# Biotech Daily

Monday September 5, 2011

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN:**
**- SUNSHINE HEART UP 5%; ADVANCED SURGICAL DOWN 19%**

*** MESOBLAST TO BEGIN EUROPEAN CARDIAC ARREST STEM CELL TRIAL**

*** CBIO BOARD SPILL CALL**

*** CBIO 3-FOR-8 RIGHTS ISSUE TO RAISE UP TO $10.8m**

*** BASILDENE, SEVERAL TRUSTS TAKE 5.5% OF CBIO**

*** SUNSHINE HEART PLACES $2.2m**

*** FERMISCAN EGM TO PLACE 571m SHARES, DOUBLE DIRECTORS' PAY**

## MARKET REPORT

The Australian stock market fell 2.38 percent on Monday September 5, 2011 with the S&P ASX200 down 101.0 points to 4,141.9 points.

Just four of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and six were untraded. All three Big Caps fell.

Sunshine Heart was the best for the second trading day in a row, up 0.2 cents or 4.65 percent to 4.5 cents with 500,000 shares traded, followed by Sirtex and Tissue Therapies up more than two percent; with Nanosonics up 1.7 percent.

Advanced Surgical led the falls, down 3.5 cents or 18.9 percent to 15 cents, with 3,500 shares traded, followed by Genetic Technologies down 9.5 percent to 19 cents with 994,846 shares traded.

Circadian lost 8.3 percent; Reva and Starpharma were down more than five percent; Cellmid, Mesoblast, Optiscan and Patrys fell more than four percent; Biota, Cathrx, Clinuvel and LBT were down three percent or more; Anteo, Cochlear, Prima, Psivida, QRX, Resmed and Viralytics shed more than two percent; with Alchemia, Bionomics and Living Cell down more than one percent.

MESOBLAST

Mesoblast says it will begin a European 225-patient phase II trial of Revascor with angioplasty and stent procedures to prevent heart failure after cardiac arrest.

Mesoblast said the European Medicines Agency cleared the placebo-controlled, multi-center trial of the adult stem cell product Revascor, which would initially recruit myocardial infarction patients at sites in the United Kingdom, the Netherlands and Belgium.

The company said the trial was expected to involve sites in additional European nations, Australia and the US.

Mesoblast said the primary endpoint of the study would be safety and efficacy at six months in cardiac arrest patients who received either Revascor at one of two doses or placebo, with the durability of effect monitored for up to 36 months.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that he hoped the first patient would be recruited “within the next few weeks”.

“We are hoping to recruit through more than 30 sites so it should take a year or so to complete recruitment,” Prof Itescu said.

Prof Itescu said he expected to complete the six-month follow-up data and have the results available in 2013.

Prof Itescu said that the number of patients was statistically powerful enough that if the data was good, the company could move straight to a phase III pivotal trial.

Mesoblast said that cardiac arrest was “the biggest killer of people in the industrialized world” with more than 1.7 million people in Europe and more than 1.1 million in the US having arrests.

The company said that most patients had an early angioplasty of the blocked artery accompanied by implantation of a metal stent to keep the artery open for the long-term, but a significant number of the surviving patients subsequently became disabled with heart failure.

Mesoblast said the allogeneic, or off-the-shelf, Revascor product derived from its mesenchymal precursor cell technology, was injected by an intra-coronary infusion at the same time as the angioplasty and stent procedure, within 12 hours of the cardiac arrest.

The company said that in preclinical trials, the intra-coronary infusion of the cells increased the number of blood vessels in the infarcted region, prevented scar formation and significantly improved heart muscle function, preventing heart failure.

The study’s principal investigator and head of molecular cardiology at the Netherlands Erasmus University Hospital Prof Eric Duckers said the preclinical data “were very compelling, and formed the basis for this innovative clinical trial”.

“We are excited to be pioneering a novel and minimally invasive clinical approach that has the potential to greatly improve the quality of life for patients suffering acute heart attacks,” Prof Duckers said.

The UK lead investigator and cardiologist at King’s College Hospital Dr Jonathan Hill said the Mesoblast stem cell product had “the potential to change the medical paradigm for treatment of large heart attacks and to provide for the first time a validated and effective off-the-shelf therapy for routine use”.

Prof Silviu Itescu said in a media release that “if the preclinical results are reproduced in this trial, we will have a product that will make a significant impact on the lives of patients after a debilitating heart attack”.

Mesoblast said it had a strategic partnership with the US-based Cephalon which owns 19 percent of the company to commercialize Revascor for the broad treatment of cardiovascular diseases including congestive heart failure, chronic angina and acute myocardial infarction.

Mesoblast fell 39 cents or 4.9 percent to $7.56.

CBIO

CBio says it is has received a requisition for a meeting of members, to consider the removal of certain directors and the election of other persons in their stead.

CBio made the announcement to the ASX in a media release entitled ‘S249D Notice’ and provided no details of who called the meeting.

Section 249D of the Corporations Act 2001 says that “the directors of a company must call and arrange to hold a general meeting on the request of: a) members with at least five percent of the votes that may be cast at the general meeting; or b) at least 100 members who are entitled to vote at the general meeting”.

The Act says directors must call the meeting within 21 days after the request and the meeting is to be held not later than two months after the request.

Earlier this year, CBio chairman Stephen Jones expressed concern that two shareholders had requested copies of the share register ahead of a general meeting to issue 9.1 million free ‘performance rights’ to directors along with other resolutions (BD: Jun 29, 2011).

CBio subsequently reduced the number of performance rights by 6,000,000 (BD: Jul 13, 2011), with 10 percent of shareholders opposing the remaining rights (BD: Jul 15, 2011).

Last month, CBio said it had missed the primary endpoint in it phase II XToll rheumatoid arthritis trial (BD: Aug 1, 2011).

CBio said it was considering the requisition.

CBio fell 5.5 cents or 21.15 percent to 20.5 cents.

CBIO

CBio hopes to raise $10,810,446 through an underwritten non-renounceable three-for-eight share rights issue at 18 cents a share.

CBio said it would issue about 62,686,862 shares.

The company said the rights issue would be underwritten to $10.8 million by Zheng He Securities Pty Ltd and applications would be accepted for any shortfall shares.

The company said the funds raised would be applied to on-going development and commercialization of its lead drug candidate, XToll.

CBio said the funds would go towards costs associated with discussions with pharmaceutical companies, a phase I study in lupus, drug manufacturing and production activities, intellectual property activities and general working capital.

CBio said the record date for the rights issue was September 13, 2011, the offer would open on September 19 and close on October 7, 2011.

CBIO

Basildene Pty Ltd as trustee for Warren Brown & Associates has become a substantial shareholder in CBio with the acquisition of 8,818,049 shares or 5.5 percent of the company.

The initial substantial shareholder notice said the holders included Warren Brown & Associates Superannuation Fund, Warren and Roslyn Brown, Retirewell Commercial Services for the Gillett Superannuation Fund, White turtle Pty Ltd, Pella Comino for the Pelagia Family Trust and Alan and Julie Baker for the Baker Family Trust.

All gave their addresses as Queensland except for the Chifley Square Sydney-based White Turtle.

The notice said the shares were acquired between May 24 and August 10, 2011 at prices ranging from 28.5 cents to 58.27 cents a share, with the Gillett Superannuation Fund saying it bought 5317 shares for $850.72 or 16 cents a share on June 29, 2011.

## SUNSHINE HEART

Sunshine Heart says it has agreements with institutional and high net worth investors to place about 55.8 million shares raising $2.2 million.
Sunshine Heart said the placement completed the Australasian portion of the financing plan.
In July, Sunshine Heart placed 115 million shares of common stock in the US at four cents a share, raising $4.6 million, with each share having one attaching warrant or option to acquire 0.3 of a share exercisable at 5.6 cents in four years (BD: Jul 25, 26, 2011).
Sunshine Heart said at that time it would place a further $9.1 million in the US, Canada and Australia.
The company said that proceeds from the placement would support the US pivotal trial and the continued development of the C-Pulse heart assist system.
Sunshine Heart said that so far, $6.8 million has been raised.
Sunshine Heart was up 0.2 cents or 4.65 percent to 4.5 cents.

## FERMISCAN

Fermiscan shareholders will vote on the placement of up to 571,428,571 shares 0.35 cents a share to raise $2,000,000 and 160,000,000 options at 0.05 cents to raise $80,000.
Fermiscan said the options would be exercisable at one cent.
The company said that about 10 percent of the funds would go to the company's Italian and French trial of a non-invasive diagnostic test for the detection of breast cancer, with 30 percent to identify any potential new businesses and 60 percent for working capital.
Fermiscan has previously published a prospectus for its one-for-two share rights issue at one cent a share to raise up to $767,000 (BD: Nov 23, 2010; Feb 4, 2011).
Fermiscan said at that time the funds were to complete Italian and French trials of the x-ray diffraction of hair test for breast cancer developed by Prof Veronica James, acquired by Fermiscan and subsequently sold to the SBC Research which disputes Fermiscan's ownership of the intellectual property (BD: Jan 16, 2011).
Today, Fermiscan asked shareholders to approve the prior issue of 75,000,000 shares, the issue of 282,142,855 placement shares, 107,142,858 shares to director Richard Wright and 107,142,858 shares to director Carmelo Bontempo.
The company has asked shareholders to approve the grant of 25,000,000 options each to Mr Wright and Mr Bontempo and 5,000,000 each to directors Peter Dykes and Robert Whitton, along with a further 100,000,000 options through the placement manager.
Fermiscan will ask shareholders to double, the directors' remuneration pool from $250,000 to $500,000.
The meeting will be held at Level 29, 66 Goulburn Street, Sydney on October 7, 2011 at 11am (AEST).
Fermiscan fell 0.1 cents or 6.7 percent to 1.4 cents with 1.2 million shares traded.