Biotech Daily

Thursday December 15, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHOSPHAGENICS UP 8%, AVITA DOWN 9%**

*** BIOTECH DAILY: THE YEAR IN REVIEW**

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MARKET REPORT

The Australian stock market fell 1.21 percent on Thursday December 15, 2011 with the S&P ASX 200 down 50.7 points to 4,139.8 points.

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

Phosphagenics was the best, up 1.5 cents or 8.3 percent to 19.5 cents with 6.5 million shares traded, followed by Bionomics up four cents or eight percent to 54 cents with 279,104 shares traded.

Prana and Universal Biosensors climbed more than six percent; Allied Health was up five percent; Resmed rose 2.1 percent; Mesoblast and QRX were up more than one percent; with Clinuvel, Cochlear and Sirtex up by less than one percent.

Avita led the falls, down one cent or 9.1 percent to 10 cents, with 315,050 shares traded.

Circadian and Phylogica both lost 8.2 percent; Viralytics was down 7.7 percent; Patrys and Sunshine Heart fell five percent or more; Acrux, Alchemia, Neuren, Nanosonics and Prima were down more than three percent; Anteo and Impedimed shed more than two percent; Biota, Psivida, Reva and Starpharma were down more than one percent; with CSL, Heartware and Pharmaxis down by less than one percent.

BIOTECH DAILY: THE YEAR IN REVIEW

The past 12 months have seen great caution in the biotechnology sector with the stand-out performance **Pharmaxis** snatching marketing victory from the jaws of European defeat.

It was a nervous few months for Pharmaxis staff and investors following the May 25 rejection by the European Committee for Medicinal Products for Human Use and subsequent 74 percent share slide, but **Australian Ethical**, **Orbis Investment Management**, several senior biotech executives and this writer placed their faith in Dr Alan Robertson and were rewarded on October 24 with a 70 percent share price improvement. Not to mention a successful $80 million capital raising completed earlier this week.

Both **Mesoblast** and **Starpharma** received significant encouragement from the London M&G Group becoming substantial in their companies, but both are now in the waiting game for results and deals. Starpharma also raised the not inconsiderable amount of $35 million in a heavily oversubscribed placement and share plan and **Phosphagenics** raised $27 million. **Biota** was awarded $224 million by the US Government and **Neuren's** trial costs are covered primarily by US Army grants.

Which brings to the fore the major raisings of late last year and earlier this year by three offshore companies.

Bioniche ($30m) has had an Australian share liquidity problem and we have not yet seen advances in its bladder cancer treatment. **Reva** ($85m) faced a six month delay to scale-up manufacturing quantities of its cardiac stent and **GI Dynamics** ($80m) has repositioned its Endobarrier from weight loss to diabetes treatment.

You can't say there isn't money available. If a company has the right board, right management, right technology and right story, funds seem to be available. There have been other promising companies that have struggled to survive and the turn-around in the fortunes of Neuren and **Avita** – both supported by Australian Ethical, amongst others – has been welcome. Not to mention **Qiagen** paying $365 million for Melbourne's **Cellestis**.

There have been some setbacks at the top, with **Cochlear's** recall of its Nucleus 5 implant hitting the share price from a high of $85 a share to a low of $45, while **CSL** has had repeated questioning about its processes from the FDA.

Other disappointments this year include **Alchemia's** fondaparinux parade being rained on by **Glaxosmithkline's** authorized generic, the failure of **Psivida** and **Alimera's** FDA approval for Iluvien, non-significant data for **CBio's** XToll, **Bionomics** anti-cancer drug BNC105 failed mesothelioma trial and Biota's Inavir missing a prophylaxis trial endpoint.

Overall, for the year to November 30 the Biotech Daily Top 40 Index (**BDI-40**) was up 9.25 percent compared to the ASX200 falling 10.1 percent.

But in the five years to November 30, the BDI-40 was up 51.9 percent compared to the ASX200 falling 23.5 percent. Reasons to be cheerful.

The Biotech Daily CEO of the year award has to go to Dr Paul MacLeman for repairing **Genetic Technologies** from a low of 2.8 cents to a high of 35 cents. The company has been revitalized with licencing deals, new technology and a short AGM with no options for directors on the agenda.

The difficult choice came from a field including, but not limited to, Mesoblast's Prof Silviu Itescu, Starpharma's Dr Jackie Fairley, Cellestis's Dr Tony Radford, **QRX's** Dr John Holaday, **Antisense's** Mark Diamond, Phosphagenics' Dr Ezra Ogru and Harry Rosen, as well as **Acrux's** Dr Richard Treagus.

Perhaps the most significant event of the year will turn out to be the appointment of Greg Combet as Innovation Minister.

While Senator Kim Carr grew to understand and support innovation in general and biotechnology in particular, he was unable to transform the sector with the infrastructure a pro-active Federal Government could. He was no John Brumby or Peter Beattie.

Mr Combet has much greater clout in Cabinet and although his Hunter Valley electorate is a coal mining area, there are many biotech companies nearby to assist his understanding of how beneficial sunrise industries are to the economy. He also has people close to him who strongly support innovation, and he in turn is close to the Prime Minister.

The engagement with biotechnology by Victoria's new Minister for Innovation Louise Asher and her Minister for Technology Gordon Rich-Phillips has been very welcome, especially Ms Asher's acknowledgment of the role of the previous Government. The first investment of $55 million has been relatively small, compared to say a Synchrotron, but these are tough times and we should be grateful not to have faced cuts.

The Biotech Daily award for industry campaigning goes to **Walter and Eliza Hall Institute** director Prof Doug Hilton for steering the Discoveries Need Dollars campaign to avoid savage Federal Budget cuts to the **National Health and Medical Research Council**, the core research that leads to the biotechnologies the sector attempts to commercialize.

We also salute all those who donned lab coats to take to the streets of Australia's cities to let the Federal Government know the campaign had both in vitro and in vivo support.

Biotech Daily's last formal edition for 2011 will be published tomorrow and we return on January 23, 2011. Any major breaking news over the summer holiday period will be reported as a news flash with details in the January 23 catch-up edition. A market cap update will be published on January 3, 2012.

The subscription price will have a slight increase in line with the Consumer Price Index of 3.5 percent to a base rate of $820 in the New Year.

We wish all our readers a very relaxing Summer holiday break, Merry Christmas, a sunny Summer Solstice and a better biotech New Year in 2012.

David Langsam
Editor

CLINUVEL PHARMACEUTICALS

Clinuvel says that interim safety analysis of data from its phase II study shows Scenesse (afamelanotide) 16mg is safe in organ transplant recipients.

Clinuvel said the analysis was conducted on blinded safety data from patients who had completed at least 12 months of therapy and the results did not raise any significant safety concerns in the patient population.

The company said Scenesse was being evaluated to determine if the drug could protect organ transplant recipients from ultra-violet light-induced damage, specifically actinic keratoses or pre-malignant skin cancers and squamous cell carcinomas of the skin.

Clinuvel said that some patients had completed the 24 month study with the final patient due to complete treatment by July 2012.

Clinuvel said Scenesse was the first drug to be developed as an overall photoprotective agent in organ transplant patients.

The company said that due to the long-term use of immunosuppressant drugs to prevent organ rejection, transplant patients were at an extreme risk of skin cancer and other co-morbidities compared to the general population, and were up to 250 times more likely to develop skin cancer than those who had not had an organ transplant.

Clinuvel said the most common skin tumors in patients post-transplantation were squamous cell carcinomas, basal cell carcinoma and melanoma, with squamous cell carcinomas and basal cell carcinomas the result of chronic exposure of skin to UV light and the highest incidence of skin cancers was in countries with high UV exposure.

Clinuvel said transplant recipients with fair skin were at higher risk for skin carcinoma than those with dark skin, suggesting that melanin protected skin cells from UV light.

The company said that a prophylactic treatment or photoprotective therapy to diminish the rate of the disorders was “of high interest to the patient and medical community”.

Clinuvel said the phase II study organ transplant trial was a randomized, double-blind, placebo-controlled study of 24 months in 85 patients, involving 10 specialist skin cancer centres in Australia and Europe, designed to analyze the prophylactic effect of Scenesse on the development of actinic keratoses and squamous cell carcinomas in Caucasian patients who were highly prone to develop thes skin lesions after organ transplantation.

The company said the data from all 85 patients were evaluated with no significant safety concerns identified.

Clinuvel said that a low rate of skin conditions, including all forms of skin cancer, was reported across the patient group and no melanomas were reported and treatment was not shown to interfere with immune suppressive medications.

The company said that the most frequent adverse events were abdominal pain, fatigue, headaches, nausea and vomiting, mostly of mild severity, across the patient groups.

Clinuvel chief scientific officer Dr Hank Agersborg said the initial results were “meaningful in many ways”.

“Treatment in this study appears safe, an important parameter for a new drug in patients who are already susceptible to a range of disorders due to their lifelong immune suppression,” Dr Agersborg said. “Additionally, although we know that Caucasian patients are prone to experience multiple sequential skin cancers on sun exposed skin, there are only a few reports of skin tumors in the first 12 months.”

“These results suggest that treatment does not interfere with systemic immuno-suppressive drugs or with the donor organ graft,” he said. “From a safety point of view, it was a novel and important approach to investigate the safety in this group of patients.”

Final efficacy and safety data from the 24 months treatment in study CUV011 for organ transplant patients is expected to be available by the end of 2012.

Clinuvel was up half a cent or 0.33 percent to $1.505.

MAYNE PHARMA GROUP

Mayne Pharma says it is required to respond to questions raised following a review of its Subacap anti-fungal drug dossier by the UK's Commission for Human Medicines.
Mayne said that following discussions with the UK Medicines and Healthcare products Regulatory Agency it would be required to respond to the questions about its super-generic formally known as Suba-itraconazole. Itraconazole is marketed as Sporanox.
Mayne said that questions would delay the approval of Subacap beyond June 30, 2012 as further clinical work could be required.
In 2009, the UK regulator required a further pharmacokinetic study to show that Suba-itraconazole performed as well against European Sporanox as US Sporanox and in 2010, Mayne (then Halcygen) said the UK pharmacokinetic study showed clinical bioequivalence of a halfdose of its anti-fungal drug Suba-itraconazole with Sporanox and it hoped to have marketing authority in 2011 (BD: Aug 29, 2009; Mar 2, 2010).
Today, Mayne said the UK Medicines and Healthcare products Regulatory Agency advised the company that while clinical data presented in the dossier showed superiority over placebo, no conclusions on the non-inferiority of Subacap compared to the reference drug could be made as the reference drug did not show superiority over placebo.
The company said it would complete a review of the questions raised once formally received from the Commission for Human Medicines.
Mayne said that following the review, it would either supplement its marketing authorization application or withdraw its application and complete further clinical work.
Mayne chief executive officer Dr Roger Aston said the company was "obviously surprised with these recent developments given the previous feedback we have had and we remain absolutely committed to gaining marketing approval for Subacap in Europe and the US".
Dr Aston said the company would use the advice from the MHRA to finalize the details of a phase III clinical trial to be presented to the US FDA in 2012.
Mayne fell three cents or 6.9 percent to 40.5 cents.

PRANA BIOTECHNOLOGY

Prana says it has begun recruitment and screening of patients for a 12 month phase II imaging trial testing PBT2 for Alzheimer's disease.
Prana said the screening began last week with psychological tests to measure cognition and this week, the first patient was tested for evidence of significant levels of amyloid-beta deposits in the brain.
Prana consultant and Victoria Mental Health Research Institute director Prof Colin Masters said Prana was "selecting patients with established Alzheimer's disease, as well as targeting those very early in the disease process".
Prof Masters said Prana was using positron emission tomography imaging to measure the drug's effects on the insoluble form of amyloid-beta as well as a blood test to measure levels of the soluble oligomers of amyloid-beta.
Prof Masters said Prana was taking pre-drug dosing measures of eligible patients to compare with measures that will be taken throughout the trial.
"In my opinion PBT2 has the best and highest chance of all drugs currently in development to have a major impact on the disease process and help avoid the global epidemic of Alzheimer's which, left untreated, is poised to become unmanageable," Prof Masters said. "This trial that is now in progress will establish for the first time not only that PBT2 can improve cognition, as already shown, but that it can actually modify the course of the disease."
Prana was up one cent or 6.9 percent to 15.5 cents.

PATRYS

Patrys has appointed former Genentech executive Suzy Jones as a non-executive director effective immediately.

Patrys said the appointment marked its “ongoing transition … to a clinical development company with its lead anti-cancer compound PAT-SM6 moving into a second trial for the treatment of multiple myeloma and PAT-SC1 moving towards out-licencing in 2012”.

The company said that Ms Jones was most recently Genentech’s head of business development, responsible for identifying external opportunities and overseeing the negotiation of collaboration agreements to support strategic alliances.

Patrys said Ms Jones was the founder and managing partner of DNA Ink LLC, a life sciences business development and licencing firm in San Francisco.

The company said that Ms Jones joined Genentech in 1990 as a research associate where she conducted basic immunology research, contributing to the development of two drug candidates.

Patrys said Ms Jones worked in the product development group where she managed several products at various stages of their life-cycles, including two cancer products, Rituxan and Avastin and from 2001 joined the business development group overseeing Genentech’s licensing efforts in immunology, infectious diseases, neurobiology, ophthalmology, metabolism, cardiovascular diseases as well as technology licensing.

Patrys fell 0.2 cents or five percent to 3.8 cents.