Biotech Daily

Thursday September 22, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: HEARTWARE UP 5%; CATHRX DOWN 18%**

*** SUNSHINE HEART: 'MOST IMPROVE' IN 20-PATIENT CARDIAC TRIAL**

*** AUSBIOTECH HAILS SENATE GENE PATENT REPORT, LONG WAY TO GO**

*** MAYNE WINS PRELIMINARY INJUNCTION AGAINST MYLAN**

*** ANTEO AGM FOR 9.6m DIRECTOR OPTIONS, EMPLOYEE OPTION PLAN**

*** HELICON EGM ON 155m SHARES, OPTIONS, NAME CHANGE**

*** BONE EGM ON SHARES, OPTIONS FOR LA JOLLA COVA, PROXIMA FEES**

*** BAILLIE GIFFORD TAKES 6% OF COCHLEAR**

*** AUTUS REDUCES 3% IN FERMISCAN**

*** VIRAX LOSES DIRECTOR TIM COOPER**

MARKET REPORT

The Australian stock market tumbled 2.63 percent on Thursday September 22, 2011 with the S&P ASX200 down 106.9 points to 3,964.9 points.

Five of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and eight were untraded.

Heartware was best, up 16.5 cents or 10.9 percent to $1.675 with 10,500 shares traded.

LBT climbed 3.7 percent; Biota, QRX and Resmed were up more than one percent; with Mesoblast up 0.24 percent.

Cathrx led the falls, down 2.5 cents or 17.9 percent to 11.5 cents with 51,000 shares traded, followed by Benitec down 13 percent to two cents with 9.6 million shares traded.

Impedimed lost 9.1 percent; Prana fell 8.3 percent; Genera, Pharmaxis and Prima shed more than seven percent; Phosphagenics and Sirtex were down more than six percent; Allied Health and Viralytics fell five percent or more; Cochlear, Optiscan and Starpharma lost more than four percent; Acrux, Circadian and Living Cell were down three percent or more; Bionomics, Genetic Technologies and Tissue Therapies shed more than two percent; with CSL down 1.65 percent.

SUNSHINE HEART

Sunshine Heart says that most of the 20-patients in its pilot trial of the C-Pulse aorta cuff pump improved heart failure categories.

Sunshine Heart did not provide detailed results, but said that one patient died in an infection-related operation and two patients improved to the point that they were disconnected permanently from the heart pump system.

The summarized data was published by the Ohio State University Medical Center and the company said the detailed results would be presented at the Transcatheter Cardiovascular Therapeutics meeting in San Francisco on November 8, 2011.

Ohio State University Medical Center said that 20 patients, eight women and 12 men with an average age of 56, were enrolled in the trial, of which 18 were classified with New York Heart Association (NYHA) class III heart failure and two were class IV, the most severe forms of heart failure.

All patients had cardiac resynchronization therapy, implantable cardiac defibrillators or combination devices implanted, the Medical Center said.

The Medical Centre said three patients were successfully bridged to transplant with one patient being supported for 22 months, the longest of any patient participating in the trial.

The Medical Centre said that all but one patient either improved or maintained NYHA heart failure classification.

Sunshine Heart chief executive officer Dave Rosa told Biotech Daily that the results were still being finalized, with some detail being held back for the San Francisco conference.

“The majority of patients improved, rather than maintained classification, and this is a condition in which patients normally deteriorate,” Mr Rosa said.

Mr Rosa said that two patients improved to the point that they did not require the device, due to the absence of heart failure symptoms, and along with the overall reduction in patient medication, were positive indicators for the device.

Mr Rosa said that one patient was disconnected after the six month follow-up and the second patient after 11 months on therapy.

The Medical Centre said that overall, other improvements were realized as measured by quality of life scores, six-minute walk times, ejection fractions, or the heart’s pumping ability, and reductions in medications.

Mr Rosa said that the patient who died had a non-device-related infection and died following surgery to treat the infection.

Mr Rosa said there were a number of contributing factors in the death from an aortic disruption, as a result of a re-sternotomy surgery to treat the procedure-related infection.

The Medical Centre said no neurologic events or heart attacks were reported, while six superficial exit site infections were successfully treated with antibiotics.

The Medical Centre said there was one instance of post-operative, non-device related bleeding.

The Medical Centre said that the results warranted a larger pivotal trial.

The Medical Centre’s director of cardiovascular medicine and co-lead principal investigator Dr William Abraham said the trial results to date “show positive trends of efficacy with a strong safety profile as compared to later stage mechanical support devices”.

“We believe further investigation is needed as hundreds of thousands of heart failure patients in this country remain substantially symptomatic despite currently available treatments,” Dr Abraham said.

The C-Pulse aorta cuff uses an electrocardiogram-sensing wire to inflate and deflate the cuff to assist the heart, reducing aortic pressure and the heart’s workload.

Sunshine Heart was unchanged at 4.7 cents.

AUSBIOTECH, FEDERAL GOVERNMENT

Ausbiotech has welcomed a Senate report recommending that the Patent Amendment (Human Genes & Biological Materials) Bill 2010, should not be passed.

Ausbiotech said the Senate Legal and Constitutional Committee Inquiry into the Bill was tabled in the Senate last night.

A Senate officer told Biotech Daily that the Bill was a private members bill sponsored by Liberal Senators Helen Coonan and Bill Heffernan, Greens Senator Rachel Siewert and independent Senator Nick Xenophon.

The Senate officer said the only opportunities for the Bill to have its Second Reading were on Thursday mornings when the Senate was sitting and it was unlikely the Bill would be read this year.

The Government dominates the Senate Legal and Constitutional Committee, but the Greens and Coalition could command a majority in the Senate to pass the Bill.

Ausbiotech chief executive officer Dr Anna Lavelle welcomed the Committee's finding.

"This is the right outcome for patients, researchers and for innovation in this country. I now call on the Senate to abandon the Bill, as recommended," Dr Lavelle said.

Ausbiotech said there had been five Australian inquiries in recent years into patentable subject matter and each has consistently recommended that excluding specific subject matter from patentability was not the right option.

Ausbiotech said the proposed Bill "fails completely to address any of the valid concerns raised by the community about gene patents and should be rejected".

"The Bill does not serve the interests of patients, researchers or industry and, in fact, the Bill threatens the very foundations of scientific research and development of biological therapies and other technologies which are built on patents," Dr Lavelle said.

The Australian Greens told Biotech Daily they did "not believe it appropriate for pharmaceutical and biotechnology companies to be able to own the intellectual property rights and enjoy exclusive use of human genes".

"Isolated genetic material should be regarded as a discovery, not as an invention," the Greens said.

"We are particularly concerned by the prospect that such patents could see exorbitant fees charged for medical tests and treatments for many diseases, including cancer," the Greens said.

MAYNE PHARMA GROUP

Mayne Pharma says it has been granted a preliminary injunction against Mylan Inc and affiliate Mylan Pharmaceuticals preventing the launch of a generic Doryx 150mg.

Mayne said the US District Court of New Jersey granted the preliminary injunction preventing the launch before the Court rendered a decision in the on-going litigation relating to US Patent No 6,958,161 covering the tetracycline-class oral antibiotic Doryx products, and no trial date had been set.

The company said that in granting the motion, the District Court found that Mayne Pharma and its US marketing and distribution partner Warner Chilcott demonstrated a reasonable likelihood of success on the merits of their claim that the '161 Patent was valid and infringed by Mylan's 150mg generic Doryx product.

Mayne said it manufactured and supplied Doryx to Warner Chilcott in the US under a licence agreement and owned the '161 Patent.

The company said the Doryx 150mg product was more than 95 percent of the Doryx franchise in the US based on total prescriptions.

Mayne fell 2.5 cents or 6.3 percent to 37 cents.

ANTEO DIAGNOSTICS

Anteo's annual general meeting will vote to issue 9,600,000 options to three directors, re-elect those directors and approve an employees and consultants option plan.
The Anteo notice of meeting proposed the issue of 5,000,000 options to chairman Mark Bouris, 3,000,000 options to Sandra Andersen and 1,600,000 options to Richard Martin, all exercisable at 12 cents and expiring fours year from the date of issue.
Anteo said shareholders would be asked to approve an option plan for officers, employees and consultants, along with adoption of a new constitution.
The meeting will be held at the Royal Exchange of Sydney, 1 Gresham Street, Sydney on October 24, 2011 at 11am (AEDT).
Anteo was unchanged at 6.6 cents with 3.3 million shares traded.

HELICON GROUP

Helicon says shareholders will vote to issue about 154,533,333 shares and 44,900,000 options and change its name to Consegna Group.
The Helicon resolutions propose the approval of the prior issue of 29,633,333 shares for payment to advisors; 44,900,000 shares and options for working capital and the acquisition of the Linguet buccal drug delivery technology; $1,500,000 in shares which at today's price of two cents would be 75,000,000 shares for the Aspen Medisys acquisition; and five million shares.
The company has asked shareholders to approve a name change to Consegna Group .
The meeting will be held at Level 31, RBS Tower, Aurora Place, 88 Phillip Street, Sydney on October 25, 2011 at 10am (AEDT).
Helicon fell 0.1 cents or 4.8 percent to two cents.

BONE MEDICAL

Bone says shareholders will vote to approve the issue of shares and options to La Jolla Cove, $1,444,343 in lieu of fees to Proxima Concepts and for a placement.
The first seven of 14 resolutions call for the approval of shares to La Jolla Cove for convertible notes as part of its equity draw down facility.
Resolutions eight to 11 provide for the issue of shares and attaching options to Proxima Concepts for $1,444,343 in "fees owed".
Proxima's website says that Bone chairman Dr Roger New is the co-founder and research and development director of Proxima.
In its most recent substantial shareholder notice the Channel Islands-based Proxima said it increased and was diluted from 49,028,952 shares (46.82%) to 52,214,829 shares (42.72%) (BD: Jul 11, 2011).
Other resolutions include the issue to chief executive officer Peter Young of 1,000,000 options exercisable at five cents each within 36 months, the issue of 1,780,000 shares to Gifford Securities and shares with attaching options to Hall Phoenix Inwood and David Stoup.
The meeting will be held at Ledger Corp, Level 3, 46 Ord Street, West Perth on October 20, 2011 at 4pm (AWST).
Bone was untraded at 1.6 cents.

COCHLEAR

Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 2,903,127 shares (5.11%) to 3,506,482 shares (6.16%).
The Edinburgh-based Baillie Gifford became substantial in Cochlear last month and continued acquiring shares between August 18 and September 21 (BD: Aug 19 2011).
Cochlear fell $2.49 or 4.7 percent to $50.01 with 1.2 million shares traded.

FERMISCAN

Autus Investments has reduced its substantial holding in Fermiscan from 110,000,000 shares (16.7%) to 96,428,571 shares (14.66%).
The King Street, Sydney-based Autus said the 13,571,429 shares were sold for $173,923 or an average price of 1.28 cents a share.
Fermiscan fell 0.1 cents or 5.9 percent to 1.6 cents with 3.8 million shares traded.

VIRAX HOLDINGS

Virax says director Tim Cooper has resigned from the company and its subsidiaries with effect from September 21, 2011.
Biotech Daily attempted to contact Virax for further details but no one was available to comment.
Virax was unchanged at 1.7 cents.