Biotech Daily

Friday December 18, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: TISSUE THERAPIES UP 10.5%, OPTISCAN DOWN 17%**

*** OSPREY DATA ANALYSIS BACKS AVERT REDUCED KIDNEY DAMAGE**

*** 3D: 'ROCHE HAILS ROLE IN FDA ALECTINIB LUNG CANCER APPROVAL'**

*** ANTEO $15m NOTE TO BUY BELGIUM'S DIASOURCE**

*** ADMEDUS RAISES $7m FROM US INVESTOR**

*** ASIC FINES LIVING CELL $33k FOR ALLEGED INVESTOR NEWS LEAK**

*** EUROPEAN PATENT FOR IMUGENE'S HER-VAXX**

*** ALLAN GRAY REDUCES TO 15% OF STARPHARMA**

*** UBS REDUCES TO 8% OF GI DYNAMICS**

*** MEDADVISOR APPOINTS THEO ANTONOPOULOS SALES, MARKETING**

MARKET REPORT

The Australian stock market edged up 0.09 percent on Friday December 18, 2015 with the ASX200 up 4.7 points to 5,106.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 11 traded unchanged and five were untraded.

Tissue Therapies was the best, up 0.4 cents or 10.5 percent to 4.2 cents with 194,822 shares traded.

Psivida climbed 9.5 percent; Genetic Technologies was up 8.7 percent; Bionomics and Starpharma improved more than seven percent; Antisense and Benitec were up more than six percent; Oncosil was up 5.3 percent; Cellmid climbed 4.35 percent; Medical Developments, Pharmaxis and Viralytics rose more than three percent; Pro Medicus was up 1.8 percent; with Cochlear up 0.5 percent.

Optiscan led the falls, down 0.6 cents or 17.1 percent to 2.9 cents with 400,700 shares traded.

Biotron lost 5.9 percent; Neuren fell 4.55 percent; Atcor and Clinuvel shed more than two percent; Compumedics, Ellex, Reva and Sirtex were down more than one percent; with Acrux, Mesoblast and Resmed down by less than one percent.

OSPREY MEDICAL

Osprey says that further data analysis shows that its using ‘standard criteria’ its Avert system showed a non-significant trend for contrast-induced nephropathy reduction.

In October, Osprey fell 71.6 percent to 19 cents on news that its 578-patient trial of the Avert system failed to reduce contrast-induced nephropathy (CIN), with 76 CIN events in the Avert arm and 74 CIN events in the control arm, but the trial achieved three US Food and Drug Administration expanded claims of dye savings, image quality and reflux reduction (BD: Jul 16, Oct 19, 2015).

Today, the company said the physician steering committee reviewed the full data set to investigate the contrast-induced nephropathy co-primary endpoint and noted that the FDA-directed criteria for CIN measurement of serum creatinine increase of more than 0.3mg/dl captured subtle changes in kidney function and based on the FDA criteria, it was not able to show a reduction of CIN events.

Osprey said the FDA criteria was a more recent methodology that captured subtle changes in kidney function and the standard criteria for CIN of a serum creatinine increase of more than 0.5mg/dl or more than 25 percent was “the classic measurement which captures significant changes in kidney function”.

Osprey said that the standard criteria was the typical measurement used by hospitals and physicians when evaluating contrast-induced nephropathy.

The company said it was “pleasing” that the steering committee noted that the patient population who suffered more significant changes in kidney function, as measured by the standard criteria had an 8.4 percent reduction in contrast-induced nephropathy events in the Avert-treated patients as compared to the control group.

Osprey said that in the analysis of dye savings the patient data was analyzed according to the type of procedure, whether it was diagnostic or a percutaneous coronary intervention, that is a ‘stenting’ procedure and separately on the number of lesions treated.

The company said that the steering committee observed that the trial’s overall dye savings endpoint of 15 percent “was skewed downward due to the high number of diagnostic procedures in the trial”.

Osprey chief executive officer Mike McCormick told Biotech Daily that 59 percent of the 578 patients were diagnostic patients, while 41 percent were stented.

The company data table showed that dye savings of eight percent were achieved in the diagnostic group compared to an average 23 percent for the stented group.

The Osprey data showed that dye saving increased with the number of lesions treated from 15 percent savings with one lesion to a 31 percent dye saving with two lesions and a 46 percent dye saving with three or more treated lesions.

The company said that the analysis indicated that in more complex multi-lesion, high dye volume cases, the Avert system gave increased levels of dye savings for patients.

Osprey said that while the findings were not statistically significant, the demonstrated “a key trend for CIN reduction in patients with significant kidney function changes”.

The company said that the steering committee reasoned that the trend might “reflect a masking of the technology’s true CIN benefit due to small trial size”.

Osprey said the study findings would be submitted to the Society for Cardiovascular Angiography and Interventions meeting to be held in Orlando, Florida in May 2016.

Avert study principal investigator Prof Roxana Mehran said the trial was “an important study that clearly demonstrates the Avert system reduces dye in angiography procedures”.

Osprey said that the findings provided additional information about the clinical trial but did not affect the FDA-cleared claims of dye savings, reflux reduction and image quality.

Osprey was unchanged at 22 cents.

D3 MEDICINE

D3 Medicine says it supported the clinical pharmacology components of the successful Roche Genetech pivotal alectinib development program.

D3 said that it was hired by Roche for the project and on December 11, 2015 Genentech said that the US Food and Drug Administration had granted accelerated approval to Alecensa or alectinib, for the treatment of anaplastic lymphoma kinase-positive, metastatic non-small cell lung cancer who have progressed on, or are intolerant to, crizotinib.

The company said that in the pivotal studies, Alecensa shrank tumors in up to 44 percent of the anaplastic lymphoma kinase-positive patients who progressed on crizotinib, with an objective response rate of 38 percent.

D3 said that in a subset of people with tumors that spread to the brain or other parts of the central nervous system Alecensa shrank central nervous system tumors in about 60 percent of people.

Roche head of clinical oncology pharmacology Dr Alex Phipps said that Alectinib “had an extensive and complicated clinical pharmacology program that required flexible and progressive thinking to complete”.

“Our decision to use D3 Medicine as a development partner was one of our smarter moves,” Dr Phipps said.

“To work with people on the same wavelength and with extensive experience and integrity removes one of the unquantifiable uncertainties in drug development,” Dr Phipps said.

Roche head of clinical pharmacology Richard Peck said “the FDA remarked that this was the best clinical pharmacology package they had ever seen for a cancer drug”.

D3 is a private company.

ANTEO DIAGNOSTICS

Anteo says it has an EUR10 million ($A15.2 million) convertible note from an unnamed Canadian investment house to buy Diasource Immunoassays.

Anteo said that the convertible note provided for repayment of principal and interest over two years, with 10 percent a year coupon and could be converted into ordinary Anteo shares up to 48 months from the date of issue, with a minimum conversion price of 15 cents in tranches of EUR500,000.

The company said the Brussels, Belgium-based Diasource developed, manufactured, marketed and distributed clinical diagnostic products for endocrinology, with a portfolio of vitamin D products, operated in 75 countries and sold products directly and through 90 distributors and 40 original equipment manufacturers.

Anteo was unchanged at 7.5 cents with 2.7 million shares traded.

ADMEDUS LIMITED

Admedus has raised $6,930,000 from “a single US investor” at 66 cents a share, a 16.5 percent discount to the closing price of 79 cents prior to requesting a trading halt.

Admedus disclosed the capital raising in an ‘Appendix 3B’ notice which said it had issued the investor 5,250,000 options exercisable at 79 cents by December 18, 2020.

Admedus chief operating officer Dr Julian Chick told Biotech Daily that the fund raising was “a strategic US investment” in the company and he expected it to attract wider coverage.

Admedus last traded at 79 cents.

AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION, LIVING CELL

The Australian Securities and Investments Commission says Living Cell has paid a $33,000 fine “for allegedly failing to comply with continuous disclosure obligations”.
ASIC said that on June 15, 2015 Living Cell filed an announcement entitled, ‘NTCell Clinical Study in Parkinson's Meets Endpoints’ (BD: Jun 12, 15, 2015).
After the market closed on Friday June 12, Living Cell requested a trading halt at 4.29pm and the company filed the Parkinson’s announcement to the ASX at 8.54am on Monday June 15, 2015.
Today, ASIC said that at 2:07pm on Friday June 12, 2015 an email was sent by Living Cell’s chief executive officer to seven New Zealand based investors attaching a copy of an announcement entitled ‘NTCell Clinical Study in Parkinson's Meets Endpoints’, as well as a copy of the NTCell poster to be presented at the International Congress of Parkinson's Disease and Movement Disorders and information regarding an investor call to discuss the phase I/IIa study findings.
ASIC said the proposed announcement attached to the email was identical in all material respects to the one released on the ASX platform on June 15 2015.
ASIC alleged that by 2:07pm on June 12, 2015 Living Cell was aware of the results and that “by failing to immediately provide the announcement to the ASX on June 12, 2015, [Living Cell] was in breach of its continuous disclosure obligations”.
ASIC said it had issued the company with an infringement notice and Living Cell had complied with the infringement notice and paid the penalty on December 17, 2015.
In its announcement to the ASX today, Living Cell said it “planned to release the announcement to [the] ASX on June 15, after trade in the company’s [American depository receipts] had ceased on [the over-the-counter quality exchange] on June 12, so as not to pre-empt trade on [the] ASX and prior to the release of the results to the Congress of Parkinson’s Disease Movement Disorders in California”.
“ASIC considered that the information should have been released earlier,” Living Cell said.
“The board considers it in the best interests of the company’s shareholders not to contest the issuing of the infringement notice, to pay the penalty of $33,000 and focus on completing the planned phase IIb clinical trial of NTCell in Parkinson’s disease and then applying for provisional consent to treat and charge patients,” Living Cell said.
“The issuing of an infringement notice, and subsequent satisfaction of it, is not an admission of liability, nor does it represent a finding that the Corporations Act has been breached,” Living Cell said.
Living Cell was untraded at 3.8 cents.

IMUGENE

Imugene says the European Patent Office has granted a patent protecting its HER-Vaxx cancer immunotherapy until 2030.
Imugene said the patent, entitled ‘Multiepitope Vaccine for HER2/Neu-associated Cancers’ protected the method of composition and method of use of HER-Vaxx for the generation of a therapeutic antibody response against HER-2/Neu.
The company said the patent applied to the immunotherapy it was developing for gastric cancer, which stimulated a polyclonal antibody response to HER-2/Neu, the same biomarker targeted by the drug Herceptin.
Imugene was unchanged at one cent.

STARPHARMA HOLDINGS

Allan Gray Australia has reduced its holding in Starpharma further from 49,848,435 shares (15.91%) to 47,381,272 shares (14.85%).
Allan Gray said that between May 12 and November 24, 2015 it sold 2,718,747 shares for $2,108,374 or 77.6 cents a share.
In May, Allan Gray sold 2,467,163 shares, with the single largest sale at 50.5 cents a share having bought 8,529,403 shares in 2014 with the majority acquired in a placement at 65 cents a share (BD: Sep 22, Oct 1, 2014; May 11, 2015).
Starpharma climbed five cents or 7.1 percent to 75 cents.

GI DYNAMICS

UBS Group AG and its related bodies says it has reduced its substantial shareholding in GI Dynamics from 44,304,916 shares (9.32%) to 38,752,716 shares (8.15%).
UBS said that it sold shares between September 25 and December 15, 2015 with the single largest sale 493,660 shares for $17,278 or 3.5 cents a share.
GI Dynamics was up 0.1 cents or 3.3 percent to 3.1 cents.

MEDADVISOR

Medadvisor says it has appointed Theo Antonopoulos as head of sales and marketing.
Medadvisor said that Mr Antonopoulos previously spent nine years in sales and marketing roles with Glaxosmithkline.
Medadvisor fell 0.1 cents or 2.6 percent to 3.8 cents.