Biotech Daily

Monday December 8, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: BENITEC UP 21%, NOVOGEN DOWN 6%**

*** HEALTHLINX: NEW CANCER MARKER, 2nd TEST '98% ACCURATE'**

*** GENE-MARKING OBSERVED IN BENITEC HIV RNAi TRIPLE THERAPY**

*** MEDICAL THERAPIES' REVENUE-EARNING ANIMAL TEST VALIDATED**

*** PHOSPHAGENICS PHASE I TRIAL DELIVERS TRANSDERMAL LIDOCAINE**

*** ACRUX APPLIES FOR ELLAVIE'S FIRST EUROPEAN SALES**

*** ATCOR SIGNS $2.3m SPHYGMACOR DEALS**

*** $2.5m FUNDING FOR HATCHTECH PHASE II HEAD LICE TRIALS**

*** VIRALYTICS OFFERS 4¢ A SHARE PLAN, PLACEMENT**

*** EASTLAND COMPLETES AFRICAN RESTRUCTURE**

*** SAFETY MEDICAL REQUESTS NEW PRODUCT, FINANCE TRADING HALT**

MARKET REPORT

The Australian stock market climbed 3.7 percent on Monday December 8, 2008 with the All Ordinaries up 126.6 points to 3,553.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, four traded unchanged and 12 were untraded.

Benitec was best, up 0.7 cents or 21.21 percent to four cents with 166,300 shares traded, followed by Cytopia up 11.11 percent to 20 cents and Heartware up 10 percent to 55 cents.

Labtech climbed 9.09 percent; Acrux and CSL were up more than six percent; Avexa, Chemgenex, Sirtex, Starpharma and Ventracor were up five percent or more; Cochlear and Resmed climbed more than three percent; Pharmaxis rose 2.68 percent; with Cellestis up 1.09 percent.

Novogen led the falls, down five cents or 6.1 percent to 77 cents with 5,400 shares traded, followed by Polartechnics down 5.88 percent to eight cents. Alchemia fell four percent; Biota, Circadian and Universal Biosensors were down more than three percent; Clinuvel and Viralytics both fell 2.44 percent; with Arana and Phosphagenics down more than one percent.

HEALTHLINX

Healthlinx expects its second generation ovarian cancer test using previously undetectable bio-markers to be available within 12 months.

At a media briefing organized by Monsoon Communications, Healthlinx chief executive officer Nick Gatsios said two novel markers for ovarian cancer were introduced to the test and "one identifies tumor types not seen by CA125 [the standard test] at all".

"That is a very powerful thing to have," Mr Gatsios said.

"One marker has never been found to circulate in plasma. We have developed an Elisa [enzyme-linked immuno-sorbent assay] with our partners and it is definitely circulating in women's blood - and we've found it," Mr Gatsios said.

In its media release to the ASX, Healthlinx said it had completed an initial phase II biomarker trial on the second generation ovarian cancer diagnostic that "increased the diagnostic efficiency of the panel to 98 percent for early stage diagnosis".

"This compares with the world's most commonly used diagnostic CA125 with diagnostic efficiency of less than 60 percent for early stage detection," Healthlinx said.

In October, Healthlinx and ARL Pathology launched the Ovplex first generation ovarian cancer test with an efficiency of 92.9 percent (see Biotech Daily; October 29, 2008).

The market interest in the first generation Ovplex has resulted in ARL Pathology establishing a wider collection network to meet the needs of women seeking the test.

Healthlinx chairman Prof Greg Rice said that the study of 107 samples of 46 disease subjects and 61 controls was small but sufficient to encourage a larger study of up to 800 samples in all.

Mr Gatsios said that trial was likely to be conducted in Singapore, Israel and the United Kingdom and cost less than $500,000.

The company said the second generation product used two new biomarkers HTX005 and HTX010.

Among the disease subjects, 35 were early stage (stage I/II) and 11 were stage III.

The sample tested included seven confirmed disease subjects where CA125 failed.

As individual biomarkers, HTX005 correctly identified five of the seven, and HTX010 correctly identified six of the seven.

Healthlinx said that where CA125 failed to detect the seven disease subjects (false negatives) the second generation Ovplex panel identified six of these cases.

"This would result in six of the seven subjects being diagnosed with early stage disease and treated accordingly," Healthlinx said. "All seven false negatives were early stage cancers."

The samples included four high CA125 results, assessed as being diseased (false positives) but two were subsequently confirmed by Ovplex as without disease.

CA125 would have claimed cancer in samples where Ovplex confirmed correctly in two of the four that no cancer existed.

The Ovplex second generation test used five biomarkers and achieved diagnostic efficiency of 98.13 percent, the company said.

This means that the new biomarkers identified six subjects that had been missed by CA125 (false negatives) and eliminated two subjects who would have been told they had the disease but did not (false positives), the company said.

Mr Gatsios said a Healthlinx director had provided the company with $500,000 through a convertible note arrangement and the company would undertake a private placement to raise $1.5 million to fund the development of the second generation test.

He said it would take three years from the first sales to a major country for the company to be in profit.

Healthlinx climbed one cent or 25 percent to five cents with 62,000 shares traded.

BENITEC

Benitec says it lentivirus transduced haematopoietic stem cell therapy for HIV, co-developed with California's City of Hope medical centre is safe and feasible.
Benitec said gene marking was observed in all patients treated and was consist with the ratio of transduced to untransduced cells infused and the duration of gene-marking in peripheral blood continues to be followed.
Benitec said a poster on the human HIV trial was presented at the American Society of Hematology conference in San Francisco by the principal clinical investigator of the pilot study Dr Amrita Krishnan.
The presentation entitled 'First in Human Engraftment of Anti-HIV Lentiviral Vector Gene Modified CD43+ Peripheral Blood Progenitor Cells in the Treatment of AIDS Related Lymphoma' was the first human trial and used a triple therapy delivered using a lentiviral vector developed at City of Hope (see Biotech Daily; October 23, 2008).
The study transplanted autologous or patient-derived blood stem cells which were genetically modified using the lentivirus vector into four AIDS patients with lymphoma who first received high doses of chemotherapy.
The study showed new blood cells expressing the anti-HIV RNA, with no complications.
"We have shown that we can deliver gene-modified cells which have the potential to limit the HIV infection," Dr Krishnana said.
"If we can continue to develop this approach and successfully apply it to other AIDS patients, then genetic therapy for HIV could become a reality," Dr Krishnan said.
Benitec chief executive officer Sue MacLeman said the trial was "the first human clinical trial with expressed RNA interference trigger" and the first triple gene therapy combination trial for HIV/AIDS.
"It is the also the first human trial for AIDS using hematopoietic stem cells transduced with lentiviral vectors," Ms MacLeman said.
Benitec was up 0.7 cents or 21.21 percent to four cents.

MEDICAL THERAPIES

Medical Therapies has completed independent validation of its veterinary cancer diagnostic test which measures blood midkine levels to detect cancer in mammals.
Medical Therapies said the test was sold in Japan for diagnosing cancer in dogs.
The company said it would seek approval for the marketing of the product in Australia and in large pet-diagnostic markets such as the US and Europe.
Medical Therapies said the diagnostic test relied on blood midkine measurements by an immunoassay, essential components of which are Medical Therapies' proprietary anti-midkine antibodies.
The company said the test complemented its human diagnostic portfolio and ensured it had full intellectual property ownership in relation to using midkine for early cancer detection in humans and animals.
Medical Therapies said the incidence of canine cancer was very high with 25 percent of dogs affected at some stage in their life.
As with humans, successful treatment correlates well with early detection.
The company said there was no test to indicate early stage solid tumors in dogs and they often developed large growths before owners became aware of the disease.
Medical Therapies said its validated midkine diagnostic test was able to detect tumors early and would contribute to improved survival rates of animals.
Medical Therapies was untraded at 3.6 cents.

PHOSPHAGENICS

Phosphagenics says a phase I trial has shown that its transdermal tocopheryl phosphate mixture lidocaine formulation safely delivered the pain relief drug.

Phosphagenics said the tocopheryl phosphate mixture or TPM formulation delivered "a significantly greater amount of lidocaine into the localized area of the skin compared to a leading commercial product".

The company said lidocaine was a topical anaesthetic, used for the relief of rashes, stings, sprains, strains, bites and burns, with sales of more than $US1.2 billion in 2007.

Phosphagenics said the trial compared the dermal penetration and measured the systemic exposure of lidocaine between one of the leading marketed products, Xylocaine (5% lidocaine), and Phosphagenics' TPM-lidocaine (5% lidocaine).

One hour after application, TPM-lidocaine delivered 500 percent more ($p<0.001$) lidocaine into the stratum corneum, the outer layer of the skin, than Xylocaine.

Phosphagenics' TPM-lidocaine also augmented the depth of penetration, with 450 percent ($p<0.01$) more lidocaine found in the deepest layers of the skin sampled.

Phosphagenics said TPM-lidocaine significantly increased the amount, rate, and depth of lidocaine penetration into the skin compared to Xylocaine, parameters that are normally expected to produce a local analgesic effect.

Despite the increase in dermal drug delivery, TPM-lidocaine did not increase the plasma lidocaine concentration compared to Xylocaine after six hours.

Phosphagenics' executive vice president of research and development Dr Esra Ogru said the company had previously demonstrated the penetrative power of the TPM technology.

"The success of this trial validates the versatility and precision of Phosphagenics' drug delivery platform in humans," Dr Ogru said. "We view this as a major achievement for our company and look forward to moving ahead with further clinical trials," she said.

The open label, single centre study was conducted at the Centre for Pharmaceutical Research, University of South Australia, under principal investigator Dr David Foster.

Eleven healthy adult volunteers enrolled in the bioavailability trial of dermal and systemic pharmacokinetics, which incorporated secondary endpoints of safety and tolerability.

Phosphagenics fell 0.1 cents or 1.25 percent to 7.9 cents.

ACRUX

Acrux has submitted a marketing authorization application for Ellavie to Sweden's Medical Products Agency.

Following approval of the application, Acrux intends to gain marketing authorization in other European Community countries.

Acrux said Ellavie was marketed in the US as Evamist by Acrux's licensee.

The company said the product was an estradiol spray for treating menopause symptoms using its liquid technology for delivering drugs across the skin.

Acrux is in discussions with potential distributors for Ellavie in Europe and in other territories outside the US.

The company said Ellavie targeted the non-US estrogen therapy market of approximately $US360 million a year.

In Europe, transdermal therapies such as skin patches and gels have a 53 percent market share.

Acrux chief executive officer Dr Richard Treagus said the first European marketing application was "another important commercial milestone for the Acrux business and technology".

Acrux was up three cents or 6.38 percent to 50 cents.

ATCOR MEDICAL

Atcor says it has agreements to supply Sphygmocor systems and clinical trial support services worth $US1.51 million ($2.3 million) to two pharmaceutical companies.
The company said the orders brought the minimum total value of pharmaceutical trial contracts secured in the past six months to more than $US5.7 million.
Atcor said the Sphygmocor system measured central blood pressures and arterial stiffness non-invasively.
Atcor chief executive officer Duncan Ross said the growing use of Sphygmocorsystems in clinical trials and the increasing volume of publications concerning central blood pressures and arterial stiffness “continue the push toward establishment of a new standard for cardiovascular risk assessment and management”.
Atcor was untraded at 12.5 cents.

HATCHTECH

Hatchtech has secured $2.5 million in further funding from the University of Melbourne Endowment Trust and from Uniseed.
Hatchtech said the university trust was advised by GBS Venture Partners, which is also an investor in Hatchtech.
The company said the funds would be used to progress its Deovo head lice treatment into phase II safety and efficacy studies in humans in Australia and India.
Hatchtech said Deovo was its lead product of technology to control a variety of insect, arachnid and nematode pests.
An investigation new drug application for the product was accepted by the US Food and Drug Administration earlier this year, the company said.
Hatchtech said Deovo was designed as “a breakthrough treatment for head lice infestations through its ability to kill lice eggs or nits”.
Existing products suffer treatment failure in large part due to an inability to kill the nits.
The company said the product had been shown to be safe in adult volunteers.
Hatchtech said Deovo “should potentially enable a cure at a single time and treatment point making redundant the current routines of multiple labor-intensive treatments”.
Hatchtech’s chief executive officer Dr Paul MacLeman said the funding allowed the company to take Deovo to proof-of-clinical concept in affected patients.
“This is an important and valuable milestone,” Dr MacLeman said.
Hatchtech said about 12 million children are affected by head lice each year in the US and the global annual market for head lice control products was more than $US450 million.
Hatchtech is a private unlisted company.

VIRALYTICS

Viralytics is offering eligible shareholders up to $5,000 worth of shares at four cents a share.
Viralytics said the funds raised would be used to continue development of its Cavatak cancer treatments.
Viralytics said it was also considering the placement of shares with professional and sophisticated investors and said the terms may be different to the terms of this plan.
The company said shareholders at the record date of December 5, 2008 would be eligible to participate in the plan which opens on December 8, 2008 and closes on December 22.
Parcels of shares can be bought in a range from $500 to $5,000.
Viralytics was down 0.1 cents or 2.44 percent to four cents.

EASTLAND MEDICAL SYSTEMS

Eastland Medical says it has concluded two corporate restructures of its African subsidiaries Eastland Medical Systems South Africa and Star Medical (Botswana).
The first restructure was the acquisition of 100 percent of the shares of Eastland Medical Systems South Africa which acquisition was immediately followed by the transfer of one million Hc Berlin Pharma AG shares as recovery of debt on November 11, 2008.
Under Protopharma's agreements with Star and Eastland Medical, Star's rights and obligations in respect of the malaria project have vested in Eastland.
Eastland said the consolidation allowed it and its project managers Protopharma to continue the African field trials on children suffering from malaria infestation.
The consolidations assist the working relationship between Eastland and Hc Berlin Pharma AG in progressing the malaria project to production during 2009.
Eastland was unchanged at 10 cents cents.

SAFETY MEDICAL

Safety Medical has requested a trading halt pending an announcement on "new product lines and finance arrangements".
Trading will resume on December 10, 2008 or on an earlier announcement.
Safety Medical was up half a cent or 4.55 percent to 11.5 cents prior to the request.