Biotech Daily

Thursday April 4, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BENITEC UP 15%, OSPREY DOWN 11%**

*** STARPHARMA TO TAKE VIVAGEL TO PHASE III VAGINOSIS TRIAL**

*** BENITEC TRIBETARNA IMPROVES LUNG CANCER TREATMENT IN MICE**

*** ALCHEMIA SELLS FONDAPARINUX IN INDIA, PATENT EXTENSIONS**

*** PRANA RECEIVES $2.5m FEDERAL R&D TAX REFUND**

*** AUSTRALIAN ETHICAL REDUCES BELOW 5% IN NEUREN**

*** ASX RELEASES 8m BIOXYNE ESCROW SHARES**

*** DAVID ZOHAR REDUCES, DILUTED TO 21% OF ACTINOGEN**

*** ELLEX R&D MANAGER MALCOLM PLUNKETT RESIGNS AS A DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.89 percent on Thursday April 4, 2013 with the S&P ASX 200 down 44.2 points to 4,913.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and four were untraded.

Benitec was the best, up 0.2 cents or 15.4 percent to 1.5 cents with 31.8 million shares traded.

Genetic Technologies climbed 7.1 percent; Starpharma closed up 4.6 percent (see below); QRX was up 3.15 percent; Ellex, Prana and Prima rose more than two percent; Bionomics and Circadian were up more than one percent; with Cochlear up 0.2 percent.

Osprey led the falls, down five cents or 10.9 percent to 41 cents with 25,000 shares traded.

Allied Health and Patrys lost more than six percent; Anteo, Clinuvel and Phylogica fell more than five percent; Phosphagenics fell four percent; Cellmid, Psivida and Viralytics were down more than three percent; Optiscan and Neuren shed more than two percent; Alchemia, Medical Developments, Pharmaxis and Sirtex were down more than one percent; with Acrux, CSL, Heartware, Mesoblast and Resmed down by less than one percent.

STARPHARMA

Starpharma chief executive officer Dr Jackie Fairley says the company “fully intends to go to phase III trials on the back of the results” of the phase II Vivagel bacterial vaginosis trial.
The company said the phase II trial did not meet its primary endpoint with one percent Vivagel “clinically” but not statistically significant ($p = 0.0588$) at preventing recurrence of bacterial vaginosis as compared to placebo (BD: Apr 3, 2013).
Dr Fairley said told an investor teleconference that Vivagel should be considered a chronic use product for bacterial vaginosis, like anti-hypertensive drugs for blood pressure or lipid lowering drugs for high cholesterol and potential commercial partners were interested in Vivagel as a chronic use drug.
Asked the cost to consumers, Dr Fairley said the market was worth “north of $1 billion” but did not disclose a potential cost of the product to consumers.
Dr Fairley said that she was not surprised that the three percent Vivagel group had similar rates of recurrence to placebo, because bacterial vaginosis was a combination of organisms and the stronger dose was potentially killing “good bacterial like lactobacillus as well as bad bacteria like gardnerella” whereas the one percent dose was acting more on the gardnerella.
“We fully intend to go to phase III trials on the back of the results,” Dr Fairley said.
Dr Fairly said she was “highly confident” that a phase III trial of Vivagel for prevention of recurrence of bacterial vaginosis would be successful.
Starpharma jumped as much was 28.5 cents or 26.3 percent to $1.37 closing up five cents or 4.6 percent at $1.135 with 1.8 million shares traded.

BENITEC BIOPHARMA

Benitec says that gene silencing significantly increases the effectiveness of chemotherapy in a mouse model of non-small cell lung cancer (NSCLC).
Benitec said that research by the University of New South Wales Children’s Cancer Institute showed that mice treated with a combination of its DNA-directed RNA interference (ddRNAi) silencing molecule targeting the beta III tubulin gene Tribetarna and chemotherapy survived significantly longer than those treated with chemotherapy alone.
Principal investigator Prof Maria Kavallaris said that human lung cancers used in the model were strongly resistant to chemotherapy, but “we were able to demonstrate that intravenous administration of Tribetarna, in combination with cisplatin, a standard chemotherapy drug, was able to significantly [$p < 0.02$] extend the survival of the animals when compared to control animals”.
Benitec said that after 60 days, 50 percent of the mice with the active ddRNAi construct were alive compared to 14 percent in the control group.
“This is the first study to demonstrate that a ddRNAi approach can potently silence beta III tubulin expression and increase chemo-sensitivity in vivo, highlighting this as a potentially very promising treatment strategy for drug resistant NSCLC,” Prof Kavallaris said.
Benitec chief executive officer Dr Peter French said that advanced stage lung cancer had a very poor prognosis and genetic therapy using ddRNAi to silence the beta III tubulin gene was a novel approach to overcoming resistance.
Dr French said previous early-phase trials had difficulty delivering therapeutic molecules, but the program overcame this with a polyethylenimine transfection reagent, delivering Tribetarna to lung tumor cells with high specificity and no apparent adverse effects.
Benitec said it was involved with US clinical research organization Ground Zero Pharmaceuticals to prepare documentation for discussions with regulatory authorities.
Benitec was up 0.2 cents or 15.4 percent to 1.5 cents with 31.8 million shares traded.

ALCHEMIA

Alchemia says partner Dr Reddy's Laboratories has launched its generic anti-coagulant fondaparinux in India.

Alchemia said India was the first country outside the US to sell its injectable fondaparinux, a bioequivalent generic version of Glaxosmithkline's Arixtra.

The company said the product would sold and marketed by Dr Reddy's as a branded generic under the name Fondared to prevent and treat deep vein thrombosis.

Alchemia said that Fondared will be available in pre-filled color-coded single dose syringes (2.5mg/0.5mL).

The company said Arixtra had Indian sales of about $US2.7 million for the year ended December 31, 2012 and it expected to receive 25 percent of all profits from sales in India, with the same economics from sales to any further territories outside the US.

Alchemia chief executive officer Charles Walker said the India launch was the first outside the US and the company looked forward to fondaparinux's expansion into additional territories.

The company said that fondaparinux US net sales were $12.3 million in the three months to December 31, 2012, with its profit share $3.4 million, 90 percent higher than the previous quarter.

Alchemia said that Dr Reddy's filed a regulatory submission in Europe for market approval for generic fondaparinux in April, 2012.

Separately, Alchemia said that the US Patent and Trademark Office had granted a further patent term adjustment both a key Hyact patent and a fondaparinux manufacturing patent.

The company said that a review of a recently granted US patent, entitled 'Hyaluronan-Chemotherapeutic agent formulations for the treatment of colon cancer', which was "critical to Alchemia's platform oncology technology" resulted in the patent term being adjusted by an additional 504 days.

Alchemia said the patent provided protection for the use of the company's proprietary drug HA-irinotecan in the treatment of metastatic colorectal cancer and protected the Hyact drug delivery platform as applied to a range of other anti-cancer drugs when used to treat drug resistant colorectal cancer.

The company said that based on a patent term adjustment issued by the US Patent and Trademark Office, the patent term extended to March 24, 2025, subject to any terminal disclaimers or restrictions imposed by the USPTO.

Alchemia said that it had been granted a US patent entitled 'Synthetic Heparin Disaccharides' which was part of a suite of patents securing the method of synthesis of intermediates for the manufacture of fondaparinux sodium and the new patent had been granted to September 2022 with the parent patent entitled to a further 260 days of patent term adjustment beyond September 2022.

Alchemia fell half a cent or 1.5 percent to 32.5 cents.

PRANA BIOTECHNOLOGY

Prana says it has received $2.5 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Prana said it expected to receive a total of $5.8 million for research and development expenditure on PBT2 for Alzheimer's disease and Huntington's disease in the 2011-'12 and 2012-'13 financial years.

Prana was up half a cent or 2.4 percent to 21.5 cents.

NEUREN PHARMACEUTICALS

Australian Ethical Smaller Companies Trust has reduced its substantial shareholding in Neuren from 68,335,436 shares (5.78%) to 58,335,436 shares (4.93%).
Australian Ethical's substantial shareholder notice said it sold 10,000,000 shares for $335,000 or 3.35 cents a share on March 20 and 21, 2013.
In 2012, 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 2.9 percent to 3.3 cents.

BIOXYNE

Bioxyne says that 7,987,199 shares were released from ASX escrow on March 27, 2013.
Bioxyne said that 14,999,046 shares would remain in escrow until April 4, 2014.
The company said it had a total of 163,059,587 shares on issue with 148,060,541 available for trading.
Bioxyne was up 0.1 cents or 6.7 percent to 1.6 cents.

ACTINOGEN

Actinogen executive director David Zohar has again reduced his substantial holding and been diluted through a share rights issue.
Mr Zohar said in a substantial shareholding that he had reduced and been diluted from 20,675,449 shares (23.62%) to 18,725,449 shares (20.98%).
Last year, David Zohar Associates reduced and was diluted from 20,875,449 shares (25.94%) to 20,675,449 shares (23.62%) (BD: May 23, 2012).
Actinogen was untraded at 2.1 cents.

ELLEX MEDICAL LASERS

Ellex says that Malcolm Plunkett has resigned as a director of the company but continues as the manager of research and development.
Ellex said that throughout his four and a half year tenure as a director, Mr Plunkett remained a full-time executive responsible for research and development and made a significant contribution to the business.
The company said Mr Plunkett continued in his executive role concentrating on bringing the 2RT medical laser project to market and managing the research portfolio.
Ellex was up half a cent or 2.6 percent to 19.5 cents.