



# Biotech Daily

Monday September 29, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECHS DOWN: VIRALYTICS UP 15%, GENETIC TECH DOWN 20%**
- \* **ALCHEMIA SUBMITS CANCER DRUG IND TO FDA**
- \* **STEM CELL CENTRE APPOINTS PROF GRAHAM MACDONALD CHAIR**
- \* **BIOTA'S PETER MOLLOY APPOINTED VIRALYTICS' DIRECTOR**
- \* **SELECT VACCINES APPOINTS JULIE NUTTING INTERIM CEO**

## MARKET REPORT

The Australian stock market fell 1.9 percent on Monday September 29, 2008 with the All Ordinaries down 95.4 points to 4,839.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 17 fell, four traded unchanged and 10 were untraded.

Viralytics was best, up 0.7 cents or 14.89 percent to 5.4 cents on small volumes followed by Phosphagenics up 10.61 percent to 7.3 cents.

Clinuvel climbed 4.55 percent; Pharmaxis was up 3.21 percent; Progen rose 2.78 percent; with Cellestis, Novogen and Peplin up more than one percent.

Genetic Technologies led the falls, down 1.5 cents or 20.0 percent to six cents, followed by Antisense down 12.7 percent to 5.5 cents and Phylogica down 9.0 percent to 9.1 cents.

Arana lost 6.82 percent; Bionomics and Neuren were down more than five percent; Polartech and Sirtex fell more than four percent; Avexa, Chemgenex, Mesoblast and Starpharma were down more than three percent; Cathrx, Heartware, Labtech and Ventracor shed more than two percent; with Acrux and Resmed down more than one percent.

## ALCHEMIA

Alchemia has submitted its investigational new drug application to the US Food and Drug Administration for HA-Irinotecan solution for infusion for cancer.

Alchemia said the compound uses its Hyact technology which selectively targets the chemotherapeutic drug irinotecan to the tumor.

The investigational new drug application supports Alchemia's planned pivotal phase III trial which will compare the efficacy of HA-Irinotecan with irinotecan, with both to be used in combination with cetuximab (Erbix) in Kras (Kirsten rat sarcoma viral oncogene homolog) wild-type metastatic colorectal cancer patients.

Alchemia said the study was supported by data from its phase II trial which randomized 80 patients to either HA-Irinotecan or irinotecan (Pfizer's Camptosar).

The company said the results showed that HA-Irinotecan produced a statistically significant increase in progression free survival (up 116 percent), disease control and the number of cycles of therapy that could be administered to patients (see Biotech Daily; April 26 and May 29, 2007).

Alchemia said its Hyact technology combined the chemotherapeutic drug irinotecan with hyaluronic acid (HA) to enhance delivery and retention of the drug at the site of the tumor. Alchemia's chief executive officer Dr Pete Smith said HA-Irinotecan's advance to a phase III trial made Alchemia "one of the few biotech companies in Australia that has two late-stage assets in its drug development portfolio.

Alchemia expects its generic synthetic heparin to be approved and launched in 2009.

"The FDA requires only one pivotal trial for registration of HA-Irinotecan ... as opposed to the usual two trials required in a full new drug application," Dr Smith said.

Alchemia said the trial was expected to begin in 2009 and would recruit 740 patients with metastatic colorectal cancer from Australia, Europe and the US.

The company said the FDA would review the submitted documentation and, assuming there were no requests for additional information, Alchemia would have an open investigational new drug application in about one month.

Alchemia was unchanged at 22 cents.

## AUSTRALIAN STEM CELL CENTRE

The Australian Stem Cell Centre has appointed Prof Graham Macdonald as the independent executive chair of its interim board.

The Centre said Prof Macdonald had "a wealth of experience in clinical medicine, basic biomedical science and ... licencing and commercialization".

The Centre said Prof Macdonald was an academic nephrologist before joining the pharmaceutical industry and holding the positions of medical director and external licencing coordinator at Merck Sharp and Dohme (Australia) where he brokered agreements including a \$US100 million deal with Amrad, now Zenyth Therapeutics, to develop a new asthma treatment.

The Centre said Prof Macdonald led initiatives to support Australian biomedical science including research scholarships, commercial training for science and medical graduates, sponsorship of conferences and representative bodies, and funding research projects.

The Australian Stem Cell Centre interim board is composed of Prof Edwina Cornish, Prof David Siddle and Dr Henry De Aizpurua, who recently replaced the seven member board, which resigned citing differences with member institutions over its direction and independence (see Biotech Daily; September 5, 2008).

In July the previous board sacked chief executive officer Dr Stephen Livesey (see Biotech Daily July 30, 2008).

## VIRALYTICS

Viralytics has appointed former Biota managing director and chief executive officer Peter Molloy as a director.

Viralytics said Mr Molloy was a “high profile ... successful Australian pharmaceutical and biotechnology executive” and a US-based industry consultant.

The company said the California-based Mr Molloy was with Biota from 2002 to 2005, when Biota’s market valuation grew from \$25 million to more than \$250 million.

Mr Molloy was previously president and chief executive officer of Wisconsin-based cancer and viral research company SLIL Biomedical Corp and chief executive officer of Melbourne’s Florigene focused on genetic modification of plants as well as president of Boston based transdermal drug delivery company Moleculon Inc.

He worked as a pharmaceutical marketing executive for 17 years with his last role as vice-president of strategic marketing for Pharmacia, then a top 20 pharmaceutical company and now part of Pfizer.

Mr Molloy holds a BSc in microbiology and biochemistry from the University of Melbourne and an MBA from the University of Adelaide.

Viralytics climbed 0.7 cents or 14.89 percent to 5.45 cents

## SELECT VACCINES

Select Vaccines has appointed Julie Nutting as interim chief executive officer.

Ms Nutting joins Select Vaccines from the Sydney-based Savine Therapeutics, an unlisted vaccine development company where she was managing director.

Select Vaccines said Ms Nutting had a background in the biotechnology and pharmaceutical industry, having worked been chief executive officer of Psiron (now Viralytics) and in senior positions for Sandoz and Covance.

Previous she has been responsible for technology acquisition and commercialization, fund raising, licencing and regulatory affairs.

The company said Ms Nutting had experience as a director of ASX-listed companies and was on the boards of Bio Ops, Milvella and the Cooperative Research centre for Asthma and Airways.

Select Vaccines’ chairman Robin Beaumont said Ms Nutting’s “skills and experience will assist in driving the company through the next stage of development once a thorough review of corporate strategy has been undertaken”.

Ms Nutting said there were “multiple opportunities for vaccine development companies”.

“Vaccines represent a fast growing market, which is seeing a renaissance as novel technologies come into the clinic and to market,” Ms Nutting said.

“I am looking forward to leading Select Vaccines through the development and commercialization of its Anavax vaccine candidates,” she said.

Select Vaccines was untraded at 0.9 cents.