Biotech Daily

Monday September 6, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: GENETIC TECHNO UP 15%; OPTISCAN DOWN 12%**

*** BROADVECTOR $8.5m IPO FOR PROSTATE, PROSTHETIC GENE THERAPY**

*** US PATENT FOR CIRCADIAN VEGF-D DIAGNOSTIC KITS**

*** FDA ALLOWS 54 MORE PATIENTS ACCESS TO HEARTWARE PUMP TRIAL**

*** AVEXA ATTACKS CALZADA**

*** SELECT VACCINES PLACEMENT TO RAISE $115k**

*** BPH RIGHTS ISSUE RAISES $2.6m OF HOPED-FOR $8.3m; MINING EGM**

*** PHARMAUST REQUESTS OIL TRADING HALT; EPICHEM API SCALE-UP**

MARKET REPORT

The Australian stock market was up 0.76 percent on Monday September 6, 2010 with the S&P ASX 200 up 34.3 points to 4575.5.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and six were untraded.

Genetic Technologies was best, up 0.4 cents or 15.4 percent to three cents with 510,860 shares traded, followed by Clinuvel up 7.1 percent to 22.5 cents with 283,790 shares traded.

Circadian climbed 6.9 percent; Prima was up 5.6 percent; Bionomics, Nanosonics, Resmed and Virax were up more than three percent; Alchemia, Pharmaxis, Starpharma and Tissue Therapies rose more than two percent; with Acrux, CSL, Genera, Heartware and Mesoblast up more than one percent.

Optiscan led the falls, down 0.5 cents or 11.9 percent to 3.7 cents with 136,400 shares traded, followed by Prana down 7.4 percent to 12.5 cents with 57,096 shares traded.

LBT lost seven percent; Cellmid and Living Cell fell five percent or more; Cellestis and Viralytics were down more than three percent; with Patrys and Phosphagenics shedding more than two percent.

BROADVECTOR

Broadvector hopes to raise up to $8.5 million and list on the ASX to conduct trials on two disparate indications with a common transient gene-delivery technology.

Broadvector chief executive officer Dr Andrew Bray told a media lunch in Melbourne that his company's "gene-directed enzyme pro-drug therapies" could be used to treat both prostate cancer and aseptic prosthetic loosening.

In both cases the therapies destroy unwanted tissue without surgery by "directly injecting a vector or a vessel carrying a gene to the cells in the tissue which manufactures an enzyme and when it comes into contact with a small molecule pro-drug, becomes a drug which destroys the … tissue".

In the case of prostate cancer, a technology developed by the Commonwealth Scientific and Industrial Research Organisation, the vector is injected into the prostate, an incubation time of about one day is allowed and then the pro-drug can be given in a systemic infusion, which kills prostate cells.

The dead cells are removed by the lymphatic system.

Dr Bray said that if proven to work, the procedure would remove the problems of collateral damage from surgery and radiotherapy, including incontinence, erectile dysfunction, impotence and the risk of infection.

Dr Bray said aseptic loosening was caused by changes to the cells behind the hip cup in patients who have had hip replacements.

He said that they lose their strength and become "like rubber".

Dr Bray said that current treatment was surgical scraping of the tissue and many older patients would not be able to endure the treatment.

He said Broadvector was hoping for European orphan drug designation for the treatment.

He said that with aseptic prosthetic loosening the vector would carry a different gene which would be injected into the deteriorating tissue and again allowed an incubation period, followed by a direct injection of the relevant pro-drug.

Dr Bray said orthopaedic surgeons would extract the now-liquefied sinovial-like tissue and fill the space with orthopaedic cement to reanchor the prosthesis.

Dr Bray said that the priority following the initial public offering would be a first-in-human 18 to 20-patient phase I safety trial for prostate cancer at Sydney's St Vincent's Hospital followed by a 20-patient European phase IIa trial for aseptic prosthetic loosening at Leiden University Medical Centre in the Netherlands in 2011.

He said all the intellectual property would be within his company.

Dr Bray said the company expected to take these two therapies to phase II trials and licence or sell the programs to major companies.

A third program at a very early stage was a vaccine delivery system which had been shown to work in pre-clinical work with monkeys at Oxford's Radcliffe Infirmary.

The initial public offering is of 42,500,000 shares at 20 cents each.

The implied market capitalization on listing will be up to $24.5 million if the $8.5 million is raised. A minimum subscription has been set at $5 million.

Following the offer, the CSIRO and Pharmabank are expected to each own about 14 percent of Broadvector with two Melbourne individuals each holding about five percent.

The board of directors includes chairman Dr Wayne Millen, who is also Pharmabank's chairman, Dr Bray, Dr Roland Toder and Iain Kirkwood.

Dr Gerald Both is the chief scientific officer, Malcolm Booth is the chief financial officer with company secretary Lee Mitchell.

The offer is expected to open on September 13 and closes on October 7, 2010.

Shares are expected to begin trading on October 14, 2010.

Broadvector's prospectus is at: www.broadvector.com.au/irm/content/prospectus.html.

CIRCADIAN TECHNOLOGIES

Circadian says wholly-owned subsidiary Vegenics has been granted a US patent for diagnostic kits for the detection of VEGF-D in human samples such as blood.

Circadian chief executive officer Robert Klupacs said the patent was entitled 'Antibody diagnostic kits and methods of use'.

Circadian said vascular endothelial growth factor D (VEGF-D) was a major novel target for cancer and other diseases, had been shown to be a prognostic indicator of survival or disease progression in a number of different cancer types as well as a biomarker for various respiratory diseases.

Circadian said it was undertaking collaborative studies with a number of groups as part of its development of VEGF-D diagnostics.

Mr Klupacs said the use of targeted therapies in human healthcare was becoming more prevalent.

"In line with this trend, regulatory bodies and clinicians are increasingly in need of validated diagnostic tests to identify selected biomarkers and therefore assess a patient's likelihood to respond to these therapies," Mr Klupacs said.

"VEGF-D's role as a biomarker in cancer and other diseases is becoming more widely recognized," Mr Klupacs said.

"This patent adds to our considerable estate of intellectual property covering VEGF family members, in particular building on the US patent granted to us last year covering VEGF-D antibodies," he said. "It is an important protection for our internal programs and represents a major asset for commercial partnerships with other companies seeking to pursue the use of VEGF-D as a biomarker."

Circadian was up four cents or 6.9 percent to 62 cents.

HEARTWARE

Heartware says the US Food and Drug Administration has approved the enrolment of a second group of 54 patients for its bridge-to-transplant heart pump clinical trial.

Heartware said the FDA approved an investigational device exemption supplement for the extra patients under a continued access protocol.

The company said the FDA granted an initial allotment of 54 patients in April 2010 and the final patient was implanted in August 2010.

Heartware said the trial was designed to evaluate its ventricular assist system as a bridge-to-heart transplantation for patients with end-stage heart failure with a primary endpoint of survival at 180-days, defined as alive on the originally implanted device or transplanted or explanted for recovery.

Under the study, 140 patients at 30 US clinical sites received Heartware Ventricular Assist Devices, making it the largest bridge-to-transplant pivotal trial to date, the company said.

Heartware said the final implant in the original trial was performed in February 2010 and the last follow-up evaluation at 180-days was in August 2010.

The company said that trial results were scheduled to be announced at the American Heart Association's scientific sessions meeting in Chicago, November 13-17, 2010.

Heartware said it expected to submit a pre-marketing application for approval of the system for the bridge-to-transplant indication in December this year.

Separately, the company said the FDA had granted full approval for enrollment in its destination therapy clinical trial for the Heartware system.

In June 2010, the FDA granted conditional approval to begin enrollment in the destination therapy study, which was designed to enroll up to 450 patients at 50 US hospitals.

Heartware was up four cents or 1.8 percent to $2.26.

AVEXA, CALZADA

Avexa has made a number of allegations relating to Calzada's request for board representation.
Avexa said that its announcement was a response to Calzada's announcement of September 2, 2010, itself a response to previous statements by Avexa.
Avexa said Calzada rebuffed its "attempts to engage with it in good faith" and said that on July 9, 2010 Avexa wrote to Calzada chairman David Franklyn "asking for information including the experience of Calzada's proposed board nominees and an outline of Calzada's intentions in respect of its shareholding in Avexa".
Avexa said this was "to properly consider Calzada's request for board representation".
Avexa alleged that by email on the same day Mr Franklyn, "expressed surprise that Avexa would require such information and questioned whether Avexa was considering its request seriously".
Avexa alleged that in his email, Mr Franklyn set a deadline of July 12, 2010 for Avexa to appoint himself and fellow Calzada director, George Cameron-Dow, as directors.
Avexa said that on July 15, 2010 Avexa informed Calzada that after due consideration Avexa had decided not to invite Calzada's representatives to join its board.
Avexa made further allegations regarding Calzada, but said it decided not to "pursue the approach".
Avexa said "Calzada has still not outlined a strategy for Avexa … Calzada has not outlined a strategy or vision for Avexa".
Avexa said it had "a strong and independent board, the directors … [and] have the right blend of technical, commercial and financial skills and experience to lead the company".
"Importantly, the board is fully independent and has extensive pharmaceutical industry and biotechnology experience, which is critical at this stage of Avexa's drug development program," Avexa said.
The Avexa board confirms its recommendation that shareholders say no to all resolutions.
Avexa was unchanged at 3.1 cents.
Calzada was up 0.1 cents or 3.7 percent to 2.8 cents.

SELECT VACCINES

Select Vaccines says it hopes to raise $114,907 through the placement of 38,300,000 shares to professional and sophisticated investors at 0.3 cents a share.
Select Vaccines said the funds would go to working capital and Patersons Securities would be the lead manager.
The company said it expected to announce board changes and arrangement for an underwritten rights issue, shortly.
Select Vaccines last traded at 0.4 cents.

BPH CORPORATE

BPH says it has raised $2,605,045 from the issue of 32,563,065 shares including shortfall applications at eight cents a share.
BPH hoped to raise up to $8,278,170 through the issue of up to 103,477,123 shares (BD: Jul 30, 2010).
BPH said that it was yet to make an allotment of the remaining shortfall shares.
BPH also announced an extraordinary general meeting to approve the acquisition of a mining asset from a substantial holder.
BPH was unchanged at 8.1 cents.

PHARMAUST

Pharmaust has requested a trading halt pending an announcement on its oil and gas drilling projects.

Trading will resume on September 8, 2010 or on an earlier announcement.

Separately Pharmaust's wholly-owned subsidiary Epichem said it had "an expanded range of hard to find analytical standards of [active pharmaceutical ingredient] impurities … available in gram quantities including those for phenylephrine".

Epichem said it was "the premier supplier of analytical standards of [phenylephrine] impurities and degradants.

Epichem said it had a wide range of impurities, degradants and metabolites for many other active pharmaceutical ingredient, especially over-the-counter products.

Epichem managing director Dr Wayne Best said following requests from customers, "we have developed this range of high purity analytical standards that are readily available to ship, importantly in multigram quantities if required".

Dr Best said there was an unmet demand for the products.

"Additionally, we have assisted a number of companies to identify trace impurities in new formulations and then synthesize standards for quantification, enabling them to register new products with the regulatory authorities," Dr Best said.

Pharmaust last traded at 2.6 cents.