balance sheet in anticipation of the forthcoming US clinical trial.

The company said holding statements would be dispatched on or before June 16, 2008.

Sunshine Heart was untraded at seven cents.

## HEARTWARE

Heartware has cancelled its 50 cents a share purchase plan.

Heartware received commitments for more than \$30 million in a private placement (see Biotech Daily; May 23, 2008) from institutional and sophisticated investors in the US and Australia, but the share price has fallen below 50 cents and the share purchase plan has been cancelled.

Heartware was unchanged at 45 cents.

## CHILDREN'S CANCER RESEARCH

Philanthropist Neil Balnaves has provided a \$500,000 gift over three years to the Children's Cancer Institute Australia for Medical Research.

The Balnaves Foundation Young Researcher's Fund at the Children's Cancer Institute will increase the number of researchers who are competitive for major national research funding such as from the NHMRC, Cancer Institute NSW or Cancer Council.

The Children's Cancer Institute Australia for Medical Research is affiliated with the University of New South Wales and Sydney Children's Hospital.

Mr Balnaves said young researchers "do it tough in my view".

"They're in an incredibly fiercely competitive environment where only the best ideas win and some of the best ideas come when you're at the beginning of your career when it's hardest to have your voice heard," Mr Balnaves said.

The director of Children's Cancer Institute Prof Murray Norris said the grant would "provide fresh ideas which will help unlock key information about childhood cancer".

"Through the Balnaves Foundation Young Researcher's Fund, we're now offering the first two grants of up to two years duration to a maximum value of \$50,000 each per year for young scientists employed by CCIA to develop original ideas and to build their track records."

Applications have and the first two projects will be announced on June 30, 2008.

The Children's Cancer Institute was founded in 1976 by parents and doctors who wanted to do something more in the fight against childhood cancer and opened its first laboratory in 1984.

The Institute employs more than 160 staff and students, including more than 100 scientists.

Research at CCIA comprises a multifaceted approach to improving the outcome of childhood cancer sufferers. Our programs focus on translational research aimed at defining and achieving improved treatment for children with cancer.

### UNIVERSAL BIOSENSORS

Wilson HTM Investment Group has become a substantial shareholder in Universal Biosensors with a holding of 16,406,745 shares or 10.45 percent of the company. Universal Biosensors was up six cents or 7.89 percent to 82 cents.

### BIOPROSPECT

The ANZ Bank has reduced its substantial shareholding in Bioprospect shares acquired from the Opes Prime Stockbroking collapse from 70,242,343 shares (14.42%) to 52,698,656 (10.82%).

Bioprospect fell 0.2 cents or 9.09 percent to two cents.

### BIOLAYER

Biolayer has appointed Shane Hartwig as company secretary replacing Michelle Morrison. Biolayer fell 0.8 cents or 16 percent to 4.2 cents.