Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 37.5%, CELLMID DOWN 9%**

*** PRANA'S PBT2 'SAFE, SOME EFFICACY FOR HUNTINGTON'S DISEASE'**

*** INDIA APPROVES 'FLU DRUG USING BIODIEM'S LAIV TECHNOLOGY**

*** OPTISCAN, MR SUPPLY AGREEMENT**

*** CENTRE FOR CANCER BIOLOGY WINS $7m NHMRC LEUKAEMIA GRANT**

*** SIRTEX H1 REVENUE UP 27% TO $59m, PROFIT UP 44% TO $11m**

*** ALCHEMIA H1 REVENUE DOWN 47% TO $5m, LOSS DOWN 7% TO $5.5m**

*** COGSTATE H1 REVENUE DOWN 11.5% TO $5m, LOSS UP 442% TO $3m**

*** BENITEC FIRST TT-034 DOSING DELAYED ANOTHER MONTH**

*** PERPETUAL REDUCES TO 10% OF SIRTEX**

*** RHINOMED REQUESTS CAPITAL RAISING TRADING HALT**

*** EX-ACTINOGEN DAVID ZOHAR PLEADS GUILTY TO MISLEADING ASX**

MARKET REPORT

The Australian stock market climbed 0.18 percent on Tuesday February 18, 2014 with the S&P ASX 200 up 9.9 points to 5,392.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and five were untraded.

Optiscan was the best, up 1.5 cents or 37.5 percent to 5.5 cents with 137,500 shares traded. IDT climbed 5.6 percent; Avita and Nanosonics were up more than four percent; Admedus, Benitec, Sirtex and Viralytics were up more than three percent; Ellex, Impedimed and Tissue Therapies rose more than two percent; Bionomics was up 1.5 percent; with Acrux and CSL up by less than one percent.

Cellmid led the falls, down 0.3 cents or 8.8 percent to 3.1 cents, with 5.7 million shares traded. Living Cell lost six percent; Atcor and Reva fell more than three percent; Alchemia, Circadian, QRX and Universal Biosensors shed more than two percent; Neuren was down 1.1 percent; with Cochlear, Mesoblast and Resmed down less than one percent.

PRANA BIOTECHNOLOGY

Prana says its phase II clinical trial of PBT2 for Huntington's disease demonstrated safety, tolerability and some efficacy, but was not significant on several secondary measures.

Prana said that 95 percent of the 109 participants completed the six months of treatment in the Reach2HD trial of PBT2 for early to mid-stage Huntington's disease.

Prana said the phase II trial was a randomized, double-blind, placebo-controlled trial testing the safety and efficacy of 100mg and 250mg PBT2 for Huntington's disease, in collaboration with the Rochester, New York-based Huntington Study Group at 20 sites in the US and Australia (BD: Jul 23, Sep 13, 2013).

Prana previously said that the primary outcome of the trial was safety and tolerability and included a number of secondary outcome measures from the cognitive, motor and behavioral domains affected in Huntington's disease.

Prana said that a positive result would identify signals of therapeutic benefit in one or more of the domains measured, which would inform the design of the next clinical trial.

Today, Prana said that "the primary endpoint of the study was met".

Prana said there were no substantial differences in adverse events across the two PBT2 dose groups and the placebo group.

"Only one of the 10 reported serious adverse events was deemed by the clinical site investigator to be related to drug treatment [and] this occurred during the four-week follow-up period, that is, not on study drug, after completing the six month treatment," Prana said.

Prana said that the effects of PBT2 were tested on cognition, motor performance, behavior and functional capacity, of which cognition was pre-specified as the main efficacy outcome.

The company said that there was a statistically significant improvement in performance on the trail-making test part B, which measured executive function, in the PBT2 250mg group compared to placebo at both 12 weeks ($p < 0.001$) and 26 weeks ($p = 0.042$).

There was little difference in the trail making test between the 100mg PBT group and the 0mg control group.

Prana said there was a statistically significant improvement among patients with early stage disease ($p = 0.038$) but not across all patients, which showed an improvement trend ($p = 0.069$).

"The improvement in executive function was accompanied by a small but favorable signal in a key measure of functional capacity. No significant improvements were seen on other secondary efficacy measures in the study," Prana said.

Prana said it planned to advance PBT2 into a confirmatory phase III trial that could allow PBT2 to be approved for the treatment of Huntington disease.

Prana chief scientific advisor and professor of neurology at Harvard Medical School Prof Rudy Tanzi said that "the observation of significant improvement in executive function with PBT2 in this clinical trial for Huntington disease and the previously reported Alzheimer's trial, suggests a common mechanism for neuro-degeneration in these diseases based on metal interactions".

"In my opinion, these findings significantly elevate the potential for PBT2 as an effective therapy for both Huntington disease and Alzheimer's disease," Prof Tanzi said.

Prana said Huntington's disease was a complex and severely debilitating genetic, neurodegenerative disease, for which there was no cure, it often affected young adults, was associated with severe physical symptoms and impacted the mind and emotions.

Prana said that Huntington's disease caused incapacitation and death about 15 to 25 years after onset and affects more than 30,000 people in the US and 70,000 worldwide.

Prana was in a trading halt and last traded at 91.5 cents.

BIODIEM

Biodiem says that a seasonal influenza vaccine using its live attenuated influenza virus (LAIV) technology has been approved for sale in India.
Biodiem said that the Serum Institute of India developed the trivalent influenza vaccine.
Biodiem chief executive officer Julie Phillips said the approval was an important milestone, and heralded the ability of the Serum Institute of India to produce and market a vaccine every year, targeting seasonal influenza in the world's second most populous country.
Ms Phillips said that sales of the vaccine would result in a new revenue stream for Biodiem through royalty payments.
"This is also the first approval of the seasonal 'flu vaccine based on our technology outside Russia and so is an important threshold for us to cross," Ms Phillips said.
Ms Phillips said that the Serum Institute of India was "a world-class vaccine producer distributing their products to more than 120 different countries".
Ms Phillips said that the research and trials that formed the basis for this approval confirmed the value of the LAIV in protecting against influenza and the Serum Institute was closer to export approval to other developing countries.
Biodiem said it had licenced its LAIV influenza technology to the Serum Institute in exchange for royalties on sales into the private markets in India, South Africa, Argentina, Peru, Mexico, Bangladesh, Bhutan, Pakistan, Nepal, Sri Lanka and New Zealand.
The company said that public market usage in developing countries was royalty-free and was subject of an agreement with the World Health Organisation.
Biodiem said that in 2010 the Serum Institute launched and marketed Nasovac, an LAIV technology-based monovalent influenza vaccine targeting prevention of swine influenza.
The company said that like Nasovac, the trivalent vaccine would be administered by a nasal spray, which was pain-free and mimicked the route of infections through the nose.
Biodiem said it also had licenced the LAIV influenza technology to China's Changchun BCHT Biotechnology Co.
Biodiem is a public unlisted company.

OPTISCAN

Optiscan says it has a supply agreement with the UK-based MR Solutions for its second generation research fluorescence in-vivo endomicroscopy system, the Five-2.
Optiscan technical director Peter Delaney told Biotech Daily that under the original equipment manufacturer contract Optiscan should receive payment on receipt of goods.
Mr Delaney said small modifications were being made for MR Solutions branding.
Optiscan said that MR was "the leading developer and manufacturer of the world's first range of commercial, pre-clinical, 3 Tesla and cryogen free, bench-top magnetic resonance imaging systems and the systems were specifically designed for mice and rat studies, molecular imaging, multi-nuclear and multi-modality applications.
Optiscan said that the systems cryogen-free superconducting magnet technology complemented and operated in close proximity to other imaging modalities, including single-photon emission computed tomography, positron emission tomography and optical.
The company said that magnetic resonance imaging systems offered superior soft tissue contrast and high spatial resolution.
Optiscan said that MR had sales and marketing staff in Europe, North America and Australia, a presence at pre-clinical imaging trade shows and customers in China, Taiwan, Japan, Korea, Russia, Spain, France, Germany, Belgium, UK, the US and Canada.
The company said that more that 1,000 institutions had been identified as sales targets.
Optiscan was up 1.5 cents or 37.5 percent to 5.5 cents.

CENTRE FOR CANCER BIOLOGY

The Centre for Cancer Biology says it has secured a five-year $6.67 million grant from the National Health and Medical Research Council for leukaemia research.

The Centre said it was an alliance between the University of South Australia and SA Pathology and led by Prof Angel Lopez the research was designed to identify the mechanisms that controlled blood cell formation and how cell abnormalities played a part in the progression of the disease, as well as its return post-remission and the development and application of therapies.

Prof Lopez the research was part of the work in cancer treatment which sought to identify how to better target the cancer to prevent disease progression and what was particularly going wrong in the cancer cells.

“Our research team includes experts in cell-signalling, the wiring inside the cell, structural biology and drug design that gives us a 3D picture of the machine that malfunctions in leukaemia, and specialists in diagnostics and therapy that put into practice our discoveries,” Prof Lopez said.

SIRTEX MEDICAL

Sirtex says revenue for the six months to December 31, 2013, was up 27.2 percent to $58,581,000 with net profit after tax up 43.6 percent to $11,170,000.

Sirtex said that dose sales of its SIR-Spheres for liver cancer were up 11.3 percent to 3,919 units for the six months to December 31, 2012.

Sirtex said in the six months to December 31, 2013, US dose sales rose 14.9 percent to 2,648 doses, Asia Pacific sales were up 14.4 percent to 397 doses, with Europe, Middle East and Africa up 0.5 percent to 874 doses.

Sirtex chief executive officer Gilman Wong told a teleconference that the company had 38 consecutive quarters of growth and the company was positioned for further growth.

“The real strength of Sirtex is the potential into the future … through moving SIR-Spheres further up the treatment chain,” Mr Wong said.

Mr Wong said that five separate trials were underway with the 532-patient Sirflox trial for metastatic colorectal cancer fully-recruited and awaiting data maturity.

Mr Wong said the company had expected Sirflox results by the end of 2014 but “due to the amount of data being collected it is taking longer than anticipated” and was expected by April 2015.

Sirtex said it had invested in “a pipeline of promising new technologies which comprise two different nanotechnology platforms and also a radio-protector technology … [with] the potential to be developed into new products to address unmet medical needs”.

Sirtex chief financial officer Darren Smith told the teleconference that Sirtex had paid five consecutive years of fully-franked dividends and .

Sirtex said that a fully-franked final dividend of 12 cents was paid on October 25, 2013 for the financial year to June 30, 2013.

The company said that research and development expenditure increased 34.8 percent to $4,000,000 or 6.8 percent of revenue.

The company said that net tangible asset per share fell 0.85 percent from 94.4 cents at December 31, 2012 to 93.6 cents at December 31, 2013 and diluted earnings per share was up 43.4 percent to 19.5 cents.

Sirtex said that cash and cash equivalents at December 31, 2013 was $13,850,000 compared to $20,094,000 at June 30, 2013.

Sirtex was up 55 cents or 3.8 percent to $14.96 with 894,699 shares traded.

ALCHEMIA

Alchemia's revenue for the six months to December 31, 2013 fell 46.66 percent to $5,035,000 with a net loss after tax down 7.14 percent to $5,474,000.
Revenue for the six months to December 31, 2012 included $4.5 million from the fondaparinux profit share with partner Dr Reddy's and $4.4 million in research and development tax refund (BD: Feb 27, 2013).
Today, Alchemia said that the fondaparinux profit share was $4.7 million compared to last year's $4.5 million.
In US dollars, fondaparinux net profit share fell 2.95 percent from $US4.4 million to $US4.27 million.
Alchemia chief executive officer Charles Walker told Biotech Daily the fall in net profit share was due to a number of one-off events.
"Dr Reddy's are being aggressive in a competitive market," Mr Walker said. "There were also one-off events such as returns of expired stock."
The company said that the operating expenditure of $10.7 million was lower than $15.5 million in the previous corresponding period, due to a reduction in administration and corporate costs compared to the previous year's failed bid to list on the Nasdaq, as well as reduced costs of the phase III hyaluronic acid-irinotecan metastatic colorectal cancer trial (BD: Dec 21, 2012, Feb 4, 2013).
The company said its diluted loss per share fell 19.05 percent to 1.7 cents at December 31, 2013 and net tangible asset backing per share was up 282 percent to 4.2 cents.
Alchemia said it had cash and cash equivalents of $6,670,000 at December 31, 2013 compared to $5,064,000 at June 30, 2013.
Alchemia fell 1.5 cents or 2.5 percent to 58.5 cents.

COGSTATE

Cogstate says revenue for the six months to December 31, 2013 was down 11.5 percent to $5,435,721, with a net loss after tax up 442.3 percent to $2,679,666.
Cogstate said that revenue from its sports segment was up 84.4 percent to $500,967, while revenue from clinical trials fell 16.8 percent to $4,828,429 for the six months to December 31, 2013.
Cogstate said its net tangible assets per share was up 22.2 percent to 0.11 cents and diluted loss per share was up 371.4 percent from 0.7 cents to 3.3 cents.
The company said it had cash and cash equivalents of $8,888,210 at December 31, 2013 compared to $3,392,617 at June 30, 2013.
Cogstate was up half a cent or 1.3 percent to 38.5 cents.

BENITEC BIOPHARMA

Benitec says it expects to dose the first of 14 patients in its phase I/IIa trial of TT-034 for hepatitis C "in early to mid March 2014".
The company had previously hoped to begin dosing by the end of 2013 but said today that "despite the severe weather conditions being experienced on the East Coast of the United States, patient screening has commenced at Duke Clinical Research Unit in North Carolina" (BD: Oct 8, 2013).
Benitec was up three cents or 3.3 percent to 95 cents.

SIRTEX MEDICAL

Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 6,387,618 shares (11.38%) to 5,730,328 shares (10.21%).
Perpetual said it sold the shares between February 3 and 14, 2014 for prices ranging from $14.00 to $14.29, except for the sale of a single share for $12.87 on February 13, 2014.

RHINOMED

Rhinomed has requested a trading halt pending the release of an announcement in relation to a capital raising.
Trading will resume on February 20, 2014 or on an earlier announcement.
Rhinomed last traded at 5.3 cents.

THE AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION

ASIC says that former Actinogen executive director, David Alan Zohar, has pleaded guilty to three counts of providing false and misleading information to the ASX.
ASIC said that Mr Zohar appeared in the Perth District Court on February 14, 2014 and admitted to providing the information in connection with Aluminex Resources September 2008 float (BD: May 29, 2012).
ASIC said that following Aluminex's suspension from the ASX in October 2008, ASIC made the company pay back the money to subscribers of the shares under its prospectus and Mr Zohar was charged in May 2012.
ASIC said that each charge carried a maximum five-year jail penalty.
The regulator said that Mr Zohar was bailed to appear at Perth District Court on March 28, 2014 for sentencing.