# Biotech Daily

Tuesday June 24, 2008

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECHS DOWN:**
**TISSUE THERAPIES UP 15%, CYTOPIA DOWN 9%**

*** OPPOSITION, INDUSTRY BODIES PROTEST COMMERCIAL READY AXING**

*** ACRUX BEGINS PHASE III TESTOSTERONE TRIAL; EVAMIST US SALES UP**

*** VIRALYTICS COMPLETES DOSING FIRST PHASE I CANCER PATIENTS**

*** AVANTOGEN'S HAWAII BIOTECH TRIALS WEST NILE VIRUS VACCINE**

*** PORTLAND 1-FOR-1 RIGHTS ISSUE TO RAISE UP TO $4m**

*** PHARMAXIS APPOINTS MERCK'S WILL DELAAT DIRECTOR**

## MARKET REPORT

The Australian stock market climbed 0.2 percent on Tuesday June 24, 2008 with the All Ordinaries up 9.9 points to 5,418.8 points.

Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and three were untraded.

Tissue Therapies was best, up 1.5 cents or 15.0 percent to 11.5 cents on modest volumes, followed by Portland up 0.2 cents or 8.33 percent to 2.6 cents.

Neuren climbed 4.94 percent; Cellestis and Sirtex were up more than three percent; Chemgenex, Living Cell and Optiscan rose more than two percent; with Benitec, Pharmaxis and Peplin up more than one percent.

Cytopia led the falls, down two cents or 8.89 percent to 20.5 cents, followed by Agenix down 0.3 cents or 7.32 percent to 3.8 cents.

Mesoblast and Universal Biosensors lost more than five percent; Proteome fell four percent; Avexa, Circadian and Novogen were down more than three percent; Cochlear, Heartware, Phylogica, Resmed and Ventracor shed more than two percent; with Antisense, Biota, Clinuvel, CSL and Genetic Technologies down more than one percent.

## COMMERCIAL READY GRANTS

Industry organizations and the Federal Opposition have attacked the Federal Government's axing of the Commercial Ready Grant program.

In the Senate, Opposition Senators led by Senator Eric Abetz attacked the Government's axing of the program quoting Victoria's chief scientist Prof Gus Nossal and Cochlear chief executive officer Dr Chris Roberts.

Senator Abetz told the Senate that Dr Roberts had said it was "the saddest and dumbest decision out of the entire budget".

Separately the CEOs of Ausbiotech, Dr Anna Lavelle, Australian Private Equity and Venture Capital Association Limited Dr Katherine Woodthorpe and Research Australia, Rebecca James have written to the review of the national innovation system to "emphasize the implications this decision will have on our national innovation system, as well as the potential costs to innovative companies, the community and the economy if this issue is not addressed as a matter of urgency".

The three said their organizations represent the discovery and commercialization pathway and all agree on the need for government to play an active role.

They said a number of companies had "been left severely compromised, having spent significant sums of money to reach the point of acceptance by Ausindustry".

The three organizations said the statement cited as the basis for the decision to end Commercial Ready was "flawed".

"In justifying the decision, much was made of a comment the Productivity Commission made in its 2007 report into Public Support for Science and Innovation that 'There is robust evidence indicating that the Commercial Ready program supports too many projects that would have proceeded without public funding assistance.' There is little supporting evidence for the statement and no understanding of the impact of delay has been recognized," the three organizations said.

"There is general market consensus that there is little basis for the statements of the Productivity Commission. Not least, this is because the research would have been carried out, but due to lack of funds it would be much more slowly, resulting in a higher risk that they would fail to achieve commercial success," they said.

They said products would not be commercialized, intellectual property would be lost overseas, there would be reduction in capital flowing to early stage sector, lost leverage and Australia's reputation as a clever country diminished.

"In your capacity as chair of the National Innovation Review Panel, we urge you to strongly recommend appropriate measures to redress this problem as a matter of urgency. AVCAL, Ausbiotech and Research Australia have each made submissions that outline a number of options for replacement programs," the three organizations said.

Ausbiotech said separately that its recommendations relating to Commercial Ready, as included in the original submission, stand.

"However as a result of the Budget decision and the major disruption and financial losses caused to the industry and to small businesses who submitted their applications in good faith, there are now short and long term imperatives that the Government must consider," Ausbiotech said.

"The Government must allow the 71 applications lodged with the Department for a Commercial Ready grant to continue through the assessment process.

"The Government should introduce a transitional period to allow the processing of these applications.

"The Government must act swiftly to implement a replacement program that will be in place and ready for operation by the beginning of the 2009-10 financial year at the latest," Ausbiotech said.

ACRUX

Acrux expects the first patient in its US Food and Drug Administration approved pivotal phase III trial of Testosterone MD-Lotion to begin treatment within a month.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily that the company would "start screening patients within a week" with the first patient expected to begin treatment during July.

Acrux said the FDA had approved the trial in a media release to the ASX and said the trial was designed to support global registration of the product.

Acrux said it was "on schedule" to submit marketing applications to the FDA and European regulatory authorities by the end of 2009.

The open-label trial will enrol up to 150 hypogonadal men at 27 sites in the US, Europe and Australia.

The men will use Testosterone MD-Lotion (metered dose lotion) for four months, during which blood samples will be analyzed to determine the level of testosterone in the blood.

At least 50 subjects will continue treatment for a further two months to demonstrate skin safety following six months of continuous use.

The primary objective of the trial is to demonstrate that Testosterone MD-Lotion restores average blood levels of testosterone into the normal range.

Secondary objectives include the assessment of quality of life and sexual health.

Acrux said the beginning of the trial follows a meeting with the FDA in March this year during which the trial design and endpoints were confirmed.

The trial is being conducted under an approved investigational new drug application.

Acrux said the global market for testosterone replacement therapy was $US800 million a year, growing at 20 percent a year.

Growth is expected to continue as awareness of the condition increases and more user-friendly treatments become available.

The market is dominated by testosterone gels, with US sales of approximately $570 million per annum, growing at 23 percent.

Acrux recently conducted detailed independent market research with current users of gels in the US.

After trying the Acrux product for four days, two thirds of patients said they would prefer it to their existing gel treatment.

Acrux's Dr Treagus said "the global development program remains on time and within budget".

"The results of our phase II trial last year, as well as the outcome from our meeting with the FDA, give us a high level of confidence as we initiate this final clinical trial," Dr Treagus said.

Data supplied to Biotech Daily showed that US sales of Acrux's estradiol transdermal spray Evamist have been increasing.

Evamist received FDA approval on July 31, 2007 and became available in the US on April 15, 2008.

US licencee KV Pharmaceutical said in its end of year financial report the menopause treatment targeted an annual $1.4 billion estrogen replacement market.

KV said Evamist "continued to show increasing prescription trends, on track with company expectations and comparing favorably to prior analogous product launches".

"Total prescriptions are trending to more than 2,000 per month based on recent weekly data," KV said.

"In addition, the product is receiving positive feedback from physicians and patients alike," the company said.

Acrux was unchanged at $1.01.

## VIRALYTICS

Viralytics says the first group of patients has completed treatment in its phase I intravenous trial of Cavatak for melanoma, prostate and breast cancer.

Following a meeting of the data safety monitoring committee, the company has been given permission to commence treatment of the next patient group.

Viralytics said it was the first time the company's oncolytic virus Cavatak had been delivered intravenously.

Each patient received a single infusion and treatment determined that there were no serious adverse events considered to be related to the study medication or causing withdrawal from the study.

A single infusion of 1 x 106 TCID50 of Cavatak into patients with Stage IV metastatic melanoma appears to be well tolerated.

The primary purpose of the trial was to assess the safety of Cavatak with secondary endpoints including the monitoring of early stage biological activity of Cavatak through the assessment of tumor size and signs of viral replication.

The next cohort of patients in this trial will receive two separate infusions of Cavatak seven days apart.

The phase I trial forms part of the company's overall clinical development strategy.

Viralytics said it had completed an initial phase I single dose intra-tumoral trial in late stage melanoma patients and was performing a larger phase I multi-injection intratumoral trial in late stage melanoma patients with increasing doses of Cavatak up to 100 times the original dose.

Based on the successful intravenous and intratumoural delivery of Cavatak, the company said it was developing more extensive clinical trials to characterize the performance and efficacy of the product in cancer therapy.

Viralytics fell 0.1 cents or 1.52 percent to 6.5 cents.

## AVANTOGEN

Hawaii Biotech chief executive officer Dr Elliot Parks says the company has begun a phase I clinical trial of its West Nile vaccine candidate.

Hawaii Biotech said it was the first clinical trial for the company of which Avantogen is a major shareholder.

Avantogen chief executive officer Dr William Ardrey said Hawaii Biotech's "move to becoming a clinical stage company … goes a long way towards proving the proprietary, recombinant DNA manufacturing platform ideal for vaccine production".

"We are hopeful that this West Nile Virus vaccine progress positions Hawaii Biotech well to initiate a second clinical trial later this calendar year, that for Dengue Fever," Dr Ardrey said.

Hawaii Biotech said West Nile Virus was spread by infected mosquitoes and could cause serious and even fatal disease. The most serious manifestation is fatal encephalitis.

The company said cases of infections in humans had been reported in all US states except Hawaii, Alaska and Maine. It has been reported in Europe, west and central Asia, Oceania, Africa and the Middle East.

The Hawaii Biotech West Nile vaccine candidate is a recombinant sub-unit vaccine developed with the intent to induce protective immunity in recipients.

The phase I trial is designed to assess safety, determine a dosage range and identify potential side effects and will recruit volunteers in Honolulu for four treatment groups.

Results should be known within a year.

Avantogen was untraded at eight cents.

## PORTLAND

Portland Orthopaedics hopes to raise up to $4 million in a non-renounceable rights issue.
Portland shareholders will be able to subscribe for one new share for each share held on the record date of July 3, 2008 at 2.5 cents a share.
The company said the three largest shareholders were considering an irrevocable commitment of support for the offer.
As such commitments are made, Portland will update the market.
Portland chairman John Lee, chief executive officer John Brassil, chief technology officer, director and founder Dr Ron Sekel and chief financial officer James Wynn have provided commitments to take up a minimum of their share of entitlements.
Mr Brassil said the company was "on-track in meeting our development milestones".
"Funds raised will be used prudently to build inventory so we can accelerate our sales and marketing efforts in the US and Australia," Mr Brassil said.
"We have established a successful track record in the high value, high margin US orthopaedics market with our M-Cor hip replacement implant which has been described by a leading US surgeon as the best product in the market," he said.
"Additional product launches will exploit our current strong relationship with US and Australian orthopaedic surgeons," Mr Brassil said.
Portland climbed 0.2 cents or 8.33 percent to 2.6 cents.

## PHARMAXIS

Pharmaxis has appointed senior pharmaceutical executive Will Delaat as a director.
Pharmaxis said Mr Delaat had 35 years experience in the global pharmaceutical industry, most recently as the managing director of the Australian subsidiary of Merck & Co, a position he held from 1997 until his recent retirement.
The company said Mr Delaat had held executive positions in Europe and Australia for Merck and Astrazeneca with experience in sales and marketing.
He has been responsible for international product launches and commercialization of respiratory products.
Mr Delaat is also the chairman of the Australian pharmaceutical industry's peak body, Medicines Australia and is chairman of the Pharmaceuticals Industry Council.
Pharmaxis was up three cents or 1.95 percent to $1.57.