



Biotech Daily

Tuesday April 29, 2008

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECHS EVEN: NEUREN UP 14%, HEARTWARE DOWN 6%**
- * **BENITEC ACQUIRES OPTIONS ON 5 RNAi PATENTS FOR HIV**
- * **CE MARK FOR NANOSONICS ULTRASOUND DISINFECTOR**
- * **DR ROLAND SCOLLAY QUILTS METABOLIC**
- * **VIRAX REQUIRES OP-HIT GASMERE TO BUY \$500k CONVERTIBLE NOTES**
- * **ANZ'S OPES PRIME BIOTECHS: NO SALES**
- * **HEARTWARE APPOINTS DR DAVID HATHAWAY CMO**
- * **PEPLIN LOSES CMO DR ARTHUR BERTOLINO**

MARKET REPORT

The Australian stock market climbed 0.1 percent on Tuesday April 29, 2008 with the All Ordinaries up 2.3 points to 5,672.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, six were unchanged and five were untraded.

Neuren was best, up 1.5 cents or 13.64 percent to 12.5 cents followed by Antisense up 0.8 cents or 11.94 percent to 7.5 cents and Cytobia up 11.11 percent to 30 cents.

Optiscan climbed 9.52 percent; Pharmaxis rose 8.23 percent; Portland was up 7.41 percent; Peplin, Starpharma and Ventracor were up more than six percent; Bionomics rose 5.26 percent; Polartechnics climbed 4.17 percent; Benitec and Prana were up more than two percent; with Circadian and Resmed were up more than one percent.

Heartware led the falls, down 2.5 cents or 6.33 percent to 37 cents, followed by Sirtex down 26 cents or 6.27 percent to \$3.89.

AcruX, Genetic Technologies and Progen fell more than four percent; Alchemia, Clinuvel and Mesoblast lost more than three percent; Chemgenex and Phosphagenics shed more than two percent; with Biota, Novogen and Psivida down more than one percent.

[BENITEC](#)

Benitec has secured further intellectual property rights underpinning its HIV/AIDS lymphoma compound.

The compound is a viral vector in clinical trials at the City of Hope research and treatment centre in Duarte, California.

Benitec said the viral vector therapeutic uses RNAi technology covered by its patent portfolio.

City of Hope has granted Benitec an option on a global licence to a suite of its patent rights and if exercised, City of Hope will grant Benitec a worldwide royalty-bearing licence to research and develop, manufacture and commercialize products.

Benitec chief executive officer Sue MacLeman said the RNAi global revenues were forecast to reach \$US146.4 million in 2010 with the US dominating the total RNAi market. "Benitec's newly-acquired option to patent rights has the potential to generate considerable investment returns," Ms MacLeman said.

"This move strengthens Benitec's collaborative relationship with City of Hope which is managing the HIV clinical trial," Ms MacLeman said.

City of Hope's chair of virology, Dr John Zaia said "the close collaboration between our scientists, physicians and Benitec has been instrumental to moving this exciting study ahead".

The pilot study is Benitec's first human trial and uses a triple therapy delivered using a lentiviral vector for the treatment of HIV.

The rHIV7-shI-TAR-CCR5RZ vector suppresses HIV by expressing three therapeutic nucleic acids that are directed against key steps in HIV replication.

Under the agreement, Benitec has an option to exclusive rights to US patents and patent applications for the patent entitled 'Nucleolar targeting of therapeutics against HIV' and has US patents and patent applications as well as non-US equivalents to four more patents: 'Ribozymes targeted to human CCR5 mRNA'; 'Methods and kits for synthesis of siRNA expression cassettes'; 'Methods for producing interfering RNA'; and 'Adenoviral VA1 Pol III'.

The Benitec-City of Hope study is a pilot study of the safety and feasibility of stem cell therapy for AIDS lymphoma using stem cells treated with a lentiviral vector-encoding multiple anti-HIV RNA's. It is designed to determine the safety and feasibility of RNA-based anti-HIV therapy with lentivirus-transduced haematopoietic progenitor cells in patients undergoing autologous haematopoietic stem cell transplantation for intermediate and high grade AIDS lymphoma.

The lentivirus vector encodes three forms of anti-HIV RNA: RNAi in the form of a short hairpin RNA (shRNA) targeted to an exon in HIV-1 tat/rev, a decoy for the HIV TAT-reactive element and a ribozyme that targets the host cell CCR5 chemokine receptor (CCR5RZ).

The vector, used to transduce autologous CD34-selected haematopoietic progenitor cells (HPC), is called rHIV7-shI-TAR-CCR5RZ and was manufactured by the Center for Biomedicine and Genetics at the City of Hope.

Following standard mobilization of HPC and collection by apheresis (HPC-A), a portion of the cells will be cryo-preserved and left non-manipulated for use as a treatment. The remaining cells will be enriched for CD34+ cells using a Miltenyi Clinimacs system, cryo-preserved, and later genetically modified by infection with rHIV7-shI-TAR-CCR5RZ.

The subjects will undergo conditioning therapy and at the time of autologous haematopoietic stem cell transplantation, the rHIV7-shI-TAR-CCR5RZ transduced cells will be infused, followed 24-hrs later by the infusion of non-transduced autologous HPC-A. Benitec was up 0.2 cents or 2.11 percent to 9.7 cents with 3.9 million shares traded.

NANOSONICS

Nanosonics says it has been received Conformité Européenne (CE) Mark approval for its ultrasound probe disinfection device.

The CE Mark allows Nanosonics to manufacture and sell the ultrasound probe disinfection device in Europe and submit applications to other countries that recognize the CE Mark process, including New Zealand and several Asian and South American countries.

Nanosonics acting chief executive officer Chris Grundy told Biotech Daily that the device nebulizes hydrogen peroxide for the disinfection process, which takes less than six minutes.

He said it was expected to be used at the point of care rather than in a centralized sterilization unit.

Nanosonics said the approval permits the company to self-assess product enhancements that may be developed in future.

The company said the authorization to self-assess product improvements was recognition that it had developed advanced internal quality control systems and expertise.

Nanosonics said this level of authorization was more commonly associated with larger established medical device companies.

The company said the CE Mark was “a pivotal event” in its development, as it transforms its sterilization and disinfection technology platform into commercial products targeting substantial global markets.

Nanosonics said it was preparing the regulatory file for the Australian Therapeutics Goods Administration.

There are a number of differences between the requirements for CE Mark and the TGA.

The TGA submission was expected to be lodged in the next two months.

Nanosonics said the more substantial submission for approval by the US Food and Drug Administration would be ready for lodgment later this year.

Scale-up manufacturing will begin with the letting of contracts for tooling, allowing commercial volume production of the device.

Nanosonics said the final design incorporated “many improvements over the earlier prototype”.

Initial product launch is scheduled for late 2008 with manufacturing scale-up to occur in early 2009.

Nanosonics said the CE Mark enabled it to finalize product distribution agreements in Europe and elsewhere.

Nanosonics was up six cents or 25.0 percent to 30 cents.

METABOLIC

Metabolic chief executive officer Dr Roland Scollay has resigned from the board of directors effective immediately and will leave the company.

A media release said Dr Scollay would continue to work with the board as chief executive officer in the interim “to ensure a smooth transition and [he] will be leaving the company to pursue other interests”.

Dr Scollay was unavailable for comment due to personal reasons unrelated to the announcement.

Metabolic chairman Rob Stewart said that the board was grateful to Dr Scollay for his contributions during his term, “in particular for his high level of professionalism in the last year, which has been a difficult time for the company”.

In 2007 clinical trials resulted in the closure of Metabolic's programs for its obesity drug AOD9604 (see Biotech Daily; February 21, 2007) and the neuropathic pain drug ACV1 (see Biotech Daily; August 14, 2007).

The company's share price fell from 80 cents in February 2007 to 5.8 cents in August 2007.

Yesterday, Circadian announced the sale of its 12 percent of Metabolic to Edward St Investments and on April 8, 2008 Acorn Capital sold its eight percent holding to as yet unidentified buyers.

Metabolic said it would "continue to focus on finding a merger and acquisition transaction that will build shareholder value in the medium term", as its research stage projects were at an early stage.

The company said it had about \$16.8 million in cash and additional assets acquired would diversify its activities and reduce the risk inherent in its existing portfolio.

Metabolic fell 0.4 cents or 10.0 percent to 3.6 cents.

VIRAX

Virax has asked Gasmere Pty Ltd to acquire and pay for \$500,000 of convertible notes under an agreement related to its December 19, 2007 rights issue.

Virax said Gasmere had lost its substantial shareholding in the company to the ANZ Bank following the collapse of Opes Prime Stockbroking.

The ANZ said on April 7, 2008 that it held 6.2 million Virax shares or 5.8 percent of the company.

Gasmere was a party to a convertible note shortfall placement agreement for \$500,000.

Virax said it had required Gasmere to apply for and pay for \$500,000 of convertible notes.

Virax is in discussions with Gasmere to conclude the arrangements.

No convertible notes have been issued to Gasmere.

Virax was unchanged at 4.2 cents.

ANZ OPES PRIME

The ANZ says it has not sold any Acrux shares, maintaining its holding at 10,357,618 shares or 6.502 percent of the company.

In its substantial shareholder notice the ANZ said it had not sold any of its 124,484,003 Bioprospect shares or 25.6 percent of the company.

The ANZ has not sold any of its 4,250,400 Incitive shares.

The bank has not sold any of its 55,991,827 ordinary Solagran shares representing 42.5 percent of the company nor any of the 9,857,865 partly paid shares or 20.5 percent of the partly paid share issue.

PEPLIN

Peplin says chief medical officer and vice-president of medical affairs Dr Arthur Bertolino has resigned.

Peplin's chief scientific officer and vice president of research and development, Dr Peter Welburn, will assume responsibility for all clinical development and medical affairs.

Dr Welburn has been chief scientific officer and vice president of research and development since April 2001 and has been responsible for all aspects of the development of Peplin's lead compound PEP005.

Peplin was up three cents or 6.25 percent to 51 cents.

HEARTWARE

Heartware has appointed Dr David Hathaway as chief medical officer, reporting to chief executive officer Doug Godshall.

Dr Hathaway has served as chief medical officer for several drug discovery and medical device companies.

Heartware said Dr Hathaway had overseen the preclinical and clinical development of multiple products in the cardiology arena and led the strategic development, out-licencing and commercial launch of a number of pharmaceuticals and medical technologies.

He has extensive regulatory experience, having served on two successful new drug application teams and led partnering programs for Bristol-Myers Squibb, Knoll, Restoragen and Arginox Pharmaceuticals.

Dr Hathaway was previously vice-president of medical affairs with Knoll Pharmaceutical until it was acquired by Abbott.

Prior to his corporate career, Dr Hathaway was division chief and director of the Krannert Institute of Cardiology at the Indiana University School of Medicine, where he practiced for more than 14 years.

Dr Hathaway has been cardiovascular diseases section editor of Kelley's Textbook of Medicine and was a member of the editorial boards of the Journal of Clinical Investigation, the Journal of the American College of Cardiology and Circulation.

He has authored more than 80 scientific and medical publications and is an inventor on 13 US patents and eight pending US patent applications.

Heartware was down 2.5 cents or 6.33 percent to 37 cents.