Biotech Daily

Thursday April 8, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: CATHRX UP 13%; CLINUVEL DOWN 7%**

*** ORPHAN PI-88 COMES HOME TO PROGEN**

*** BIOMD'S PAEDIATRIC CARDIAC MRI DATA SHOWS NO CALCIFICATION**

*** FDA APPROVES HEARTWARE BRIDGE-TO-TRANSPLANT EXTENSION**

*** SELECT'S MARTIN SOUST AWAITS FEDERAL COURT PENALTY**

*** PSIVIDA: DURASERT DELIVERS NEUROPROTECTANT STEROID IN RATS**

*** BIOTRON 'PIGGY-BACK' OPTIONS RAISE $642k**

*** CHINESE PAY AGENIX DROP BY DROP**

*** KARMELSONIX WINS CE MARK FOR WHOLTER WHEEZE RECORDER**

*** MEDICAL DEVELOPMENTS APPOINTS JOHN SHARMAN CEO**

MARKET REPORT

The Australian stock market retreated 0.46 percent on Thursday April 8, 2010 with the S&P ASX 200 down 23 points to 4937.9 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and seven were untraded.

Cathrx was best, up two cents or 13.3 percent to 17 cents with 16,587 shares traded, followed by Impedimed up 6.8 percent to 71 cents with 143,603 shares traded.

Psivida climbed 5.6 percent; Phosphagenics was up 4.8 percent; Biota, Compumedics and Tissue Therapies rose more than two percent; with Bionomics, Cellestis and Circadian up more than one percent.

Clinuvel led the falls, down two cents or 7.4 percent to 25 cents with 98,103 shares traded, followed by LBT, Living Cell and Phylogica down five percent or more.

Prima lost 3.3 percent; Universal Biosensors shed 2.4 percent; with Acrux, Chemgenex, Heartware, QRX and Resmed down more than one percent.

PROGEN

Progen's potential liver cancer treatment muparfostat or PI-88 has returned to its wholly-owned subsidiary Pharmasynth from licencee Global Transbiotech Inc.

In July 2008, Progen discontinued its PI-88 phase III study in liver cancer, despite phase II trial data indicating safety and some efficacy (BD: Jul 23, 2008).

Progen chief financial officer Linton Burns told Biotech Daily at that time that the company had to make a commercial decision in the absence of a partner, the emergence of a competitor and slow patient recruitment.

Mr Burns said that it was difficult to convince a major pharmaceutical company to partner for a drug targeted more at Asian markets than US or European ones.

The PI-88 study as an adjuvant treatment of hepatocellular carcinoma or primary liver cancer began in March 2008 and was to recruit 600 patients at 65-70 hospitals in more than a dozen countries, but only 12 patients were recruited from five centres.

Progen raised funds for the phase III trial and went through a series of battles over its $70 million in cash (BD: Jul 23, Nov 10, Dec 1, 22, 2008; Jan 28, Mar 9, 27, 2009).

Avexa and Cytopia were potential partners in proposed friendly and hostile mergers, respectively, but a series of extraordinary general meetings saw those attempts fail, institutional investors wanted their funds back and Taiwanese interests related to Medigen wanted to continue development of PI-88.

Medigen was contracted to run trials of PI-88 and was entitled to a $2 million payment should the drug be licenced.

Those issues were resolved with the appointment of the current board and the departure of former chief executive officer Justus Homburg (BD: Nov 19, 2009).

Today, Progen said Pharmasynth had terminated the licence agreement for PI-88 with Global Transbiotech for failing to begin a promised trial.

Progen said that one "critical aspect of the licence agreement for muparfostat required [Global Transbiotech] to initiate a pivotal registration trial within nine months of the commencement date of the said agreement".

Progen said Global Transbiotech "failed to comply with this requirement and as a result, Pharmasynth has today provided written notice … that the agreement is terminated with immediate effect".

The company said all rights to muparfostat reverted to Pharmasynth and it intended to regain all rights to muparfostat from Pharmasynth in the coming weeks.

Director Dr John Chiplin said muparfostat was "a significant asset".

"We have recently re-analyzed the results of the previous phase II study, combining them with new data on long term patient survival," Dr Chiplin said.

"We will be updating the market more on future progress in due course," Dr Chiplin said.

Progen said muparfostat was a multi-targeted cancer therapeutic which inhibited both angiogenesis or tumor promoting factors such as vascular endothelial growth factor (VEGF), fibroblast growth factors (FGF) 1 and 2, and heparanase, an enzyme implicated in metastasis or tumor spread.

Dr Chiplin said Progen would make plans "to commence additional clinical trials on muparfostat in the future and will be seeking commercial partners on a worldwide basis."

"The directors of Progen are committed to the commercialization of muparfostat and are confident that this product will assist Progen to deliver long-term, sustainable growth," Dr Chiplin said.

Progen said it was conducting a phase II trial in patients with melanoma, a second indication which has US Food and Drug Administration orphan drug designation, with results expected by the end of 2010.

Progen was up one cent or 1.96 percent to 52 cents.

BIOMD

Biomd says 12 month magnetic resonance imaging of paediatric cardiac patients receiving its Adapt-treated bovine pericardium tissue patch has demonstrated positive results.

Biomd has implanted 30 children aged from three months to 14 years, with a mean age of 3 years and 10 months, with the Adapt-treated Cardiocel patches in various cardiac surgical procedures.

Executive director Robert Towner told Biotech Daily that all patients were being evaluated with echocardiographic examination with 10 patients selected for magnetic resonance imaging (MRI), of which the first five had been completed.

Biomd said the MRI assessments showed that in all cases, no calcification was detected.

The company said this was "a significant result as calcification is a limiting factor in the longevity of biomaterial patches after implantation" and the need for further surgery would be significantly reduced.

Summaries of the five examinations said they had: "no signal loss in [ventricular septal defect] area – no calcification detected"; "no abnormal thickening of patch area … no signal loss in area of repair which indicates no calcification in that area"; "high signal without loss in signal strength indicates absence of calcification in that area"; "repair appears intact on images … no visible leakage"; and "repair appears intact … presence of high signal in area indicates absence of calcification".

"This data confirms our belief in the technology," Mr Towner said.

"We can begin targeting the surgical heart repair and tissue heart valve markets," he said

Biomd said the 30 patients were implanted between May 2008 and July 2009.

The company said the 12 month clinical evaluations were undertaken at South Africa's Universitas Hospital in Bloemfontein under principal investigator Prof Francis Smit and included a general evaluation of each patient's heart condition, a full blood count and an echocardiographic examination.

Biomd said the 12 month follow-up examinations would continue until September 2010, with Prof Smit's final report expected shortly after.

Biomd was up one cent or 20.8 percent to 5.8 cents with 1.7 million shares traded.

HEARTWARE

The US Food and Drug Administration has approved Heartware's investigational device exemption supplement to enroll up to 54 more patients in its bridge-to-transplant trial.

Heartware said the approval was under a continued access protocol for its 'Advance' trial to evaluate the Heartware ventricular assist system as a bridge to heart transplantation for patients with end-stage heart failure.

The company said the primary endpoint was survival at 180-days, defined as alive on the originally implanted device or transplanted or explanted for recovery.

Heartware said secondary endpoints include adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life.

Heartware said the 140 patient trial was the largest bridge-to-transplant pivotal trial to date and the final implant was conducted on February 25, 2010, which will result in the final patient reaching the 180-day follow up point by the end of August 2010.

The company said that enrolment under the continued access protocol could begin at the 30 centers participating in the trial, subject to institutional review board approvals.

Heartware said it expected to submit its pre-market authorization to the FDA by the end of this year.

Heartware fell two cents or 1.4 percent to $1.40.

SELECT VACCINES, FEDERAL COURT, ASIC

The Federal Court's Justice Alan Goldberg has reserved his decision on penalties for former Select vaccines chief executive officer Dr Martin Soust.

In February, Justice Goldberg found that Dr Soust engaged in market manipulation and false trading (BD: Feb 16, 2010).

The Australian Securities and Investments Commission said in a media release at that time that Dr Soust's market manipulation and false trading related to the purchase of shares by Dr Soust in his mother's name on December 31, 2007, shortly before the close of the market for the calendar year" (BD: Jan 16, 2009).

A Federal Court media officer told Biotech Daily that Justice Goldberg had reserved his decision on penalties in the civil matter brought by ASIC against Dr Soust and the penalties would be announced in due course.

Select Vaccines fell 0.1 cents or 14.3 percent to 0.6 cents.

PSIVIDA

Psivida says that its Durasert device to deliver the steroid fluocinolone acetonide in the back of the eye preserves retinal function in a rat model of retinitis pigmentosa.

Psivida said its chief executive officer Dr Paul Ashton co authored a paper on the effectiveness of the Durasert technology for the neuroprotective properties of low-dose sustained-release intravitreous fluocinolone acetonide as a means of reducing retinal neuroinflammation, preventing cell death and preserving retinal function.

The article, entitled 'Intravitreous Delivery of the Corticosteroid FluocinoloneAcetonide Attenuates Retinal Degeneration in S334ter-4 Rats' was published in the journal Investigative Ophthalmology and Visual Science, with an abstract available at: http://www.iovs.org/cgi/content/abstract/iovs.09-4492v1.

Psivida said retinitis pigmentosa was a hereditary condition that affected about 100,000 people in the US.

The company said there was no known cure or effective treatment for the condition, which causes gradual loss of peripheral vision and night vision and eventually most individuals become legally blind.

Dr Ashton said the results were "very encouraging" and the company would "pursue further studies using our technologies for the treatment of eye diseases for which there currently are very few effective treatments".

Psivida was up 24 cents or 5.6 percent to $4.55.

BIOTRON

Biotron has raised a further $641,805 through its "piggy back" options rights issue.

Biotron said 110 shareholders exercised 6,418,049 options at 10 cents each by March 31, 2010 raising the $641,805.

In December 2009, Biotron offered investors one option exercisable at 10 cents by December 11, 2011 for each share held (BS: Dec 11, 2009).

The offer included the incentive that for each option exercised by March 31, 2010, a free option exercisable at 20 cents by March 30, 2012 would be granted.

At that time Biotron chief executive officer Dr Michelle Miller told Biotech Daily that if one quarter of the new options were exercised early, the company would raise a further $2.6 million.

Biotron was untraded at 10 cents.

AGENIX

Agenix says it has recovered a further $1,472,000 from its attempt to acquire two Chinese bio-pharmaceutical companies.
Agenix said the amounts paid in February and March 2010 brought the total recovered since November 2009 to $1,952,000 or RMB12,200,000.
Agenix began a process to acquire two Shanghai pharmaceutical in February 2007 but it stalled when a four percent Chinese landlord failed to provide a waiver for the completion of the share transaction (BD: Feb 14, Jun 6, 2007; Jul 24, 2008).
Agenix was in a voluntary suspension at 1.7 cents.

KARMELSONIX

Karmelsonix says it has been granted Conformitée Européenne (CE) mark approval for its Wholter portable wheeze and cough recorder.
Karmelsonix said the CE mark was a requirement for European sales and distribution and was also the basis for obtaining regulatory approvals in non-European jurisdictions such as Australia's Therapeutic Goods Administration.
The company said the Wholter was the only continuous portable recorder for the quantification and measurement of wheeze and cough to receive regulatory approval.
Karmelsonix said it was used to record the respiratory sounds and breathing activity of patients who suffer from asthma, chronic obstructive pulmonary disease and chronic cough.
Karmelsonix was up 0.2 cents or 7.1 percent to three cents with 4.5 million shares traded.

MEDICAL DEVELOPMENTS

Medical Developments has appointed John Sharman as chief executive officer.
Medical Development said Mr Sharman had more than 20 years experience in senior executive roles in listed ASX medical device and pharmaceutical companies as well as the financial services industry.
Mr Sharman was previously with Vita Life Sciences and Cyclopharm.
Most recently Mr Sharman rejoined the private equity firm CVC Venture Managers as its chief executive officer.
Medical Developments was untraded at 19 cents.