Biotech Daily

Tuesday July 5, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 25%; PSIVIDA DOWN 8.5%**

*** AFANDIN TO FUND ANTISENSE ATL1101 PROSTATE CANCER TRIAL**

*** MAYNE PHARMA PROFIT WARNING, FDA DORYX REJECTION HIT PRICE**

*** PHARMAXIS REQUESTS FORMAL EUROPEAN RE-EXAMINATION**

*** BIONICHE TO BUY PLASVACC HORSE, DOG PLASMA BUSINESS**

*** BIO-MELBOURNE: REIMBURSEMENT FROM BREAKFAST TO WORKSHOP**

*** STIRLING TAKES BOARD, CEO, FUNDING HALT TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 0.27 percent on Tuesday July 5, 2011 with the S&P ASX 200 down 12.6 points to 4598.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and eight were untraded. All three Big Caps fell.

Antisense was best, up as much as 50 percent to 1.2 cents before closing up 0.2 cents or 25 percent at one cent with 98.8 million shares traded, followed by Bionomics up five cents or 9.1 percent to 60 cents with 132,861 shares traded.

Genetic Technologies climbed 7.1 percent; Genera was up 5.6 percent; Pharmaxis was up 4.7 percent; Alchemia, Nanosonics, Phylogica and Prana rose more than two percent; with Circadian up 1.7 percent.

Psivida led the falls, down 34 cents or 8.5 percent to $3.66, with 132 shares traded, followed by Anteo down 5.4 percent to seven cents with 2.8 million shares traded.

Benitec lost 3.6 percent; Impedimed, Mesoblast and Patrys shed more than two percent; with CSL, Living Cell, QRX, Resmed, Tissue Therapies and Viralytics down more than one percent.

ANTISENSE THERAPEUTICS

Antisense and the private consultancy Afandin will collaborate to raise funds to take ATL1101 into phase I/II prostate cancer clinical trials.

Antisense said it had an agreement for an option to licence its antisense compound ATL1101 for cancer to Afandin Pty Ltd, a privately-owned Melbourne-based consultancy founded by Verva chairman and former Meditech chief executive officer Dr Ian Nisbet and former head of corporate development at Meditech, Metabolic and Xenome, Dr Anthony Filippis.

Antisense said that the Afandin option to licence ATL1101 to further develop and commercialize its cancer applications was subject to Afandin securing funding within six months and that funding would take ATL1101 into a phase I/II clinical trial in prostate cancer patients.

Dr Filippis told Biotech Daily that Afandin hoped to raise funds to cover the initial costs of clinical trials and would create a new company to hold the intellectual property and manage the trials.

Antisense chief executive officer Mark Diamond told Biotech Daily that Antisense would have “a significant equity position” in the new company if Afandin was able to raise the funds and licence ATL1101.

Dr Nisbet is also the former chief executive officer of Xenome, whose directors include Queensland Biotechnology Fund’s Dr Cherrell Hirst and GBS Venture’s Dr Andrew Baker and Dr Brigitte Smith.

Verva was spun-out from Chemgenex, which was also associated with GBS Ventures.

Antisense said that both Dr Nisbet and Dr Filippis were ”highly experienced biotechnology business executives with a strong track record in cancer drug development and commercialization”.

The company said ATL1101 targeted the insulin-like growth factor I receptor (IGF-IR) and had shown to suppress human prostate tumor growth in mice (BD: Oct 15, 2008).

Antisense said that IGF-IR inhibition was known to suppress the growth of a variety of tumors, making ATL1101 a potential treatment for a range of different cancer types.

The company said that if the required funds were raised and the option exercised to licence ATL1101, a new corporate entity would be created that would be co-owned by the two companies and managed by Afandin.

In return for the licence to ATL1101, Antisense would receive a significant equity stake in the new entity and will also receive a significant percentage of the commercialization benefits including a percentage of any future licencing income received and a percentage of the royalties on ATL1101 sales.

The company said the arrangement allowed for the further development of ATL1101 by a team experienced in oncology clinical drug development while providing non-dilutive funding for the project.

“The blocking of IGF-1R is an exciting approach for the treatment of cancer,” Dr Filippis said. “The team at Antisense Therapeutics has developed a high quality pre-clinical data package for ATL1101 and we look forward to the opportunity of progressing the drug into the clinic,” Dr Filippis said.

Mr Diamond said the deal allowed Antisense to focus its resources on its growth hormone receptor targeting drug ATL1103 which has moved into clinical development, while providing the potential to derive value from the ATL1101 asset”.

Antisense has previously held licencing discussions for ATL1101 but the unnamed company did not proceed to a licence (BD: Mar 18, 2011).

Antisense jumped as much as 50 percent to 1.2 cents but closed up 0.2 cents or 25 percent at one cent with 98.8 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma fell as much as 31.25 percent to 33 cents on news that it expects earnings to fall by about $3 million compared to last year's net profit after tax of $3,253,119.

Mayne Pharma said US Food and Drug Administration delays in approving a higher strength of Doryx had affected sales and the FDA had refused an application for the new strength, requiring further clinical trials.

Mayne Pharma chief executive officer Dr Roger Aston told Biotech Daily that Doryx or doxycycline was a broad-spectrum tetracycline antibiotic used against a wide variety of bacterial infections and the new version was for the new indication of Chlamydia.

In its media release Mayne said it expected revenue in the range of $49 million to $51 million and underlying operating earnings or earnings before interest, taxation, depreciation and amortization adjusted for any significant one-off items in the range of $8 million to $10 million for the year to June 30, 2011.

Dr Aston said in the media release that "unfavorable exchange rate movements have also had a significant impact reducing earnings by approximately $3 million year on year".

In 2010 the then Halcygen reported total revenue of $36,712,915, earnings before interest, taxation, depreciation and amortization of $12.2 million and net profit after tax of $3,253,119 (BD: Aug 31, 2010).

Dr Aston said that "repositioning the Doryx portfolio in preparation for the introduction of new dosage forms and the continued and unprecedented strength of the Australian dollar has meant the results are significantly less than the annualized [2009-'10] result."

Dr Aston said Doryx was the company's key proprietary product sold in the US market and sales were down 47 percent on the year to June 30, 2010, with the fall in sales "driven by the delay in FDA approval for new dosage forms and a contraction in pipeline inventories in the US as stocks of the current product were run down in preparation for the launch of the new dosage form by … US marketing and distribution partner, Warner Chilcott".

"Unfavorable exchange rate movements have also had a significant impact reducing earnings by approximately $3 million year on year," Dr Aston said.

Mayne said cash at June 30, 2011 was $5.9 million down from $13.4 million at December 31, 2010, due to the dividend payment of $1.5 million, $2.6 million in loan repayments and $6.5 million to Hospira for the acquisition of Mayne Pharma in November 2009.

Mayne said a $US10 million loan facility had been reduced to $US2.5 million and would be paid down completely by the end of 2011, making the company debt free.

The company said the results were subject to the completion accounting and audit.

Mayne said the FDA had told Warner Chilcott that its application for the new dose strength of Doryx had been rejected and the FDA had "indicated that the deficiencies in the submission could be addressed by undertaking an additional trial".

Mayne said it would provide more information on the next steps once they were finalized and would continue to sell the 150mg form of Doryx to Warner Chilcott.

Mayne said it owned of a US patent covering the Doryx formulation and with Warner Chilcott would vigorously defend its patent and take legal action against infringements.

The company also said it had met with the UK Medicines and Healthcare products Regulatory Agency on June 22, 2011 to discuss the regulator's questions on the marketing authorisation application for Subacap.

Late last year, Mayne submitted a European Union marketing authorization application for Subacap, formerly known as Suba-itraconazole for fungal infection (BD: Dec 17, 2010).

Mayne said that during the meeting the Agency "indicated that no additional clinical work would need to be conducted in order to respond to the questions", reinforcing that the regulatory strategy remains on track with expectations for approval by the end of 2011.

Mayne closed down eight cents or 16.7 percent at 40 cents with 5.6 million shares traded.

PHARMAXIS

Pharmaxis has formally requested the European Medicines Agency's Committee for Medicinal Products for Human Use re-examine its Bronchitol application for cystic fibrosis.
Pharmaxis said the request followed dialogue between the company and the European Medicines Agency and discussions with the company's external advisors.
The company said that at the July meeting of the Committee for Medicinal Products for Human Use (CHMP), two new rapporteurs would be appointed to lead the re-examination process.
Pharmaxis said that the new rapporteurs usually were one individual who voted for the approval of and one who voted against the approval of Bronchitol.
The company said it had the right to request that a scientific advisory group be established by the Committee, which would include clinicians and experts in the field of respiratory medicine, to assist with the re-examination process and to make a recommendation to the committee.
Pharmaxis said patient groups could also be invited to join the advisory group.
The company said that a change of label from the original marketing application may occur during the re-examination process.
Pharmaxis has previously said that adolescent data reduced the significance of trial results and that the adult and child data showed significant improvement in lung function (BD: May 25, Jun 27, 2011).
One option for the company is to restrict Bronchitol for adult use or caution against child and adolescent use.
Pharmaxis said that it must submit the detailed grounds for re-examination before the end of August and these should be based on the grounds for refusal outlined in the negative opinion (BD: Jun 27, 2011).
The company said that during September and October it would work with the CHMP rapporteurs and scientific advisory group in preparing a recommendation.
Pharmaxis said the Committee would be expected to vote on the re-examination at its October meeting.
Pharmaxis said Bronchitol had orphan drug designation from the European Medicines Agency and was approved for marketing in Australia.
Pharmaxis was up 4.5 cents or 4.7 percent to $1.005 with one million shares traded.

BIONICHE LIFE SCIENCES

Bioniche says it intends to purchase the business and assets of Plasvacc Holdings, an Australian horse and dog hyper-immune plasma production and distribution company.
The Ontario, Canada-based Bioniche listed on the ASX to develop its Urocidin bladder cancer treatment but was originally a veterinary health company and retains a large animal health division (BD: Jan 27, 2011).
Bioniche said Pasvacc had manufacturing operations in both Australia and the US and the assets to be acquired included inventories, property, plant, equipment and intellectual property owned by Plasvacc and its subsidiaries.
The company said the transaction was conditional on due diligence, receipt of regulatory approvals and the signing of definitive transaction documents and was expected to close later this month.
Bioniche said the acquisition would meet its objective of selectively acquiring rights to commercially-important animal health products and technologies and contribute to the growth of its revenue-generating animal health business unit.
Bioniche was untraded at 90 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will follow the July 12, 2011 Bio-Breakfast on reimbursement and pricing strategies with a July 20, 2011 workshop.

Bio-Melbourne Network chief executive officer Michelle Gallaher said that reimbursement and pricing was "vital to any business strategy and is essential for any biotech company developing drugs, small molecules, cell therapies or antibody products, particularly those in the clinical trial stages".

Ms Gallaher said that "traditional reimbursement and pricing strategies won't work now as we have the 'perfect storm' with Governments and payers requiring more rigorous quantification of the value and cost effectiveness of products, increased healthcare costs and generics companies increasing their competitiveness through lower-cost, me-to products".

The Bio-Melbourne Network said the July Bio-Workshop panel would include Pharmaxis chief operating officer Gary Phillips, Neuroscience Trials Australia general manager Dr Tina Soulis and Glaxosmithkline senior health outcomes specialist Dr Mark Haberl.

The Network said the panel would provide strategic advice for biotechnology businesses and discuss the pitfalls in local and international markets.

The July 20 2011 Bio-Workshop will be held at the Calzada offices Unit 2, 320 Lorimer Street, Port Melbourne.

Registration is from 8:45am and the workshop concludes at 12:30pm followed by a light lunch.

For more information or to register go to http://biomelbourne.org/events/view/194.

STIRLING

Stirling has requested a voluntary suspension to follow the trading halt it requested on July 1, 2011, an announcement on board changes, the appointment of a chief executive officer its proposed UK Alternative Investment Market listing and funding.

Stirling last traded at 0.2 cents.