Biotech Daily

Friday December 14, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH FLAT: PRIMA UP 10%, PSIVIDA DOWN 7%**

*** BIONOMICS NAMES ALPHA-7 BNC375 FOR ALZHEIMER'S DISEASE**

*** BIOTRON COMPLETES PHASE I/II HIV TREATMENT**

*** MAYNE BUYS GSK'S KAPANOL OPIOID FOR $14m; PLACEMENT, PLAN**

*** DR PHILLIP COMANS REPLACES BIOXYNE CEO DAVID RADFORD**

*** AVEXA AGM DEFEATS DIRECTOR; 47% SHUN ALABAMA COAL MINE**

*** COMMONWEALTH DIRECTOR OF PUBLIC PROSECUTIONS v JM**

*** IDT LOSES M-D DR ROBYN ELLIOTT**

MARKET REPORT

The Australian stock market was even, up 0.01 percent on Friday December 14, 2012 with the S&P ASX 200 up 0.3 points to 4,583.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and nine were untraded. All three Big Caps fell.

Prima was the best, up one cent or 9.5 percent to 11.5 cents with 2.5 million shares traded.

Antisense climbed 8.3 percent; Benitec was up 7.1 percent; Anteo rose 5.3 percent; Genetic Technologies and Sunshine Heart were up more than three percent; GI Dynamics, Optiscan, Patrys and Prana rose more than two percent; with Sirtex and Universal Biosensors up more than one percent.

Psivida led the falls, down 10 cents or 7.4 percent to $1.25 with 17,270 shares traded.

Impedimed and Phosphagenics lost more than six percent; Acrux and Bioniche were down more than five percent; Avita and Tissue Therapies fell four percent or more; Clinuvel, Pharmaxis and Reva shed more than two percent; Mesoblast, QRX and Resmed were down more than one percent; with Cochlear, CSL and Starpharma down by less than one percent.

BIONOMICS

Bionomics says that following validation in preclinical models of memory deficit it has nominated BNC375 as its drug candidate for Alzheimer's disease.
Bionomics said that it was preparing for both clinical trials and strategic partnering of BNC375.
The company said BNC375 was a positive allosteric modulator of the alpha-7 nicotinic acetylcholine receptor (alpha-7 nAChR), an important target for the improvement of memory and learning deficits that occur in illnesses like Alzheimer's disease.
In October, Bionomics presented two posters showing the alpha-7 compounds outperformed benchmark compounds including Pfizer's donepezil, marketed as Aricept, that reported $US2.5 billion in sales in 2011 (BD: Oct 16, 2012).
Bionomics said it would begin manufacturing scale-up and formal toxicology studies with the objective of filing an investigational new drug application with the US Food and Drug Administration and further enhanced the licencing package around BNC375.
The company said BNC375 was effective across a panel of animal models of impaired learning and memory and to date had shown no signs of side-effects.
Bionomics said BNC375 had a rapid onset of action combined with a high degree of selectivity; it modulated alpha-7 nAChR without causing side-effects or lack of response due to receptor desensitization; preserved normal signaling patterns of the receptor; there was no potential for development of tolerance; and was suitable for concomitant use with other medicines in Alzheimer's disease.
Bionomics chief executive officer Dr Deborah Rathjen said the company was "at the forefront of a new therapeutic approach in treating Alzheimer's disease".
"The alpha-7 nicotinic acetylcholine receptor is a highly promising target for treatment of memory impairment associated with Alzheimer's disease, which contrasts with the historical focus on [amyloid beta] in the search for new therapies," Dr Rathjen said.
"A new Alzheimer's drug candidate is a valuable addition to our drug development pipeline and caps off a productive year for Bionomics that includes the $US345 million deal on the BNC210 anxiety drug candidate with Ironwood Pharmaceuticals, a new BNC105 phase II clinical program targeting ovarian cancer and the acquisition of highly promising California-based cancer stem cell company Eclipse Therapeutics," Dr Rathjen said.
Bionomics said the estimated worldwide costs of dementia, was $604 billion with an estimated 35.6 million people affected by dementia in 2010 and expected to double every 20 years reaching 65.7 million people in 2030 and 115.4 million people in 2050.
Bionomics was unchanged at 35 cents.

BIOTRON

Biotron says it has completed the clinical stage of its 24-patient phase Ib/IIa proof-of-concept human trial of BIT225 for HIV.
Biotron said the placebo-controlled, double-blinded study was undertaken at an international clinical trial unit in Bangkok, Thailand.
In October, Biotron reported delays in recruiting patients to the trial (BD: Oct 11, 2102).
Today, the company said patients enrolled in the trial were HIV-positive, with high levels of virus and good CD4 T cell counts and had not previously received treatment with anti-retroviral drugs.
Biotron said that patients received either 300mg BIT225 twice daily or placebo for a period of 10 days.
The company said that preliminary data was expected by April 2013.
Biotron was up one cent or 9.1 percent to 12 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has a binding agreement with Glaxosmithkline to acquire the oral opioid Kapanol and related assets in Australia for $14 million.

Mayne said it would acquire the Kapanol trademark, marketing authorizations, product dossier, technical data and product inventory.

The company said that the existing licence arrangement between Mayne and Glaxosmithkline would be amended so that Mayne acquired the rights to sell Kapanol in Australia.

Mayne said it would pay $10,125,000 upfront and up to $500,000 for inventory at completion of the acquisition on February 1 2013 and $3,375,000 on February 1, 2014.

Mayne said that Kapanol was a modified release oral opioid used for the relief of chronic, moderate to severe pain.

A Mayne spokeswoman told Biotech Daily that it was sustained release morphine and came in 10mg, 20mg, 50mg and 100mg doses.

The company said Kapanol had 6 percent of the $90 million modified release oral opioid analgesic market, which was growing at five percent per annum driven by strong underlying fundamentals such as an ageing population, increasing incidence of cancer and increased use in non-malignant chronic pain.

Mayne said it originally developed Kapanol in the 1990s in collaboration with Glaxosmithkline and manufactured the product for Glaxosmithkline which distributed it in Australia and other markets.

The company said that for the 12 months to October 31, 2012, Kapanol generated gross sales of $5.5 million in Australia.

Mayne said the transaction did not effect its existing distribution arrangements with Glaxosmithkline for international markets.

Mayne chief executive officer Scott Richards said that Kapanol was “a natural bolt-on opportunity for Mayne Pharma enabling us to now market and distribute this product in Australia in addition to manufacturing it”.

“We know the product well and have been manufacturing the product for GSK for almost 20 years,” Mr Richards said.

“We are very attracted by the underlying fundamentals of the opioid analgesic market and see Kapanol as providing the foundation to establishing a specialty product franchise in Australia,” Mr Richards said.

“Kapanol provides us with the necessary scale to invest in a sales force which will reinvigorate sales of Kapanol and support our other existing products such as Astrix, Doryx, Eryc, and Magnoplasm, as well as positioning Mayne Pharma as a more attractive in-licensing partner for international specialty pharmaceutical companies and their products,” Mr Richards said.

Mayne said that prior to the acquisition of Kapanol, it was on track to achieve the earnings guidance for 2012-‘13 as stated at the time of the Metrics acquisition (BD: Oct 4, 2012).

Mayne said the acquisition was expected to be immediately additive to its adjusted net profit after tax and earnings per shares in its first full financial year to June 30, 2014.

Mayne said the acquisition would be funded by an $18.0 million placement to institutional and sophisticated investors at 29.5 cents a share, underwritten by Credit Suisse (Australia) and UBS AG Australia, expected to be settled on December 20, 2012.

The company said that a share purchase would allow shareholders at December 13, 2012, to subscribe for up to $10,000 in shares.

Mayne said it reserved its right to scale back applications if the plan exceeded $5.0 million.

Mayne was in a trading halt at 32 cents.

BIOXYNE

Bioxyne says former Hunter Immunology chief executive officer Dr Phillip Comans has replaced David Radford as chief executive officer, on an interim basis.

Bioxyne said that Mr Radford left the company by “mutual agreement” effective on December 12, 2012.

The company said Mr Radford would remain available to assist the company during the transition.

Bioxyne said Dr Comans had extensive global experience in the development and marketing of pharmaceutical products and was previously with Ciba-Geigy, now Novartis, and based in Switzerland for several years.

The company said he was previously the founding chief executive officer of Hunter Immunology and through its merger with Bioxyne and was a substantial shareholder.

Bioxyne said that Dr Comans held a Bachelor of Science from the University of Queensland, a Doctorate of Philosophy in neurobiology from the Australian National University and a Masters of Business Administration from the University of Reading Henley Business School.

Dr Comans is also the managing director of Mariposa Health, of which former Bioxyne chairman Ian Mutton is chairman and Bioxyne chairman Anthony Ho is a director.

Bioxyne said that Bioscience Managers (formerly Octa Phillip) managing director and former Bioxyne director Jeremy Curnock Cook, who was removed from the board in a spill in October (see below) had “consented to re-join the board”.

In October an Octa Phillip investment group attempt to replace the Bioxyne board narrowly failed with investors supporting the previous Hunter Immunology directors (BD: Oct 30, 2012).

Bioxyne said at that time that chairman Ian Mutton and chief executive officer David Radford were not removed as directors, while Octa Phillip executive Dr Jeremy Curnock Cook was removed and his colleague Dr Stewart James Washer failed to win election as a director, with Mr Ho elected a director and Glenn Crisp defeated as a director.

Mr Crisp was removed by the narrowest margin, with 51.04 percent in favor of the resolution and 48.96 percent against, with other votes about 53 percent to 47 percent against the Octa Phillip proposals. Director Dr Douglas Wilson resigned from the company before the vote (BD: Oct 25, 2012).

The meeting overlapped with Bioxyne’s announcement that the Adelaide-based Vaxine would buy its probiotics business for $3.4 million and the two companies would redo the phase II HI-164OV chronic obstructive pulmonary disease trial (BD: Sep 24, 2012).

Earlier this year Bioxyne lost 87.5 percent of its share price on the release of results from a 320-patient phase IIb trial showing that HI-164OV had not met its exacerbations of chronic obstructive pulmonary disease endpoints (BD: June 28, 2012).

In November, Bioxyne’s annual general meeting defeated the remuneration report, the election of Dr William Harrison and a placement capacity; chairman Ian Mutton resigned, and new director Mr Ho was appointed chairman (BD: Nov 29, 2012).

Bioxyne said at that time that the remuneration report was defeated by 62.91 percent to 37.09 percent with the other two resolutions were defeated by about 55 percent of the votes to 45 percent.

Bioxyne said that expenses and cash burn were reduced with the reduction of the previous board of six non-executive directors and one managing-director to the current board of three directors and a chief executive officer.

The company said the board comprised Mr Ho, Patrick Ford, Mr Curnock Cook and Dr Comans.

Bioxyne was untraded at two cents.

AVEXA

Avexa shareholders defeated the election of Dr Duncan Worthington and narrowly passed the proposal to go coal mining in Alabama.
The remuneration report was passed with 91.76 percent of votes in favor and 8.24 percent against and director Bruce Hewett was re-elected by a similar margin.
But investors defeated Dr Worthington with 195,524,764 votes (50.60%) against and 190,880,300 votes (49.40%) in favor.
The Alabama coal mine proposal was passed with 206,642,405 votes (53.47%) in favor and 179,828,346 votes (46.53%) against.
In the notice of meeting Avexa said the board did not support the election of Dr Worthington a shareholder in the company (BD: Nov 14, 2012).
The company's 2012 annual report said that Avexa had 847,688,779 shares on issue, meaning that the votes against the Alabama coal mine amounted to 21.2 percent of the company, sufficient to requisition extraordinary general meetings.
Avexa fell 0.1 cents or 4.8 percent to two cents.

COMMONWEALTH DIRECTOR OF PUBLIC PROSECUTIONS v JM

The High Court meeting in Melbourne has referred the matter of the Commonwealth Director of Public Prosecutions versus JM to an enlarged bench of the High Court.
An officer of the High Court of Australia told Biotech Daily that the enlarged bench of the Court was not likely to hear the matter before March 2013.
An officer of the Commonwealth Director of Public Prosecutions previously told Biotech Daily today that the matter related to "the meaning of an artificial price" in relation to Section 1041A of the Corporations Act and the CDPP had sought leave to appeal the decision to the High Court.

IDT AUSTRALIA

IDT Australia says managing director Dr Robyn Elliott will resign effective from February 28, 2013.
IDT said that Dr Elliott had been with the company for 18 years, with five years as managing director.
Chairman Dr Graeme Blackman said the directors would begin a search for a suitable replacement.
IDT fell half a cent or 2.1 percent to 23 cents.