Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: SUNSHINE HEART UP 14%, OPTISCAN DOWN 10%**

*** BIOPHARMICA HLS5 SCREENING YIELDS 43 NEW CANCER DRUG LEADS**

*** NEW INTERSUISSE BIOTECH FUND TAKES 4.3% OF SUNSHINE HEART**

*** PSIVIDA EARLY MEDIDUR FA DATA SHOWS EFFICACY, SAFETY**

*** AVEXA NEEDS AN APRICITIBINE PARTNER BY SEPTEMBER**

*** FMR, FIDELITY DROPS 3% OF COCHLEAR IN JUNE**

*** NOVOGEN'S MARSHALL EDWARDS ON RUSSELL 3000 INDEX**

*** EASTLAND MEDICAL TAKES 90% OF STAR MEDICAL**

*** SIRTEX APPOINTS DARREN SMITH INTERIM CFO**

MARKET REPORT

The Australian stock market closed down 1.3 percent on Friday June 27, 2008 with the All Ordinaries down 72.1 points to 5,349.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and two were untraded.

Sunshine Heart was best, up 0.6 cents or 14.29 percent to 4.8 cents on modest volumes, followed by Acrux up seven cents or 6.36 percent to $1.17.

Cytopia, Prana and Progen climbed five percent or more; Novogen and Proteome were up more than four percent; with Avexa, Clinuvel and Heartware up more than three percent.

Optiscan led the falls, down 2.5 cents or 10.42 percent to 21.5 cents on modest volumes, followed by Neuren down 8.54 percent to 7.5 cents.

Agenix and Alchemia lost more than seven percent; Living Cell and Sirtex were down more than five percent; Benitec, Pharmaxis, Psivida and Tissue Therapies fell more than four percent; Arana, Cochlear, CSL, Genetic Technologies, Peplin, Universal Biosensors and Ventracor shed more that two percent; with Cellestis, Mesoblast, Phylogica and Starpharma down more than one percent.

BIOPHARMICA

Biopharmica says the researchers at the Western Australian Institute for Medical Research who discovered the HLS5 gene have found 43 potential anti-cancer molecules.
Biopharmica says the Western Australian Institute for Medical Research (WAIMR) scientists have shown that increased expression of the HLS5 gene in human cancer cells can profoundly suppress tumor growth and they have found that HLS5 interacts with a number of proteins which control cell growth and maturation.
Biopharmica said a screening program of 70,000 synthetic compounds that can modulate HLS5 activity, "yielding 43 molecules that demonstrate potential for further anti-tumor analyses and drug development".
The company said the evaluation of the growth-inhibitory activity and therapeutic potential of these molecules was being pursued at WAIMR in conjunction with other leading specialist research facilities in Australia.
Biopharmica said research results indicated that nearly half of the compounds can suppress the growth of human cancer cells.
Further, by computer modeling it has been determined that nearly all of these growth-inhibitory molecules demonstrate drug-like qualities and are therefore highly suitable candidates for pharmaceutical development.
Biopharmica intends to progress this drug pipeline toward pre-clinical testing of anti-cancer activity.
Biopharmica was up half a cent or 14.29 percent to four cents.

INTERSUISSE, SUNSHINE HEART

The IB Australian Bioscience Fund hopes to have a final close of $100 million to invest in the Australian biotechnology sector.
Intersuisse managing director Andrew Smith told Biotech Daily that the company's goal was "a final close of $100 million".
Biotech Daily became aware of the fund in a 'ceasing substantial' notice to Sunshine Heart which said Asia Union Investments has transferred 11.8 million shares in exchange for units in IB Australian Bioscience Fund.
"We have a selection of leading Australian biotechnology stocks," Mr Smith said.
Mr Smith was not able to disclose the other companies in which the fund has invested.
"The ultimate goal is to hold substantial holdings and be able to participate in the companies," he said.
"It has been some time in the making and we are delighted to have industry super funds supporting the fund," Mr Smith said.
The IB Australian Bioscience Fund is associated with Intersuisse, the UK-based Bioscience Managers and Jeremy Curnock Cook.
Asia Union said in the ceasing substantial notice said it retained a direct interest of 5.0 million shares in Sunshine Heart
Sunshine Heart said it welcomed the formation of a new fund in the biotech sector and to have its shares form part of the new fund's initial investments.
Separately CM Capital VT 4A as trustee for CM Capital Venture Trust 4A increased its holding in Sunshine Heart from 53,333,333 shares (24.93%) to 82,112,479 shares (28.14%).
Sunshine Heart was up 0.6 cents or 14.29 percent to 4.8 cents.

PSIVIDA

Psivida says interim three-month data from a phase II trial indicates that Medidur FA is safe and efficacious for patients with diabetic macular oedema.

Psivida said the data from the first human pharmacokinetic study of Medidur Fluociniolone acetonide (FA) was designed to support the ongoing pivotal phase III clinical trial of Medidur for diabetic macular oedema.

A total of 37 subjects were enrolled with 20 patients on the low dose (0.23µg per day) of Medidur and 17 patients on the high dose (0.45µg per day) with the same inclusion and exclusion criteria as the ongoing phase III study.

The three month data showed 20 percent of the low dose patients and 18 percent of the high dose patients had an improvement in best-corrected visual acuity of 15 letters or greater from baseline on an eye chart.

In addition, both the low dose and the high dose of Medidur resulted in a significant reduction in retinal thickness as compared to the baseline.

No adverse events related to intraocular, or inner eye, pressure were seen in the low dose patients, while 12 percent of the high dose patients experienced intraocular pressure increases of greater than 30 mmHg.

The only adverse event related to cataract formation was reported in a patient in the high dose group.

Medidur releases Fluociniolone acetonide directly into the eye.

The phase II study is primarily designed to assess systemic exposure to the drug after administration of Medidur into the eye.

The study is secondarily designed to provide information on the safety and efficacy of Medidur in a diabetic macular oedema population.

Psivida said the pharmacokinetic study provided further insight into the dose-response of Fluociniolone acetonide in the treatment of the disease.

By comparison, the Retisert intravitreal implant, which releases Fluociniolone acetonide at an initial rate of 0.6 µg per day, was also studied in a diabetic macular oedema population.

Previously released Retisert data showed that at six months between 15 percent and 20 percent of diabetic macular oedema patients receiving Retisert gained 15 letters from baseline on an eye chart and after two years this increased to 27 percent, but there were some steroid related side effects, particularly cataract and elevation of intra-ocular pressure.

Psivida said Medidur was designed to achieve similar efficacy to Retisert, with sustained therapeutic effect, for up to 24 months for the low dose and up to 36 months for the high dose while reducing the side effects and to be easier to administer.

The company said the preliminary data indicated similar efficacy at three months with few side effects. Additional data will be available at six, 12, 18, 24 and 36 months.

The first efficacy and safety assessment on the fully recruited pivotal phase III study will be conducted after the last patient completes their two years assessment in late 2009.

Psivida said diabetic macular oedema was a disease of the retina which affects individuals with diabetes and can lead to severe vision loss and blindness.

Medidur is inserted into the patient's eye with a 25-gauge needle in an office visit in a procedure very similar to intravitreal injections, commonly employed by retinal specialists.

Psivida managing director Dr Paul Ashton said the early results "supports our hypothesis that lower doses of FA delivered via our Medidur system will provide visual acuity improvements whilst reducing the risk of ocular side effects commonly associated with the use of corticosteroids".

If approved, it is anticipated Medidur will be marketed under the name Iluvien.

Psivida fell 14 cents or 4.91 percent to $2.71.

AVEXA

Avexa will need to secure a partner for its lead drug apricitabine for HIV by September or be forced to either slow down its phase III trials or seek alternative funding.

In its 'Quarterly news report to shareholders' Avexa said it had a negative net operating cash flow of $19,225,000 for the quarter ending March 31, 2008 with $53,469,000 cash at the end of that quarter, implying the company had sufficient funds for a little more than two quarters, as disclosed in its Appendix 4C document filed to the ASX on April 22, 2008.

Avexa's chief financial officer Alan Boyd told Biotech Daily that the company had significant start-up costs associated with its phase III HIV trials across 150-170 centres and those costs "may continue for a portion of the current quarter" but were expected to fall in the quarter ending September 30, 2008.

Apricitabine manufacturing costs were expected to be included in the current quarter.

Mr Boyd said that if a suitable partner had not been found by the end of the September quarter alternative measures would have to be implemented and they included either slowing down the rate of trials or finding additional funds.

Avexa was up one cent or 3.23 percent to 32 cents.

COCHLEAR

The US based FMR Corp and Fidelity Investments has again reduced its substantial shareholder in Cochlear from 4,931,724 shares (8.87%) to 4,238,512 shares (7.62%) on June 25, 2008.

FMR Corp and Fidelity reduced its holding in Cochlear by one percent on June 4, 2008 and a further one percent on June 13, 2008.

FMR and Fidelity had been increasing its holding in both Cochlear and CSL.

This is the third reduction in Cochlear since Biotech Daily begun monitoring the holdings.

FMR and Fidelity have not changed their CSL holdings.

Cochlear fell $1.23 or 2.76 percent to $43.37.

NOVOGEN

Novogen's 72 percent subsidiary Marshall Edwards expects to be included in the Russell 3000 Index.

Citing "a preliminary list of additions recently posted on www.russell.com" Marshall Edwards said the addition to the broad market Russell 3000 Index, which remains in place for one year, means automatic inclusion in the Russell 2000 Index.

The 2008 reconstitution of the Russell indexes will take place after the market closes on June 27, 2008.

Novogen chief executive officer Christopher Naughton said that with phenoxodiol in a pivotal phase III trial for recurrent ovarian cancer, "the Russell 3000 Index has recognized our potential".

"Marshall Edwards inclusion in the Russell 3000 Index offers us visibility to more investors," Mr Naughton said.

Novogen said the Russell 3000 Index measured the performance of the largest 3,000 US companies based on total market capitalization, representing approximately 98 percent of the investable US equity market according to Russell Investments.

The Russell 2000 Index is a subset of 10 percent of the total market capitalization of that index and includes 2,000 of the smallest securities based on a combination of their market capitalization and current index membership in the Russell 3000 Index.

Novogen was up five cents or 4.17 percent to $1.25.

EASTLAND MEDICAL

Eastland Medical has taken 90 percent of Star Medical (Botswana).
Eastland said it increased the holding by acquiring the interests of another shareholder on the same terms and conditions as previously announced for the acquiring of the Star interests of Fee-Zone and Dr Isaac Kwame Amuah.
In May, Eastland said it had acquired the interests from an African shareholder for about $604,000 (see Biotech Daily; May 22, 2008).
The company acquired 55 percent of Star though its interests in Fee-Zone in November 2007 for 3,506,180 Eastland shares issued as fully paid at a deemed issue price of 30 cents a share.
Star holds the exclusive rights to the intellectual property for the patented sub-lingual anti malaria treatment Artimist for Africa.
Eastland chief executive officer Dermot Patterson said the company “previously indicated that we would be strengthening our position in Africa and this announcement reinforces our intent to see Eastland having full control in Africa for this major project ahead of the market introduction of Artimist, our sub lingual delivered anti malaria treatment, which is currently preparing for phase III field trials in Africa”.
Eastland was unchanged at 16 cents.

SIRTEX

Sirtex has appointed Darren Smith as interim chief financial officer while chief financial officer and company secretary Angela Axisa takes six months' maternity leave.
Mr Smith takes up the appointment on June 30, 2008 and will work with Ms Axisa until her leave begins on September 9, 2008.
Mr Smith has extensive financial and management experience most recently as chief financial officer of Michel's Patisserie a franchise group with more than 340 shops.
Sirtex said it looked forward to Ms Axisa’s return in March 2009.
Sirtex was fell 16 cents or 5.06 percent to $3.00.