Biotech Daily

Thursday December 12, 2013

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: ADMEDUS UP 10%; ELLEX DOWN 7%**

*** FDA AGREES HATCHTECH PHASE III TRIALS; EURO, JAPAN PATENTS**

*** ADMEDUS BUYS GENZYME FULLY-EQUIPPED PLANT FOR CARDIOCEL**

*** META-ANALYSIS BACKS ATCOR SPHYGMOCOR FOR CARDIOVASCULAR**

*** ANTISENSE COMPLETES TOXICOLOGY DOSING**

*** AVEXA HIRES NEXTPHARMA FOR ATC CAPSULES**

*** TISSUE THERAPIES $7m RIGHTS ISSUE TAKES TOTAL TO $10m**

*** SIMAVITA BACKDOORS INTO GENETIC TECHNOLOGIES GTECH**

*** WILSON HTM REDUCES TO 5.3% OF UNIVERSAL BIOSENSORS**

*** GENETIC TECHNOLOGIES APPOINTS DR PAUL KASIAN DIRECTOR**

*** PHOSPHAGENICS TPM COW SUPPLEMENTS 'REDUCE ANTI-BIOTIC USE'**

MARKET REPORT

The Australian stock market fell 0.82 percent on Thursday December 12, 2013 with the S&P ASX 200 down 41.7 points to 5,062.5 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Admedus was the best, up 1.5 cents or 10.3 percent to 16 cents with 16.9 million shares traded.

Avita climbed 7.8 percent; Antisense was up 6.25 percent; Living Cell, Neuren and Prana were up five percent or more; Phosphagenics was up 4.35 percent; Atcor was up three percent; with Nanosonics and Starpharma up more than one percent.

Ellex led the falls, down 2.5 cents or 7.35 percent to 31.5 cents with 66,861 shares traded.

Patrys lost six percent; Pharmaxis fell 5.7 percent; GI Dynamics and Tissue Therapies fell more than four percent; Genetic Technologies was down 3.3 percent; Benitec, Mesoblast, Osprey, Prima, Resmed and Viralytics shed more than two percent; Acrux, Bionomics, Cochlear, Medical Developments and Reva were down more than one percent; with Alchemia, Clinuvel, CSL, QRX and Sirtex down by less than one percent.

HATCHTECH

Hatchtech says the US Food and Drug Administration has agreed the design of phase III trials of Deovo for headlice, with patents allowed in Europe and granted in Japan.
Hatchtech said that the phase III trials were allowed under the special protocol assessment scheme providing an agreement from the FDA that the design, endpoints and statistical analyses were acceptable to support efficacy claims and regulatory approval.
The company said it was in the final stages of preparing for the studies, with dosing expected to begin in February 2014.
Hatchtech chief executive officer Hugh Alsop said that the special protocol assessment "marks another important milestone".
"We believe this phase III study design will allow us to thoroughly demonstrate the clinical benefits of Deovo for treating head lice which is a common problem experienced by many children and adults alike," Mr Alsop said.
Hatchtech said that the European patent office has allowed the core patent, entitled 'Methods and Compositions for Controlling Ectoparasites' and Japan had granted the patent entitled 'Compositions and Methods for Controlling Infestations'.
The company said the Japan patent was the first granting in a major market for its second patent family, which provided further protection for products effective against all stages of the lice life cycle.
Hatchtech is a public unlisted company.

ADMEDUS, (ALLIED HEALTHCARE GROUP)

Admedus says it will acquire Sanofi's Genzyme Australasia established manufacturing site in Malaga Western Australia for a "nominal" amount.
Admedus chief operating officer Dr Julian Chick told Biotech Daily that the plant included equipments, infrastructure, clean rooms and staff, most of whom would be retained.
Dr Chick said the acquisition was "very cost effective".
In its media release, Admedus said the facility would enable scaled-up production of its bovine cardiac tissue product Cardiocel and to meet demand for the repair and reconstruction of congenital heart defects.
Admedus said it expected to complete the transaction on December 31, 2013.
The company said the facility was built in 2009 and would provide fully operational infrastructure enabling the company to service the expected global market for Cardiocel and provide additional facilities to support the development and commercial manufacture of additional Adapt tissue engineering process products currently in the pipeline.
Admedus chief executive officer Lee Rodne said the site was "an important acquisition for us as it allows Admedus to accelerate its manufacturing capabilities in anticipation of growing Cardiocel sales over the next 12 months and beyond".
Admedus said the "recently completed multi-million dollar state of the art facility" was leased fully fitted with the required clean room facilities and supporting infrastructure for Admedus to manufacture Cardiocel.
The company said that the purchase price was "nominal and includes all existing equipment at the site … [and provided] access to highly skilled staff to support both manufacturing requirements and new product development".
Admedus said the retained Genzyme staff were trained in operating clean room facilities as well as experienced in producing medical products for human treatments.
"This will accelerate our ability to increase the manufacturing of Cardiocel as market demand grows," Mr Rodne said.
Admedus was up 1.5 cents or 10.3 percent to 16 cents with 16.9 million shares traded.

ATCOR MEDICAL

Atcor says a 17,635 subject meta-analysis shows aortic pulse-wave velocity measurement of arterial stiffness better predicts cardiovascular events than conventional methods.
Atcor said the analysis, entitled 'Aortic pulse wave velocity improves cardiovascular event prediction: an individual participant meta-analysis of prospective observational data from 17,635 subjects' was published in the Journal of The American College of Cardiology and was lead-authored by the University of Bristol's Dr Yoav Ben-Shlomo.
An abstract is at http://www.ncbi.nlm.nih.gov/pubmed/24239664.
Atcor said that the benefits of using aortic pulse wave velocity (aPWV) were most strongly demonstrated in patients under 61 years of age, deemed at intermediate risk.
The company said that following an assessment of cardiovascular risk which added aPWV analysis to conventional risk methods, 24 percent of the patients under 61 years of age were reclassified into a more appropriate risk group and overall 13 percent of the patients were reclassified for cardiovascular disease mortality across the entire study population.
The company said the meta-analysis combined the individual results of 17,635 patients from 16 studies, the majority of which used Sphygmocor to find systematic patterns.
The abstract concluded: "Consideration of aPWV improves model fit and reclassifies risk for future cardiovascular events in models that include standard risk factors … aPWV may enable better identification of high-risk populations who may benefit from more aggressive cardiovascular risk factor management."
In a discussion the authors said: "The main finding of the current study is that aortic stiffness, assessed by measurement of aPWV, predicts future cardiovascular events and mortality, even after accounting for other established cardiovascular risk factors".
Atcor said that pulse wave velocity was an alternate method for physicians to determine large artery aortic stiffness and was recommended by the European Society of Hypertension for the clinical management of hypertension.
Atcor said it was the market leader in aortic pulse wave velocity and its Sphygmocor XCel was the first device to have its aPWV test measurements certified as 'excellent' by European Artery Society guidelines.
Atcor chief executive officer Duncan Ross said that showing clinical significance when analyzing and compiling individual patient records encompassing multiple studies was "amongst the highest-quality evidence that can be presented to support the clinical value of a testing technology".
"We are clearly very pleased by this result," Mr Ross said. "While Europe has led the way in the use of aPWV, we are seeing increased demand globally."
"This trend has also been evident in our pharmaceutical trials business where now a significant number of trials not only measure central aortic pressures but also aortic pulse wave velocity using Sphygmocor," Mr Ross said.
Atcor was up 0.5 cents or three percent to 17 cents.

ANTISENSE THERAPEUTICS

Antisense says that dosing has been completed in its primate toxicology study of ATL1102 with results expected to be reported by April 2014.
Antisense said the study was being conducted to clear an appropriate dose for use in a potential phase IIb clinical trial of ATL1102 for multiple sclerosis patients.
The company said that all scheduled doses of ATL1102 had been received by all animals in the six month chronic toxicology study being conducted at the Beijing China-based Pharmaron contract research organization.
Antisense was up one cent or 6.25 percent to 17 cents.

AVEXA

Avexa says it will convert part of its stockpile of apricitabine (ATC) for drug-resistant-HIV into capsules “for clinical use”.
Avexa said it had hired the UK-based Nextpharma to manufacture the ATC capsules, which had a shelf life of three years.
The company said it was working with partner Link Healthcare to meet the demand for requests for ATC treatment, with the drug expected to be available by the end of 2014.
Apricitabine is yet to receive regulatory approval in any jurisdiction but has previously announced a planned trial and distribution partners (BD: Apr 27, Dec 10, 2012).
Avexa was unchanged at 1.5 cents.

TISSUE THERAPIES

Tissue Therapies says its one-for-nine, fully underwritten, non-renounceable rights issue at 21 cents a share has raised at total of about $7,075,000.
Tissue Therapies said that with its recent $3 million placement, it had raised $10,075,000 to take the company beyond the start of [Vitrogro] sales to start shortly after the granting of Conformité Européenne (CE) mark expected by July 2014 (BD: Nov 4, 2013).
The company said that the entitlement offer was fully underwritten by Morgans Corporate.
Tissue Therapies said received valid applications for 22.67 shares or about $4.76 million, or 89.17 percent of the 25.4 million shares on offer and a shortfall of 2.75 shares or about $578,166, to total of $5,338,000.
The company said that its largest shareholder Allan Gray Australia had taken up the shortfall and also elected to receive a top up application, resulting in the issue of 8,270,640 shares for a further $1,737,000, taking its total sub-underwriting commitment to $2,315,000 and the total raised in the rights issue to $7,075,000.
Tissue Therapies fell one cent or 4.35 percent to 22 cents.

GENETIC TECHNOLOGIES, SIMAVITA

Genetic Technologies says its former Canadian subsidiary, Gtech International Resources has completed its acquisition of Simavita.
Simavita chief executive officer Philippa Lewis told Biotech Daily the company had paid about $700,000 for the Canadian back-door listing.
Last week, Simavita said its initial public offer raised $14 million to list on the Toronto Stock Exchange Ventures market to commercialize its smart incontinence management Sim platform technology and said it hoped to list on the ASX this year (BD: Dec 3, 2013).
Today, Genetic Technologies said that as part of the Gtech changed its name to Simavita and shares began trading on the TSXV under the symbol SV on December 6, 2013.
The company said that on December 9, 2013, Simavita lodged documents with the Australian Securities Exchange to seek a listing of CHESS depositary interests and if accepted, the ASX code SVA had been reserved.
Genetic Technologies said it held 1,306,166 Simavita shares or about 2.3 percent of the company.
The company said Gtech had been deconsolidated from the Genetic Technologies group and changes had been made to the board to reflect the new ownership.
Genetic Technologies acting chief executive officer Tom Howitt said that the company was “extremely pleased to see the successful conclusion of this transaction that will benefit all Simavita shareholders”.
Genetic Technologies fell 0.2 cents or 3.3 percent to 5.8 cents.

UNIVERSAL BIOSENSORS

Wilson HTM Investment Group has ceased its substantial holding in Universal Biosensors selling a further 690,966 shares for $364,682 or 52.8 cents a share.
Wilson HTM said it bought and sold share between August 27 and December 9, 2013.
In August, Wilson HTM reduced its holding to 9,284,910 shares (5.31%) with 10,500,000 shares sold for $7,143,778 or an average price of 68.0 cents a share (BD: Aug 28, 2013).
Universal Biosensors was unchanged at 49 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Dr Paul Kasian as a non-executive director.
Genetic Technologies said that Dr Kasian was “an experienced executive director with demonstrated domestic and international success in funds management, encompassing senior leadership, investment and risk roles”.
The company said that previously Dr Kasian held senior positions at investment groups, including HSBC Asset Management and HSBC Global Financial Team and was founding director of Accordius and Wallara Asset Management.
Genetic Technologies said that Dr Kasian was previously a project leader at ICI Australia and held a Doctor of Philosophy in microbiology and a Master of Business Administration from the University of Melbourne.

PHOSPHAGENICS

Phosphagenics says that with licensee Mastitis Management Australia the Udder-Mate feed inclusion technology had “promising results” when fed to cows on farms.
Phosphagenics said that the provision of feed inclusion supplementation in cows’ diets with the Udder-Mate technology to a commercial dairy cow herd in northern Victoria for three months enabled the farmer to reduce the use of antibiotics by 50 percent in cows whose somatic cell count were more than one million cells per millilitre when compared to the same period in the previous year.
The company said that Mastitis Management Australia had been granted a licence for the use of its tocopheryl phosphate mixture or TPM technology for cow supplements in Australia and New Zealand.
Phosphagenics said that oral Udder-Mate delivered key antioxidants and nutrients to maintain and support general animal health and wellbeing.
Phosphagenics was up half a cent or 4.35 percent to 12 cents with 1.3 million shares traded.