# Biotech Daily

Monday October 13, 2008

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECHS REBOUND: CATHRX UP 27%, PROTEOME DOWN 17%**

*** MESOBLAST UP 20% ON EARLY CARDIAC TRIAL SAFETY DATA**

*** US TRADE COMMISSION '2nd REQUEST' FOR CSL ON TALECRIS**

*** CANADIAN PATENT FOR PRIMA'S CANCER VACCINE**

*** ADVANCED OCULAR COMPLETES $US2m PATENTS SALE TO LENSTEC**

*** FMR, FIDELITY INCREASE TO 9.4% OF HEARTWARE**

*** CHEMGENEX SHARE PLAN RAISES $128k**

*** CLINUVEL VOTES ON 350k DIRECTOR OPTIONS, DIRECTORS**

MARKET REPORT

The Australian stock market rebounded 5.1 percent on Monday October 13, 2008 with the All Ordinaries up 202.4 points to 4,141.9 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and four were untraded.

Cathrx was best, up 16 cents or 26.67 percent to 76 cents on low volumes, followed by Polartechnics up 25 percent to 10 cents and Clinuvel up 21.43 percent to 25.5 cents.

Mesoblast climbed 19.88 percent; Sunshine Heart was up 18.18 percent; Living Cell rose 17.24 percent; Avexa and Peplin were up more than 16 percent; Antisense was up 12.5 percent; Neuren and Ventracor climbed more than 11 percent; Sirtex was up 10.53 percent; Starpharma was up 9.26 percent; Cellestis and Optiscan were up more than six percent; CSL climbed 4.2 percent; Cochlear was up 3.09 percent; Prana rose 2.63 percent; with Acrux Psivida and Resmed up more than one percent.

Proteome led the falls, down 1.3 cents or 16.67 percent to 6.5 cents, followed by Novogen down 9.17 percent to 99 cents and Stem Cell down 8.7 percent to 21 cents.

Bionomics and Viralytics lost more than seven percent; Benitec and Labtech fell more than six percent; Phosphagenics fell 4.35 percent; with Chemgenex and Heartware down more than one percent.

MESOBLAST

Mesoblast rebounded 20 percent on early safety results in the world's first clinical trial of its allogeneic adult stem cells for patients with congestive heart failure.

Mesoblast said that safety data from the first seven patients in the phase II trial by its US sister company Angioblast Systems was presented at the Transcatheter Cardiovascular Therapeutics Conference in Washington DC.

Mesoblast owns 39 percent of Angioblast.

The company said the trial was being undertaken at medical centres in Arizona, California and Minnesota to test the safety and effectiveness of Revascor, Angioblast's mesenchymal precursor cell product injected by catheter into damaged heart muscle of patients with congestive heart failure.

Mesoblast and Angioblast founder Prof Silviu Itescu told Biotech Daily the company reported safety and some efficacy in six patients receiving their own or autologous adult stem cells at a 2007 Australian pilot trial (see Biotech Daily; August 10, 2007).

Prof Itescu said the 60 patients in the US trial were in three dose arms of 15 patients and five controls and the first arm was expected to be enrolled by the end of 2008.

Key measures of efficacy include cardiac contractility and ejection fraction through echo cardiogram and multi-gated acquisition (Muga) scan or radionuclide angiography, as well as a stress test of patient symptoms.

He said the adult stem cells appeared to create new blood vessels and assisted the growth of new heart muscle.

Prof Itescu said the Newcastle patients had heart failure and angina and the trial demonstrated a decrease in angina and an increase in cardiac output ejection fraction.

But he said there were only six patients and no controls.

"This is the first time allogeneic cells have been implanted into patients with chronic heart failure," Prof Itescu said.

"It's one thing to do it with heart attack (acute myocardial infarction) patients, it's another to do it with patients with chronic heart failure."

He said he expected to have early efficacy results from this trial in February 2009.

The director of cardiovascular research at Arizona's Chandler and Mercy Gilbert Medical Center Dr Nabil Dib told the Transcatheter conference that no cell-related adverse events had occurred in any of the first patients implanted.

Mesoblast said Revascor was delivered by a cardiac catheterization procedure performed under local anaesthesia while the patient was awake.

"We hope that these stem cells will increase the potential for myocardial repair and restoration of heart function," Dr. Dib said.

"These cells, obtained from a healthy young adult donor, are isolated, expanded and cultured to produce treatments potentially for thousands of patients," Dr. Dib said.

Prof Itescu said heart failure was a major cause of hospital admissions and patient deaths and Revascor had "the potential to make a significant impact in patients with heart failure and to address this major clinical need".

"This phase II clinical trial is an important step toward our entry into this vital and growing market," Prof Itescu said.

Mesoblast said five million people in the US had congestive heart failure, with more than 550,000 new cases annually.

The extensive morbidity and mortality associated with this disease make it a principal health and economic burden in the Western world.

Existing therapies do not result in repair or regeneration of heart muscle. Revascor is being developed to rebuild both blood vessels and heart muscle.

Mesoblast climbed 16.5 cents or 19.88 percent to 99.5 cents on small volumes.

## CSL

CSL has received a request for additional information in a Second Request from the US Federal Trade Commission over its proposed acquisition of Talecris Biotherapeutics
CSL said it intended to respond “expeditiously” to the Second Request (see Biotech Daily; August 13, 2008).
CSL said the Trade Commission had not reached any conclusions on the acquisition and the request for additional information was “a normal part of the US regulatory review process under the Hart-Scott-Rodino Antitrust Improvements Act of 1976”.
CSL climbed $1.54 or 4.2 percent to $38.19 with 2.0 million shares traded.

## PRIMA BIOMED

The Canadian Patent Office has granted Prima Biomed subsidiary, Cancer Vac Pty Ltd, a patent covering ovarian cancer immunotherapy product mannan fusion protein.
Prima said the patent entitled ‘Antigen carbohydrate compounds and their use in immunotherapy’ claims priority from November 1994 and expires in November 2014.
Prima director Martin Rogers told Biotech Daily that the granting of orphan status gave the company a further seven years of patent coverage.
In its media release to the ASX Prima said the granted patent claims protected the manufacture of an immunotherapy comprising the patient’s own dendritic cells that have been pulsed with a tumor antigen conjugated to mannan fusion protein (MFP).
The company said the Canadian patent strengthened its development pipeline “as the granted claims cover multiple antigens that may potentially be conjugated to MFP, not just those antigens associated with ovarian cancer”.
Prima said the patent was the final major territory to be granted for the MFP product.
Patents have been granted in Australia, the US, Europe and Japan.
Prima is developing an ovarian cancer vaccine, CVac that has successfully completed phase II trials as a maintenance therapy for women with end stage ovarian cancer.
An investigational new drug application has been submitted with the US Food and Drug Administration for the ongoing development of CVac in the US.
Prima climbed 0.1 cents or 16.67 percent to 0.7 cents.

## ADVANCED OCULAR SYSTEMS

Advanced Ocular Systems has settled the agreement to sell its Intra Ocular Lens patents supporting the Tetraflex product licences to Lenstec Inc.
Under the agreement Lenstec would pay $US1.0 million in cash at closing and issue $US1.0 million of Lenstec stock to Advanced Ocular (see Biotech Daily; September 29, 2008).
The company said the cash had been received by electronic transfer and the stock certificate was in transit by courier.
If Lenstec is successful in achieving an accommodating label for Tetraflex with the US Food and Drug Administration and a Medicaid reimbursement, Advanced Ocular will receive a further $US2.0 million of Lenstec shares.
Following the settlement, Advanced Ocular has about $3.5 million cash on deposit.
The company retains one further eye care asset as well as an investment in a property development near Perth.
Advanced Ocular has previously said it would pursue business opportunities not limited to the life sciences sector.
Advanced Ocular was unchanged at 0.4 cents.

## HEARTWARE

The US based FMR Corp and Fidelity Investments have increased their substantial shareholding in Heartware from 25,807,667 (8.32%) to 29,112,558 shares (9.38%).
The group bought 3,304,891 shares in small to moderate parcels at prices varying from 36 cents to 53 cents a share.
Heartware fell one cent or 1.82 percent to 54 cents.

## CHEMGENEX

Chemgenex says 150,568 shares raising $127,982.80 have been allotted despite the share plan price being higher than the market price.
Chemgenex said that during the period the share placement program was open from September 22 to October 3, 2008, its shares traded between 83 cents and 72.5 cents.
A placement raised $12.9 million through the issue of 15,216,153 shares at 85 cents a share (see Biotech Daily September 17, 2008).
Chemgenex fell one cent or 1.69 percent to 58 cents.

## CLINUVEL

Clinuvel's annual general meeting will vote on the grant of 350,000 options to director L Jack Wood.
Clinuvel said the options were exercisable at 110% of the volume weighted average price in the 20 trading days preceding, the grant within one month of the annual general meeting.
Shareholders will also vote on the reelection of directors Dr Roger Aston and Mr Wood.
The meeting will be held at Karstens, Level 9, 123 Queen Street, Melbourne on November 13, 2008 at 10am.
Clinuvel climbed 4.5 cents or 21.43 percent to 25.5 cents.