Biotech Daily

Tuesday April 27, 2010

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: LIVING CELL UP 8.5%; AVEXA DOWN 7%**

*** HEARTWARE RECALLS 'QUIET' CARDIAC PUMP CONTROLLERS**

*** IM MEDICAL, INVENTOR TAKE 5 YEARS TO END JOB LITIGATION**

*** US PATENT FOR USCOM ALGORITHM**

*** HEARTWARE PRESENTS 'POSITIVE' 100 PATIENT DATA**

*** FDA ACCEPTS RESUBMITTED PHARMAXIS ARIDOL NDA**

*** US FOUNDATION'S $540k FOR LIVING CELL TRIAL**

*** EASTLAND REQUESTS ARTIMIST TRADING HALT**

*** NOVOGEN APPOINTS DR DANIEL GOLD US CEO**

*** PROBIOTEC APPOINTS DIRECTORS; CLOSES CELEBRITY SLIM DEAL**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Tuesday April 27, 2010 with the S&P ASX 200 down 1.5 points to 4880.0 points.

Twelve of the Biotech Daily Top 40 stocks were up, 14 fell, 10 were unchanged and four were untraded. All three Big Caps fell.

Living Cell was best, up 2.5 cents or 8.5 percent to 32 cents with 975,762 shares traded, followed by Phosphagenics up 6.25 percent to 17 cents with 934,529 shares traded.

Novogen and Patrys climbed more than four percent; Cathrx was up 3.1 percent; Circadian, Genera, Heartware and QRX rose more than two percent; with Alchemia and Bionomics up more than one percent.

Avexa led the falls, down one cent or 7.1 percent to 13 cents with 1.0 million shares traded, followed by Antisense and LBT both down five percent.

CSL, Tissue Therapies and Viralytics fell more than four percent; Cellmid, Sirtex and Starpharma lost more than three percent; Biota, Clinuvel, Cochlear and Resmed shed more than two percent; with Chemgenex and Optiscan down more than one percent.

HEARTWARE INTERNATIONAL

Heartware has begun a voluntary recall of some of its left ventricular pump controllers for immediately in-field repairs and replacements.

Heartware said it was taking the action “because a small number of controllers exhibit reduced levels of speaker volume”.

The company said the controller managed the Heartware Ventricular Assist Device (HVAD) by sending power and operating signals to the pump while providing information to the patient and physician via visual and audio feedback.

Heartware said the controller incorporated a three-tier alarm redundancy comprising an audible alarm, together with a color-coded visual display and written text on a screen.

The company said the visual text and color-coding were visible to the patient and caregivers at all times and each of the three alarms was tested multiple times each day when the patient or caregiver replaced the batteries in the normal course of use.

“Although a small number of controllers have exhibited reduced levels of speaker volume, no patient has experienced any form of resultant medical complications due to the abovementioned alarm redundancies and daily testing,” Heartware said.

Heartware said that in July 2009, it revised its controller to incorporate waterproofing, but during air transportation of the revised controllers to clinics, “a small number of controllers developed excess air vacuum that subsequently reduced levels of speaker volume”.

Heartware said it expanded its product testing processes to include an air pressure simulation to screen-out susceptible units and from December 2009 implemented a further revision of the controller adding a small Teflon vent to the underside of the controllers to prevent the occurrence of excessive air vacuums during transportation to the clinic.

Heartware chief executive officer Doug Godshall said the implementation of the waterproof controllers in July 2009 “unfortunately generated an air-tight vacuum within our controller with the result that our speaker may be quieter than expected in a small number of cases, including just one occurrence in the US since the commencement of implanting in our [investigation device exemption] trial in August 2008”.

“We have since rectified this issue but there are still patients being supported by our now waterproof controllers that do not have the current, vented controller,” Mr Godshall said.

“This field program will enable these older versions to be upgraded to the current vented configuration,” he said.

“We will also take this opportunity to replace approximately 80 controllers which were introduced since we received our [investigation device exemption] for our US bridge-to-transplant trial,” Mr Godshall said.

Heartware said the reduced speaker volume did not otherwise impede the controller and there were no patient deaths or adverse patient consequences reported to date.

The aggregate cost of implementing this voluntary repair and replacement project was expected to be less than $US400,000 ($A432,000), inclusive of inventory, travel, freight and related costs, and the program was expected to be completed within 60 days, the company said.

Heartware was up four cents or 2.6 percent to $1.56.

IM MEDICAL

IM Medical says litigation commenced by Dr Zissis (Jack) Minas over the termination of his employment “has been settled to the satisfaction of both parties”.

IM’s chief executive officer Roman Najdecki told Biotech Daily that Dr Minas was the inventor of the Intelliheart technology and departed the company from June 30, 2005.

IM Medical was unchanged at 0.3 cents with 8.1 million shares traded.

USCOM

Uscom says the US Patent and Trademark Office will issue a new patent covering its monitor's algorithm.
Uscom said the algorithm was a method which allowed the pulmonary valve diameter to be calculated from the subject height.
The company said the US patent recognized the novelty of the science and afforded competitive protection for a period of 20 years in the US jurisdiction.
Uscom said the algorithm had been "extensively validated as an integral component of the Uscom device" and might have additional commercial application in cardiac surgery and general ultrasound.
Uscom was untraded at 49 cents.

HEARTWARE INTERNATIONAL

Heartware says its ventricular assist system has a survival rate of 90 percent at six months and an actuarial survival rate of 86 percent at 12 months post implant.
Heartware said the results were presented by Hannover Medical School cardiothoracic surgeon Dr Martin Strueber at the annual meeting of the International Society for Heart and Lung Transplantation in Chicago.
The company said the presented data included all 50 patients in its clinical trial, as well as the first 50 commercial patients.
Heartware said the survival rates were identical between the commercial and clinical groups, with 45 of 50 patients (90 percent) alive at the 180-day mark, with the reported adverse events similar in each group.
The company said trial enrollment was completed in December 2008, while the first 50 commercial implants were between January and September in 2009.
The average age across all 10 centers in five countries was 50.5 years, with the youngest patient a 16 year-old.
Dr Strueber said 14 percent of the implants were conducted by thoracotomy, with 86 percent through a typical sternotomy, showing "the versatility of the pump … and potential for less invasive procedures in the future".
Heartware said the duration of support averaged 444 days in the clinical trial population, compared with 203 days in the more recently implanted commercial group.
The longest duration of support was 1,108 days, and seven patients were transplanted within 180 days in the clinical trial group, compared to four in the commercial group.
Heartware chief executive officer Doug Godshall said that "in a sicker cohort … strong survival data was maintained in the commercial setting".
Heartware said its US trial of 140 patients was the largest bridge-to-transplant pivotal trial to date, enrollment was completed in February 2010 with completed patient follow-up expected in August 2010, and a pre-market application to the US Food and Drug Administration by the year of 2010.
In a separate presentation at the International Society for Heart and Lung Transplantation meeting the University of Louisville's Dr Mark Slaughter presented 'Design and Feasibility Testing of a Miniaturized Transapical Mechanical Circulatory Support Device: MVAD'.
Heartware said Dr Slaughter reported that the miniaturized ventricular assist device (MVAD) provided support for a 30-day period without complications.
In 12 bovine studies, all MVAD pumps were successfully implanted via left thoracotomy, without sternotomy and with no cardiopulmonary bypass.
The company said the MVAD demonstrated good haemodynamic performance and haemocompatability in the test model.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has acknowledged receipt of its resubmitted new drug application for Aridol for asthma management.

Pharmaxis said the resubmission for Aridol (mannitol inhalation powder) followed "an action letter received from the FDA dated December 23, 2009".

On December 29, 2009 Pharmaxis said the FDA determined that the Aridol application "cannot be approved in its present form" and listed deficiencies observed at three subcontract manufacturing and testing facilities; submission of revised labeling; and agreement to post-marketing requirements.

Pharmaxis said at that time that it filed the application for Aridol in February 2009 and following a meeting on November 20, 2009 the FDA's pulmonary-allergy drugs advisory committee recommended the approval of Aridol.

Today Pharmaxis said the resubmission included a safety information update, revised labeling and further information regarding the chemistry manufacturing and control.

Pharmaxis chief executive officer Dr Alan Robertson said he believed that the resubmission "fully addresses all of the issues raised in the action letter".

Pharmaxis was up one cent or 0.3 percent to $3.18.

LIVING CELL TECHNOLOGIES

Living Cell has received a $US500,000 ($A540,000) Juvenile Diabetes Research Foundation International grant for its New Zealand phase II trial of Diabecell.

Living Cell said the Foundation was a leader in diabetes research and the largest charitable funder and advocate for research in type 1 diabetes.

The company said the first four patients had received implants and early observations show clinical benefit without remarkable adverse events.

Living Cell said the data safety monitoring board had approved proceeding with implants of a higher dose for the next four patients.

The company said the Juvenile Diabetes Research Foundation (JDRF) grant would contribute to the second part of the phase II trial, which will test the safety and efficacy of Diabecell in higher doses in patients with type 1 diabetes.

The director of beta cell therapies at the Foundation Dr Julia Greenstein said the initial results from the first phase of the trial "showed us a significant feature of [Living Cell's] product in its ability to protect the cells from immune rejection without the use of immunosuppressive anti-rejection drugs".

"Encapsulation for immuno-protection is one of JDRF's research priorities and the success of this trial could have an important impact on this field of research and the development of a commercially-viable cell replacement therapy for people with type 1 diabetes," Dr Greenstein said.

Living Cell medical director Prof Bob Elliott said that "at this early stage, we have seen the abolition of unaware hypoglycaemia in the first patient".

"This diabetes complication occurs in up to 17 percent of long term type 1 diabetic people, and is responsible for up to eight percent of all deaths in type 1 diabetes," Prof Elliott said.

"The grant from the JDRF is most welcome as we share the same concerns for diabetes patients who endure life threatening episodes of low blood glucose without warning symptoms," Prof Elliott said.

Living Cell said that the Juvenile Diabetes Research Foundation collaboration was part of the Foundation's industry and discovery and development partnership program.

Living Cell was up 2.5 cents or 8.5 percent to 32 cents.

EASTLAND MEDICAL SYSTEMS

Eastland has requested a trading halt pending an announcement on its sublingual paediatric malaria treatment, Artimist.
Trading will resume on April 29, 2010 or on an earlier announcement.
Eastland last traded at 9.1 cents.

NOVOGEN

Novogen's 71.3 percent US subsidiary, Marshall Edwards, has appointed Dr Daniel Gold its US-based chief executive.
Novogen said Dr Gold had more than 25 years of drug discovery and development experience as well as academic qualifications in pathology and immunology.
Novogen said Dr Gold would focus on the clinical and commercial development of the group's anti-cancer compounds.
Novogen said the Sydney-based David Seaton would continue as the company's acting chief executive officer.
The company said Marshall Edwards was focused on the development of four anti-cancer therapeutics - phenoxodiol, triphendiol, NV-143 and NV-128 - which have been originated by Novogen.
Dr Gold was most recently president and chief executive officer of Prospect Therapeutics, a mid-stage oncology company and was founder and chief scientific officer of the oncology company Favrille Inc.
Novogen was up two cents or 4.8 percent to 44 cents.

PROBIOTEC

Probiotec has appointed Robert Maxwell Johnston and Wesley Stringer as directors.
Probiotec said that prior to his retirement in December 2009, Mr Johnston had 20 years in senior executive positions with Johnson & Johnson and had been chief executive officer of Johnson & Johnson Pacific for 11 years.
The company said Wesley Stringer was its chief operating officer with responsibilities including the management of the company's five manufacturing sites and the coordination of its new product development.
Prior to joining Probiotec, Mr Stringer was employed by KPMG in taxation and finance and he had worked for Deutsche Bank and BNP Paribas Investment Bank in London.
Separately, Probiotec said it had acquired the 50 percent of the Celebrity Slim "food replacement" brand it did not previously own, including all associated trademarks and intellectual property and held 100 percent of the brand.
Probiotec said the brand was acquired as part of a wider settlement with Hi-Performance Health in which Probiotec made a net payment of $3.8 million in exchange for the acquisition of the remaining 50 percent of the brand; full settlement of the case and all future claims; and sole and exclusive manufacturing and distribution rights for the brand worldwide.
Probiotec was unchanged at $1.70.