Biotech Daily

Friday December 16, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 10%, GENETIC TECHNOLOGIES DOWN 8%**

*** NOVO NORDISK DROPS CBIO XTOLL OPTION**

*** ALCHEMIA 140% OVERSUBSCRIBED SHARE PLAN RAISES $5m**

*** GENETIC TECHNOLOGIES APPOINTS DR MEL BRIDGES CHAIRMAN**

*** MIT PAPER BACKS PRANA PBT2 FOR NEURODEGENERATIVE DISEASES**

*** HARVARD TRIALS IMMURON COLOSTRUM FOR RADIATION EFFECTS**

*** HATCHTECH CLAIMS DEOVO KILLS LICE, EGGS IN 10-MINS**

*** TEXAS' CANCER CENTRE APPROVES VIRALYTICS TRIAL**

*** HUNTER DIRECTORS BACK PROBIOMICS 'TAKEOVER'**

*** HEALTHLINX 742-SAMPLE DATA: 'OVPLEX STILL BETTER THAN CA125'**

*** ANTISENSE GRANTS AFANDIN 6 MORE MONTHS FOR ATL1101**

*** LIFE SCIENCES QUEENSLAND ELECTS BOARD**

*** BIO-MELBOURNE APPOINTS DR PHIL KEARNEY, MAUREEN O'KEEFE**

*** NUSEP'S PROF JOHN AITKEN WINS EUR50,000 PRIZE**

*** ASIC: BIOTECH SOLUTIONS SIMON FINNIGAN GAOLED FOR 10 YEARS**

MARKET REPORT

The Australian stock market was up 0.47 percent on Friday December 16, 2011 with the S&P ASX 200 up 19.4 points to 4,159.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and seven were untraded.

Avita was the best, up one cent or 10 percent to 11 cents with 1.5 million shares traded. Alchemia climbed 8.6 percent; Benitec was up 7.1 percent; Heartware rose 6.7 percent; Optiscan was up 5.3 percent; Acrux and Biota were up more than four percent; Resmed and Sunshine Heart were up more than three percent; Phosphagenics, Starpharma and Viralytics rose more than two percent; with CSL and Impedimed up more than one percent.

Genetic Technologies led the falls, down one cent or 7.7 percent to 12 cents. Antisense and QRX lost more than six percent; Allied Health fell 4.8 percent; Neuren and Prana were down more than three percent; Patrys and Tissue Therapies shed more than two percent; with Anteo and Cochlear down more than one percent.

CBIO

CBio says Denmark's Novo Nordisk AS has declined to exercise its option to licence XToll for further development and commercialization.
CBio said that as a result of the decision, it had the right to develop and commercialize XToll either independently or in collaboration with third parties.
The company said that XToll had a novel mechanism of action which could provide safer and more effective treatment of autoimmune diseases such as rheumatoid arthritis and lupus.
CBio chairman Dr Ralph Craven said XToll was thought to modulate the immune system "and bring it back into balance".
"The board believes that XToll could potentially become an important therapy for autoimmune and inflammatory diseases and we continue to explore all opportunities for the commercialization of this drug candidate," Dr Craven said.
The company said that XToll (Chaperonin 10) had been trialed in more than 330 patients with no pattern of treatment-emergent serious adverse effects.
CBio said its phase IIa trial was completed in July with XToll showing biological activity and signs of clinical effect in patients with moderate to severe rheumatoid arthritis.
But the non-significant phase IIa trial results led to the recent board spill and change of management (BD: Aug 1, Sep 5, Nov 4, 2011)
CBio said that in October, it published research conducted in an animal model that indicated XToll could have utility in the treatment of systemic lupus erythematosis a disease in which the body's immune system attacks all organs and could result in death.
The company said that about five million people worldwide had lupus and the global market was expected to reach $2.5 billion a year by 2017.
CBio fell 4.4 cents or 32.6 percent to 9.1 cents with 4.6 million shares traded.

ALCHEMIA

Alchemia said its share purchase plan at 24 cents a share had applications for $12 million in shares but was capped at $5 million.
The share plan followed last month's $15 million placement (BD: Nov 7, 2011).
Alchemia was up 2.5 cents or 8.6 percent to 31.5 cents with 1.2 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies has appointed Dr Mel Bridges as chairman replacing Sid Hack.
Genetic Technologies said Dr Bridges had more than 30 years' experience in the diagnostic and healthcare industries.
The company said Dr Bridges founded and managed diagnostics, therapeutics and medical device businesses, co-founding Panbio and Impedimed.
Genetic Technologies said that Dr Bridges was the chairman or a director of companies including Alchemia, Impedimed, Campbell Brothers, Benitec, Peptech (later Arana) and Domantis.
"Genetic Technologies has been one of the most compelling turnaround stories on the ASX and Nasdaq this year and looks especially poised for growth as we head into 2012," Dr Bridges said. "The company's progress to commercialization and recent US expansion is a credit to the existing board and management."
Genetic Technologies said departing chairman Sid Hack retired having served as a director since November 2008 and as chairman since November 2009.
Genetic Technologies fell one cent or 7.7 percent to 12 cents.

PRANA BIOTECHNOLOGY

Prana says the Journal of Biological Chemistry has published research "that provides strong validation of [its] strategy to treat neurodegenerative diseases".

Prana said the authors, led by Massachusetts Institute of Technology professor of biology Prof Susan Lindquist, discussed the broad therapeutic potential of 8-hydroxyquinolines, which were identified as being protective against the neuro-toxic proteins that cause disease in disorders such as Alzheimer's, Huntington's, Parkinson's and other neurodegenerative disorders.

The company said that its PBT2 was a specific type of 8-hydroxyquinolines or 8-OHQ designed and selected for enhanced efficacy and tolerability as a therapeutic intervention and the authors cited the positive therapeutic results of PBT2.

Prana said the paper, entitled 'Different 8-OHQ's Protect Models of TDP-43, alpha-synuclein and Polyglutamine Proteotoxicity through Distinct Mechanisms' described the identification of selected 8-OHQ compounds, from 200,000 tested, as protective against neuro-degeneration due to their influence on metal homeostasis in the brain. The article is at: http://www.jbc.org/content/early/2011/12/06/jbc.M111.308668.full.pdf+html.

Prana quoted the authors saying that the "ability of different 8-OHQ's to impinge on diverse proteotoxicities, or neurotoxicity caused by overabundant mutant or misfolded proteins, further links metal homeostasis to neurodegenerative diseases including Alzheimer's, Parkinson's and Huntington's diseases".

The company said the authors made the point that subtle changes to the chemical backbone of this class of drug could permit rational drug design for different disease indications.

Prana said that PBT2 was selected on the basis of unique chemical modifications designed to confer subtle but effective redistribution of metals in the brain, ability to prevent amyloid induced neurotoxicity and neuro-regenerative effects.

The company said its 800-strong novel compound library had yielded PBT2 as a phase II candidate for Alzheimer's and Huntington's disease, PBT434 for Parkinson's disease and PBT519 for brain cancer.

Prana's head of research Prof Robert Cherny said the report was "a landmark paper supporting Prana's therapeutic strategy".

"The findings by the authors that precise chemical modifications to the 8-OHQ compounds altered metal binding and metal transport properties resulting in various mechanisms of action supports findings by Prana scientists that the therapeutic benefits of selected members of this class of compound arise from a unique combination of metal recovery and redistribution," Prof Cherny said.

Prana fell half a cent or 3.2 percent to 15 cents.

IMMURON

Immuron says it has a partnership with Dana-Farber Cancer Institute and the Children's Hospital Boston to trial its bovine colostrum to reduce cancer radiation side effects,

Immuron said the Hospital was the primary paediatric teaching hospital of Harvard Medical School and the research on specific preparations of its antibody-rich colostrum product would involve people undergoing radiation to reduce treatment side-effects.

The company said the agreement extended to research using its technology to treat newborn lung inflammation and early data generated from animal studies had been encouraging to date, providing impetus for the research.

The company said it retained the rights to any data generated relating to its technology.

Immuron was unchanged at four cents.

HATCHTECH

Hatchtech says its phase IIb clinical trial in subjects with head lice infestation has shown its head lice ovicide Deovo is safe and effective following a single application.

Hatchtech said the phase IIb trial evaluated efficacy, safety and tolerability at two dose levels of a single application of Deovo compared to vehicle in 140 healthy subjects with head lice infestation, two years of age and older, at two US study centers.

The company said that the primary efficacy results demonstrated a statistically significant ($p < 0.001$) and clinically relevant outcome in both the 0.74 percent weight/volume (85.7% treatment success) and 0.37 percent weight/volume (67.4% treatment success) treatment groups compared to the vehicle control group (23.4% clearance).

Hatchtech said that treatment success was defined as subjects who were lice-free 14 days following a single 10-minute treatment with Deovo and no serious adverse events were reported in any of the three groups.

Hatchtech founder and chief scientific officer Prof Vern Bowles said the results built on “an extensive body of preclinical and clinical data that have confirmed the effectiveness of a single 10-minute treatment of Deovo against both lice, lousicidal activity, and more importantly their eggs or nits, ovicidal activity.

“Deovo is the only known lousicidal and ovicidal agent requiring a single application for effective treatment,” Prof Bowles said.

“An outcome of essentially nine of 10 patients being cleared of their lice infestation is an outstanding result,” Prof Bowles said.

Hatchtech said that Deovo was a topical formulation of an inhibitor of metalloproteinases that were key to biological processes involved in egg development and in survival of the crawling lice.

Hatchtech chief executive officer Tim Waugh said it was “very promising news for the many parents and children who constantly face the challenge of head lice outbreaks”.

“There is currently no effective product available offering the ease and convenience of a single application regimen.” Mr Waugh said.

Hatchtech is a private company

VIRALYTICS

Viralytics says it has institutional review board approval from the Mary Crowley Cancer Research Center, in Dallas, Texas for its phase II Cavatak melanoma trial.

Viralytics said the trial would comprise up to 63 patients with 54 evaluable and was a single arm intra-tumoral trial, injecting Cavatak (Coxsackievirus A21) into multiple tumors on up to 10 separate occasions over an 18 week period, with a primary endpoint of immune-related progression-free survival at six months.

Viralytics was up one cent or 2.8 percent to 37 cents.

PROBIOMICS, HUNTER IMMUNOLOGY

Hunter Immunology says its independent directors unanimously recommend the acceptance of the Probiomics takeover offers in the absence of a superior proposal.

Hunter said its directors were chairman Ian Mutton, managing director David Radford, Glenn Crisp, Dr Jeremy Curnock Cook and Dr Doug Wilson.

Probiomics is offering nine of its shares and options for each Hunter share and option in what Biotech Daily believes is effectively a reverse takeover (BD: Dec 14, 2011).

Hunter is a public unlisted company

Probiomics was untraded at one cent.

HEALTHLINX

Healthlinx says that data from 742 samples has shown its Ovplex ovarian cancer test to be superior to CA125, enabling the closing of recruitment by April 2012.
Healthlinx said the analysis of the showed “excellent interim results from parts one and two of the trial already analyzed”.
The company said the data comprised a sample set with 222 women with malignant epithelial ovarian cancer, 53 women with confirmed borderline ovarian tumors, 223 women with benign gynecological conditions and 244 apparently healthy controls.
Healthlinx managing director Nick Gatsios said the company expected to reach the 1150 samples it had wanted in time for the results to be reported by the middle of 2012.
The company said that the Ovplex multi-marker test which includes the current industry standard of CA125 with other biomakers for ovarian cancer was compared with CA125 alone and “the increased diagnostic efficiency was apparent for all patients groups within the sample cohort”.
Healthlinx said the overall diagnostic power of the Ovplex test compared with CA125 was significantly better, with p values ranging from 0.035 to 0.003, over a wide range of threshold values.
The company did not publish sensitivity and specificity data, identifying the numbers of false positives as well as false negatives.
Healthlinx chief scientific officer Dr Dominic Autelitano said the interim analysis was “very encouraging and shows a significant advantage of the multimarker test over CA125 alone for correctly classifying a broad range of patients presenting with benign, borderline tumors and early stage malignant tumors”.
“The McNemar’s analysis focuses only on discordant results between the two tests and so it is very pleasing to see a positive result in this interim sample set,” Dr Autelitano said.
Mr Gatsios said company’s focus was to obtain regulatory approvals in key markets such as the US, China and South Korea and “any additional studies will be to satisfy regulatory requirements in respective jurisdictions”.
The company said it would submit the data to a peer-reviewed journal for publication.
Healthlinx was up 0.1 cents or 8.3 percent to 1.3 cents with 21.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says biotechnology consultancy Afandin has been granted a six month extension to its initial six month period to commercialize ATL1101.
Antisense said that ATL1101 was a second generation antisense inhibitor of insulin-like growth factor 1 receptor (IGF-IR), which had shown potent activity in laboratory studies, including in human cancer cells and drugs targeting IGF-IR were designed to slow down tumor growth and make tumor cells more susceptible to cell death.
The company said that the Afansin option to a licence to develop and commercialize ATL1101 was subject to Afandin securing suitable funding for the program.
Antisense said that Afandin had reported that it has made significant progress in attracting interest in the further development of ATL1101 and was in discussions with a number of corporate and investor groups, some of which we undertaking due diligence on ATL1101.
Antisense chief executive officer Mark Diamond said that “given the reported interest that Afandin has generated in what has been a difficult investment market over the last six months, we believe that it is reasonable to allow Afandin an extension period in order to advance discussions with parties interested in the further development of ATL1101”.
Antisense fell 0.2 cents or 6.9 percent to 2.7 cents with 23.7 million shares traded.

LIFE SCIENCES QUEENSLAND

Life Sciences Queensland says its inaugural board will be chaired by the founder of Ausbiotech Dr Peter Riddles the director of the Vicibio consultancy.

The directors of Life Sciences Queensland are Ernst & Young assurance Winna Brown, the director of the Australian Institute for Bioengineering and Nanotechnology Prof Peter Gray, Queensland University of Technology research and development manager Michael McArdle and Alchemia chief executive officer Dr Peter Smith.

Life Sciences Queensland said it was "the representative industry body for the Queensland life sciences industry" established with the support of 14 key stakeholders and the Queensland Government.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says Merck Sharp & Dohme licencing and external research director Dr Phil Kearney has been elected to the board as a nominated member.

The Network said Dr Kearney had represented Merck Sharp and Dohme as a member of the Bio-Melbourne Network since 2007.

The Network said that the Walter and Eliza Hall Institute general manager Maureen O'Keefe joined the board in August 2011.

The Network said Ms O'Keefe and Dr Kearney replace Dr Andy Gearing and Niall Byrne.

NUSEP

Nusep says that University of Newcastle's Prof John Aitken, the developer of its Spermsep technology has won the International Congress of Animal Reproduction EUR50,000 ($A65,351) Simmet Prize.

Nusep was up two cents or 20 percent to 12 cents with 12,400 shares traded.

AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION

The Australian Securities and Investments Commission says former company director, Simon Finnigan, 48, has been sentenced to 10 years gaol.

ASIC said Mr Finnigan of Potts Point, New South Wales, appeared in the Downing Centre District Court after pleading guilty to nine charges of dishonest conduct relating to a financial product or a financial service totaling $1.8 million.

ASIC said Mr Finnigan raised funds from nine investors between January 2003 and April 2007 through his companies Financial Partners Pty Ltd, Venture Capital Management Pty Ltd and Biotech Solutions Pty Ltd, none of which held an Australian financial services licence and are presently in liquidation.

Last year when Mr Finnigan was charged an ASIC spokeswoman told Biotech Daily that it was believed that no money was invested in biotechnology companies (BD: Nov 10 2010).