Biotech Daily

Thursday August 2, 2012

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: BIONICHE UP 17%, PSIVIDA DOWN 17%**

*** BATHURST USCOM STUDY REDUCES SEPTIC SHOCK MORTALITY 90%**

*** 'DRUG EXPORTS BIGGER THAN CARS' - MEDICINES AUSTRALIA**

*** VIRALYTICS US PATENT FOR KILLING CANCER CELLS PRE-TRANSPLANT**

*** PHARMAXIS FILES BRONCHITOL CYSTIC FIBROSIS NDA TO FDA**

*** PSIVIDA: ALIMERA RESUBMITS REJECTED ILUVIEN NDA TO US FDA**

MARKET REPORT

The Australian stock market was up 0.16 percent on Thursday August 2, 2012 with the S&P ASX 200 up 6.7 points to 4,269.5 points.

Seven of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and nine were untraded.

Bioniche was the best, up 9.5 cents or 17.3 percent to 64.5 cents with 48,000 shares traded.

Viralytics climbed 9.8 percent; Patrys was up five percent; Pharmaxis and Phosphagenics rose more than three percent; Anteo was up 1.6 percent; with Sirtex up 0.9 percent.

Psivida led the falls, down 45 cents or 16.7 percent to $2.25 with 9,000 shares traded, followed by Impedimed down 11.9 percent to 18.5 cents with 19,876 shares traded and Allied Health down 10.5 percent to 1.7 cents with 29,183 shares traded.

Genetic Technologies lost 8.3 percent; Phylogica was down 6.25 percent; Neuren and Prima fell four percent or more; Clinuvel, QRX and Universal Biosensors were down more than three percent; CSL and Tissue Therapies shed more than two percent; Cochlear, Heartware, Reva and Starpharma were down more than one percent; with Biota and Mesoblast down by less than one percent.

USCOM

Uscom says that a study of 479 Bathurst Base Hospital septic shock patients combining its monitor with advanced clinical protocols reduced mortality by 90 percent.

Uscom said the Bathurst Base Hospital, about 200kms west of Sydney, New South Wales, had reported that along with 90 percent reduced mortality, emergency transport costs were reduced by 90 percent.

The company said that the data was collected over six years and analyzed by the Australian and New Zealand Intensive Care Society Centre for Outcomes and Resource Evaluation.

Uscom said the Centre's database was collected from intensive care units in Australia, New Zealand and Hong Kong and used to benchmark standards of care against comparable units and international standards.

The company said that Charles Sturt University's Bathurst-based School of Biomedical Sciences' Prof Brendan Smith and Veronica Madigan worked with the critical care team at Bathurst Base Hospital and researchers from the University of Queensland to develop new concepts around the use of its ultra-sonic cardiac output monitor to treat septic shock.

Uscom said that the new method, based on early diagnosis and rapid Uscom-guided individualized treatment reduced the mortality of septic shock in Bathurst from about 50 percent to less than five percent, a 90 percent mortality reduction with a saving of more than 50 lives a year.

The company said there was a 90 percent reduction in emergency transfers from Bathurst of septic shock patients from 2006 to 2012, with emergency transport costs about $8000 per transfer.

"This protocol saves lives and money," Prof Smith said.

"It's as simple as that, and there is no reason every hospital in Australia shouldn't be adopting this approach to treat septic shock," Prof Smith said.

Uscom executive chairman Rob Phillips said Prof Smith's results "set new standards by proving that septic shock is curable and Uscom is central to this management".

"They treat each patient individually and rapidly and achieving a less than five percent mortality is unprecedented," Mr Phillips said.

"If his work were duplicated Australia-wide, 25,000 lives would be saved per year and many millions of dollars," Mr Phillips said.

Uscom said that sepsis occurred in one to two percent of all hospitalizations and was responsible for up to 25 percent of all intensive care admissions, affecting more than 18 million people worldwide a year, and was responsible for the same number of deaths as cardiac arrests and 9.3 percent of all US deaths, with a predicted increase in incidence of 1.5 percent a year.

Uscom said that global mortality from septic shock ranged from 30 percent to 60 percent with treatment costs in the order of $US22,100 per case.

The company said that a less than five percent mortality and improvements in the effectiveness of treatment worldwide would have significant health economic consequences.

Uscom was unchanged at 12 cents.

MEDICINES AUSTRALIA

Medicines Australia says that medicines were the Australian manufacturing sector's biggest high-technology export earner in 2011-'12.

Quoting the Australian Bureau of Statistics a Medicines Australia media release said that exports of pharmaceutical and medicinal products totaled $4.059 billion in 2011-'12, up from $3.744 billion in 2010-'11.

The industry organization said that by comparison, exports for the car industry in 2011-'12 were $2.767 billion and for the wine industry $2.032 billion.

Medicines Australia chief executive Dr Brendan Shaw said the growth of pharmaceutical exports highlights the Australian medicines industry's sustained contribution to the economy.

"By any measure, this is an outstanding export performance," Dr Shaw said.

"While the majority of other manufacturers are losing ground, medicines industry exports grew seven per cent over the last year," Dr Shaw said.

"In terms of export earnings for 2012, the medicines industry was almost $1.3 billion ahead of its nearest rival, the car industry," Dr Shaw said.

"This is an incredible achievement when you take into account the performance of the broader manufacturing sector, the high dollar and the fact that the medicines industry receives no co-investment from government," Dr Shaw said.

"This kind of result highlights just how resilient the medicines industry is, given the prevailing market conditions, and underscores the industry's potential to be a key player in the post-mining boom economy," Dr Shaw said.

"The Australian medicines industry is a high-skill, high-wage, science-based, innovative, low carbon footprint industry and an equal opportunity employer," Dr Shaw said.

"As a nation we already earn more in exports from medicines than cars or wine, but with revamped policy settings and incentives from Government we could build the Australian medicines industry into one of our key innovative export industries," Dr Shaw said.

"Asian countries currently account for approximately half of pharmaceutical exports from Australia," Dr Shaw said.

"With the right policy incentives, Australian medicines exports to Asia could increase five-fold by 2020," Dr Shaw said.

VIRALYTICS

Viralytics says that the US Patent and Trademark Office has allowed cover the use of Picornaviruses to destroy cancerous blood cells in stem cell grafts prior to transplantation.

Viralytics said that Picornaviruses included Coxsackievirus A21, the basis of Cavatak, currently in US phase II melanoma trials (BD: Oct 20, Dec 9, 2011).

The company said that the patent entitled 'Method and Compositions for the Treatment of Hematologic Cancers' was expected to be granted on August 7, 2012.

Viralytics chief scientific officer Dr Darren Shafren said the use of Picornaviruses, including Cavatak to target and destroy cancerous cells in stem cell transplants used in treatment of blood cancer was "a new and exciting application of Viralytics' oncolytic viruses".

"Our current clinical strategy for Cavatak is to focus on both intra-tumoral and intravenous routes of delivery," Dr Shafren said.

"This novel application means that Cavatak could be used to destroy cancerous cells during stem cell transplants, significantly enhancing its clinical appeal in the field of oncolytic virotherapy," Dr Shafren said.

Viralytics was up 2.5 cents or 9.8 percent to 28 cents.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has accepted its new drug application for Bronchitol for cystic fibrosis, with a decision expected on March 18, 2013.
Pharmaxis said that if the application was approved, Bronchitol could be available for US patients with cystic fibrosis by July 2013.
Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily that the application was submitted on May 18, 2012 and had been deemed by the FDA "sufficiently complete to permit a substantive review".
"The application is about 200,000 pages and brought together all of the work undertaken by all the staff that have assisted Pharmaxis on the Bronchitol project over the last 10 years," Dr Robertson said.
The company said the application sought approval for Bronchitol for the management of cystic fibrosis patients six years of age or older to improve pulmonary function.
Bronchitol has been approved in Europe for people aged 18 years and over, and the company has been required to provide further data for European approval for children aged six to 17 years (BD: Oct 24, 2012).
Pharmaxis said that cystic fibrosis affected about 30,000 people in the US and was the most common life-limiting genetic disease.
The company said the new drug application included results from two phase III trials, presented at the 2011 North American Cystic Fibrosis annual meeting and recently at the 2012 European Cystic Fibrosis Society annual meeting.
Dr Robertson said the company was "looking forward to discussions with the FDA as we work to make Bronchitol available to patients in the US".
The company said that Bronchitol had orphan drug designation in the US and was approved for marketing in Australia and throughout the European Union.
Yesterday, Bronchitol was formally listed on the Australian Pharmaceutical Benefits Scheme for the treatment of cystic fibrosis, the first jurisdiction to provide reimbursement.
Pharmaxis was up four cents or 3.5 percent to $1.18.

PSIVIDA

Psivida says that licencee Alimera Sciences intends to resubmit its application for Iluvien for diabetic macular oedema to the US Food and Drug Administration.
Last year, Psivida's share price tumbled following the FDA refusal to approve Iluvien, with the complete response letter, saying "it was unable to approve the Iluvien [new drug application] because the NDA did not provide sufficient data to support that Iluvien is safe and effective in the treatment of patients with DME" (BD: Nov 14, 2011).
Today, Psivida said that based on a meeting with the FDA, Alimera intended to use data from two previously completed pivotal phase III clinical trials and the resubmission was expected to address the issues raised in the November 2011 complete response letter.
Psivida said it expected the resubmission to focus on the population of patients with chronic diabetic macular oedema considered insufficiently responsive to available therapies, the same indication for which regulatory approval for Iluvien had been granted in a number of European Union countries.
The company said that Alimera had not reported an expected time for resubmission.
Psivida fell 45 cents or 16.7 percent to $2.25.