Biotech Daily

Thursday November 15, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ALLIED HEALTH UP 5%, PATRYS DOWN 9%**

*** ALLIED, CORIDON DNA VACCINE PROTECTS MICE FROM HPV TUMORS**

*** PRANA PHASE IIa PBT2 HUNTINGTON'S DISEASE TRIAL ON-TRACK**

*** CLARIFICATION: BIONOMICS AGM DISSENT**

*** MESOBLAST TALKS TEVA, PLEADS TRADING TO ASX 21% FALL QUERY**

*** MAYNE COMPLETES METRICS ACQUISITION**

*** CIRCADIAN LICENCES VEGF TO BIO-RAD FOR RESEARCH PRODUCTS**

*** BIOTA APPOINTS RUSSELL PLUMB CEO, DR JOSEPH PATTI STRATEGY**

*** INVESTORS MUTUAL TAKES 6.5% OF MAYNE PHARMA**

*** MELANIE LEYDIN REPLACES BIODIEM CO SEC RICHARD WADLEY**

*** NUSEP'S PROF JOHN AITKEN WINS NSW SCIENTIST OF THE YEAR**

MARKET REPORT

The Australian stock market fell 0.89 percent on Thursday November 15, 2012 with the S&P ASX 200 down 39.2 points to 4,349.2 points. Five of the Biotech Daily Top 40 stocks were up, 21 fell, nine traded unchanged and five were untraded.

Allied Health was the best, up 0.1 cents or 4.55 percent to 2.3 cents with 11.9 million shares traded.

QRX climbed 4.1 percent; Clinuvel rose 2.2 percent; Optiscan was up 1.1 percent; with Resmed and Reva up by less than one percent.

Patrys led the falls, down 0.3 cents or 8.6 percent to 3.2 cents with 30,830 shares traded.

Prima and Universal Biosensors lost more than seven percent; Bionomics, Cellmid and Genera were down more than six percent; Impedimed, Mesoblast, Phylogica and Tissue Therapies fell more than four percent; Living Cell, Starpharma and Sunshine Heart were down more than three percent; Pharmaxis, Prana and Viralytics shed more than two percent; Acrux, Alchemia, Cochlear, Heartware and Nanosonics were down more than one percent; with CSL and Sirtex down by less than one percent.

ALLIED HEALTHCARE GROUP

Allied Health says Coridon's human papillomavirus DNA vaccine induces an immune response that can protect mice from developing associated cancer tumors.

Allied Health said that the preclinical research by its 44.4 percent investment company Coridon, led by Prof Ian Frazer, was part of the development for a therapeutic vaccine to combat existing human papillomavirus infection and to prevent and treat cancer onset.

The company said that existing human papillomavirus (HPV) vaccines, Gardasil and Cervarix, both developed by Prof Frazer, were only effective in preventing transmission of the virus which was a common precursor to cervical cancer.

Allied said that the preclinical study confirmed that the Coridon vaccine "induces an immune response that can protect mice from developing cancer tumors associated with HPV infection".

The company said that the immunized animals showed no tumors at the end of the study compared to the control animals, all of which developed large tumors.

Allied said that three groups of 10 mice were vaccinated intra-dermally with the Coridon HPV mixed DNA vaccine with coding for both E6 and E7 proteins and compared to no vaccination or control animal model vaccine consisting of E7 protein with adjuvant.

The company said that after two immunizations three weeks apart, tumor cells were implanted and tumor formation was monitored.

Allied said that mice receiving no vaccine developed large tumors, whereas all mice immunized with Coridon's DNA vaccine or the positive control survived with no tumors to the completion of the study.

Allied group managing director Lee Rodne said the results were "very promising".

We are moving another step closer to developing a therapeutic treatment for HPV-associated cervical cancer," Mr Rodne said.

"Given the wide benefits associated with Prof Frazer's blockbuster vaccines Gardasil and Cervarix, we are very excited by the possibility of developing a vaccine, that can not only prevent infection, but can also stop the development of disease in people that have already been infected," Mr Rodne said.

Allied said that Coridon's human papillomavirus DNA vaccine was designed to target and clear human papillomavirus (HPV) transformed cells and was a new strategy to protect against cancers caused by existing infections with this virus.

"This finding further confirms through preclinical studies the potential of Coridon's technologies for developing successful immuno-therapies" Prof Frazer said.

Allied said that despite the availability of prophylactic vaccines such as Gardasil, surveys in the US showed that about 30 percent of women complete the vaccination schedule required for protection from HPV infection and if proven safe and effective, Coridon could offer an alternative that both protected from HPV infection and reduced associated cancer risk in those already exposed.

Allied said that human papillomavirus was one of the most common sexually transmitted diseases in the world and, as well as cervical cancer, was associated with a variety of ano-genital cancers and head and neck cancer.

The company said that cervical cancer was the second largest cause of cancer deaths in women worldwide with 510,000 cases a year and about 288,000 deaths.

Allied said that an estimated 26.8 percent of 14 to 59-year old females were infected and more than 25 million people had human papillomavirus infection and another 6.2 million people would become infected each year and that there were 11,270 new cases and 4,070 deaths from cervical cancer in the US with about $US1.7 billion spent in the US each year to treat cervical cancer.

Allied Health was up 0.1 cents or 4.55 percent to 2.3 cents with 11.9 million shares traded.

PRANA BIOTECHNOLOGY

Prana says it expects to have dosed 80 of the targeted 100 patients in its phase IIa trial of PBT2 for Huntington's disease by the end of November, with all patients dosed this year.
Prana said that chief operating officer Dianne Angus reported progress in the 'Reach2HD' phase IIa trial at the Huntington Study Group conference in Seattle, Washington, last weekend, November 10 and 11, 2012.
The company said the 100 patients with early to mid-stage Huntington's disease in the phase IIa, six-month trial were being treated with one of two doses of PBT2 or placebo.
Prana said that enrollment began in April 2012 following US Food and Drug Administration approval and all 20 sites were open and recruiting.
The company said the trial recruitment was in line with its completion target with reporting of results expected by the end of 2013.
Ms Angus told the conference that PBT2 had "a unique therapeutic action because of its specialized ability to prevent the toxic relationship between disease proteins and biological metals in the brain".
Prana said that PBT2 had been shown in animal models to reduce the aggregation of a mutant form of the Huntingtin protein that was associated with the disease, improve motor function, preserve neuronal tissue and significantly improve life expectancy.
The company said that PBT2 has demonstrated a significant ability to improve cognitive executive function in a phase IIa study in Alzheimer's disease.
Prana said the Huntington's disease trial was designed to investigate safety and tolerability of PBT2 in Huntington disease patients and to measure potential cognitive, functional and motor benefits in patients and also explore mechanistic biomarker readouts.
Prana executive chairman Geoffrey Kempler said the first patient had completed the six month treatment period "and no patients have withdrawn from the trial for any safety or other reasons, so we are very pleased with our progress to date".
The company said Huntington's disease was a complex and severely debilitating genetic, neurodegenerative disease, for which there is no cure, affecting more than 30,000 people in the US and about 70,000 worldwide.
Prana said there was only one marketed drug for Huntington's disease, with limited utility and there were no drugs either available or in development that had established clinical evidence for treating the cognitive decline associated with Huntington's disease.
Prana fell half a cent or 2.3 percent to 21 cents.

BIONOMICS

Yesterday's edition reported that all Bionomics annual general meeting resolutions were passed 'on a show of hands' but with up to 47.2 percent opposition on directors' fees and options resolutions.
Bionomics has told Biotech Daily that the opposition to the issue of 500,000 options each to directors chairman Graeme Kaufman and Dr Jonathan Lim was at a lower level than the simple calculation of 46.0 percent opposing the issue and 54.0 percent in support.
Bionomics has calculated a lower percentage of votes in opposition, 38 percent, based on a large number of unused proxy votes held by the chairman.
The 43 million votes opposing the resolutions comprises about 11.8 percent of Bionomics 364,719,694 shares on issue, sufficient to requisition extraordinary general meetings.
Bionomics fell two cents or 6.25 percent to 30 cents.

MESOBLAST

Mesoblast has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price fell from $5.36 on November 14, to $4.22 today November 15, 2012 a 21.3 percent fall and noted an increase in trading volume.

Mesoblast restated the chief executive Prof Silviu Itescu's report in the 2012 Annual Report saying that Teva Pharmaceutical Industries and Mesoblast were committed to jointly developing innovative products for major cardiovascular and neurologic markets.

Prof Itescu told Biotech Daily that Teva was directly involved in the ongoing placebo-controlled, phase II trial in 225 patients with acute myocardial infarction actively recruiting in Europe under Europe's voluntary harmonization procedure and in Australia under the guidance of the Therapeutic Goods Administration

In the response to the ASX, Mesoblast said the two companies were in discussion on a phase III design which would involve an early interim analysis to evaluate evidence of efficacy and that additional cardiovascular indications were being investigated with Teva, including the European phase II trial of intracoronary injection of mesenchymal precursor cells for prevention of heart failure after an acute myocardial infarction, with other potential studies including chronic refractory angina.

Mesoblast said that following its 60-patient phase II congestive heart failure trial (BD: Nov 2011), Mesoblast and Teva met with both the US Food and Drug Administration and the European Medicines Association in relation to a proposed phase III trial protocol to evaluate the effectiveness of a single mesenchymal precursor cells dose to prevent hospitalization and death in CHF patients.

Mesoblast said it also noted "that the average trade today, at time of writing, is less than $4,000 per trade which may imply that the trading this morning has been substantially generated as the result of high frequency computer generated trading patterns".

"While the company is unable to express a view on why trader/s may utilize high frequency trading patterns for Mesoblast stock, the company also notes that historically there is a significant proportion of share lending in Mesoblast stock, which means at some point traders who have 'borrowed' Mesoblast shares may seek to position themselves to be able to cover that short trading," Mesoblast said.

Biotech Daily is aware of speculation in the market in regard to delays in published trial results in peer-reviewed journals and the start date for the Teva supported phase III congestive heart failure trial.

Mesoblast closed down 24 cents or 4.5 percent at $5.12 with three million shares traded.

MAYNE PHARMA GROUP

Mayne says the $US105 million acquisition of Metrics has been completed with $65 million in placements and a rights offer at 20 cents a share, and a $US44.5 million debt facility.

Mayne said that both the retail and institutional components of the equity raising received strong support from shareholders and were oversubscribed.

Mayne Pharma chief executive officer Scott Richards said the acquisition of Metrics was "extremely exciting and positive for Mayne Pharma and will transform the existing business by diversifying its product range, technologies and international footprint".

"The two businesses are highly complementary and significant upside is expected in the medium to long term from cross-selling opportunities," Mr Richards said.

Mayne fell one cent or 3.6 percent to 26.5 cents with 1.4 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian it has provided a non-exclusive worldwide licence to Bio-Rad Laboratories to market research assays for the detection of VEGF-C and/or VEGF-D in biological fluids.
Circadian says that its wholly owned subsidiary Vegenics licenced the use of the vascular endothelial growth factor C and D (VEGF-C and VEGF-D) intellectual property to the Hercules, California-based Bio-Rad for use in research reagents.
The company said that it owned extensive intellectual property rights for the use of VEGF-C and VEGF-D for diverse therapeutic applications and diagnosis and its own internal product programs were focused on the development of novel therapeutics for cancer and eye disease.
Circadian chief executive officer Robert Klupacs told Biotech Daily that the licence included undisclosed up-front fees as well as royalties on sales of the resulting reagents.
“We are committed to maximizing the potential of our intellectual property through collaborative relationships with leaders in their field,” Mr Klupacs said in a media release.
“Bio-Rad, a world leading provider of products to the cancer and angiogenesis research markets, has recognized the importance of providing improved tools, and has identified the increasing importance of VEGF-C and VEGF-D as key angiogenic proteins in the international research and drug discovery community,” Mr Klupacs said.
“This partnership is also another example of the diverse range of commercial opportunities and value of our VEGF intellectual property,” Mr Klupacs said.
Circadian was untraded at 37.5 cents.

BIOTA PHARMACEUTICALS

Biota says it has appointed Russell Plumb as its chief executive officer and a director and Dr Joseph Patti as executive vice-president of corporate development and strategy.
Mr. Plumb said that Biota's move to the US “marks the beginning of a transformative period for the company”.
“With two drugs on the market and a robust pipeline anchored by laninamivir, Biota represents a truly unique opportunity and I'm excited to play a role in maximizing the Company's potential,” Mr Plumb said.
Biota said that Mr Plumb was previously the president, chief executive officer and chief financial officer of Inhibitex Inc, a US clinical-stage drug development company, from December 2006 to February 2012, when it was acquired by Bristol-Myers Squibb for about $US2.5 billion.
The company said that Inhibitex was developing antiviral, small molecules, including compounds to treat hepatitis C virus infection.
Biota said that from 2000 to December 2006, Mr Plumb was the chief financial officer of Inhibitex, during which time he oversaw numerous financing transactions, including the company's initial public offering in 2004.
The company said that Dr Patti was a co-founder of Inhibitex and its chief scientific officer and senior vice-president of research and development from 2007 to February 2012, vice-president of preclinical development and chief scientific officer from 1998 to 2007 and vice-president of research and development from 2005 to 2007.
Biota said that former chief executive officer Peter Cook resigned on completion of the merger with Nabi and remains a director.
Overnight on the Nasdaq, Biota was up 14 US cents or 3.3 percent to $US4.41.

MAYNE PHARMA

Investors Mutual has increased its substantial shareholding in Mayne Pharma from 18,504,767 shares (5.29%) to 30,008,818 shares (6.47%).
The substantial shareholder notice said that the Sydney-based company acquired 11,504,051 shares for $2,300,810 or 20 cents a share in the $65 million capital raising for $65 million to acquire Metrics Inc (see above, BD: Oct 4, 2012).

BIODIEM

Biodiem says that Melanie Leydin will replace Richard Wadley as company secretary effective from today.
Biodiem said that Ms Leydin was a chartered accountant and registered company auditor and had 20 years' experience in the accounting profession.
The company said that Ms Leydin was a company secretary for a number of resources and biotechnology entities listed on the Australian Stock Exchange.
Biodiem thanked Mr Wadley "for his dedicated service to the company".
Biodiem was untraded at 4.5 cents.

NUSEP

Nusep says the chairman of its scientific advisory committee Prof John Aitken has been named New South Wales Scientist of the Year.
Nusep said the award was made at the 2012 New South Wales Science and Engineering awards and the award was for "an outstanding individual who has made a significant contribution to the advancement of science and/or engineering that benefits or has the potential to benefit our community".
The company said the award was announced by the State Minister for Regional Infrastructure and Services Andrew Stoner, recognizing Prof Aitken's work in reproductive biology.
Nusep said that Prof Aitken identified oxidative stress as a major cause of male infertility, a finding that resulted in new methods of therapeutic intervention, including sperm isolation using Nusep's sperm separation device, the Spermsep.
The company said that Prof Aitken directed research on mammalian sperm function, fertilization and early embryonic development with applications in fertility treatments.
Nusep said that Prof Aitken's team developed potential contraceptive agents that could prevent pregnancy and simultaneously inhibit the spread of sexually transmitted diseases.
Nusep fell 0.3 cents or 3.7 percent to 7.8 cents.