Biotech Daily

Monday November 15, 2010

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: LBT UP 8%; USCOM DOWN 20%**

*** HEARTWARE PUMP EQUALS COMPETITORS**

*** ATEC TO ESTABLISH BAHRAIN BIOTECHNOLOGY CENTRE**

*** PROGEN STARTS PHASE I PG545 TUMOR TRIAL**

*** BIONOMICS RAT DATA SHOWS BNC210 'HIGHLY EFFECTIVE' IN ANXIETY**

*** PATRYS REQUESTS CAPITAL RAISING TRADING HALT**

*** ADVANCED SURGICAL SAYS SALES INCREASING**

*** TYRIAN REQUESTS CAPITAL RAISING TRADING HALT**

*** PRATT'S TIGA TRADING TAKES 6% OF HALCYGEN**

*** CELTIC CAPITAL, JERSEY INVESTMENTS EACH TAKE 10.6% OF ACUVAX**

MARKET REPORT

The Australian stock market closed down 0.1 percent on Monday November 15, 2010 with the S&P ASX 200 down 4.7 points to 4688.0 points.

Twelve Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and six were untraded. All three Big Caps were up by less than one percent.

LBT was best, up 0.6 cents or 7.6 percent to 8.5 cents with 73,530 million shares traded.

Heartware, QRX, Starpharma and Tissue Therapies were up more than four percent; Clinuvel, Impedimed and Prana were up more than three percent; Viralytics rose 2.7 percent; with Sirtex up 1.2 percent.

Uscom led the falls, down eight cents or 20 percent to 32 cents with 25,000 shares traded, followed by Psivida down 7.7 percent to $5.30 with 1,835 shares traded.

Bionomics, Cellmid, Living Cell and Virax lost more than five percent; Genera and Phosphagenics fell more than four percent; Benitec was down 3.2 percent; Advanced Surgical, Cellestis and Immuron shed more than two percent; with Cathrx, Chemgenex, Mesoblast and Pharmaxis down more than one percent.

HEARTWARE INTERNATIONAL

Heartware says data from its bridge-to-transplantation heart pump study shows that 92 percent (126 patients) of the 137 investigational device patients met the primary endpoint.

Heartware said the trial protocol for the pivotal trial of its left ventricular assist system, defined the primary endpoint as alive on the originally implanted device, transplanted or explanted for recovery at 180 days.

Heartware said the clinical study showed that 94 percent of the investigational device patients achieved a survival endpoint at 180 days and the study projected one-year survival of 91 percent using the Kaplan-Meier analysis.

Heartware said the US Food and Drug Administration-approved investigational device exemption study was designed to evaluate the Heartware ventricular assist system as a bridge to heart transplantation for patients with end-stage heart failure.

The company said that between August 2008 and February 2010, 140 patients at 30 hospitals in the US received the Heartware investigational device and the analysis included 137 patients in the investigational device cohort.

Heartware said that results for the comparator arm of the study, derived from 499 contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support had 90 percent success of the primary endpoint at 180 days, as well as Kaplan-Meier survival at 180 days of 90 percent and 86 percent at 360 days.

The company said that based on these results, non-inferiority of the investigational device was established [$p<0.001$].

Heartware said the data would be presented today in Australia (November 14, 2010 in the US) as a late breaking clinical trial at the 2010 scientific sessions of the American Heart Association by co-principal investigator Prof Keith Aaronson who was also the medical director of the Heart Transplant Program and Center for Circulatory Support at the University of Michigan.

“Implantation of the investigational device was associated with a high probability of success at 180 days,” Prof Aaronson said.

“We observed marked improvement in two heart failure specific and two generalized quality of life measures from initial patient baseline,” Prof Aaronson said.

“Heartware patients were able to walk 113 meters farther in six minutes when tested three months after surgery and patient assessment of their own quality of life more than doubled,” Prof Aaronson said.

“The adverse event profile from the trial data appears to be favorable, with observed bleeding, infection and ventricular arrhythmia rates at relatively low levels,” he said.

Co-principal investigator Prof Mark Slaughter said that investigators found that “the small device size, with implantation in the pericardial space adjacent to the heart, reduced the complexity of the implant procedure”.

“These device attributes and overall performance help account for the acceleration of enrollment rate we observed during the Advance study,” Prof Slaughter said.

Heartware said its bridge-to-transplant trial was “the largest BTT study conducted to date”.

The final implant was performed in February 2010 and the last follow-up evaluation at 180-days was in August 2010.

Heartware said that through an FDA continued access protocol, a further 75 patients had been implanted in the clinical study and a submission for premarket approval application for the bridge-to-transplant indication was expected in December of this year.

Heartware said it received Conformité Europé (CE) mark for the system in 2009 and about 700 advanced heart failure patients had received its cardiac pump.

Heartware said it was recruiting 50 US sites for a 450-patient destination therapy study.

Heartware was up nine cents or 4.25 percent to $2.21.

AUSTRALIAN TISSUE ENGINEERING CENTRE

The Australian Tissue Engineering Centre (ATEC) says it will establish “a major biotechnology centre for Bahrain”.

The Melbourne-based Centre said the multi-million dollar project “confirms Melbourne as a leader in the development of tissue engineering and stem cell research”.

ATEC said the Bahrain Economic Development Board would fund the Centre of Excellence in Tissue Engineering and Stem Cells, created with the University of Bahrain.

The Centre said the three-year project was a significant step in the commercialization of Melbourne know-how in the new biological sciences.

ATEC said it was established as a technology commercialization company with a research grant from the Victorian Department of Innovation, Industry and Regional Development and was housed at the O’Brien Institute adjacent to St Vincent’s Hospital in Melbourne.

The media release said the O’Brien Institute established Australia’s stem cell bank in 2009 and was “a world leader in microsurgery research and training” with microsurgery developing alongside a broader field of tissue engineering.

The media release said that scientists at the O’Brien Institute had created beating heart cells from fat tissue and, with Neopec, the Institute was about to start clinical trials of a technique for women to re-grow breasts after mastectomy (BD: Apr 16, 2010).

ATEC chief executive officer Dr Phillip Marzella said Melbourne staff would live in Bahrain for a period to guide the development of the centre under project leader Dr Buzz Palmer.

Dr Marzella said Bahrain and other Middle East centres were investing heavily in health sciences and other knowledge-based industries as they prepared to dilute their dependence on petroleum.

“Our aim is to help Bahrain build a world-class biotechnology hub,” Dr Marzella said.

PROGEN PHARMACEUTICALS

Progen says its first in-human trial of anti-cancer drug PG545, which has been “entirely developed in-house”.

Progen said PG545 was a dual-mechanism anti-angiogenesis compound that blocked blood vessel growth in tumors and attempted to stop the cancer cells from spreading.

The company said the study was an open-label, single centre phase I safety and tolerability trial of PG545 in about 25 patients with advanced non-haematologic, malignant solid tumors, excluding primary brain or spinal tumors with a primary objective to determine the maximum tolerated dose as defined by significant dose limiting toxicity.

The company said secondary objectives were the assessment of the safety and tolerability of PG545 following multiple doses in subjects with advanced solid malignancies; estimating the pharmacokinetic parameters of PG545 and exploring pharmacokinetic and pharmacodynamic relationships; and the documentation of any anti-tumor activity.

Progen said the trial was expected to take 12 months for patient recruitment and the principal investigator was the head of medical oncology at Perth’s Sir Charles Gairdner Hospital Prof Michael Millward.

Progen chief executive officer Sue MacLeman said PG545 was entering the clinic ahead of schedule and was “potentially the best-in-class heparanase inhibitor with superior drug-like properties and we believe PG545 has the potential to extend and enhance the lives of cancer patients through its dual mechanism of action of stopping both tumor growth and tumor spread”.

Progen said the PG545 product was manufactured by its wholly-owned contract manufacturing subsidiary Pharmasynth.

Progen was up 2.5 cents or 8.3 percent to 32.5 cents.

BIONOMICS

Bionomics says new data demonstrates its anti-anxiety drug BNC210 is “highly effective in preclinical models of drug-induced anxiety”.

Bionomics said the rat data indicated that BNC210 modulated molecular pathways that were targeted by several marketed drugs, including selective serotonin reuptake inhibitors (SSRIs) such as Prozac, Lexapro, Effexor and Zoloft which were used to treat chronic forms of anxiety and depression.

Unlike these drugs, BNC210 demonstrated rapid onset of action in animal studies and did does not require prolonged treatment for its activity to develop, Bionomics said.

The company said animal studies indicated that chronic use of BNC210 did not lead to symptoms of physical dependence and was unlikely to produce the withdrawal symptoms experienced by benzodiazepam (Valium) and SSRI users.

Bionomics said BNC210 did not inhibit important drug metabolizing enzymes in the liver, indicating that it was safe to take with other medications and BNC210 was active in reducing stress-induced anxiety in animal studies.

The company said the data supported the potential of BNC210 for treating anxiety disorders and expanded its anxiolytic profile to include panic disorder.

Bionomics said the poster entitled, ‘The Novel Anxiolytic Compound BNC210 Reverses the Effects of Anxiogenic Compounds in the Rat Elevated Plus Maze’, would be presented at the Society for Neuroscience annual meeting in San Diego, California and was available at: http://www.bionomics.com.au/siteFiles/files/news/Announcements_414.pdf.

Bionomics said BNC210 had “a clear competitive advantage over current anxiety and panic attack drugs, including billion dollar products like Xanax and Valium, because it lacks their sedative, memory impairing and addictive properties”.

The company said that clinical trials of BNC210 earlier this year confirmed it was safe, well tolerated and without sedative side-effects (BD: Jun 21, 2010).

Bionomics said that blood levels of BNC210 in trial participants indicated that BNC210 would need to be taken only once a day, which would promote patient compliance.

Bionomics chief executive officer Dr Deborah Rathjen said the new animal data on the activity of BNC210, its safety profile in human clinical trials and indications that it lacked a withdrawal syndrome, “highlights its potential to become the therapy of choice”.

“It is a solid candidate to replace current multibillion dollar sales drugs used for anxiety and depression,” Dr Rathjen said.

“We look forward to the completion of the current European clinical trials, one of which is investigating BNC210 effects in drug-induced anxiety and panic, with data anticipated in March 2011,” Dr Rathjen said.

Bionomics said anxiety affected 40 million people over the age of 18 years in the US alone with global drug sales to treat anxiety estimated at about $US15 billion a year, depression affected about 121 million people worldwide, with antidepressant drug sales of more than $US11 billion a year.

Bionomics fell two cents or 5.7 percent to 33 cents.

PATRYS

Patrys has requested a trading halt pending an announcement “in respect of a capital raising”.

Patrys had a cash burn for the three months to September 30, 2010 of $1,503,000, with cash at hand at that date of $5,583,000.

Trading will resume on November 17, 2010 or on an earlier announcement.

Patrys last traded at 13 cents.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says it has its first Australian orders for one of its new products and increased international sales of its own Total Active Knee.
The company said that during the past four weeks it announced its commitment to dramatically expanding sales and profits.
Advanced Surgical has made several announcements relating to third party distribution rights (BD: Sep, 20; Oct 11, 20; Nov 4, 2010).
Advanced Surgical said it had "actively commenced pre-marketing to new and existing client surgical groups" and secured a number of advance orders including "many" from surgeons new to the company.
The company said it had appointed sales representatives over the past 12 months.
Advanced Surgical chief executive officer Dr Greg Roger said the company was "delighted with the response we're getting from the market".
The company said sales to the US and Europe were experiencing solid growth, with the Active Total Knee being implanted in more than 100 patients.
Advanced Surgical fell one cent or 2.4 percent to 40 cents.

TYRIAN

Tyrian has requested a trading halt pending an announcement on "a proposed capital raising".
Trading will resume on November 17, 2010 or on an earlier announcement.
Tyrian last traded at 1.2 cents.

HALCYGEN PHARMACEUTICALS

Tiga Trading says it has become a substantial shareholder in Halcygen with the acquisition of 9,488,557 shares or 6.31 percent of the company.
Tiga Trading is associated with the Pratt Industries-related company Thorney Investment Group Australia.
Tiga said the most recent 1.7 million shares were bought on market between August 6, 2010 and November 12, 2010.
Halcygen was up half a cent or 0.8 percent to 63.5 cents.

ACUVAX

Celtic Capital says it has become a substantial shareholder in Acuvax with the acquisition of 99,000,000 shares or 10.6 percent of the company.
Celtic Capital said it acquired the shares for $148,500 or an average price of 0.15 cents a share and Jason Peterson was the sole shareholder and director of Celtic Capital.
In a separate announcement, Jersey Investments as the Fraser Family said it had become a substantial shareholder in Acuvax with the acquisition of 99,000,000 shares or 10.6 percent of the company at the same price as Celtic Capital.
The notice said Anthony Detata was the sole shareholder of Jersey Investments.
Acuvax was up 0.1 cents or 50 percent to 0.3 cents with 2.5 million shares traded.