



Biotech Daily

Wednesday May 14, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECHS DOWN: STEM CELL UP 20%; PRANA DOWN 8%**
- * **BUDGET 2008: LITTLE JOY FOR BIOTECHNOLOGY, FOR NOW**
- * **PRIMA ON ROAD TO RECOVERY**
- * **BRAZIL'S CIRCADIAN ROUTE TO 15% OF METABOLIC VIA EDWARD ST**
- * **STEM CELL GRANTED US PATENT FOR CELL PURITY**
- * **HALCYGEN FILES ANTI-FUNGAL IND**
- * **ANZ CHANGES OPES PRIME SHARE SALES NOTICE**

MARKET REPORT

The Australian stock market climbed 1.0 percent on Wednesday May 14, 2008 with the All Ordinaries up 57.1 points to 5,940.3 points.

Eleven of the Biotech Daily Top 40 stocks were up, 15 fell, nine were unchanged and five were untraded.

Stem Cell Sciences was best, up six cents or 20.0 percent to 36 cents with 85,180 shares traded, followed by Optiscan up four cents or 16.0 percent to 29 cents.

Proteome climbed 7.69 percent; Bionomics was up 5.63 percent; Circadian and Ventracor were up four percent or more; Resmed rose 3.06 percent; Sirtex was up 2.34 percent; with Antisense and Clinuvel up more than one percent.

Prana led the falls down 3.5 cents or 7.78 percent to 41.5 cents on small volumes, followed by Mesoblast down four cents or 5.37 percent to 70.5 cents.

Agenix, Cellestis, Cytopia, Progen and Tissue Therapies lost more than three percent; Pharmaxis and Polartechnics shed more than two percent; with Avexa, Chemgenex, Peplin and Starpharma down more than one percent.

BUDGET 2008 EDITORIAL

The first Rudd Labor Government Budget is disappointing for the biotechnology sector. The word "biotechnology" did not feature once in Treasurer Wayne Swan's speech, but there was worse to come.

The Commercial Ready Grants system was closed as of today with no replacement in sight for at least another year, until after the Innovation Review has been completed.

A spokesperson for Innovation Minister Senator Kim Carr told Biotech Daily that there were three programs replacing the Commercial Ready Grant system "retooling, green buildings and climate ready". None appear directed at innovative biotechnologies.

While Biotech Daily welcomes many of the tax and social reforms announced by Mr Swan, biotechnology has fared as badly as the environment, in which the oxymoron of clean coal received the same amount of funds (\$500 million) as renewable fuels.

Despite admirable spending on all levels of pre-tertiary education and a doubling of post-graduate scholarships, there is no certainty for the commercialization of research.

A Department of Innovation spokeswoman said \$707 million would be "saved" over four years by closing the Commercial Ready Grants scheme. She said \$160 million would be given to "clean business".

On the other hand, the National Health and Medical Research Council received a 25 percent increase in funds from \$495 million in 2006-'07 to \$617.8 million for 2007-'08.

Mr Swan announced a \$10 billion fund to finance health infrastructure with spending on "hospitals, medical technology equipment, and medical research facilities and projects" and a spokesman said a significant amount would go to medical research.

The Health Department's allocation included \$15 million over three years for clinical trials as well as \$100 million over several years for other research and treatment centres.

Marc Sinatra writes:

To be fair, the government had other fish to fry.

They wanted to produce a budget with their ideological stamp on it, pay back those who voted for them, be seen to be looking after the economy and create a series of funds that could be used to help them get re-elected the next time around.

This is political realism and they delivered.

We could say that after 12 years in opposition Labor could have come up with at least a few good biotechnology ideas to push through on Budget night. But political parties are unlikely to do anything that won't win kudos.

Other events were always going to overshadow biotechnology last night and even if the Labor Party did have ideas, they wouldn't gain anything by releasing them in the Budget.

One positive announcement that will impact the biotechnology sector is the funding of more places for post graduate students at universities.

Supply and demand would suggest that this may help biotechnology industry through the provision of cheaper labor, although this impact may be small.

But the money ear-marked for more post-graduate places may have been better spent on producing better post-graduates with a clear and well-rewarded career structure.

The more important announcement is the close of the commercial ready grant program, which just about every company involved in biotechnology seems to have used.

There may be better ways to support the biotech industry other than the program, but they haven't announced anything to replace it and won't until Labor completes a review of its innovation policy, which is at least a year away.

Given the popularity of the Commercial Ready program, why axe it now without a replacement or even a change of tack? It just seems like a grab for a little bit of savings. We got what we expected this year, but we can hope for more next year.

PRIMA BIOMED

Prima Biomed appears to be on the road to recovery with a new board, cash in the bank and a planned pivotal phase II/III trial of its ovarian cancer vaccine.

Director Martin Rogers told Biotech Daily that the company had raised \$2.3 million, had \$1.5 million cash in the bank with a cash burn rate of \$100,000 a month.

Mr Rogers said Prima also had an offer of \$500,000 in further available funds.

He said the had appointed world-leading cancer specialist, Prof Ian Frazer, as a scientific advisor and discussions were underway with the US Food and Drug Administration for a investigational new drug application for the cancer vaccine platform CVac.

The board is chairman Ata Gokyildirim, Dr Richard Hammel and Mr Rogers.

Prima said in a notice to the ASX that subsidiary Oncomab had been granted a patent for the use of therapeutic antibodies that target the tumor antigen, cripto-1, in the treatment of cancer.

Mr Rogers said more funds could be raised by Prima through the sale of non-core assets like Oncomab.

Prima said it was in confidential discussions with a number of international pharmaceutical and biotechnology companies regarding the sale or sublicensing of Oncomab.

The company will hold an extraordinary general meeting on June 4, 2008 to consider the issue of options to the board, the issue of shares in payment of services by the company to a number of parties and the adoption of a new constitution.

Prima said a "gap analysis" of CVac was "an important step" towards a pre-IND meeting with the FDA.

CVac is being developed as a maintenance therapy for ovarian cancer that is most likely to be administered post-surgery and post-chemotherapy to delay relapse and control metastases.

The global market for ovarian cancer therapeutics was \$2.1 billion in 2007.

Regulatory approval for CVac over the next six to nine months "is the core focus for Prima" the company said.

Prima said CVac was potentially useful in the treatment of other solid tumors including lung, breast, colon, renal and prostate cancer, as it targeted the tumor protein, mucin-1, which all these tumors express at relatively high levels.

Prima was unchanged at 1.2 cents.

METABOLIC

Brazil Farming Pty Ltd has become a substantial shareholder in Metabolic with a holding of 45,492,701 shares or 15.2 percent of the company.

In a substantial shareholder notice to the ASX Brazil Farming said it had bought the 36,012,701 shares (12%) originally acquired from Circadian by Iain Kirkwood and Edward St Consulting (see Biotech Daily; May 13, 2008).

Lyn Brazil told Biotech Daily that he and his wife, Bobbie, were Queensland-based investors who already owned about three percent of Metabolic.

Mr Brazil said he had "a few ideas" about where he would like Metabolic to go, but nothing solid enough to discuss.

"The cash is there and we can get involved in other things that are short of cash," Mr Brazil said.

Metabolic has about \$17 million in cash.

Metabolic fell 0.2 cents or 5.0 percent to 3.8 cents.

STEM CELL SCIENCES

Stem Cell Sciences has been granted a US patent for technology improving the efficiency of the culture and derivation of embryonic stem cells, increasing the purity of the cells. Stem Cell said the technology offered advantages for cell-based drug discovery applications, where the prevention of uncontrolled differentiation facilitated the efficient expansion of the cells prior to their use.

The patent claims cover the culture and derivation of embryonic stem cells using a medium that contains leukemia inhibitory factor and an inhibitor of an enzyme which activates mitogen-activated protein kinases, the enzyme is named MEK.

Stem Cell said that when embryonic stem cells differentiate they secrete factors that lead to the differentiation of other embryonic stem cells and the proliferation of these cells results in the purity of the embryonic stem culture being lost.

A MEK inhibitor in combination with leukemia inhibitory factor suppresses undesired differentiation and maintains the pluri-potent nature of the embryonic stem cells.

This patent broadens the claims already granted under a previous US patent.

Stem Cell chief scientific officer Dr Tim Allsopp said purity and homogeneity were "critical factors" when embryonic stem cell growth from single cells was required.

Dr Allsopp said the probability of a cell being an embryonic stem cell in a culture becomes very low when differentiation is not controlled.

Stem Cell Sciences chief executive officer Dr Alastair Riddell said the technology was an advance in cell culture that would be used in the revenue-generating division.

Dr Riddell said the improved cell cultures in the patent were "of particular interest to pharmaceutical companies wanting to use our technology for drug screening".

Stem Cell Sciences climbed six cents or 20 percent to 36 cents.

HALCYGEN

Halcygen has filed an investigational new drug application with the US Food and Drug Administration for pivotal pharmacokinetic studies of SUBA-Itraconazole.

Halcygen said the application was part of the registration strategy and was designed to examine the bioequivalence of Halcygen's SUBA-Itraconazole with the market's leading product Sporanox which is owned by Janssen Pharmaceutical Products, part of the Johnson & Johnson Group.

The FDA initially required Halcygen to undertake a phase III registration study (see Biotech Daily; November 29, 2007), but "following further discussions, the FDA now has guided Halcygen to undertake a [pharmacokinetic] program to examine the antifungal drug's bioequivalence to Sporanox" Halcygen said.

Halcygen said it would undertake a clinical pharmacokinetic program and seek further guidance from the FDA.

Halcygen chief executive officer Dr Roger Aston said his company's product "potentially has important advantages over the current market leader Sporanox".

Dr Aston said SUBA-Itraconazole could be taken with or without food making patient compliance easier.

Halcygen said it had clinically evaluated SUBA-Itraconazole, a proprietary formulation, in five successful pharmacokinetic studies.

These studies have demonstrated that Halcygen's formulation has significantly improved bioavailability or absorption by the gastrointestinal track compared with the market leader, enabling the use of a lower dose of the drug.

Halcygen was up eight cents or 29.63 percent to 35 cents.

ANZ OPES PRIME

For the third trading day in a row the ANZ Bank has not sold any shares in Solagran or Biopropect acquired through the collapse of Opes Prime Stockbroking.

An ANZ Bank spokeswoman told Biotech Daily the Bank would no longer issue a daily general statement covering all remaining stocks, but would post standard substantial shareholder notices when sales of shares exceeded one percent of the relevant company. The ANZ Bank holds 118,478,421 Biopropect shares (24.3%); 55,822,662 ordinary Solagran shares (42.4%); and 9,828,258 partly paid Solagran shares or 20.4 percent of the share issue.

Biopropect was unchanged at two cents.

Solagran was unchanged at 40 cents.