Biotech Daily

Monday April 27, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN; BIOTA UP 82%, CLINUVEL DOWN 13%**

*** BIOGUIDE: BIG PHARMA GETS IT WRONG - PEPLIN IS A FIVE-BANGER**

*** BIOTA JUMPS 90% ON SWINE FLU; RELENZA PR CHALLENGE**

*** BIOTA'S DR JIM FOX: GOVERNMENTS MUST INVEST IN EDUCATION**

*** PROGEN BUY-BACK UNDERSUBSCRIBED, PAYS $1.10 A SHARE**

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*** HEARTWARE CLAIMS ONE YEAR 86% HEART PUMP SURVIVAL RATE**

*** BIOSIGNAL REQUESTS 'CAPITAL REQUIREMENTS' TRADING HALT**

*** QIC CEASES SUBSTANTIAL IN CHEMGENEX**

*** LIVING CELL SAYS PORCINE INSULIN CELLS SAFE FROM SWINE FLU**

*** INCITIVE VOTES ON 21.625m DIRECTORS' SHARES, 20m OPTIONS**

*** CEPHALON EDGES UP TO 35% OF ARANA**

MARKET REPORT

The Australian stock market climbed 0.52 percent on Monday April 27, 2009 with the S&P ASX 200 up 19.28 points to 3,731.6 points. Nine of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and four were untraded.

Biota was best, climbing as much as 90.2 percent to $1.655 before closing up 71 cents or 81.6 percent at $1.58 with 17.3 million shares traded, followed by Antisense up 25.8 percent to 3.9 cents, Cytopia up 21.05 percent to 11.5 cents and Genetic Technologies up 14.3 percent to 4.3 cents. Novogen climbed 6.5 percent; Progen was up 5.9 percent; Phosphagenics was up 3.12 percent; and Psivida rose 2.44 percent.

Clinuvel led the falls, down 4.5 cents or 13.24 percent to 29.5 cents with 362,197 shares traded, followed by Universal Biosensors down 12.5 percent to 70 cents. Sunshine Heart lost 9.1 percent; Tyrian fell eight percent; Alchemia was down 7.25 percent; Living Cell fell 5.6 percent; Acrux, Chemgenex, Polartechnics and Starpharma were down more than three percent; Avexa, Bionomics, Cellestis and Viralytics shed two percent or more; with CSL, Genera, Mesoblast, Phylogica and Sirtex down one percent or more.

MARC SINATRA'S BIOGUIDE: PEPLIN

Overview: I gave up following Peplin back in 2004, when Allergan handed back PEP005 after licencing the non-melanoma skin cancer drug from them in 2002.

The willingness of investor of note, MPM Capital, to lead a $40 million dollar capital raising for Peplin in 2006 should have been the signal for me to take another look at them.

Ultimately, it wasn't until August of last year, when they raised $US24 million in very difficult conditions that they again caught my eye. The positive signal of the raising was reinforced by the fact that arguably Australia's leading life science investment firm, GBS Venture Partners, led the raising.

Could big pharma Allergan have got it wrong?

Financials: Market cap: $181 million; cash: $33.8 million; last quarter cash burn: $6.1 million.

Directors: Executive chairman and chief executive officer, Thomas Wiggans; president and chief medical officer, Dr Eugene Bauer; non-executive directors, Dr Joshua Funder, Cherrell Hirst, Dr Gary Pace, Michael Spooner and Jim Scopa.

Peplin's board is excellent - members Wiggans, Bauer and Scopa, particularly so. Chairman and CEO Tom Wiggans looks purpose-built for the job.

Products in Development: Peplin is developing various topical formulations of PEP005 (ingenol mebutate), a plant-derived compound thought to cause local necrosis and activation of the immune system, for applications including actinic keratoses (AK), basal cell carcinoma (BCC) and squamous cell carcinoma (SCC).

1) AK (non-head treatment sites): Treatment consists of a single application of PEP005 (0.05%) to AK's for two consecutive days. A phase IIb study found a statistically significant 44% complete clearance rate of AKs when applied to contiguous areas of skin containing 4-8 AKs in 55 patients. Enrolment in a phase III trial is complete with results due in the current quarter.

2) AK (head treatment sites): Treatment is likely to consist of a single application of PEP005 (0.015%) for three consecutive days. With this treatment regimen, a phase IIb study found a statistically significant 50 percent complete clearance rate of AKs. A phase III trial is due to start in the current quarter.

3) Superficial BCC: In a phase IIa study, PEP005 (0.05%) cleared a statistically significant 71 percent of cancers when used as in 1, above. A second phase IIa study to determine the maximum tolerated dose in BCC patients is continuing.

4) SCC in situ: In a pilot study, PEP005 (0.05%) cleared 36 percent and 64 percent cancers on histological and clinical basis, respectively, when used as in 1 above.

5) Cutaneous Warts: PEP005 is currently in preclinical trials for this indication.

Significant Product Markets: Seventy-five percent of Americans over 80 years of age have at least one AK and, according to the US National Ambulatory Medical Care Survey database (average 2001-'05), AKs result in 5.6 million doctor office visits in the US annually. It is believed that in 2008 there were more than one million diagnoses of BCC and 250,000 of SCC in the US.

Treatments for AK, BCC and SCC vary, ranging from surgical excision and cryotherapy to topical treatments.

There are several topical treatments. From an application point of view, Efudex, a 5-fluorouracil cream, is the least burdensome to use. It requires daily application for four weeks. All of the available drugs come with uncomfortable and unsightly side effects that are compounded by the treatment duration.

Aldara (imiquimod 5%), which is thought to activate the immune system, is the highest selling topical treatment generating revenues of $US288 million in 2007. Efudex is thought to generate revenues of $US75 million a year, while Solaraze (diclofenac sodium 3%) generated $US61.7 million in 2008.

Complete AK clearance rates for marketed drugs range from about 30-50 percent.

Opinion: Today's Peplin is dramatically different to that of years past. It has a clear dermatological focus and much better understanding of its products.

PEP005 (0.05% and 0.015%) with two and three day treatment times is much easier to use than present drugs, while appearing to provide equivalent clearance rates. In addition, while side effects last longer than the treatment, they are only present for a fraction of the time compared to those produced by current drugs.

The superficial BCC and SCC in situ indications are not as clear cut. Although the data is not available for BCC, almost half the SCCs clinically cleared by PEP005 were still present histologically. The current phase IIa maximum tolerated dose study in BCC should determine if higher doses of PEP005 can be used to treat the cancers and provide further insight into likely histologic clearance rates.

Peplin's strategy is to licence PEP005 in Europe and the rest of the world, while taking it to market on its own in the US. This plan appears to rely heavily on a degree of market pull for the product in the US. If this market pull doesn't eventuate, Peplin will need to do a licencing deal quickly. I believe that PEP005 will find that market pull and there is little question that Peplin's chairman and CEO, Tom Wiggans, will be able to take full advantage of it. As I wrote above, he looks tailor-made for the job.

Allergan seems to have got it wrong, while GBS Ventures appears to have found another solid investment, like Chemgenex, amongst Australia's small cap biotechnology companies.

Based on discounted cash flows, I have arrived at a value of $3.02 per Peplin share. Peplin closed down half a cent or 0.83 percent at 59.5 cents.

Marc Sinatra's Bioguide marc@biotechdaily.com.au

BIOTA

Biota jumped as much as 90.2 percent to $1.65.5 in trading as news spread about the global swine influenza outbreak.

Biota chairman Dr Jim Fox and chief executive officer Peter Cook told Biotech Daily that Relenza, along with is competitor, Roche's Tamiflu, had been shown by the US Centres for Disease Control to be effective in combating the influenza strain also known as A/H1N1.

A Federal Ministry of Health official told Biotech Daily that the Australian stockpile of 8.6 million courses was composed of 6.8 million courses of Tamiflu and 1.8 million course of Relenza.

In a prearranged meeting as part of the company's introduction to the new chairman, Mr Cook said that should a pandemic occur in Australia, the essential services personnel such as ambulance paramedics, hospital staff, police and undertakers who received the anti-viral drugs would require weekly dosing for up to 13 weeks as the outbreak ran its course.

Mr Cook quoted the previous Federal Minister for Health Tony Abbott saying that the stockpile covered 55 percent of the population but that was an estimate for a single course not three months of weekly courses.

Both Mr Cook and Dr Fox were concerned that radio broadcasts by the Australian Broadcasting Corporation frequently referred to their Swiss-based competitor but not the Australian developed and manufactured Relenza.

Biotech Daily has also raised this issue with the ABC without receiving any substantial response.

"On day one of my tenure with this company I flicked on the news to hear the Queensland Health spokesman and all he mentioned was Tamiflu," Dr Fox said.

"There is a serious lack of penetration of Relenza, right up to senior levels of healthcare," Dr Fox said.

"It's an Australian story and is more effective in some cases than Tamiflu."

Mr Cook said that the previous Federal Government had a 100 percent Tamiflu policy which was changed.

"It's Swiss owned and creates no jobs in Australia. All Relenza is from Boronia [in Victoria]," Mr Cook said.

Mr Cook said that the new management at licencee Glaxosmithkline had created an influenza marketing centre of excellence established in mid-2008 to manage stockpiles for governments.

"Glaxosmithkline is looking to commercialize ongoing stockpile management for all governments that are stockpiling Relenza," Mr Cook said.

"We have seen serious advances," Mr Cook said.

He said Glaxosmithkline had increased Relenza's availability to pregnant women and had increased its uptake in the United Kingdom and Japan.

"We still have an issue that the ABC can't spell or pronounce Relenza," Mr Cook said.

He said the US had an $US8 billion market for Tamiflu and Relenza, and that would need to be replaced as stock reached its shelf-life expiry.

He said Canada's stockpile included 10 percent Relenza and was expected to "rebalance the stockpile" increasing the percentage of Relenza.

Mr Cook said the US had enough anti-viral doses to cover 25 percent of the population; France 40 percent; the UK 33 percent; and Australia 55 percent, but only for one course per person.

Biota closed up 71 cents or 81.6 percent to $1.58 with 17.3 million shares traded.

BIOTA

Biota's chairman Dr Jim Fox told Biotech Daily he strongly supports investment in research and development and that Governments had wasted the opportunity of a minerals boom to make that investment.

Formerly the chief executive officer of Vision Systems, Dr Fox said that company employed 60 doctorate-level researchers working on cancer diagnostics in Newcastle (New South Wales) and in one year alone spent $60 million on research and development.

Dr Fox holds Bachelor and Masters degrees in engineering from the University of Melbourne as well as a Doctorate of Philosophy in engineering.

Appointed Biota's chairman on February 27, 2009 he is on the record in an Academy of Technological Science and Engineering submission on education calling for an increase in education funding to equal or better than international standards as well as calling for an increase in the ratio of staff to students, better funding for teaching, public investment in higher education, recognition for applied research and describing education fees as "a threat".

"The greatest tragedy is that we had a boom and did we reinvest?" Dr Fox asked.

"We actually cut back on research and development and the focus of universities is disproportionately on foreign students, leading to a question mark over standards," Dr Fox said.

Asked how the changes at board level would alter Biota's direction, he said board renewal had been executed "however it depends on the executive team".

Dr Fox said that from the first approach by Biota's headhunters the process took six months of "to-ing and fro-ing" and he would not have taken the job if he was not happy with the executive team.

In the notice of appointment, Biota described Dr Fox as "a successful businessman with strong financial and commercial skills" with significant experience in commercializing innovative technologies and growing a global business.

Apart from Vision Systems, which he led until its $1 billion takeover by the US-based company, Danaher, Dr Fox is also a director of Air New Zealand, MS Research and the Technology Partnership PLC.

A former South Melbourne Swans player, he confesses to barracking for Collingwood.

Biotech Daily editor David Langsam owns shares in Biota and supports Essendon.

PROGEN

Progen says its buy-back was under-subscribed, with 98.55 percent of the maximum 36,363,636 units accepted.

Progen said shareholders who participated in the buy-back would therefore receive full payment of $1.10 for all shares tendered.

The company said payment would be distributed by cheque on May 6, 2009.

Progen climbed five cents or 5.88 percent to 90 cents.

AGENIX

The committal hearing of former Agenix chief executive officer, Neil Ian Leggett, 55, has been adjourned to June 9, 2009.

A Queensland Director of Public Prosecutions spokesman told Biotech Daily that Mr Leggett's matter was reviewed and adjourned to April 27, 2009 at the Brisbane Magistrates Court (BD: Sep 16, 2008).

Agenix is in a voluntary suspension and last traded at 1.7 cents.

HEARTWARE

Heartware says that 42 of 50 European and Australian bridge-to-transplant trial patients have survived to 180 days with three more expected to reach the endpoint by June.
Heartware says about 86 percent have survived to 12 months.
The company said the clinical trial data on its left ventricular assist system was presented by Hannover Medical School cardiothoracic surgeon Dr Martin Strueber at the annual meeting of the International Society for Heart and Lung Transplantation in Paris last week.
The company said the data showed that on average, the patients were supported by the Heartware system for 300 days each with the cumulative duration of support across the group exceeding 41 years.
Heartware said the patients' quality of life "showed significant improvement at all points post-implant and the rates of adverse events were relatively low despite the unusually long average duration of pump support across the patient group".
Heartware chief executive officer Doug Godshall said the results "appear again to confirm the benefits we believe to be inherent in the design of this device".
He said that at the International Society for Heart and Lung Transplantation meeting 12 months ago "we reported a 90 percent survival among our initial patient cohort".
"It is pleasing to observe that this success rate has been maintained over a far larger patient group and over a longer period of time," Mr Godshall said.
"We anticipate these positive data providing a meaningful stimulus as we make the system more broadly available in our international markets and as we accelerate enrolment in our US bridge-to-transplant clinical trial," Mr Godshall said.
Heartware has completed an international clinical trial for the device involving five investigational centres in Europe and Australia.
The device is in a separate 150-patient US bridge-to-transplant clinical trial.
Heartware was unchanged at 95 cents.

BIOSIGNAL

Biosignal has requested a trading halt pending an announcement on the "capital requirements for the company".
Biosignal said the halt would "allow completion of discussions regarding capital requirements for the company".
The company announced that it had less than one quarter's cash on April 22, 2009.
Biosignal said its net operating cash burn was $248,934 for the three months to March 31, 2009 with cash at the end of the quarter of $214,443.
Trading will resume on April 29, 2009 or on an earlier announcement.
Biosignal was untraded at 1.6 cents.

CHEMGENEX

The Queensland Investment Corporation has ceased its substantial shareholding in Chemgenex through the sale of 352,529 shares for $146,294 or 41.5 cents a share.
On Friday April 24, 2009 the Queensland Government-owned Queensland Investment Corporation reduced its substantial shareholding in Chemgenex from 14,557,313 shares (6.07%) to 12,031,599 shares (5.02%).
Biotech Daily analyst Marc Sinatra has valued Chemgenex at $5.50 a share (BD: May 5, 2008).
Chemgenex fell 1.5 cents or 3.7 percent to 39 cents.

LIVING CELL TECHNOLOGIES

Living Cell says that its pig cell product Diabecell in phase I/IIa clinical trials for Type 1 diabetes is “free of pig viruses, bacteria and parasites”.

Living Cell said that following reports of a new strain of influenza virus in Mexico and the US, the company referred to Massey University emeritus professor Prof Roger Morris, an expert on pig infections, who said that swine influenza was not endemic in New Zealand.

The company said that the appearance of pig-avian-human viruses was a consequence of human co-existence with pigs and birds in nature.

Living Cell said viral infections from pigs to humans have never arisen from pig tissue implanted into humans.

The company said New Zealand’s geographical isolation, historical bio-security and strict animal quarantine practice kept the country free from a number of pig pathogens including swine influenza.

Living Cell said its pig herd was derived from the sub-Antarctic Auckland Islands and bred in bird-proof pathogen-free facilities.

The company’s medical director Prof Bob Elliott said that “as swine influenza infection has not been endemic in New Zealand, there has been no opportunity for pig, bird and human viruses to recombine as has occurred naturally elsewhere”.

He said the company’s pig cell treatment used cells from pigs bred from its own facilities in New Zealand.

“The complete isolation of our herd in a containment facility means that even if swine influenza did happen in other New Zealand pigs it is very unlikely to occur in this herd,” Prof Elliott said.

“Those who have received pig cell implants without immunosuppressive drugs have a normal immune system and are not at any additional risk and should follow the same travel precautions and advice that public health authorities have for healthy citizens,” Prof Elliott said.

Living Cell was untraded at 14.5 cents.

INCITIVE

Incitive shareholders will vote on the issue of 21,625,000 shares and 20,000,000 options to directors and former directors in lieu of wages and directors’ fees.

The resolutions propose issuing 5,000,000 shares to Don Home; 4,125,000 shares to Dr Tracey Mynott; 12,500,000 shares to Winton Willesee; 10,000,000 options to Mel Bridges and 10,000,000 options to Eric de Mori.

The meeting will be at Level 16, 190 Queen Street, Melbourne on June 2, 2009 at 4.30pm.

Incitive was untraded at 0.9 cents.

ARANA

Cephalon International Holdings increased its substantial shareholding in Arana from 77,735,303 shares (34.15%) to 80,250,940 (35.25%) on April 27, 2009.

The change was through an increase in takeover acceptances (BD: Feb 27, Mar 2, 2009).

Arana was unchanged at $1.375