

# Biotech Daily

# Tuesday January 19, 2010

Daily news on ASX-listed biotechnology companies

- \* ASX DOWN, BIOTECH UP: VIRALYTICS UP 200%; PHOSPHAGENICS DOWN 13%
- \* VIRALYTICS UP 200% ON PHASE I CAVATAK MELANOMA SUCCESS
- \* WEHI, MELBOURNE UNI IDENTIFY PROTEINS FOR MALARIA VACCINE
- \* EASTLAND SUBSIDIARY SALE IMPROVES CASH POSITION \$1.8m
- \* BIO-MELBOURNE BREAKFASTS ON COMMERCIALISATION AUSTRALIA
- \* OBJ PLEADS SCHULTZ TO ASX 56% PRICE QUERY

## MARKET REPORT

The Australian stock market fell 1.02 percent on Tuesday January 19, 2010 with the S&P ASX 200 down 49.9 points to 4861.2 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and four were untraded.

Viralytics was best, up eight cents or 200 percent to 12 cents with 145.6 million shares traded, followed by Genetic Technologies up 7.3 percent to 4.4 cents.

Circadian, Living Cell and Nanosonics climbed more than six percent; Novogen was up five percent; Genera was up 4.05 percent; Cellmid and Prana were up more than three percent; Benitec, Cochlear, Compumedics and Sunshine Heart rose more than two percent; with Alchemia up 1.27 percent.

Phosphagenics led the falls, down 0.6 cents or 9.1 percent to six cents with 470,142 shares traded, followed by Phylogica down eight percent to 11.5 cents.

Antisense lost 6.7 percent; Acrux and Prima fell more than five percent; Clinuvel was down 3.6 percent, Avexa, Impedimed, Mesoblast, Starpharma and Tissue Therapies shed more than two percent; with Psivida and Universal Biosensors down more than one percent.

### **VIRALYTICS**

Viralytics says its nine-patient phase I late-stage melanoma trial of Cavatak has shown that it is safe and has some efficacy in reducing or stabilizing tumors.

Viralytics share price climbed eight cents or 200 percent to 12 cents with 145.6 million shares traded, nearly half of the total 349,204,261 shares on issue.

The company said the primary safety objective was to assess the safety and tolerability of two doses of Cavatak injected directly into a single tumor.

Viralytics said all patients tolerated the treatment and none exhibited any product-related serious adverse events.

The company said the secondary objective monitored the injected tumor and other distant tumors for signs of Cavatak activity against actively progressing metastatic melanoma. Viralytics said that injected tumors of three patients reduced in size, while the injected tumors of a further two patients remained stable.

Measurement of other distant tumors in the patients showed that the overall disease was stabilized in two of the patients, the company said.

Viralytics said that as the study was a safety trial it was only allowed to inject a single tumor and that restriction would not apply in phase II trials.

All patients in the trial had late stage disease and had previously failed or rejected standard therapies.

The principle investigator at Brisbane's Princess Alexandra Hospital Dr Mark Smithers said a successful completion of the study was "very important".

"We have now established a safety profile that allows the product to advance to phase II efficacy evaluation," Dr Smithers said.

"Cavatak offers to be an exciting alternative in the attempt to establish successful immune therapy of melanoma," Dr Smithers said.

"Immune therapy, I believe, will play a significant role in the future treatment of this disease," he said.

Viralytics said that the study conclusions supported the progress of development to phase II where repeated dosing over a longer period of time would be used to establish the efficacy of Cavatak in effectively treating melanoma.

The company said the formal study report concluded that all patients adequately tolerated the multiple single tumor injections up to a final dose of  $2 \times 10^9$  median tissue culture infective dose (TCID<sub>50</sub>).

Viralytics said there were no serious adverse events deemed to be probably, or highly probably, related to study drug.

Five of nine (55.55 %) patients experienced reductions in injected tumor volume or tumor stabilization following multiple single tumor injections with Cavatak.

The company said the findings of potential anti-tumor activity and patient tolerability of intra-tumoral-delivered Cavatak, provide a solid foundation for phase II investigations employing a multi-dose administration schedule to further study the efficacy and safety of Cavatak in patients with late stage melanoma and other advanced solid cancers.

Viralytics said it would use the report as a core source of data in the generation of its US Food and Drug Administration investigational new drug (IND) filing.

Viralytics said it would file its IND in two steps and hold a pre-IND meeting with the FDA by April 2010, allowing the US regulator to review and comment on the company's substantial clinical, manufacturing and toxicology data.

Following this meeting and the provision of additional data if requested, an IND filing would be lodged with the FDA.

Viralytics closed up eight cents or 200 percent to 12 cents with 145.6 million shares traded.

### WALTER AND ELIZA HALL INSTITUTE

The Walter and Eliza Hall Institute says its researchers have uncovered a group of proteins that could form the basis of an effective vaccine against malaria.

The Institute said that in an article published today on the Public Library of Science Medicine website infection and immunity division researchers Dr James Beeson, Dr Freya Fowkes and Dr Jack Richards, along with the University of Melbourne's Dr Julie Simpson have identified proteins produced by malaria parasites during the blood-stage that are effective at promoting immune responses that protect people from malaria illness.

The research article is expected to be published today on the PLoS Medicine website at: <a href="http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000218">http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000218</a> and at: <a href="http://www.wehi.edu.au/uploads/fowkes">http://www.wehi.edu.au/uploads/fowkes</a> et al plos medicine 19jan2010.pdf.

The Walter and Eliza Hall Institute said there was no malaria vaccine available and the findings support the development of a vaccine against the blood-stage of malaria.

The Institute said malaria was a blood cell infection transmitted by mosquitoes and the most common form was caused by the parasite Plasmodium falciparum.

The Institute said the malaria parasites burrowed into red blood cells by producing specific proteins and then rapidly multiply, leading to massive numbers of parasites in the blood stream that can cause severe disease and death.

The media release said that Dr Fowkes and Dr Beeson identified these proteins "by reviewing and synthesizing data from numerous scientific studies that had looked at the relationship between antibodies produced by the human immune system in response to malaria infection and the ability of these antibodies to protect against malaria".

Dr Beeson said malaria caused by Plasmodium falciparum was a leading cause of death and disease globally, particularly among young children.

"Malaria also has a major impact on social and economic development in countries where the disease is endemic," Dr Beeson said. "Vaccines are urgently needed to reduce the burden of malaria and perhaps eventually eradicate the disease."

"A malaria vaccine that stimulates an efficient immune response against the proteins that malaria parasites use to burrow into red blood cells would stop the parasite from replicating and prevent severe illness," Dr Beeson said.

Dr Fowkes said little was known about blood-stage malaria proteins and their suitability for vaccine development.

"Only about six blood-stage malaria proteins have been well studied out of a potential 100 proteins," Dr Fowkes said. "There is an urgent need for malaria researchers to better coordinate their research efforts on these proteins," Dr Fowkes said.

"This will take us one step closer to developing an effective vaccine," she said.

# **EASTLAND MEDICAL SYSTEMS**

Eastland will sell its wholly-owned subsidiary Medical Industries Australia to Alpine Medical for an undisclosed fee.

Eastland said that after costs the sale would increase its cash position by \$1.8 million, with settlement due on January 29, 2010.

Eastland chief executive officer Dermot Patterson said the funds would strengthen the company's balance sheet, provide working capital and funding for the Artimist malaria project.

Mr Patterson said the company had completed a major restructuring of its Western Australia-based medical supply business, Westcoast Surgical and Medical Supplies and would call for expressions of interest for sale of the division.

Eastland was unchanged at eight cents.

### **BIO-MELBOURNE NETWORK**

The Bio-Melbourne Network's first Bio-Breakfast on 2010 will be a presentation on Commercialisation Australia by its acting chief executive officer Tricia Berman.

The Bio-Melbourne Network said Ms Berman was also the general manager of the Federal Department of Innovation's innovation policy branch.

The Network said Ms Berman would discuss what support Commercialisation Australia could offer biotechnology researchers and firms for commercialisation activities.

The industry organization said there were "numerous opportunities for many in our sector to contribute to this new initiative" and Ms Berman would "provide a comprehensive overview of Commercialisation Australia and highlight how interested parties can become involved through the volunteer business mentor program".

The Bio-Melbourne Network said a key component of Commercialisation Australia was "a merit-based, competitive assistance program designed to assist researchers,

entrepreneurs and innovative companies turn ideas into successful commercial ventures".

The Network said that concerns had been raised that although Commercialisation

Australia was a positive development, "the Federal Government may have underestimated how many organizations will apply for assistance".

"With a kitty of \$196.1 million over the next four years, and ongoing funding of \$82 million a year thereafter, the offering is certainly not insignificant but the catch is that it is one of the only sources of assistance for commercialization and there will be intense competition for funds," the Bio-Melbourne Network said.

"Despite concern about capacity, the details are nonetheless attractive, funding applications can be submitted any time, proof of concept grants, assistance in recruiting skilled executives and early stage repayable grants up to \$2 million.

More on Commercialisation Australia is at <a href="www.commercialisationaustralia.gov.au">www.commercialisationaustralia.gov.au</a>. The Bio-Melbourne Breakfast will be held at the Supper Room, Melbourne Town Hall, Cnr Swanston Street and Collins Street, Melbourne on February 9, 2010, with registration from 7.15am and the presentation from 8-9am.

More information is at: <a href="http://www.biomelbourne.org/events/view/77">http://www.biomelbourne.org/events/view/77</a>.

#### OBJ

OBJ has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 2.7 cents on January 12, 2010 to 4.2 cents, a 55.5 percent increase, today January 19, 2010 and noted an increase in trading volume.

OBJ climbed as high as 4.3 cents – a 59.25 percent rise - and closed up 0.5 cents or 15.15 percent at 3.8 cents with 138.2 million shares traded.