Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: POLARTECH UP 16%, GENETIC TECH DOWN 11%**

*** POLISH STUDY: POLARTECHNICS' SUPERIOR CERVICAL CANCER TEST**

*** PHOSPHAGENICS TRIALS TPM FOR DICLOFENAC (VOLTAREN)**

*** STEM CELL IN $1.1m LICENCE TO RESEARCH PROVIDER**

*** ACRUX TO TRIAL DICLOFENAC, KETOPROFEN, IBUPROFEN SPRAY**

*** ATCOR: SPHYGMOCOR BEATS ECG FOR ATRIAL FIBRILLATION**

*** PROGEN'S HEAD OF PI-88 DR JAMES GARNER RESIGNS**

MARKET REPORT

The Australian stock market fell 1.0 percent on Wednesday November 12, 2008 with the All Ordinaries down 38.2 points to 3,883.6 points.

Six of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and 11 were untraded.

Polartechnics was best, up 1.2 cents or 15.58 percent to 8.9 cents with 20,000 shares traded, followed by Viralytics up 10.2 percent to 5.4 cents and Optiscan up 10.0 percent to 6.6 cents.

Cellestis climbed four percent; Mesoblast was up three percent; CSL and Living Cell rose more than two percent; with Peplin up 1.32 percent.

Genetic Technologies led the falls, down 2.4 cents or 28.57 percent to six cents with 480,826 shares traded, followed by Phylogica down 16.67 percent to five cents.

Neuren lost 8.33 percent; Novogen, Starpharma and Ventracor fell more than seven percent; Phosphagenics was down 6.98 percent; Alchemia fell 5.26 percent; Labtech lost four percent; Avexa was down 3.57 percent; Biota, Impedimed and Pharmaxis shed more than two percent; with Arana and Prana down more than one percent.

POLARTECHNICS

Polartechnics says a Polish study has shown that its Truscreen test is significantly superior in sensitivity and specificity to the standard Pap test for cervical cancer.

The company said that a presentation by Poznan University of Medical Sciences' Department of Gynaecology, Obstetrics and Gynaecological Oncology at the European Research Organisation on Genital Infections and Neoplasia confirmed Truscreen's effectiveness in the detection of cervical neoplastic changes and concluded that Truscreen was "an important improvement to the traditional screening processes for cervical cancer".

Polartechnics said the results showed that the specificity of Truscreen was 82 percent.

The sensitivity of Truscreen for severe grades of neoplastic change (CIN2/3 and squamous carcinoma of the cervix) was 85 percent.

Polartechnics said the global average sensitivity of cytology used in the detection of cervical cancer is 54 percent.

Polartechnics chief executive officer Ben Dillon told Biotech Daily that global average specificity for Pap tests was about 50 percent, but in trials could reach more than 90 percent.

Polartechnics said it had focused on marketing Truscreen to those markets where cytology performs at less than 50 percent sensitivity.

The Poznan University of Medical Sciences laboratory conducted a study on 234 women with normal or abnormal Pap smears from August 2006 to August 2008.

In the blinded study, Truscreen, a real time optoelectronic device, was used for primary cervical cancer screening followed by human papillomavirus (HPV) DNA test (Amplicor-Roche PCR), colposcopic examination and biopsy for histology.

The histopathological sections were evaluated by two independent pathologists.

Polartechnics said the study also concluded that a major advantage of Truscreen over cytology and colposcopy was its ability to generate an immediate and objective result while the patient was present and its ease of use.

Each Truscreen test took between one and two minutes.

Study author, Dr Dominik Pruski said a key advantage of the Truscreen examination "is the possibility of finally eliminating the human error during cervical screening, which historically has often been an issue caused by the inexperience of the doctor or colposcopist".

"The technology is objective, inexpensive, offers an immediate result and most importantly does not rely on the clinical experience of the person performing the examination," Dr Priski said.

Polartechnics said an estimated 500,000 women were diagnosed with cervical cancer each year and about 300,000 women died from the disease.

Eighty-five percent of these deaths occurred in developing countries.

The trial results from the Poznan study confirm the opportunity for many countries to significantly improve their existing screening practices, traditionally based upon cytology (the Pap smear test).

Truscreen is Polartechnics' flagship cervical cancer screening product that is quickly developing into a viable alternative to current cytology based methodologies in markets around the world.

The paper is entitled 'The Evaluation Of A Real-Time Optoelectronic Method For The Detection Of Cervical Intraepithelial Neoplasia' and is available at http://www.polartechnics.com.

Polartechnics climbed 1.2 cents or 15.58 percent to 8.9 cents.

PHOSPHAGENICS

Phosphagenics has begun a phase I human clinical trial of its tocopheryl phosphate mixture delivery system for the non-steroidal anti-inflammatory drug, diclofenac.
Phosphagenics said the trial of tocopheryl phosphate mixture or TPM would compare the bioavailability and penetration of the topically applied Voltaren gel (1% diclofenac), a leading marketed product and Phosphagenics' diclofenac (at 1% and 2% diclofenac concentrations).
The company said the trial would be conducted at the University of South Australia's Centre for Pharmaceutical Research by principal investigator Prof Allan Evans.
The trial is an open label, single centre bioavailability and penetration trial of dermal and systemic pharmacokinetics in 12 healthy adult volunteers, incorporating secondary endpoints of safety and tolerability.
Phosphagenics said it expected to obtain and announce the results by April.
Phosphagenics' executive vice president of research and development Dr Esra Ogru told Biotech Daily that the 12 subjects would be treated with 200mg doses of Voltaren followed 1% TPM diclofenac and 2% TPM diclofenac at fortnightly intervals.
In the company's media release Dr Ogru said that preclinical studies with TPM/diclofenac "demonstrated significant increases in skin penetration of diclofenac compared to the market leader, Voltaren, results we are confident we can replicate in human testing".
"The advantage of our formulated diclofenac is that it increases the amount of anti-inflammatory drug delivered to the site of action," Dr Ogru said.
She said 2007 Voltaren oral and topical sales were around $US700 million, so her company's formulation "will prove it to be a very attractive product commercially".
Phosphagenics fell 0.6 cents or 6.98 percent to eight cents.

STEM CELL SCIENCES

Stem Cell Sciences will earn $US750,000 ($A1,132,000) from licencing technology to a provider of genetically modified rodent models for medical and pharmaceutical research.
Stem Cell said that under the multi-year, non-exclusive and retroactive agreement, the undisclosed partner would gain access to the internal ribosome entry site (Ires) technology for use in its own research and development activities.
Stem Cell said the $US750,000 would be paid over and six years with further royalty payments.
The company said its Ires technology enabled researchers to monitor the activity of a particular gene of interest in living cells or tissues without blocking the normal function of the gene.
Stem Cell said Ires was important for evaluating the success of gene knock-outs or knock-ins in stem cells, which is crucial for the successful creation of transgenic mouse and rat disease models.
Stem Cell's chief executive officer Dr Alastair Riddell said a "key element" of the company's commercial strategy was to realize immediate and longer-term value from its extensive intellectual property portfolio through licence agreements such as this.
"We are therefore very pleased to have signed this agreement with one of the leading providers of transgenic animal models to the pharmaceutical research industry," Dr Riddell said.
"We are continuing discussions with other companies, which may benefit from the use of [Stem Cell's] technology in conjunction with their own and are optimistic of signing further agreements in the coming months," Dr Riddell said.
Stem Cell was unchanged at 20 cents.

ACRUX

Acrux has added of three non-steroidal anti-inflammatory drugs to its product pipeline.

Acrux said its skin spray formulations “demonstrated superior delivery of the drugs compared with currently marketed products”.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily that the company had selected three generic non-steroidal anti-inflammatory drugs (NSAIDs) diclofenac (Voltaren), ketoprofen and ibuprofen.

The three drugs are used to reduce pain and inflammation in conditions such as osteoarthritis.

Dr Treagus said the active ingredients were readily available and sourced from a variety of suppliers.

He said that the Acrux formulations of the drugs had been tested on human skin sourced from cosmetic surgery and all had demonstrated activity and performed well.

Dr Treagus said Acrux was in discussions with “several large players in the area” and the company could potentially conclude separate deals with more than one partner.

He said that he expected to progress partnerships in 2009 but said setting an expected trial date was “getting ahead of ourselves”.

In a media release Acrux said the prevalence of osteoarthritis and the market for NSAIDs was expected to grow as life expectancy increased.

The company said that gels, creams and patches applied to the affected area provided more targeted delivery of the drug to the affected joint and avoided some of the side effects associated with oral NSAIDs.

Acrux said topical NSAIDs have traditionally been used in markets outside the US and in October 2007 the first topical NSAID was approved for sale by the US Food and Drug Administration to treat osteoarthritis pain.

In 2007 sales outside the US of a leading gel containing diclofenac were $US750 million, with future sales in the US market estimated to add a further $US300 million.

Acrux said it had tested novel formulations containing diclofenac, ketoprofen and ibuprofen, which are the drugs used in many of the major marketed brands of topical NSAIDs.

The formulations and a marketed product containing each drug were compared using human skin in the laboratory, the company said.

Acrux said its formulations showed between five and nine times higher delivery of the drug through the skin.

These results show the potential to improve the effectiveness of the current marketed therapy and reduce the amount of drug in each dose.

Dr Treagus said the “compelling results” provided a new therapy area for Acrux’s technology platform.

“The recent arrival of topical NSAIDs in the US market makes this a particularly attractive commercial opportunity,” he said.

Acrux is developing and commercializing a range of pharmaceutical products using fast-drying, invisible sprays or liquids with low or no skin irritation for transdermal delivery.

Acrux’s Evamist is used to treat menopause symptoms and is marketed by its US licencee and has the brand name Ellavie outside the US.

Drugs in development include Testosterone MD-Lotion for testosterone deficiency in men, Testosterone MDTS for decreased libido in women, Nestorone MDTS contraceptive sprays for women, Fentanyl MDTS to treat chronic pain and Nicotine MDTS for smoking cessation.

Acrux was unchanged at 60 cents.

ATCOR MEDICAL

Atcor says a Mayo Clinic 800-patient trial shows that central pulse pressure is a better predictor of the onset of atrial fibrillation than clinical and echocardiographic risk factors.
Atcor says its Sphygmocor system which measures central blood pressures and arterial stiffness non-invasively was used in the trial, funded by the National Institutes of Health.
The company said atrial fibrillation was a condition in which the upper chambers of the heart beat erratically and affected an estimated two million people in the US and is common in older people.
Results of the 800-patient study which used Atcor's Sphygmocor system were reported yesterday at the annual meeting of the American Heart Association Scientific Sessions in New Orleans.
Atcor chief executive officer Duncan Ross said the Mayo Clinic study showed that every 20mm of mercury increase in central pulse pressure represented a near doubling of the risk of developing atrial fibrillation (AF).
"We anticipate this will spur further interest in examining the role elevated central pressure may play in the onset of AF, laying the groundwork for potential identification of patients at risk and intervention strategies," Mr Ross said.
"Study after study shows the importance of noninvasive central pressure assessment in identifying patients at high risk for cardiovascular events," he said.
The company said 3.8 percent of people aged over 60 years had AF and nine percent of those 80 years or older experience AF and the disorder posed "a major health and economic challenge in all developed countries with aging populations".
"Early identification of cardiovascular risk offers significant benefits to patients, as well as cost benefits to health care systems worldwide," Mr Ross said.
"The model of treating disease after full onset is no longer sustainable," Mr Ross said.
"Non-invasive central pressure assessment is vitally important in this effort," he said.
Atcor was untraded at 16.5 cents

PROGEN

Progen says its vice-president of clinical and medical affairs Dr James Garner who led the PI-88 clinical development has resigned.
Progen said Dr Garner was hired "primarily to head the PI-88 clinical development efforts including the phase III Pathway trial".
Following the company's decision in July 2008 to terminate the trial, Dr Garner has managed the orderly wind-down of this trial as well as the re-initiation of two phase I trials on Progen's cell-proliferation compound PG-11047 and the planning of other clinical development activities associated with PG-11047 and the PG-500 series, Progen said.
The company said Dr Garner had decided to pursue other opportunities and would leave at the completion of his four week notice period.
Earlier this week a consortium of shareholders narrowly failed to requisition a meeting to depose Progen's board (see Biotech Daily; November 11 and 12, 2008).
Progen has also called a trading halt to consider an external review of the company.
Progen last traded at 60.5 cents.