Biotech Daily

Tuesday October 2, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTISCAN UP 11%, PATRYS DOWN 11%**

*** FDA CONDITIONAL APPROVAL FOR SUNSHINE HEART PIVOTAL TRIAL**

*** PRANA PLACES $6m FOR PBT2 TRIALS**

*** BONE BEGINS CAPTHYMONE FOR OSTEOPOROSIS TRIALS**

*** CELLMID EARNS $748k FEDERAL R&D TAX CREDIT**

*** USCOM TARGETS HYPERTENSION**

*** CIRCADIAN DIRECTOR DR ERROL MALTA RETIRES**

*** IMUGENE DIRECTOR ROGER STEINEPREIS RESIGNS**

MARKET REPORT

The Australian stock market climbed 1.01 percent on Tuesday October 2, 2012 with the S&P ASX 200 up 44.4 points to 4,433.0 points.

Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and six were untraded. All three Big caps were up.

Optiscan was the best, up one cent or 11.1 percent to 10 cents with 100,000 shares traded, followed by Sunshine Heart up 10 percent to 4.4 cents with 1.15 million shares traded.

Antisense climbed 5.3 percent; Acrux, Alchemia and Neuren were up three percent or more; Heartware, Pharmaxis, Prima and Viralytics rose two percent or more; Resmed and Tissue Therapies were up more than one percent; with Cochlear and CSL up by less than one percent.

Patrys led the falls, down 0.4 cents or 10.5 percent to 3.4 cents with 362,500 shares traded.

Benitec and Phylogica lost more than six percent; Anteo, Impedimed and Living Cell fell more than five percent; Allied Health and Psivida were down more than four percent; Clinuvel and Sirtex were down more than three percent; Prana shed 2.2 percent; Biota, Reva and Starpharma were down more than one percent; with Mesoblast down 0.6 percent.

SUNSHINE HEART

Sunshine Heart says it has conditional approval for a 388-patient, randomized, controlled US investigational device exemption trial of its C-Pulse heart assist system.

Sunshine Heart said that with the US Food and Drug Administration conditional approval (see below) it planned to begin the pivotal trial in North America by the end of 2012.

The company said that half the patients would be implanted with the C-Pulse system and the other half would receive optimal medical therapy at up to 40 clinical sites.

Sunshine Heart said it expected to receive revenues from trial sites for device implants as the FDA had granted Centers for Medicare & Medicaid Services (CMS) category B3 status and because of the designation, the company expected that participating trial centers would be reimbursed by the CMS and most private insurance providers.

The company said that the trial would use its next-generation C-Pulse driver, which received approval for clinical trial use from the FDA in August, 2012, and had been in use in Canadian patients.

Sunshine Heart said it expected enrollment to take about two and a half years.

The company said the primary endpoint would be the reduction in worsening heart failure events leading to hospitalization, advanced heart failure therapies and heart failure related mortality, with a one year safety follow-up is expected.

Sunshine Heart's head of corporate development Dr Elaine Stead told Biotech Daily that the FDA "requested that we make minor changes to the informed consent; provide the charters for the [data safety monitoring board and clinical endpoint committee]; minor revision to investigator agreement; minor labeling updates; and a few minor potential modifications to the study design not impacting the endpoints".

The FDA website said that a conditional IDE allowed the sponsor to begin subject enrollment on receipt of institutional review board approval on the condition that, within 45 days from the date of FDA's decision letter, the sponsor submits information addressing the issues identified in the FDA's letter.

Sunshine Heart said that the lead investigator would be the Ohio State University Medical Center's cardiovascular medicine director Dr William T Abraham.

"Having led the C-Pulse feasibility study last year and witnessed the potential impact the device had in patients suffering from heart failure, I am excited to return to play an integral role in C-Pulse's final stages of development," Dr Abraham said.

"With a large and growing population of C-Pulse eligible patients and hospitals facing financial penalties for high heart failure re-hospitalization rates beginning in 2013 under the Obama Health Reform Act, the C-Pulse pivotal trial will determine if it will be beneficial to both patients and hospitals alike to improve health outcomes," Dr Abraham said.

Sunshine Heart chief executive officer Dave Rosa said the company was "thrilled to receive conditional approval from the FDA to move forward into a pivotal trial for C-Pulse".

"Today's announcement represents another significant milestone for the company, as well as for the C-Pulse system," Mr Rosa said.

"I am especially pleased that we were able to receive this approval on our initial submission," Mr Rosa said.

Mr Rosa said the company "achieved its regulatory and clinical objectives" by receiving both the Conformité Européenne (CE) mark and US investigational device exemption approval this year.

Sunshine Heart said Dr Abraham would present detailed 12 month follow up results from the pilot trial at the Transcatheter Cardiovascular Therapeutics meeting later this month.

Sunshine Heart was up 0.4 cents or 10 percent to 4.4 cents with 1.2 million shares traded.

PRANA BIOTECHNOLOGY

Prana says it has raised about $6.0 million through a placement of 32,500,000 shares at 18.5 cents a share to institutional and high net worth investors.
Prana said the placement “attracted strong demand even though the amount raised was restricted by the number of shares which could be issued by the Company under ASX listing rule 7.1, thereby not requiring a separate meeting of shareholders” and was managed by the Melbourne-based JM Financial Group.
The company said the funds would support its two ongoing phase II clinical trials of PBT2 in Alzheimer’s imaging and Huntington disease.
Prana said both trials were expected to reported results by the end of 2013.
Prana fell half a cent or 2.2 percent to 22 cents.

BONE MEDICAL

Bone says it will compare human blood levels of parathyroid hormone using two strengths of its Capthymone against injectable parathyroid hormone and a placebo capsule.
Bone said that Brisbane’s Q-Pharm would conduct the human clinical trial of Capthymone, which used its Axcess IV oral peptide formulation technology.
The company said that injectable parathyroid hormone was an important therapeutic alternative for the treatment of osteoporosis.
Bone chief executive officer Peter Young said that it would be the first clinical study the company had undertaken for Capthymone that included a direct comparison against injectable parathyroid hormone as well as an oral placebo.
“Our many partnering discussions have identified such data as an important factor in our ongoing efforts to conclude partnering deals for Capthymone, which we now consider our lead clinical-stage product,” Mr Young said.
Bone said that the trial would involve a small number of post-menopausal patients and was expected to conclude in early 2013.
The company said that the study costs were covered by an incremental funding commitment from La Jolla Cove as part of their existing funding agreement.
Bone chairman, chief scientific officer and inventor of the Axcess technology Dr Roger New said that the study “marks a new productive phase of activity that is part of a broader program of new studies and experiments we indicated we were planning a few months ago”.
Bone was unchanged at 0.4 cents.

CELLMID

Cellmid says it has received $748,193 from the Federal Government’s research and development tax credit scheme.
Cellmid said that the tax refund related to the costs of research and development conducted during the 2012 financial year, calculated as 45 percent of eligible expenditure.
The company said the funds would be used for its midkine programs.
Cellmid was unchanged at 1.6 cents with 3.1 million shares traded.

USCOM

Uscom says it is targeting hypertension, or high blood pressure, as a further indication that could benefit from its ultra-sonic cardiac output monitor.

The company said that there were three separate presentations on its monitor's role in improving the management of hypertension at the International Society of Hypertension meeting in Sydney.

Uscom said the studies were headed by researchers at the University of Queensland Department of Medicine in collaboration with China's Shandong Provincial Hospital, London's Great Ormond Street Hospital for Sick Children, the Chinese University of Hong Kong, Bathurst's Charles Sturt University, the Royal London Hospital and the Guandong General Hospital.

Uscom said the research reviewed hypertension management guidelines, identified potential areas for improvement and proposed new approaches to the management of hypertension based on guidance of therapy according to Uscom-determined haemodynamic values as well as blood pressure.

The University of Queensland's Prof Malcolm West said doctors had managed hypertension to blood pressure goals.

"The guidance of anti-hypertensive therapies to Uscom-determined haemodynamic goals as well as blood pressure has the potential for improvements to the cost-effectiveness of hypertension management," Prof West said.

Uscom executive chairman Rob Phillips said that hypertension had "always been an important target application".

"These publications suggest that managing hypertension to Uscom goals as well as blood pressure will lead to more cost-effective care," Mr Phillips said.

"We are now committed to introducing our technology into the field of hypertension and partnering with an established market leader who has effective global distribution channels," Mr Phillips said.

Uscom said that more than 25 percent of adults had hypertension and was associated with serious cardiovascular complications including cardiac arrest and stroke.

The company said that the total cost to treat hypertension in the US in 2009 was $73.4 billion, but less that 45 percent of hypertensive patients achieved blood pressure goals.

Uscom said that awareness, management and control of hypertension has plateaued since 2007 and remained poor.

Uscom was untraded at 16.5 cents.

CIRCADIAN TECHNOLOGIES

Circadian says that Dr Errol Malta has retired as a director effective from October 1, 2012.

Circadian was untraded at 36 cents.

IMUGENE

Imugene says Roger Steinepreis has resigned as a director, effective from October 1, 2012.

Imugene was up 0.1 cents or 7.1 percent to 1.5 cents.