Biotech Daily

Tuesday January 25, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN:**
ANTISENSE UP 14%; TISSUE THERAPIES DOWN 12.5%

*** FDA ALLOWS 94 MORE HEARTWARE BRIDGE-TO-TRANSPLANT PATIENTS**

*** HEARTWARE CO-FUNDS EARLY INTERVENTION HEART PUMP STUDY**

*** US PATENT FOR PROGEN'S PG500 SERIES**

*** PHARMAXIS ADDRESSES EUROPEAN OUTSTANDING ISSUES**

MARKET REPORT

The Australian stock market climbed 0.46 percent on Tuesday January 25, 2011 with the S&P ASX 200 up 21.8 points to 4807.8 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and four were untraded.

Antisense was the best, up 0.1 cents or 14.3 percent to 0.8 cents with 920,000 shares traded, followed by Biota up 4.1 percent to $1.28 with 925,499 shares traded.

Bionomics and Phylogica climbed more than two percent; with Acrux, Impedimed and Universal Biosensors up more than one percent.

Tissue Therapies led the falls, down six cents or 8.9 percent to 61.5 cents with 1.2 million shares traded, followed by Genetic Technologies down eight percent to 11.5 cents with 1.1 million shares traded.

Virax lost 6.7 percent; Circadian fell 4.1 percent; Living Cell, Optiscan, Pharmaxis, Psivida and Viralytics lost more than three percent; Alchemia, Benitec, Chemgenex, Immuron, Prima and QRX shed more than two percent; with Patrys down one percent.

HEARTWARE

Heartware says the US Food and Drug Administration has approved a third group of 94 patients, in its bridge-to-transplant clinical trial

Heartware said the FDA permission was given under a continued access protocol and was an investigational device exemption supplement

The company said the FDA had granted two prior allotments of 54 patients each in April and September 2010 and the final patient from the second cohort was implanted earlier this month.

Heartware said the 'Advance' bridge-to-transplant trial was evaluating its ventricular assist device (HVAD) for patients with end-stage heart failure and 140 patients at 30 US clinical sites had received the pumps, making it the largest bridge-to-transplant pivotal trial.

Heartware said it submitted a pre-market approval application for the HVAD system for the bridge-to-transplant indication in December 2010 (BD: Jan 16, 2011).

The company said that patient under the third continued access protocol could begin at the 30 centers in the Advance trial, subject to institutional review board approvals.

Heartware fell one cent or 0.4 percent to $2.62.

HEARTWARE

Heartware says it has co-funded a study into early access to left ventricular assist devices for less-advanced, non-transplant eligible patients with heart failure.

Heartware said it committed up to $US9.6 million for the 'Revive-It' study to be conducted by the University of Michigan Cardiovascular Center and the University of Pittsburgh which had been awarded grants from the National Heart, Lung and Blood Institute.

The company said researchers would compare whether non-transplant eligible patients with heart failure less advanced than that of current LVAD recipients do better with implanted devices than with current medical therapy.

Heartware said its left ventricular assist device would be used in the pilot study of 100 patients at about 12 US sites coordinated by the University of Michigan's Institute for Clinical Health Research.

Heartware said the HVAD pump was an investigational device and not commercially available for sale in the US.

PROGEN PHARMACEUTICALS

Progen says the US has granted a patent entitled 'Sulfated Oligosaccharide Derivatives' that protects its PG500 series of small molecule compounds.

Progen said the PG500 series of compounds was the result of an internal research program partially funded by Start and Commercial Ready grants from the Australian Government.

The company said the new US patent protected compounds in the PG500 series of heparan sulfate mimetic molecules and their use in a variety of therapeutic areas predominantly related to oncology, including solid tumor, angiogenesis and metastasis, but also encompassing inflammation and other indications where heparan sulfate mimetic compounds provide important therapeutic options, such as coagulation, thrombosis, raised blood triglyceride levels, proliferative retinopathy, HSV-1 infection, or cardiovascular disease.

Progen said that pharmaceutical and veterinary uses were also protected by the patent which expires on March 4, 2025.

Progen was up one cent or 3.1 percent to 33 cents.

PHARMAXIS

Pharmaxis says it expects the review of its European regulatory approval application for Bronchitol for cystic fibrosis will be completed by July 2011.

Pharmaxis said that the European Committee for Medicinal Products for Human Use (CHMP) had provided its "outstanding issues" and said the review timetable will conclude by July.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that the outstanding issues were part of a routine process and "we are well positioned to address these issues".

Dr Robertson said that due to confidentiality provision he was unable to expand on the nature of the issues and said it was a technical term for part of the process.

"We are pleased with the ongoing discussions with the CHMP and believe we are in a good position to provide our response to their outstanding issues in a timely manner", Dr Robertson said in a media release.

Pharmaxis said Bronchitol was the subject of two phase III clinical trials and was the only new product in registration to treat cystic fibrosis.

Biotech Daily understands that the outstanding issues do not refer to the drug's safety or efficacy.

Pharmaxis fell 10 cents or 3.4 percent to $2.86.