Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: SUNSHINE HEART UP 27%, PHOSPHAGENICS, PHYLOGICA DOWN 12.5%**

*** PEPLIN'S TOM WIGGANS: THIS ISN'T CANCER ANYMORE, TOTO**

*** ASIC CHARGES EX-GENETIC TECHNOLOGIES COO GEOFFREY NEWING**

*** BIONOMICS ANXIOLYTIC BNC210 SAFE, TOLERATED IN RATS, DOGS**

*** STARPHARMA: 'DENDRIMER REDUCES TOXICITY OF CANCER DRUG'**

*** ANTISENSE: ATL1103 FOR GROWTH, SIGHT ILLNESS 'ON SCHEDULE'**

*** PSIVIDA EVALUATED FOR CARDIOVASCULAR DRUG DELIVERY**

*** BIOTA JUMPS 11% ON DIRECTOR BARBARA GIBSON'S RESIGNATION**

*** BARCLAYS TAKES 5% OF CSL**

*** SUNSHINE HEART EX-CHAIRMAN MALCOLM MCCOMAS RETIRES**

*** HEARTWARE APPOINTS DR MARK SLAUGHTER LEAD INVESTIGATOR**

MARKET REPORT

The Australian stock market was up 0.5 percent on Wednesday December 17, 2008 with the All Ordinaries up 16.1 points to 3,515.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and nine were untraded. All three Big Caps were up.

Sunshine Heart was best, up one cent or 16.67 percent to seven cents with 142,428 shares traded, followed by Alchemia up 16 percent to 14.5 cents, Benitec up 14.29 percent to four cents and Biota up 11.43 percent to 39 cents. Bionomics climbed 9.52 percent; Psivida was up 7.41 percent; Starpharma rose 6.98 percent; Peplin climbed 5.26 percent; CSL and Sirtex were up more than four percent; Arana rose 2.5 percent; with Cochlear, Impedimed and Resmed up more than one percent.

Phosphagenics and Phylogica led the falls, down 12.5 percent to seven cents and 3.5 cents, respectively. Antisense lost 9.52 percent; Living Cell fell 8.7 percent; Mesoblast was down 6.25 percent; Ventracor fell four percent; Circadian was down 3.33 percent;, Clinuvel and Novogen shed more than two percent; with Acrux, Chemgenex and Progen down one percent or more.

CEO INTERVIEW: PEPLIN'S TOM WIGGANS

Tom Wiggans may be new to Peplin and Australia as a chief executive officer, but he has spent his life in the pharmaceutical industry crossing paths with innovative Australians.

Born and raised in the Kansas small-town, Fredonia, Tom studied Pharmacy for five years at the University of Kansas. His first Pharmacy teacher was Prof Val Stella a Melburnian who had moved from Oz to Kansas. Tom winces at the Wizard of Oz reference: in Kansas it is a standing joke, but locals wonder when the world will move on.

By the end of the course Tom said: "I don't want to work in a pharmacy, but I do want to work in the pharmaceutical industry". The assistant dean at the University of Kansas told him to "go get an MBA". An Eli Lilly representative came to the campus, Tom said he was going to do an MBA and wanted to work for the company and the representative said: "Do the MBA and we'll hire you". He did (at the Southern Methodist University in Dallas Texas) and they did.

His first job was selling antibiotics in Florida. The job entailed wearing out shoe leather visiting doctors and hospitals and he learnt an important lesson – the harder he worked and the more times he saw the doctors, the greater the sales. He was in Florida for two years, worked in marketing at the company's headquarters in Indianapolis for two years before being recruited to the Serono Group in Boston in 1980 as marketing manager.

When Tom Wiggans arrived at Serono sales were about $US1 million a year and he made the decision to make a mark at Serono, rather than coast along not making an impact at Eli Lilly.

In many ways Tom Wiggans epitomizes the American Protestant work ethic. At 56 he is enthusiastic, buoyant and on the move. The fact that he has run major companies is no reason to rest on his laurels. He is available, friendly and more than happy to spruik Peplin's skin cancer treatment PEP005 (ingenol mebutate) at any time.

He reorganized Serono which at that time was based on diagnostic tests with about $200,000 a year in sales of hormone replacement treatments. He spun out the diagnostics and over the next 10 years built the company into a $US100 million a year in vitro fertilization business.

His path crossed with a second influential Australian, Prof Alan Trouson who, with the Monash IVF team, was rapidly increasing his Australia-US frequent flyer points.

"Thanks to the Australians making it a very effective technique. It was a wonderful business because you were able to make a real difference, like a miracle," Tom says.

He ran the Serono London office from 1990 tom 1992, before setting up Cytotherapeutics with former Johnson & Johnson researcher Dr Seth Rudnick hoping to engineer cells producing dopamine to be implanted in the brain for Parkinson's disease and implantable pancreatic cells for diabetes. He says the company was about 20 years too early.

His next move was to Connetics in California to work on Relaxin a novel therapy developed at the Howard Florey Institute in Melbourne, looking for an application for the potentially fatal scleroderma disease.

"It did not work. It was a colossal failure, a spectacular failure for an unmet medical need," Tom says.

But it brought him into the world of dermatology. Connetics bought the Australian based Soltech acquiring the Luxiq mid-potency foam steroid for psoriasis, eczema and dermatitis.

"When we sold Connetics to Stiefel [for $US640 million in 2006] I was looking for something to do.

"I saw [Peplin's] phase II data and said 'I truly believe this is a potentially a great drug for an unmet market'.

“The incidence of actinic keratosis is increasing, despite all the warnings about covering up and using sun screens, but instead of two to three months of treatment, patients apply PEP005 for two days and that’s it. So I joined the board as chairman.
“In August the board and investors decided it was time to get the ball across the line, and I was appointed chief executive officer.”
Tom Wiggans gives credit to former chief executive officer Michael Aldridge for taking the company as far as he did, but with a phase III US Food and Drug Administration approved trial and two phase II trials, there was an unmet need at Peplin.
Tom has supervised six drugs through the FDA process, two at Serono and four at Connetics. Although he didn’t personally take the drugs through the process “the people who did, reported to me”.
“I’ve seen the good, the bad and the ugly of the FDA process. It’s not easy and it is suicidal to take anything for granted,” he says.
All three trials are due to report by mid 2009. The phase IIb placebo-controlled dose-ranging trial of PEP005 for actinic keratosis of the face is due before April 2009 while the phase III trial for non-face actinic keratosis and a phase IIa dose ranging trial of basal cell carcinoma are due to report before July 2009.
Tom says that 70 percent of actinic or solar keratoses are on the face due to greater exposure to the sun and Peplin is expecting to use a lower dose to treat facial lesions than non-face lesions.
He says there is “fairly conclusive evidence that some solar keratoses turn into squamous cell carcinomas”. He says the rate is debated but the general range is between one and 10 percent.
“We have three major milestones coming up. By the end of 2009 all the development work will be done in preparation for a new drug application before mid-2010 and on the market in 2011,” he says.
“We are forever indebted to Jim Aylward for wanting find out how this plant works,” Tom says.
It was Dr Aylward who took the common plant Euphorbia peplus and studied the sap that had been described for centuries for its ability to cure skin lesions. The active ingredient, ingenol mebutate, is directly cytotoxic to cancer cells disrupting the cell metabolism and causing the cell to explode and also stimulates the immune system to clean up whatever residue is left.
Tom says PEP005 is painless, easy to administer and leaves “no scarring and no discoloration”.
Asked whether the company would be seeking large pharmaceutical company partners, he smiles self-consciously and reminds Biotech Daily that he has already turned one $US1million company into a $US100 million company.
“I know the dermatology market. There isn’t a lot of innovation. We will be launching ourselves in the US and partnering in Europe and we plan to launch the product ourselves in Australia.
“Australia has the highest incidence of skin cancer, but America has the greatest number of patients.
“I truly believe you can start a company around this product and it would just be a blast to launch it,” he says, a glint of excitement in his eyes, “to bring a unique, painless, easy to use, high patient compliant drug to market.”
Peplin had a net cash burn of $US11,747,000 for the three months to September 30, 2008 and about $US43.5 million in cash.
Peplin was up 1.5 cents or 5.26 percent to 30 cents.

GENETIC TECHNOLOGIES

Genetic Technologies former chief operating officer Geoffrey Newing has been charged with 192 counts of market manipulation between May 16 and 27 September, 2006.
The Australian Securities and Investments Commission said Mr Newing appeared yesterday December 16, 2008 in the Melbourne Magistrates' Court.
ASIC said Mr Newing was the son-in-law of Genetic Technologies co-founder Dr Mervyn Jacobson, who faces 319 counts of market manipulation and is the husband of Dr Jasobson's daughter Tamara Newing who has been charged with 353 counts of market manipulation.
ASIC alleged that Mr Newing arranged for orders to be placed on the ASX for the purchase of Genetic Technologies shares through a share trading account held in the name of his related company, Palamine Pty Ltd.
ASIC said the orders "were likely to create or maintain an artificial price for trading in the company's shares".
Mr Newing was released on bail on a surety for an amount of $100,000 and was expected to appear in the Melbourne Magistrates' Court on April 23, 2009 for committal mention.
The Commonwealth Director of Public Prosecutions is prosecuting the matter.
Genetic Technologies was untraded at 3.8 cents.

BIONOMICS

Bionomics says pivotal preclinical studies of its anti-anxiety lead candidate BNC210 in rats and dogs has shown it to be safe and tolerated.
The company said the completion of the program was "a key milestone in the drug development process for BNC210, with Bionomics on track to make regulatory submissions to enable clinical development".
Bionomics chief executive officer Dr Deborah Rathjen said the studies confirmed that BNC210 "does indeed have a broad therapeutic window in animal tests".
"We believe that BNC210 has the potential to be an improved anxiolytic for the treatment of both acute and generalized anxiety disorders and in the early treatment of depression in combination with antidepressants, replacing the use of drugs such as Valium and Prozac in the treatment of anxiety," Dr Rathjen said.
BNC210 program leader Dr Sue O'Connor said the preclinical data showed that in animals BNC210 was able to reduce anxiety without the common side effects of current anxiety drugs including drowsiness, impairment of memory and motor function.
"In addition, BNC210 has been shown to be fast-acting and effective with a single daily dose," Dr O'Connor said.
"In addition to the just completed safety studies, other recent animal studies with BNC210 have shown that BNC210 affects regions of the brain involved in anxiety and have provided biomarkers for evaluation in the clinical setting," Dr O'Connor said.
Bionomics said anxiety was a common debilitating condition that affected 19 million patients in the US alone and had an estimated market value $5-$12 billion worldwide.
Many of the largest blockbuster drugs are for treating anxiety including Valium, Prozac, Paxil, Buspar and Zoloft.
Most of the current anxiety therapeutics are not ideal and have a range of side effects, including sedation and loss of memory.
Bionomics said its strategy was to partner BNC210 for clinical development as the company continued to focus on advancing its anti-cancer drug, BNC105, which was near completion of phase I trials and would begin phase II trials in 2009.
Bionomics climbed two cents or 9.52 percent to 23 cents.

STARPHARMA

Starpharma says its dendrimer-based drug-delivery technology combined with a widely-used cancer drug markedly reduces toxicity in mice.
Starpharma said its dendrimer combined with doxorubicin “achieved a significant extension of the drug’s plasma half-life and a marked reduction in drug toxicity compared to administration of the drug alone”.
Starpharma said that in the proof-of-concept animal study the efficacy of the dendrimer-drug construct was equivalent to that of the drug alone.
Doxorubicin was selected to illustrate the delivery technique because of its wide use as an anticancer agent, having application in Hodgkin's lymphoma, some leukemias, as well as cancers of the breast, lung, and ovaries.
The clinical use of doxorubicin is often constrained by its cardiac toxicity which may result in congestive heart failure and dilated cardiomyopathy.
Starpharma said the model of human breast cancer cells grafted onto a mouse showed that its dendrimer-doxorubicin construct (SPL8181) achieved the same inhibition of human breast-cancer tissue as doxorubicin alone, but with markedly reduced cardiac toxicity.
The company said a blinded histopathological examination of cardiac tissue samples from the dosed animals revealed significantly lower cardiotoxicity (p=0.019) in the dendrimer-doxorubicin construct treatment group (toxicity in 14% of samples) compared to a doxorubicin-only treatment group (toxicity in 86% of samples).
Signs of reduced toxicity in other organs were also observed for the animals dosed with the dendrimer-based molecule compared to doxorubicin alone.
Starpharma said its delivery technology worked by attaching multiple drug molecules to the surface of a dendrimer nano-particle with the result that the dendrimer nano-particle could target the drug to the tumor, in preference to other organs.
Starpharma said its dendrimer technology had been engineered to allow for the drug payload to be preferentially released from the nano-particle in close proximity to the tumor.
Starpharma chief executive officer, Dr Jackie Fairley said her company had formed “a number of partnerships based on its drug-delivery technology, including a dermal program with Stiefel Laboratories”.
“The technology has application for both small molecule drugs and protein therapeutics and Starpharma is in advanced discussions with additional potential partners who have an interest in using it to improve the delivery, efficacy, and toxicity profile of their products,” Dr Fairley said.
The animal studies were conducted in collaboration with the Victorian College of Pharmacy and the Peter MacCallum Cancer Centre.
Starpharma was up 1.5 cents or 6.98 percent to 23 cents.

ANTISENSE THERAPEUTICS

Antisense says it has completed dosing in its mouse and primate toxicology studies of ATL1103, designed to block the growth hormone receptor.
Antisense said ATL1103 was also a potential treatment for acromegaly and diabetic retinopathy disorders and the development process was on track.
The company said the studies were a major component of the ATL1103 toxicology program.
Antisense said that following completion of the post-dosing monitoring period, the study data would be analyzed and a report of the findings and conclusions prepared, “which remains on track for the second half of 2009”.
Antisense fell 0.4 cents or 9.52 percent to 3.8 cents.

PSIVIDA

Psivida says its drug delivery technology is being evaluated for its “first cardiovascular application”.

Psivida said it was “mostly known for its ocular drug delivery” and the evaluation was being funded by an undisclosed large global medical device company.

Psivida said it had received more than $500,000 from the company for this and preceding related evaluation agreements.

Psivida said its lead product Medidur FA, which would be marketed as Iluvien, was in pivotal phase III clinical trials for diabetic macular oedema.

Medidur is a tiny injectable device that delivers the corticosteroid, fluocinolone acetonide, for up to three years after being injected into the vitreous of the eye, the company said.

Psivida was up 10 cents or 7.41 percent to $1.45.

BIOTA

Biota director Barbara Gibson has resigned a fortnight ahead of her previously stated resignation date.

Ms Gibson’s resignation was announced today following the last board meeting of the year. She had previously said she would go on December 31, 2008.

Chairman John Grant has said he would resign by June 30, 2009.

Biota climbed four cents or 11.43 percent to 39 cents.

CSL

Barclays Group has become a substantial shareholder in CSL with a holding of 30,271,676 shares or 5.02 percent of the company.

Barclays Group says it holds the relevant interest with JP Morgan and others the registered holders of the securities.

The becoming substantial notice said the shares were acquired over the past four months at an average price of $35.64.

CSL was up $1.19 or 4.1 percent to $30.20, with 3.7 million shares traded.

SUNSHINE HEART

Sunshine Heart says Malcolm McComas retired as a director on December 16, 2008.

Mr McComas was chairman of Sunshine Heart from its listing on the ASX in 2004 until its last annual general meeting on October 30, 2008 when he retired as chairman but agreed to continue to serve as a non-executive director for a transition period.

The company’s chairman Nicholas Callinan said Sunshine Heart was “extremely grateful” for Malcolm McComas’ four years of leadership during which the company completed preclinical and clinical trials of its C-Pulse heart assist device in Australia and New Zealand and obtained approval from the US Food and Drug Administration to undertake US clinical trials of the device.

The board of seven members has five non executive directors Nicholas Callinan, John Brennan, Dr Geoff Brooke, Crispin Marsh, Donal O’Dwyer and two executive directors Dr William Peters and Don Rohrbaugh.

Sunshine Heart climbed one cent or 16.67 percent to seven cents.

HEARTWARE

Heartware has appointed Dr Mark Slaughter as principal investigator for its US bridge-to-transplant trial.

Heartware said Dr Slaughter was the director of the Division of Thoracic and Cardiovascular Surgery at the Jewish Hospital and the University of Louisville in Louisville, Kentucky.

The company said he was a “world-renowned expert in heart transplantation, ventricular assist devices and the surgical management of heart failure”.

He has given more than 65 invited lectures, published more than 50 peer-reviewed papers and book chapters and presented more than 85 papers and abstracts at national and international conferences, Heartware said.

The bridge-to-transplant trial will enroll 150 patients in up to 28 centers.

Two centers have begun implants. Seven more have independent review board approval and expect to enroll patients in January and February 2009.

Heartware was untraded at 55 cents.