Biotech Daily

Thursday June 28, 2012

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: IMPEDIMED UP 11%, OPTISCAN DOWN 18%**

*** BIOXYNE FALLS 88% ON FAILED PHASE IIb HI-164OV COPD TRIAL**

*** BENITEC: ddRNAi DRUG FOR HEPATITIS C 'SAFE AND DELIVERABLE'**

*** CYCLOPHARM SUES ANSTO OVER COMPETITION**

*** AUSTRALIAN ETHICAL TAKES 7% OF ATCOR**

MARKET REPORT

The Australian stock market closed up 0.04 percent on Thursday June 28, 2012 with the S&P ASX 200 up 1.6 points to 4,044.8 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and two were untraded.

Impedimed was the best, up 2.5 cents or 11.4 percent to 24.5 cents with 224,000 shares traded, followed by Genera up 9.7 percent to 17 cents with 37,236 shares traded.

Psivida climbed 7.3 percent; Benitec was up 6.25 percent; Antisense rose 5.9 percent; both Anteo and Genetic Technologies climbed 4.2 percent; Pharmaxis, Phosphagenics and Starpharma were up three percent or more; Nanosonics, Prima and Viralytics all rose two percent; Bionomics, CSL, Living Cell, Mesoblast and Sirtex were up more than one percent; with Biota, Clinuvel and Cochlear up by less than one percent.

Optiscan led the falls, down two cents or 18.2 percent to nine cents with 6,556 shares traded, followed by QRX down 14.3 percent to 60 cents with 1.2 million shares traded.

Cellmid and Compumedics lost more than six percent; Circadian, Sunshine Heart and Tissue Therapies fell more than four percent; Prana and Reva were down more than three percent; Alchemia shed 2.2 percent; Universal Biosensors and Uscom were down more than one percent; with Acrux and Resmed down by less than one percent.

BIOXYNE (FORMERLY HUNTER IMMUNOLOGY)

Bioxyne fell 87.5 percent on news HI-164OV for chronic obstructive pulmonary disease (COPD) exacerbations failed to meet the primary endpoint of its phase IIb trial.

Bioxyne said: “Analysis of the full [320] patient population indicates that there was no significant benefit of the immunotherapeutic across the study group as a whole”.

The company said that a subset of 30 percent of subjects, aged under 65 years, benefited from the treatment, but did not provide trial data.

Bioxyne was in a 15-day trading halt and suspension to evaluate the results and for the board to agree to an announcement (BD: Jun 13, 15, 25, 2012).

Bioxyne chief executive officer David Radford told Biotech Daily that the delay was due to the need to obtain further data from the contract research organization.

“We were running extensive evaluations of the data and some of it only came in late last week,” Mr Radford said.

Mr Radford said that for the 30 percent sub-group, the time to first primary exacerbation was significantly extended, the counts of primary exacerbations were significantly reduced and that hospital admissions were reduced by 50 percent.

In 2010, Bioxyne (then Hunter Immunology) said a 40-patient phase II trial of HI-164OV for chronic obstructive pulmonary disease, in 2006, reduced hospital admissions by 90 percent and reduced moderate to severe exacerbations by 63 percent (BD: Apr 22, 2010).

Today, Bioxyne said the 30 percent of patients under 65 years of age had a 50 percent reduction in hospitalization and a 65 percent reduction in duration of hospital stay in the active treatment arm.

Bioxyne said 287 patients completed the study, which confirmed that HI-164OV was safe, the number of corticosteroid treatments was reduced significantly and the sub group data supported HI-164OV having a place in the management of COPD.

The company said there appeared to be a lower incidence of haemophilus influenzae infections during the study, which could account for the decreased incidence of exacerbations across both groups and explain the difference between the studies.

Bioxyne said it was “engaged in active dialogue with a number of external companies exploring their commercial interest in HI-164OV” and would embark on a marketing plan with investment bank advisers Torreya Partners.

The company said there was interest in the use of the HI-164OV for indications other than COPD and these options would be considered for licencing.

The company said it was not uncommon for a larger study to give a different outcome to previous smaller studies.

Bioxyne said the under 65 year age group accounted for about 27 percent of COPD patients, which was still an attractive market opportunity.

In 2008, as a private company, Hunter’s then executive chairman Michael Spooner said an investigational new drug application had been submitted to the US Food and Drug Administration for a phase III trial, expected to begin in 2009 (BD: Jul 7, 2008).

In 2010, Hunter hoped to raise $10 million for a phase IIb trial, backed by Intersuisse and Indonesia’s Soho Pharmaceuticals and Intersuisse Biosciences Fund managing director Jeremy Curnock Cook was appointed a non-executive director (BD: Mar 31, 2010).

Last year, former Nanosonics chief executive officer David Radford was appointed Hunter chief executive officer replacing managing director Dr Kevin Healey (BD: Jun 16, 2011).

In October, Hunter announced a backdoor listing through Probiomics and the renaming to Bioxyne (BD: Oct 11, 2011) which was completed in April this year (BD: Apr 3, 13, 2012).

Bioxyne fell as much as 21 cents or 87.5 percent to three cents before closing down 19.6 cents or 81.7 percent at 4.4 cents with 8.7 million shares traded.

BENITEC BIOPHARMA

Benitec says Tacere Therapeutics' hepatitis C program using its ddRNAi gene silencing technology is safe and deliverable in cynomolgus (crab-eating macaque) monkeys.
Benitec said that the pre-clinical safety and delivery results were published in the journal Molecular Therapy.
The company said the study, entitled 'Safe, Long-term Hepatic Expression of Anti-HCV shRNA in a Nonhuman Primate Model' was co-written by researchers from Tacere, Pfizer and the University of Pennsylvania.
The article is at: www.nature.com/mt/journal/vaop/ncurrent/pdf/mt2012119a.pdf.
Benitec said the study reported that a single intravenous injection of Tacere's second generation anti-hepatitis C virus DNA-directed RNA interference (ddRNAi)-based drug, TT-034, produced safe and sustained levels of short hairpin RNA (shRNA) in non-human primates, the gold standard animal model for human toxicology testing.
The company said that TT-034 delivered its payload to nearly all of the hepatocytes within the liver and none of the 18 animals dosed with the second generation vector demonstrated any signs of toxicity.
Benitec said the authors concluded that a human clinical trial of the drug for treatment of hepatitis C infection was warranted.
Tacere's research director and the study's lead author on the paper Dr David Suhy said that TT-034 was well positioned to move into the clinic.
"We believe that the unique therapeutic modality has the potential to be transformative in the way patients infected with [hepatitis C] are treated," Dr Suhy said.
Benitec chief executive officer Dr Peter French said the results "indicate that TT-034 is likely to be a safe and effective single shot therapeutic for hepatitis C, a debilitating viral disease that affects two percent of the world's population".
"The next step of the program is to enter a clinical trial and we are in active discussion with Tacere's management to determine the optimal path to the clinic for this key program," Dr French said.
Benitec said the cynomolgus monkeys study followed publication of the first paper from this program last year demonstrating the capability of the lead compound to efficiently inhibit the hepatitis C virus in model systems (BD: Jan 22, 2012).
Benitec was up 0.1 cents or 6.25 percent to 1.7 cents with two million shares traded.

CYCLOPHARM

Cyclopharm says it is claiming damages against the Australian Nuclear Science and Technology Organisation in the Federal Court of Australia.
Cyclopharm said the legal action by its wholly-owned subsidiary, Cyclopet Pty Ltd, against ANSTO's wholly-owned subsidiary Petnet Pty Ltd followed the Productivity Commission finding in April that Petnet was "in ex-ante breach of their competitive neutrality requirements in the sale of their nuclear pharmaceuticals used in positron emission tomography" (BD: Apr 4, 2012).
Cyclopharm said Cyclopet was claiming damages for breach of Section 52 of the Commonwealth Trade Practices Act 1974, Section 18 of the Australian Consumer Law, Section 46 of the Trade Practices Act 1974 and Section 46 of the Competition and Consumer Act 2010 alleging misleading and deceptive conduct and misuse of market power.
Cyclopharm said that the Federal Court had set a direction hearing for August 2, 2012.
Cyclopharm was untraded at 16 cents.

ATCOR MEDICAL

Australian Ethical Smaller Companies Trust has become a substantial shareholder in Atcor with the acquisition of 4,166,667 shares or 7.22 percent.

The initial substantial shareholder notice said the shares were acquired for $250,000 or an average price of six cents a share.

Atcor fell 0.2 cents or 3.2 percent to six cents.