Biotech Daily

Wednesday November 21, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: HEARTWARE UP 11%, PRIMA DOWN 4%**

*** FDA APPROVES HEARTWARE PUMP FOR BRIDGE-TO-TRANSPLANT**

*** UNCONDITIONAL FDA APPROVAL FOR SUNSHINE HEART C-PULSE TRIAL**

*** WEHI'S $185m RESEARCH FACILITY**

*** BLUECHIIP PLACEMENT RAISES $1.5m; SHARE PLAN**

*** JAPANESE PATENT FOR BIODIEM'S ANTI-MICROBIAL BDM-I**

*** BIOTA CLEARS OVERHANG; 2013 BARDA PHASE II MILESTONE**

*** HUNTER HALL REDUCES TO 26% IN SIRTEX**

*** VIRALYTICS TAKES CAPITAL RAISING HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 0.37 percent on Wednesday November 21, 2012 with the S&P ASX 200 down 16.2 points to 4,369.5 points.

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

Heartware was the best, up 25 cents or 11.3 percent to $2.47, with 67,920 shares traded.

Ellex climbed 7.5 percent; both Benitec and Sunshine Heart rose 6.7 percent; Allied Health, Impedimed and Reva were up more than four percent; Bionomics was up 3.1 percent; Optiscan, Patrys and Prana rose more than two percent; Acrux, Alchemia, Anteo, Starpharma and Universal Biosensors were up one percent or more; with QRX up by 0.65 percent.

Prima led the falls, down 0.5 cents or 3.7 percent to 13 cents with 961,052 shares traded.

CSL, Sirtex, Mesoblast and Tissue Therapies shed more than two percent; Cochlear and Resmed were down more than one percent; with Nanosonics and Pharmaxis down by less than one percent.

HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration has approved its left ventricular assist system for bridge-to-heart transplantation patients with end-stage heart failure.

Heartware chief executive officer Doug Godshall said that FDA approval was “the culmination of an extensive clinical effort and represents an exciting advance in the treatment of late-stage heart failure patients”.

Mr Godshall thanked the trial patients and their families, as well as the nurses, coordinators, surgeons and cardiologists for their contributions.

Heartware said the system was the leading ventricular assist device implanted in patients outside the US, and received Conformité Européenne (CE) mark approval in 2009, and Australian Therapeutic Goods Administration approval in 2011.

A Heartware executive told Biotech Daily the first implant was in 2006, the US bridge-to-transplant trial began in 2008 and more than 2,500 patients had received an HVAD pump.

Prior to the US approval, in its report for the six months to June 30, 2012, Heartware said that revenue, mainly from European and Australian sales, with US trial reimbursement, was up 44.4 percent to $US55,398,000 ($A52,554,000) (BD: Aug 8, 2012).

Mr Godshall said that Heartware was ready to begin the commercial rollout of the system “immediately, first facilitating broad use by the 50 US hospitals that participated in our clinical studies and then with training and expansion to additional US hospitals”.

Heartware said that its pre-market approval submission included data from the pivotal ‘Advance’ FDA-approved investigational device exemption (IDE) study to evaluate the system as a bridge to heart transplantation for patients with end-stage heart failure.

The company said that 140 patients at 30 US hospitals received the Heartware investigational device between August 2008 and February 2010, the study achieved a 94 percent survival at six months and successfully met its primary endpoint of non-inferiority to the comparator arm, derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support (Intermacs) [$p < 0.0001$].

Heartware said that a further 250 patients in four allotments were granted FDA continued access protocol use of the pump.

The company said an FDA approval condition was a post-approval study to assess performance in a real-world setting and that 600 HVAD patients would be compared to 600 control patients from a contemporaneous group of continuous flow, intra-corporeal left ventricular assist device patients entered into the Intermacs database.

The company said that other post-approval commitments included the transfer of patients from the Advance study into a post-approval database as well as an obligation to continue training sites in accordance with an approved training program.

Texas Heart Institute cardiovascular surgery research director Dr OH Bud Frazier said he had worked on the HVAD project since its conception more than a decade ago.

“The goal was to develop a miniaturized device with an integrated inflow cannula that could be placed within the pericardial sac, avoiding the necessity of creating a pump pocket with its attendant infection risks, as well as simplifying the surgical insertion,” Dr Frazier said. “A second goal was elimination of mechanical bearings to suspend the impeller, designed to enhance durability and blood handling characteristics.”

“Those of us who treat these challenging end-stage heart failure patients are fortunate to have this pericardial, wearless system available for our patients,” Dr Frazier said.

Heartware said it had completed enrollment of a 450-patient destination therapy study at 50 US sites, with the final patients implanted in May 2012, with a two-year, primary endpoint follow-up period and the company had requested a continued access protocol allocation for destination therapy from the FDA.

Heartware was up 25 cents or 11.3 percent to $2.47.

SUNSHINE HEART

Sunshine Heart says it has unconditional approval from the US Food and Drug Administration to begin its pivotal US trial for its C-Pulse cardiac assist aorta cuff system.

Sunshine Heart said that it expected to begin the North American pivotal trial by the end of 2012.

The company said it had contacted “a number of leading heart failure centers in the US and to date is encouraged by the positive response to participate in the trial”.

Sunshine Heart said that the trial would have 388 patients of which half would be implanted with the C-Pulse system and the other half would be randomized to optimal medical therapy across 30 to 40 clinical sites.

The company said it expected enrollment for the event-driven pivotal trial to take about tow and a half years.

Sunshine Heart said the primary endpoint of the trial will be reduction in worsening heart failure events leading to hospitalization, advanced heart failure therapies and heart failure related mortality.

The company said that a one year safety follow-up was expected and the lead investigator would be for the trial will be the Ohio State University Medical Center Division of Cardiovascular Medicine director Dr William T Abraham.

Sunshine Heart said it expected to receive revenues from trial sites for device implants as the FDA has granted Centers for Medicare & Medicaid Services (CMS) Category B3 status.

The company said that because of this designation, it was also expecting that participating trial centers would be reimbursed by CMS and most private insurance providers.

Sunshine Heart chief executive officer Dave Rosa said that the company was “pleased to have expeditiously completed the approval process with the FDA”.

“We are excited to evaluate the C- Pulse system’s potential in treating patients suffering from class III and ambulatory class IV heart failure,” Mr Rosa said.

“We also are eager to evaluate its clinical and economic impact in reducing re-hospitalization rates due to worsening heart failure as this represents the highest and most costly re-hospitalization rates plaguing the US healthcare system,” Mr Rosa said.

Sunshine Heart said the trial will use its next-generation single unit C-Pulse driver, which received approval for clinical trial use from the FDA in August, 2012 and had been in use in Canadian and US patients.

The company said that the new driver had a single unit, which was lighter, quieter, about half the size of its predecessor and included numerous software updates.

In July, Sunshine Heart announced positive 12-month extended follow-up data from its preliminary feasibility study of the C-Pulse heart assist cystem (BD: Jul 24, 2012).

The company said at that time that extended data included positive efficacy trends with continued improvements in New York Heart Association class reduction, quality of life scores and six minute hall walk.

Sunshine Heart said in July that there were no additional patients with device-related serious adverse events in the 12-month time frame.

The company also received Conformité Européenne (CE) mark certification in July, allowing commercialization of the device in Europe (BD: Jul 25, 2012).

Sunshine Heart said it had been targeting leading left ventricular heart device and transplant centers in the European Union with a specific initial focus for the device in Germany and Italy, two countries that when combined, were believed to have the highest number of hospital bed days per year for heart failure in Europe.

Sunshine Heart was up 0.2 cents or 6.7 percent to 3.2 cents with 2.3 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says Victoria's Premier Ted Baillieu will open its new state-of-the-art $185 million research facility tomorrow.

The Institute said that the Federal Parliamentary Secretary for Health and Ageing Catherine King would be at the launch along with Walter and Eliza Hall Institute staff and several cancer survivors who had benefited from the discovery by Prof Don Metcalf of colony-stimulating factor hormones.

The Institute said that colony-stimulating factors were discovered 25 years ago and were used to increase dangerously low white blood cell levels in cancer patients undergoing chemotherapy to help them fight infection and were also used to collect blood stem cells for bone marrow transplants.

In a media release the Institute said the redevelopment of the Parkville building included "a number of Australian-first research services across seven new levels of laboratories and scientific support services" including a new personalized medicine research centre, volunteer blood donor registry, an insectary for breeding malaria-carrying mosquitoes and a clinical translation centre.

WEHI said that the building included a new clinical translation centre designed to make it easier for clinicians to train or work in the translation of research and helping improve patient outcomes by expediting the development of research discoveries into new treatments.

The Institute said that through a new walkover into the Royal Melbourne Hospital, the centre was more easily accessible to clinicians and clinician-scientists from hospitals and other research organizations.

The Institute said that the insectary would allow scientists to study thousands of malaria-infected mosquitoes for increased understanding of the liver stage of the disease.

WEHI said the new facility would also have a volunteer blood donor registry that could take blood from any person, including people normally excluded from giving blood, such as those who have had potential exposure to mad cow disease, to be used for research into cancer, heart disease and brain diseases as well as a swift, personalized system to assist breast cancer treatment with the Australian Centre for Translational Breast Cancer Research.

WEHI said its floor space had more than doubled and an additional 270 researchers had been employed since the upgrade began in 2008 and a further 200 staff and students were being recruited.

The Institute said that the $185 million redevelopment was funded through contributions from the Victorian and Australian governments, the Atlantic Philanthropies and a number of philanthropic organizations and individuals.

WEHI said that the new building housed the Ian Potter Centre for Genomics and Personalised Medicine, Australia's first research centre for matching disease treatments to a person's genetic makeup.

Walter and Eliza Hall Institute director Prof Doug Hilton said the centre aimed to study disease so that treatments could be tailored specifically to individuals.

Prof Hilton said that using new genomic and proteomic sequencing technologies, the centre aims to customize treatments for people with immune disorders and cancers.

"Personalized medicine is the future of medical treatment," Prof Hilton said.

"One of our key focuses is to deliver discoveries that improve lives here in Australia and globally," Prof Hilton said. "We are delighted to have the first facility in Australia dedicated to personalized medicine."

The Institute said the launch would include a special event with Prof Metcalf meeting 60 patients who have benefited from his colony-stimulating factors discovery.

BLUECHIIP

Bluechiip says it has raised $1.5 million from existing shareholders and new institutional and sophisticated investors in a private placement at 20 cents a share.
The company said it would offer a share purchase plan for eligible shareholders registered at the record date of November 20, 2012, also at 20 cents.
Bluechiip said the plan was underwritten to $500,000 by Baillieu Holst, the lead manager to the placement and shareholders could apply for parcels of up to $15,000 shares.
Bluechiip said the funds would be used for commercialization activities.
Bluechiip was unchanged at 25 cents.

BIODIEM

Biodiem has been granted a Japanese patent for its antimicrobial compound, BDM-I.
Biodiem said that it had patent coverage for BDM-I in the world's three largest jurisdictions with patents for BDM-I granted in the US, Europe, China, Russia, Singapore, South Africa and Australia, with national phase prosecution continuing in other major markets and additional divisional patents filed in Europe and the US.
Biodiem said that BDM-I was active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa.
The company said the Japanese patent provided protection around BDM-I as a treatment for vulvo-vaginitis, a general term for inflammation of the vulva or vagina, commonly caused by infection from a range of different micro-organisms and one of the most common female health complaints across all demographics.
The company said the patent covered BDM-I as an antimicrobial compound for vulvo-vaginitis caused by a number of bacterial, fungal and parasitic agents such as Neisseria gonorrhoea, Candida albicans or Trichomonas vaginalis, respectively.
Biodiem said that Candida albicans was one of the most common causes of yeast infections and was commonly referred to as thrush.
The company said that Trichomonas vaginalis was the most common sexually transmitted protozoan infection in industrialized countries and that infection with Trichomonas vaginalis had been correlated with reproductive issues and increased susceptibility to a range of other health issues including infection with HIV.
Biodiem chief executive officer Julie Phillips said that Japan was "a major regulatory market and successful granting of a Japanese patent is a milestone for BDM-I's protection for this major indication across the world's largest patent jurisdictions".
"Along with our recently initiated research project with Griffith University exploring new variants of BDM-I with enhanced commercial characteristics, this is a good progression of the BDM-I package," Ms Phillips said.
Biodiem said that the market for anti-infectives was valued at $US53 billion in 2011 and forecast to exceed $US100 billion by 2015, while the antifungals market was valued at $US9.4 billion in 2010 and estimated to reach $US11.3 billion in 2014.
Biodiem said it had been "actively accelerating its development of BDM-I through partnerships with the US Army Medical Research Institute of Infectious Diseases, the US National Institutes of Health and the Queensland Institute of Medical Research, while retaining full commercial and intellectual property rights for the work conducted.
The company said it was progressing further validation of BDM-I's antimicrobial activity through in-vivo proof-of-concept testing in models of fungal, bacterial and parasitic disease models, conducting further studies on the scope of BDM-I's indications with expanded screening studies and a new project with Griffith University.
Biodiem was untraded at four cents.

BIOTA PHARMACEUTICALS

Biota chief financial officer Damian Lismore says two share overhangs are expected to be cleared by next week and the next major milestone is a US phase II trial by July 2013.
Mr Lismore told an investors' meeting at Fortrend Securities in Melbourne that apart from former Nabi Pharmaceuticals shareholders departing the company following the merger, he was managing the sale of shares for about 662 Biota shareholders with holdings of less than 2,000 pre-merger shares (BD: Apr 23, Nov 9, 12, 2102).
Fortrend trades directly on the Nasdaq and can facilitate the purchase and sale of shares.
Mr Lismore said Biota had three products in the market, including Relenza and Inavir, as well as the Nabi-inherited calcium asset Phoslyra for end-stage kidney disease.
He said the company had a pipeline including Nabi's smoking cessation drug Nicvax, as well as its own small molecule, anti-infection agents, including BTA798 or vapendavir for human rhinovirus.
Mr Lismore said the company had programs in respiratory syncytial virus and hepatitis C as well as an anti-bacterial agent for multi-drug resistant bacteria.
Mr Lismore said that the five-year $231 million ($A223.7 million) US Office of Biomedical Advanced Research and Development Authority (BARDA) contract, to develop its laninamivir anti-influenza drug, would see phase I safety and pharmacokinetics trials early in 2013 and a milestone-earning phase II efficacy trial expected by July 2013.
Overnight on the Nasdaq, Biota was up three US cents or 0.7 percent to $US4.24.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex from 14,979,180 shares (26.86%) to 14,407,180 shares (25.83%).
Hunter Hall said that it sold shares at a range of prices between September 4 and November 19, 2012, with the single largest sale 86,157 shares for $874,934 or $10.16 a share.
In August, Hunter Hall also took profit on Sirtex shares, reducing its holding by 558,704 shares or one percent (BD: Aug 7, 2012).
Sirtex fell 29 cents or 2.5 percent to $11.51.

VIRALYTICS

Viralytics has requested a voluntary suspension to follow the trading halt it requested on November 19, pending a capital raising (BD: Nov 19, 2012).
Viralytics last traded at 36 cents.