Biotech Daily

Friday November 9, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTEO UP 6%, PRANA DOWN 10%**

*** ELI LILLY AXIRON SALES FALL HITS ACRUX PRICE**

*** BIOTA TAKES 10.5k INVESTORS TO NASDAQ**

*** BIOTRON BEGINS PHASE II BIT225 TRIAL FOR HIV WITH HEPATITIS C**

*** BPH'S CORTICAL DYNAMICS BRAIN RESPONSE TRIAL CLOSES**

*** CYCLOPHARM FIGHTING FUND, US TRIAL 1-FOR-4 RIGHTS ISSUE**

*** AUSTRALIAN ETHICAL REDUCES TO 5.8% IN NEUREN**

*** MAYNE PHARMA 16.8% AGM DISSENT AGAINST CHAIR ROGER CORBETT**

*** PRANA AGM FOR 9m DIRECTORS OPTIONS**

*** WEHI'S PROF JERRY ADAMS WINS AAS MACFARLANE BURNET MEDAL**

*** PHARMAUST LOSES MINING DIRECTOR GREG CUNNOLD**

MARKET REPORT

The Australian stock market fell 0.49 percent on Friday November 9, 2012 with the S&P ASX 200 down 21.8 points to 4,462.0 points.

Six of the Biotech Daily Top 40 stocks were up, 13 fell, 12 traded unchanged and nine were untraded.

Anteo was the best, up 0.4 cents or 6.35 percent to 6.7 cents with 368,379 shares traded. Phylogica climbed 4.55 percent; Sunshine Heart was up three percent; Clinuvel rose 2.8 percent; CSL, Mesoblast and Nanosonics were up more than one percent; with Cochlear up 0.5 percent.

Prana led the falls, down 2.5 cents or 9.8 percent to 23 cents with 881,809 shares traded. Reva lost 5.2 percent; Allied Health, Heartware, Universal Biosensors and Viralytics fell four percent or more; Prima was down 3.7 percent; Alchemia, Bionomics, Neuren and Patrys shed more than two percent; with Pharmaxis, Resmed and Sirtex down more than one percent.

ACRUX

Acrux has seen a 20 percent fall in its share price in the past month, following a similar rise, apparently on news that US sales of its Axiron testosterone replacement had fallen.

On October 26, 2012, Eli Lilly released its results for the three quarters to September 30, 2012, showing Axiron sales at $US16.3 million in the three months to March 31; $US17.7 million in the three months to June 30 and $US16.0 million in the three months to September 30, 2012.

Acrux chief financial officer Jon Pilcher told Biotech Daily that gross sales of Axiron in the market were expected to be about $US200 million per year and the treatment had about 13 percent of the total market share.

Mr Pilcher said that net sales were considerably lower with Eli Lilly providing rebates of about 65 percent to cover insurance costs while coverage was being organized.

Mr Pilcher said that one major insurer began coverage from June 2012 and another would do so from January 2013 and as the insurance increased the rebates would fall, providing a higher net sales figure and increased net-sales-related royalty payment to Acrux.

“The insurance position is improving all the time and other related measures mean that net sale value will increase from the fourth quarter,” Mr Pilcher said.

Mr Pilcher said that sales could be seasonal with the second and fourth quarters generally higher than the first and third quarters and that sales of two major competitors had not increased, with Androgel flat and Testim down.

Mr Pilcher said Acrux was continuing to pursue its patent claims through the US Patent and trademark Office and expected a resolution by April 2013 (BD: Jun 21, 2012).

In June, the US Patent and Trademark Office examiner raised objections to the Acrux underarm administration patent application, which was granted in Australia in September 2011 and allowed in New Zealand, with applications under examination in a number of other countries.

Acrux said at that time that the US examination process included a series of submissions by the company and responses from the USPTO and there was “nothing unusual about this type of objection”.

“It is not unusual to go through a process in a patent examination and you usually have a number of iterations of the application,” Mr Pilcher said in June.

Acrux closed unchanged at $2.99 with 1.1 million shares traded.

BIOTA PHARMACEUTICALS

Biota’s move to the Nasdaq, effective from tonight, has taken about 10,500 shareholders to off-shore ownership.

Biota chief financial officer Damian Lismore told Biotech Daily that at the start of the merger with Nabi Pharmaceuticals the company had about 12,000 shareholders and about 10,500 investors would move with the company to the Nasdaq (BD: Apr 23, Sep 18, Oct 30, 2012).

Mr Lismore said that at its peak during influenza scares, Biota had as many as 16,000 shareholders.

Lodge Partners analyst (and former Biotech Daily analyst) Marc Sinatra told Biotech Daily that when Biota Biopharmaceuticals begins trading on the Nasdaq tonight, he expected it to open at about $US4.90, which allowing for the share consolidation and the share distribution is equivalent to 59 Australian cents.

There had been speculation, attributed to enthusiastic but mathematically challenged shareholders, that Biota would open above the equivalent of $A1.00.

Biota last traded on the ASX on October 30, 2012 at 57 cents.

BIOTRON

Biotron says it has begun a phase II human trial of BIT225 in patients that are co-infected with both HIV and hepatitis C virus.

Biotron said that 12 HIV and hepatitis C-positive patients would receive 28 days treatment with 300mg of BIT225 twice daily, in combination with interferon and ribavirin, the standard approved treatment for hepatitis C.

The company said that at the conclusion of the treatment with BIT225 they would continue to receive interferon and ribavirin as per standard treatment guidelines for up to 48 weeks in total.

Biotron said that the patients would be interferon and ribavirin-näive, but at the time of inclusion into the trial would be on antiretroviral drugs, with HIV levels below the level of detection.

The company said the trial at the Siriraj Hospital in Bangkok, Thailand, was currently recruiting patients.

Biotron managing director Dr Michelle Miller said that “while BIT225 appears to target both HIV and HCV, in this particular study we are focusing on the HCV aspect of the disease in these dual-infected patients”.

“The pharmaceutical industry and international regulatory authorities are focused on new treatments in this difficult-to-treat population,” Dr Miller said.

“Even though HIV will be below the level of detection, the virus will be present in the underlying reservoirs,” Dr Miller said.

“BIT225 is being assessed for its ability to target HIV in these reservoir cells in a separate phase Ib/IIa clinical trial that is currently in progress,” Dr Miller said.

Biotron said that the trial was open-label and would include patients infected with hepatitis C genotypes 1, 2 and 3.

The company said that the proportion of patients infected with both HIV and hepatitis C was significant and the co-infected group had particular challenges to treatment with current therapies.

Biotron said that hepatitis C was a more serious disease in HIV-positive patients and was a leading cause of death in these patients, with up to 40 percent of HIV-positive patients in the US co-infected with hepatitis C.

Biotron said that BIT225 was “unique because of its dual anti-HIV and anti-hepatitis C activity”.

The company said that the trial’s aim was to generate the first efficacy data in this specific population as well as providing detailed pharmacokinetic information on BIT225 in the presence of other anti-HIV drugs.

Biotron said that the trial was expected to generate safety and pharmacokinetic data with BIT225 in co-infected patients, as well as extend the efficacy data to other hepatitis C genotypes, including genotypes 2 and 3.

The company said that it had previously reported that in a 24 patient phase Ib/IIa clinical trial, treatment of hepatitis C genotype 1 patients with BIT225, in combination with interferon and ribavirin, resulted in 100 percent of patients having virus below the limit of detection after 48 weeks, in comparison with 75 percent of patients who received interferon and ribavirin (BD: Oct 11, 26, 2012).

Biotron said it expected to complete the trial by July, 2013.

Biotron was up one cent or eight percent to 13.5 cents.

BPH ENERGY, CORTICAL DYNAMICS

BPH Energy says 3.6 percent subsidiary Cortical Dynamics has completed recruitment for its Brain Anaesthesia Response monitoring system at Melbourne's St Vincent's Hospital.
BPH said the 20-patient trial was entitled 'Validation of the Brain Anaesthesia Response (BAR) Monitoring System during Anaesthesia for Cardiac Surgery: a Double-Blinded, Randomised, Controlled Trial using Two Different Doses of Fentanyl' (BD: Mar 15, 2012).
The company said that the trial was designed to detect varying levels of anaesthetic agents in an operating room environment where the presence of multiple sources of artifacts is known to interfere with electro-encephalogram recording.
BPH said that the trial was the first time the complete BAR monitoring system had been employed within the operating theatre.
Cortical Dynamics chief scientific officer Prof David Liley said the completion of the trial was "a significant milestone for Cortical, as it is the first hospital trial in which all components of the BAR monitoring approach have been used".
The company said the BAR monitoring system measured a patient's brain activity to indicate how deeply anaesthetized a patient was during surgery.
In June an attempt to raise $4 million for a Cortical Dynamics initial public offer was abandoned (BD: Jun 19, 2012).
BPH Energy fell 0.1 cents or 4.8 percent to two cents.

CYCLOPHARM

Cyclopharm expects to raise about $2.1 million through a fully underwritten one-for-four pro-rata renounceable rights issue at 18 cents a share.
Cyclopharm said that the rights issue was fully underwritten by CVC Managers and there would be a shortfall facility, for eligible shareholders to subscribe for additional shares.
The company said the funds were for the operating costs of Cyclopet, support the legal proceedings Cyclopet has commenced against the Australian Nuclear Science and Technology Organisation and to fund the commencement of the phase III Technegas clinical trial in the US (BD: Dec 13, 2011, Jun 28, 2012).
Cyclopharm said that "while the market for products manufactured by Cyclopet has been encouraging in 2012, competition from government owned enterprises requires additional capital to support this venture".
The company said that the US Food and Drug Administration approved clinical trial was expected to cost about $US4.0 million with $US800,000 expected to be spent within 12 months and the balance to be funded through a subsequent capital raising next year.
Cyclopharm said that the rights issue record date would be November 19, the offer booklet would be dispatched on November 23 and the closing date was December 7, 2012.
Cyclopharm was untraded at 17 cents.

NEUREN PHARMACEUTICALS

Australian Ethical Smaller Companies Trust has reduced its substantial shareholding in Neuren from 80,835,436 shares (6.99%) to 68,335,436 shares (5.78%).
Australian Ethical's substantial shareholder notice said it bought and sold shares between May 18 and October 24 2102, with two major sales at 3.4 cents and 3.77 cents a share.
In May, Australian Ethical increased its holding, buying 12,119,000 shares with the most recent acquisition 3,000,000 shares for $72,000 or 2.4 cents a share (BD: May 25, 2012).
Neuren fell 0.1 cents or 2.5 percent to 3.9 cents with 2.3 million shares traded.

MAYNE PHARMA

All Mayne Pharma annual general meeting resolutions were passed easily with the exception of significant dissent against the re-election of chairman Roger Corbett.
Mr Corbett's re-election was supported by 137,528,639 proxy votes (83.2%) with 27,752,312 proxy votes (16.3%) against.
The company's most recent Appendix 3B said that Mayne Pharma had 349,577,657 shares on issue, meaning that the votes against Mr Corbett amounted to 7.9 percent of the company, sufficient to requisition extraordinary general meetings.
Directors Ron Best and Phillip Hodges were re-elected with more than 160 million proxy votes in favor and more than four million proxy votes against.
The remuneration report was passed with 125.5 million proxy votes (91.7%) in favor and 11.4 million proxy votes (8.3%) against.
Mayne Pharma was up one cent or 3.7 percent to 28 cents.

PRANA BIOTECHNOLOGY

Prana's annual general meeting will vote to issue directors nine million options exercisable at 50 percent above the market price on the day of issue, by December 13, 2017.
The company said the resolutions included 4,000,000 options to executive chairman Geoffrey Kempler and 1,000,000 options each to directors Peter Marks, Richard Revelins, Brian Meltzer, Lawrence Gozlan and Dr George Mihaly.
The company's notice of meeting said it would also seek shareholder approval for the remuneration report, two prior placements and the re-election of Dr Mihaly.
The meeting will be held at Giorgios Restaurant Function Room, 1235 High Street, Armadale, Victoria, on December 12, 2012 at 9.30am (AEDT).
Prana fell 2.5 cents or 9.8 percent to 23 cents.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says Prof Jerry Adams has won the Australian Academy of Science's highest biological sciences award, the Macfarlane Burnet Medal.
WEHI said the award recognized Prof Adams' "longstanding research achievements in cancer genetics and cell death".
The Institute said that Prof Adams was the joint head of its molecular genetics of cancer division and began his studies of cancer-causing genes in the early 1980s.
WEHI said that in 1988, Prof Adams, Prof Suzanne Cory and (then Ph D student) Prof David Vaux discovered that the Bcl-2 gene drove cells towards becoming cancerous by making them long-lived.
The Institute said that the discovery that cell death, known as apoptosis, was controlled by proteins such as Bcl-2 launched a new field of cancer research, with Bcl-2 and related proteins proving to be important not only in cancer development but also in resistance to cancer therapies.
"Our findings on the control of cell death have proven to have important implications for normal development and physiology, as well as for cancer and other diseases," Prof Adams said. "The award really recognizes the achievements of many scientists at the institute over the past three decades".
WEHI director Prof Doug Hilton said that along with Prof Adams' "many important discoveries in cancer and cell death research … he has mentored a new generation of outstanding researchers".

PHARMAUST

Pharmaust says that director Greg Cunnold has resigned as a director effective from the end of yesterday's annual general meeting.

Pharmaust said Mr Cunnold had been a valuable contributor as a technical director specifically with the Luke River Project.

In September the company executed a share sale deed for its wholly-owned subsidiary Pela Resources saying it would return to its Epichem focus (BD: Sep 10, 2012).

Pharmaust was untraded at one cent.