



Biotech Daily

Thursday July 10, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS DOWN: MESOBLAST UP 9%, SUNSHINE HEART DOWN 22%**
- * **GRAEME KAUFMAN: \$400m FUND DELAYED BUT STILL BULLISH**
- * **MESOBLAST STEM CELLS ENHANCE LUCENTIS FOR EYE DISEASE**
- * **PRANA ALZHEIMER'S DISEASE DRUG PBT2 RESULTS**
- * **SUNSHINE HEART APPOINTS NICHOLAS CALLINAN DIRECTOR**
- * **CYTOPIA MOVES US OFFICE APPOINTS CHIEF SCIENTIFIC ADVISOR**

MARKET REPORT

The Australian stock market fell 1.4 percent on Thursday July 10, 2008 with the All Ordinaries down 68.9 points to 5,020.5 points.

Seven of the Biotech Daily Top 40 stocks were up, 22 fell, four traded unchanged and seven were untraded.

Mesoblast was best, up eight cents or 8.89 percent to 98 cents on very small volumes followed by Living Cell up 8.7 percent to 25 cents.

Neuren climbed 4.94 percent; Pharmaxis and Ventracor were up more than two percent; with Progen and Viralytics up more than one percent.

Sunshine Heart led the falls, down 1.2 cents or 21.82 percent to 4.3 cents, followed by Labtech down 12.82 percent to 17 cents and Starpharma down 10.77 percent to 29 cents.

Acrux and Chemgenex lost more than seven percent; Universal Biosensors shed 6.25 percent; Psivida was down 5.9 percent; Cytopia and Prana fell more than four percent; Biota and Sirtex were down more than three percent; Cathrx and Optiscan shed more than two percent; with Antisense, Alchemia, Arana, Avexa, Bionomics, CSL, Novogen and Phosphagenics down more than one percent.

STRATEGIC LIFE SCIENCES

The co-founder of Strategic Life Sciences Graeme Kaufman says that although the proposed \$400 million fund has been delayed, the sector is better than ever.

Formerly CSL's chief financial officer and a senior Circadian executive, Mr Kaufman told the Life Sciences Lunch Club in Melbourne that he had read comments about the UK biotechnology sector that echoed perceptions in Australia, but said "we are in a vastly better position to take things forward than we were several years ago".

He said capital markets were more sophisticated than a decade ago, venture capitalist markets were more vibrant and Australia was better served by specialist analysts such as ABN Amro Morgans, Intersuisse and Wilson HTM "and we have better sources of news information" he said referring to David Blake and Bioshares as well as Biotech Daily.

He said a number of companies were in late stage trials and companies like "Chemgenex, Avexa and Acrux were leading the way in getting there commercially".

Mr Kaufman said it was hard not to be bullish about target markets with an ageing population and the internet increasing an informed public which demanded the availability of new treatments and reimbursement for those treatments.

"The asset side of the ledger in my view is looking pretty positive – despite the doom and gloom," Mr Kaufman said.

He said the other side of the ledger was low asset prices which created buying opportunities but with no funds available and the opportunity to raise capital very limited.

Mr Kaufman admitted that his own proposed \$400 million fund was behind schedule and had hoped to close the fund manager with \$6 million by the end of March. It has not yet closed.

In November 2007 Mr Kaufman said the Strategic Life Sciences fund would be "a fund of funds" (see Biotech Daily: November 12, 2007).

"We're not even looking at sophisticated investors," he said at that time.

The \$400 investment fund has not yet opened and in answer to questions said Strategic Life Sciences had "very small amounts locked in" but was "looking at \$150 to \$200 million" from two domestic institutions and offshore interests.

Strategic Life Sciences director of strategy and business planning Terri Clementson said the fund was looking at a totally different approach.

"We're not picking winners but putting together a supply chain," Ms Clementson said.

"That's why the Arabs and the Chinese are interested in us."

Mr Kaufman said Australia needed "to move out of the project paradigm"

"We have not so much listed companies as listed projects," he said.

"We need to be more broadly based than simply projects."

He said Strategic Life Sciences was building an investment team of four people with experience at CEO level as well as retaining an advisory group.

Asked specifically what kind of companies the fund would invest in, Mr Kaufman said he had learnt from former Circadian chief executive officer Leon Serry to "invest in people not technologies".

"Making decisions on technologies is quite difficult. People are much easier to judge."

He gave Chemgenex as a good example saying the existing technology was not going to work so the CEO brought in a new technology that would.

He said the issue of board-management relationships was "a fraught issue in the sector".

"You need some decent industry people on the board. They can be destructive if they don't understand the issues," Mr Kaufman said.

The meeting also discussed taxation measures to replace the commercial ready grants system and a need for better representation at the Federal Government level.

MESOBLAST

Mesoblast says allogeneic stem cells could enhance the effect of the anti-VEGF agent Lucentis for diabetic retinopathy and age-related macular degeneration.

Mesoblast said diabetic retinopathy and age related macular degeneration were the leading causes of blindness in the western world.

Mesoblast said its preclinical trail showed that a single injection of its allogeneic, or off-the-shelf, adult stem cells were safe and “highly synergistic” with the US Food and Drug Administration approved anti-vascular endothelial growth factor (VEGF) agent Lucentis for treatment of leaky blood vessels in the eyes of non-human primates.

The trial showed statistically significant improvements following a single injection of stem cells with Lucentis, in preventing severe blood vessel leakage and preventing disease recurrence.

Mesoblast said the trial showed that combining allogeneic stem cells with Lucentis prevented the formation of new blood vessels and protected against retinal detachment. The trial results form the basis of an investigational new drug submission to start a phase II clinical trial of Mesoblast stem cell therapy for eye diseases.

Current treatment for age-related macular degeneration is injections of an anti-VEGF agent into the eye every four to six weeks as a maintenance therapy to prevent reversal in visual improvement.

Anti-VEGF agents Lucentis and Macugen, approved by regulatory bodies and distributed by Genentech, Novartis and Pfizer, are in common use.

Mesoblast said the study objectives were to evaluate the safety and effectiveness of a single intravitreal injection of the company’s proprietary allogeneic mesenchymal precursor cells alone and in combination with a single intravitreal injection of the anti-VEGF agent Lucentis at 0.5mg.

Fluorescein angiography was performed at days 15, 28, 35 and 42 to assess and grade the degree of vessel leakage following laser damage.

The trial in forty-two non-human primates, conducted by Mesoblast’s US sister company Angioblast Systems, showed that injecting allogeneic stem cells was as effective at reducing blood vessel leakage after laser-induced damage as Genentech’s Lucentis, the most effective FDA approved anti-VEGF agent in use, while combining the anti-VEGF agent with allogeneic stem cells may lead to improved vision and a reduction in the frequency of subsequent anti-VEGF injections into the eyes.

Mesoblast founder and director Prof Silviu Itescu said: “These are extremely exciting results which raise the prospect that our cells may be able to improve vision in conditions associated with abnormal blood vessels in the eye, while at the same time enabling physicians to reduce the frequency or dosage requirements of intraocular injections of anti-VEGF agents such as Lucentis.”

The company said in the US about 1.5 million people suffer from age-related macular degeneration associated with abnormal blood vessels, with more than 200,000 new cases a year and 500,000 diabetics suffer from macular oedema caused by abnormally leaky blood vessels.

Angioblast intends forming a strategic partnership with a major global health care company for commercialization of its stem cell product for the treatment of eye diseases.

Mesoblast climbed eight cents or 8.89 percent to 98 cents.

PRANA

Prana said preclinical results published in the journal 'Neuron' for its Alzheimer's disease drug PBT2 shows profound and rapid improved cognition in transgenic mice.

Prana said that the results of the phase II clinical trials show PBT2 prevent the formation of soluble amyloid beta oligomers, the form of amyloid beta or Abeta believed to be the most toxic.

Prana said PBT2 substantially reduced the amount of all forms of amyloid beta in the transgenic mouse brain, over a nine week period.

The company said that within hours of oral administration, PBT significantly lowered soluble (interstitial) amyloid beta in the brain, sampled using in vivo microdialysis.

Prana said PBT2 protected neurons in living brain tissue from the toxic effects of amyloid beta protein which impaired the signaling between neurons in Alzheimer's disease.

Prana scientific adviser Prof Rudolph Tanzi said the "positive findings in Alzheimer's mouse models along with the encouraging results from the phase II clinical trial of PBT2 greatly strengthen my belief that this drug will ultimately be shown to slow down disease progress in Alzheimer's patients".

The authors of the research paper said that healthy brain function was dependent on tightly regulated movement of metals within and between neurons.

They said that they speculated "that with aging this restraint may be loosened, rendering the brain vulnerable to oxidative stress and the pernicious effects of Abeta accumulation".

Prana said the success of PBT2 lies in its ability in the "disaggregation of plaques, the detoxification of Abeta and the enhanced removal of Abeta from the brain."

Prana's head of research Prof Robert Cherny and co-author of the research paper said "using in vivo microdialysis, we can monitor the effects of the drug on brain Abeta in real time in the conscious, freely-moving transgenic mouse".

"We can literally see the drug altering brain chemistry," Prof Cherny said.

"The publication emphasizes that the dramatic improvements in memory in mice seen with PBT2 are associated with reduction in this soluble (interstitial) Abeta," he said.

Prana's chief executive officer Geoffrey Kempler said the company was "very confident that our drug has the potential to be marketed as a treatment for Alzheimer's disease".

"Prana's approach is different to others because PBT2 targets toxic metal interactions in the brain," Mr Kempler said

The data will be presented at the 11th International Conference on Alzheimer's Disease (ICAD) in Chicago on July 29, 2008 by Prof Cherny describing key preclinical findings of PBT2 in a lecture entitled, "The 8-hydroxyquinoline analog PBT2 rapidly restores cognition and reduces soluble Abeta in Alzheimer's transgenic mice".

An abstract of the 'Neuron' journal article is at: <http://www.neuron.org/content/current>

Prana fell two cents or 4.88 percent to 39 cents.

SUNSHINE HEART

Sunshine Heart has appointed Nicholas Callinan as a director effective from July 10, 2008.

Mr Callinan has degrees in engineering and business administration from the University of Melbourne.

Mr Callinan will replace Dr Conrad Wang, who was a representative of the substantial shareholder Three Arch Partners.

Sunshine Heart chairman, Malcolm McComas said the board changes were "part of a board renewal plan that has been under consideration for some months".

Sunshine Heart fell 1.2 cents or 21.82 percent to 4.3 cents.

CYTOPIA

Cytopia has appointed Dr Devron Averett as chief scientific advisor, closed its Rensselaer, New York office and relocated its US operations to Woodside, California.

Cytopia said Dr Averett will work with the company's executive management team part-time "providing scientific leadership and guidance".

Dr Averett worked with Glaxo Wellcome, Burroughs Wellcome, Valeant Pharmaceuticals International and co-founded Anadys Pharmaceuticals.

Cytopia said Dr Averett had a doctorate of philosophy in microbiology and immunology.

He has authored or co-authored more than 40 peer-reviewed publications and is the inventor on seventeen issued and nine pending US patents, and their international filings.

Cytopia said Dr Averett has contributed to the discovery or development of multiple oncology and antiviral medicines and drug candidates, including Zeffix, Emtriva, Ziagen, Arranon, ANA598 and ANA773.

Cytopia chief executive officer Andrew Macdonald said the appointment would bolster the work underway on small molecule compounds that are approaching the clinic and progressing through clinical trials.

Cytopia said the vice president of business and corporate development at Rensselaer Dr Shreefal Mehta would leave the company.

Consultant Richard Haiduck has been appointed chief business advisor.

Cytopia said Mr Haiduck would be responsible for its global business and corporate development.

Cytopia said Mr Haiduck holds a masters of business administration in finance, a bachelor degree in marketing and had worked for Abbott, Geron, Desmos and Biostreet and as managing director of the merchant banking group Burrill.

Cytopia fell 0.1 cents or 4.76 percent to 20 cents.