Biotech Daily

Tuesday September 23, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: BENITEC UP 25%, STEM CELL DOWN 17%**

*** PHOSPHAGENICS BEGINS PHASE I TRIAL OF TRANSDERMAL LIDOCAINE**

*** HEARTWARE MEETS FDA TRIAL CONDITIONS**

*** CLINUVEL BEGINS 5th TRIAL OF CUV1647**

*** GENETIC TECHNOLOGIES LAUNCHES DOG BREED IDENTIFICATION TEST**

*** BIOPROSPECT APPOINTS PETER MAY (ACTING) CEO**

*** AVITA'S CEO DR WILLIAM DOLPHIN STARTS ON $US300k**

MARKET REPORT

The Australian stock market fell 1.8 percent on Tuesday September 23, 2008 with the All Ordinaries down 92.4 points to 4,957.7 points.

Nine of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and nine were untraded.

Benitec was best, up 1.3 cents or 25.0 percent to 6.5 cents on small volumes, followed by Phylogica up 12.5 percent to nine cents and Viralytics up 10.87 percent to 5.1 cents.

Cytopia climbed 6.25 percent; Starpharma was up 3.57 percent; Pharmaxis and Progen rose more than two percent; with Antisense and Chemgenex up more than one percent.

Stem Cell led the falls again, down five cents or 16.67 percent to 25 cents, followed by Sirtex down 9.78 percent to $2.03 and Ventracor down 7.14 percent to 19.5 cents.

Novogen and Universal Biosensors lost more than five percent; Acrux, Biota, Clinuvel, Genetic Technologies, Heartware and Peplin fell four percent or more; Alchemia, Cellestis and Prana fell more than three percent; Avexa, Phosphagenics and Resmed shed more than two percent; with Arana and Cochlear down more than one percent.

PHOSPHAGENICS

Phosphagenics has begun a phase I human clinical trial for the transdermal targeted delivery of pain relief drug, lidocaine.

Phosphagenics said the trial would use its drug delivery platform tocopheryl phosphate mixture or TPM.

The trial will compare the dermal bioavailability and will measure the systemic exposure of lidocaine in one of the leading marketed products, Xylocaine (5% lidocaine), and Phosphagenics' lidocaine (5% lidocaine). Both formulations will be applied topically.

The company said that pre-clinical results (see Biotech Daily April 30, 2008) "demonstrated that through the utilisation of Phosphagenics' patented lidocaine formulation, skin concentration of lidocaine was approximately 900 percent higher five hours after topical application as compared to Xylocaine".

Phosphagenics said its platform was able to significantly increase the depth of lidocaine penetration by 500 percent in the thigh muscle of animals treated compared to Xylocaine.

Phosphagenics' executive vice-president of research and development Dr Esra Ogru said lidocaine was "a well-known topical anaesthetic used for a wide variety of ailments, including temporary relief of rashes, stings, sprains, strains, bites, and burns".

"However it has poor penetration into the dermis, frequently rendering it largely ineffective," Dr Ogru said.

"Our pre-clinical study showed that Phosphagenics' lidocaine formulation has the potential to provide patients with rapid pain relief, while not increasing systemic exposure," Dr Ogru said.

Phosphagenics said the trial was being conducted at the Centre for Pharmaceutical Research at the University of South Australia, with Dr David Foster as principal investigator.

The company said the trial was an open-label, single-centre bioavailability trial of dermal and systemic pharmacokinetics in 12 healthy adults incorporating secondary endpoints of safety and tolerability. The company said it expected to report results by April 2009.

Phosphagenics fell 0.2 cents or 2.67 percent to 7.3 cents.

HEARTWARE

Heartware says it has full approval from the US Food and Drug Administration for its investigational device exemption for its left ventricular assist system.

Heartware received conditional approval from the FDA for a US clinical trial of the Heartware left ventricular assist system (LVAS) for use as a bridge-to-cardiac transplant in patients suffering from end-stage heart failure (see Biotech Daily May 5, 2008).

Heartware said the conditional approval permitted the start of its US trial but included several conditions which the company was required to address to the FDA's satisfaction. The company said it had addressed all of these conditions.

Heartware chief executive officer Doug Godshall said the company was "very pleased" that Washington Hospital Center received approval from its institutional review board and had enrolled the first patient into our US clinical trial.

"We are currently finalizing the contractual arrangements with a number of additional centers," Mr Godshall. "We have completed surgical training at seven centers and have training sessions scheduled at a number of additional sites," he said.

"Further, a number of centers which previously elected not to begin their internal reviews until our IDE became unconditional can now progress their IRB approval processes," Mr Godshall said.

Heartware fell three cents or 4.72 percent to 60.5 cents.

CLINUVEL

Clinuvel says it will test its photo-protective afamelanotide (CUV1647) in a phase II trial in patients undergoing photodynamic therapy.

Clinuvel said it had met the final regulatory requirements to test its fifth indication for CUV1647 in light and ultra violet light-related skin disorders.

The company said the randomized double-blind phase II trial had started in Paris and would include multiple centres in France.

Clinuvel said the first four of 30 patients had received the single dose of afamelanotide and results were expected within 12 months.

The company said photodynamic therapy (PDT) was a treatment "mainly used in oncology (gastro-enterology) to endoscopically eradicate incipient premalignant lesions of the oesophagus (Barrett's oesophagus) and as a palliative treatment in bile duct cancer (cholangio-carcinoma)".

Clinuvel said photodynamic therapy combined the intravenous administration of a photosensitizer (porfimer sodium) with targeted illumination using a focal light source to activate photochemical tissue reactions.

Clinuvel said a consistent side effect in the use of porfimer sodium as a photo-sensitizer was phototoxicity of the skin, experienced for up to three months following treatment.

Consequently, photodynamic therapy patients are obliged to observe continuous precautions to avoid exposure to light and ultra-violet light that results in erythema, acute blistering and severe burns of the skin, causing intense pain and skin damage.

Clinuvel said conventional sunscreens were of "no value" against phototoxic reactions following photodynamic therapy and patients were forced to stay indoors for three months.

The company said afamelanotide might offer photo-protection in photodynamic therapy patients who are at high risk of phototoxicity.

Clinuvel's chief executive officer Dr Philippe Wolgen said it was a "first for Clinuvel".

"… with PDT we have obtained regulatory clearance for the broader scope of afamelanotide as a potential photo-protective drug as adjunct therapy in oncology," Dr Wolgen said.

The company said photodynamic therapy was of significance from a biochemical and development point of view as there was a strong commonality with erythropoietic protoporphyria currently in phase III trials.

The molecules (protoporphyrin IX) causing the severe skin symptoms in erythropoietic protoporphyria patients are of the same family of molecules purposefully used as photo-sensitizers in photodynamic therapy to obtain maximum effectiveness in cancer treatment.

The advantage of using afamelanotide to reduce the phototoxicity in photodynamic therapy was based on the rationale found in erythropoietic protoporphyria.

Clinuvel said advantages of photodynamic therapy over other therapies included the degree of selectivity of drug accumulation in the tumor tissue, the absence of systemic toxicity of the photo-sensitizer, the ability to irradiate only tumor and the ability to retreat a recurrent tumor.

Photodynamic therapy has proven valuable as a treatment in cancers such as Barrett's oesophagus, endobronchial, gastric, papillary bladder and gliomas, Clinuvel said.

The primary endpoint is to determine whether afamelanotide implants can reduce the period of phototoxicity experienced by patients who have undergone photodynamic therapy with porfimer sodium.

The secondary endpoints are to evaluate the effect of afamelanotide on quality of life and evaluate the safety and tolerability of afamelanotide by measuring treatment-emergent adverse events.

Clinuvel fell one cent or four percent to 24 cents.

GENETIC TECHNOLOGIES

Genetic Technologies has launched a DNA-based dog breed identification test at the Royal Melbourne Show.

The breed identification through scientific analysis (Bitsa) test is a non-invasive DNA test, which enables owners to identify the breed makeup of mixed breed dogs, Genetic Technologies said.

The company said the test used breed-specific genetic signatures to identify a dog's breed ancestry.

It is estimated that Australia has approximately three million non-pedigree dogs.

Genetic Technologies chief executive officer Michael Ohanessian said the Bitsa dog breed identification test had the potential to save dogs' lives.

"Visual identification is not always an accurate way of determining a dog's breed," Mr Ohanessian said.

"Many physical characteristics do not survive even the first crossbreeding," he said.

"Every day, hundreds of people purchase a dog only to find that it does not meet their needs or lifestyle, or that the dog exhibits a challenging behavior often characteristic of its breed," he said.

Mr Ohanessian said the pets become unwanted, end up in pounds and are subsequently killed.

Mr Ohanessian said the test could also be a useful tool in assisting local authorities identify and manage banned or restricted breeds.

The Bitsa test reports any dog breeds found as primary, secondary and distant breeds.

It includes a comprehensive report covering breed profiles, behavioral traits, physical characteristics and general health.

The test is available from Genetic Technologies at its website www.gtglabs.com/bitsa.

Genetic Technologies fell 0.3 cents or 4.48 percent to 6.4 cents.

BIOPROSPECT

Bioprospect has appointed Peter May as acting chief executive officer until his official appointment on November 3, 2008.

Bioprospect said the delay was due to Mr May completing prior commitments with his own agribusiness consultancy.

The company said Mr May would have the "goal of driving the development and commercialization of a range of natural products on an international scale".

Mr May has worked for ICI, Orica, Incitec and Crop Care Australasia.

The company said he had "achieved overseas product registration and market development of a range of pest control products, including the Suscon controlled-release formulation technology range of products.

Bioprospect said Mr May was a member of the Australian Environmental Pest Managers Association and had established contacts within the pest control industry in addition to the general agribusiness and animal health sectors.

He holds a Bachelor of Applied Science and a Masters of Business Administration.

Warwick Dowse has left the company. He announced his resignation as managing director on June 25, 2008.

Bioprospect fell 0.2 cents or 10 percent to 1.8 cents.

AVITA MEDICAL

Avita will pay chief executive officer Dr William Dolphin a base salary of $US300,000 ($A356,300) plus superannuation and performance-related bonuses.

Dr Dolphin was the chief executive officer of Visiomed until the merger with Clinical Cell to form Avita (see Biotech Daily; October 10, 2007 and February 12, 2008) and was appointed CEO of the new entity.

Avita will pay six percent of the gross salary as superannuation as well as up to 25 percent ($US75,000) of the gross salary pending performance indicators.

Pending shareholder approval Dr Dolphin will receive up to 5,000,000 options in six tranches dependent on continuous employment until June 1, 2010 and meeting key performance indicators.

The options are exercisable at 14 cents each.

Avita chairman Dalton Gooding said the company was pleased to have secured a long-term contract with Dr Dolphin.

“Dr Dolphin brings with him an exceptional background of experience in the medical technology industry and we believe his experience will be invaluable to Avita in the years ahead,” Mr Gooding said.

Dr Dolphin holds a PhD in Biophysics from Boston University, where he was a professor in the Departments of Biomedical Engineering and Biology.

Avita said Dr Dolphin had “a demonstrated history of bringing early stage technology to commercial success”.

He founded a contract research organization and founded and served as chief executive officer and chairman of Sonamed Corp, a manufacturer and distributor of neurological monitoring devices.

He has also served as a director of companies in the US, New Zealand and Australia.

Dr Dolphin is the author of more than 60 peer-reviewed scientific articles and holds five US and international patents.

He was twice recipient of the National Research Service Award from the US National Institutes of Health.

Avita climbed 0.2 cents or 3.51 percent to 5.9 cents.