



# Biotech Daily

Monday October 20, 2008

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECHS DOWN: BENITEC UP 22.5%, OPTISCAN DOWN 33%**
- \* **SENATOR CARR RELEASES PHARMACEUTICAL INDUSTRY DRAFT REPORT**
- \* **TISSUE THERAPIES CLAIMS VITROGRO WOUND HEALING 'EXCEPTIONAL'**
- \* **SWITZERLAND APPROVES PHARMAXIS' ARIDOL TEST**
- \* **CYCLOPHARM \$3.2m RIGHTS ISSUE 'FULLY UNDERWRITTEN'**
- \* **BIODIEM NOBILO US CENTRES EXTEND FLU VACCINE AGREEMENT**
- \* **PEPLIN COMPLETES \$US6.7m NEOSIL ACQUISITION**
- \* **HEARTWARE GRANTED QUALITY MANAGEMENT CERTIFICATE**
- \* **FERMISCAN'S SYDNEY CLINIC TESTS BREAST CANCER**
- \* **GIACONDA CHAIRMAN RICHARD WOODS RESIGNS**
- \* **PRANA AGM TO INCREASE SHARE POOL 50%; ISSUES 2m OPTIONS**
- \* **GBS VENTURE PARTNERS APPOINTS DR GEORGE MORSTYN DIRECTOR**
- \* **ELLEX APPOINTS TWO DIRECTORS, ADVISER**
- \* **BIOSCEPTRE APPOINTS DR PAUL KELLY DIRECTOR**
- \* **AUSBIOTECH'S 'BUILDING A BIO-ECONOMY' CONFERENCE**

## MARKET REPORT

The Australian stock market climbed 3.9 percent on Monday October 20, 2008 with the All Ordinaries up 153.8 points to 4,098.7 points. Ten of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and eight were untraded.

Benitec was best, up 0.9 cents or 22.5 percent to 4.9 cents, followed by Polartech up 11.11 percent to 10 cents and Mesoblast up 8.43 percent to 90 cents. Phosphagenics climbed 6.06 percent; Clinuvel, Cochlear and Starpharma were up more than four percent; Labtech was up 3.7 percent; Cellestis, CSL and Prana rose more than two percent; with Arana up 1.2 percent.

Optiscan led the falls, down 3.3 cents or 33.0 percent to 6.7 cents, followed by Stem Cell down 25 percent to 22.5 cents and Sunshine Heart down 18.57 percent to 5.7cents. Avexa lost 8.33 percent; Proteome and Ventracor fell more than seven percent; Biota lost 5.81 percent; Progen fell 3.6 percent; with Circadian, Universal Biosensors and Viralytics down more than two percent.

## PHARMACEUTICALS INDUSTRY STRATEGY GROUP

The Minister for Innovation, Industry, Science and Research, Senator Kim Carr, has released the draft directions paper from the Pharmaceuticals Industry Strategy Group.

"I'm glad to see that the pharmaceuticals industry has been able to come together to develop a 10 year plan to attract investment in [research and development], clinical trials and manufacturing activity in Australia," Senator Carr said.

The Strategy Group, co-chaired by Dr Brian McNamee and the Department for Innovation, Industry, Science and Research's head of innovation Craig Pennifold, is made up of industry and union leaders and worked together to generate ideas about a sustainable future, focusing on what Australia does best, world class research and development and high quality manufacturing capabilities, Senator Carr said.

The Strategy Group is due to submit the final report at the end of the year.

In their introduction Dr McNamee and Mr Pennifold said the pharmaceuticals industry "faces significant changes in the global operating environment".

"These have been triggered by the increasing cost of drug development, falling R&D productivity, rapid technological change, increasing regulatory pressures and evolving health procurement practices," they said.

"The future of the Australian pharmaceuticals industry will be determined principally by how it responds to these global challenges, none of which are easily ameliorated by national governments."

They said the Australian Government had a role to play in supporting the transition to a more technologically sophisticated, knowledge intensive, industry more resilient to external shocks and better able to thrive under these pressures.

"A ... sustainable pharmaceuticals industry requires: predictable, timely and transparent regulatory and reimbursement systems that provide companies with a clear and streamlined path to market; an appropriate and balanced intellectual property regime; strong and effective capital markets that will fund high risk projects that are of high quality and have potential commercial returns; competitive taxation arrangements that provide incentives for companies to invest in relatively high risk activities like research and development or complex, value adding pharmaceutical manufacturing; an appropriately resourced tertiary education sector capable of producing high quality, job ready, science and medical research graduates; and strong and effective collaboration between industry and academic research.

Dr McNamee and Mr Pennifold said the Group measures would increase investment in the industry and leverage its research base to compete as a centre for high quality research and development, clinical trials and value added niche manufacturing.

The measures include: 1) encouraging strategic investment in research and development, manufacturing and infrastructure; 2) increasing Australia's attractiveness as a location for clinical trials and 3) improving pharmaceuticals skills and education.

"The Group does not view these three measures as alternatives, but rather as part of an integrated package. Measures 2 and 3 are not costly and should be pursued.

"The first measure is likely to be the most costly. Hence, while it can also be expected to deliver the largest net economic and social benefit, it will require more scrutiny in the context of broader Government priorities. The Group is aware that the broader innovation framework is being examined in another forum. Pharmaceuticals is an innovation-intensive industry, likely to be affected by changes in Australia's National Innovation System," Dr McNamee and Mr Pennifold said.

The co-chairs said the Group focused its recommendations on those it considered had a significant likelihood of delivering at least initial net economic and social benefit in the short to medium term.

## TISSUE THERAPIES

Tissue Therapies says the second patient treated in Perth has responded to Vitrogro wound treatment

Tissue Therapies said the second patient was a 72-year-old male who had suffered for six months with two adjacent venous ulcers on his left ankle, which had not healed with compression bandaging applied by the patient at home.

The company said treatment with Vitrogro occurred twice weekly with compression bandaging and ceased after 15 days.

The treatment resulted in a 75 percent total reduction in ulcer area after 24 days.

As with the first patient, Ms Dot Harrison, there was also a marked improvement in the health of the tissue at the edge of the second patient's ulcers.

Since the announcement of Ms Harrison's results at the end of her trial (see Biotech Daily September 3, 2008) the ulcer treated with Vitrogro has completely healed and it was expected the ulcers of the second patient would also heal completely in the near future.

Tissue Therapies chief executive officer Dr Steven Mercer said the results from the first two patients demonstrated "an exceptional rate of healing and improvement in tissue health at the ulcer edges" with no adverse reactions.

"These results are certainly consistent with our understanding of the how Vitrogro works and we are looking forward to the rest of the clinical results with even greater anticipation," Dr Mercer said. "We are delighted that the first patient's ulcer has now healed and anticipate that the ulcers of the second patient will do the same."

Tissue Therapies was up two cents or 22.22 percent to 11 cents.

## PHARMAXIS

Swiss therapeutic regulatory agency Swissmedic has approved Pharmaxis' Aridol.

Pharmaxis said Aridol was indicated for measuring airway hyper-responsiveness and was approved in 13 European countries.

Pharmaxis chief executive officer Dr Alan Robertson said Swiss physicians were among the earliest adopters of Aridol and pioneered early clinical trials.

Dr Robertson said Aridol had attracted the attention of two multinational pharmaceutical companies who were "currently funding studies in Switzerland that utilize Aridol to diagnose asthma and [chronic obstructive pulmonary disease] patients who will respond to inhaled corticosteroids".

Pharmaxis said Aridol would be distributed in Switzerland by Trimedal, a specialist respiratory and allergy pharmaceutical company based in Zurich, with a network of contacts of pulmonary specialists, allergists and respiratory laboratories, critical for the market success of Aridol.

Pricing for Aridol in Switzerland is included under an existing reimbursement code so marketing may commence immediately, Pharmaxis said.

Pharmaxis was unchanged at \$1.55.

## CYCLOPHARM

Cyclopharm's company secretary William Richardson told Biotech Daily that its rights issue was "fully underwritten" (see biotech Daily October 17, 2008).

Mr Richardson said CVC Venture Managers had underwritten the \$3.18 million one-for-4.4 non-renounceable rights issue of up to 31,800,000 shares at 10 cents a share.

Cyclopharm was untraded at 10 cents.

## BIODIEM

Biodiem, Nobilon and the US Centers for Disease Control and Prevention will extend their live attenuated influenza vaccine research agreement to the end of August 2009.

Biodiem said that since initiation of the co-operative research and development agreement in August 2006, the research team made significant progress toward the goal of characterizing and evaluating live attenuated influenza vaccine (LAIV) candidates against influenza A (H5N1) for pandemic preparedness in pre-clinical models.

Biodiem said the research team generated an H5N1 reassortant using the LAIV master donor strains.

The company said the reassortant had undergone extensive safety testing allowing for the commencement of a comparison study in a pre-clinical model.

The project will now focus on pre-clinical studies allowing for an assessment of the immunogenicity and comparative efficacy of inactivated and live pandemic vaccines against antigenically divergent H5N1 strains.

Biodiem director Prof Larisa Rudenko said the live attenuated influenza vaccine had been shown to be effective in pre-clinical and early clinical settings for H5N2 program.

"This product is unique in its ability to confer immunogenicity from a small single dose," Prof Rudenko said.

"The study of the H5N1 strain should further our understanding of LAIV in the context of a pandemic setting," she said.

Biodiem has licensed the majority of the LAIV rights to Nobilon, part of Schering Plough. The seasonal vaccine continues to progress toward the initiation of clinical development for European registration.

Biodiem retains the right to licence out the sales and marketing rights to the world's largest market, North America. Japanese rights are to be equally shared with Nobilon. Biodiem was unchanged at 7.5 cents.

## PEPLIN

Peplin has completed its \$US6.7 million "all stock" acquisition of the privately-held, dermatology-focused Neosil.

Peplin said the total combined cash balance of \$US56 million (\$A80.1 million) at June 30, 2008 would be sufficient to fund completion of the ongoing phase III trials of PEP005 (ingenol mebutate) Gel for actinic keratosis on both head and non-head treatment sites.

The Neosil purchase price of \$US6.7 million in shares of Peplin stock represents the amount of net cash held by Neosil at signing.

Peplin shares were valued based on the volume weighted 10-day trailing average closing price of Peplin's CHESS Depository Interests on the ASX immediately preceding the signing of the agreement in June 2008 at 42.56 Australian cents.

Peplin issued about 819,000 shares of its common stock equivalent to 16.4 million CHESS Depository Interests in exchange for the all equity interests of Neosil.

Neosil shareholders now own about 7.3 percent of Peplin.

In addition to its net cash, Peplin acquires Neosil's intellectual property portfolio which comprises two early clinical stage development programs: the first a hair growth stimulation technology with potential application in the treatment of hair loss and the second, a broad spectrum anti-microbial technology with potential application in the treatment of acne.

Peplin does not expect to commence further development of these programs before 2009. Peplin was untraded at 36 cents.

## HEARTWARE

Heartware has received a certificate of registration certifying that the company's quality management system complies with the requirements of ISO 13485:2003.

The company said the certification was issued by BSI Management Systems, the independent notified body appointed to assess the company's submission for Conformité Européenne (CE) Mark for its left ventricular assist system.

Heartware said the certificate signified the company had a comprehensive quality system that conforms to the International Organization for Standardization (ISO) requirements.

Heartware's president and chief executive officer Doug Godshall said the certificate was "an important milestone for the company".

"It is a particular credit to Mr Ramon Paz, our vice president of quality assurance and his team, who have led the process of upgrading the company's systems over the past 18 months," Mr Godshall said.

"Our commitment to quality across all aspects of our operations remains an important priority as we move ever closer to our European commercial launch and as we plan for a significant scaling up of our US clinical trial activities," Mr Godshall said.

The company said it expected to gain the CE Mark for its left ventricular assist system before the end of 2008.

Heartware was unchanged at 55 cents.

## FERMISCAN

Fermiscan says that from today the Sydney Breast Clinic will use its x-ray diffusion test on patients as an addition to their multi-disciplinary diagnostic and screening practices.

Fermiscan bought the clinic for \$5.5 million in June (see Biotech Daily; June 16, 2008).

Fermiscan said it would be the first time that the Fermiscan hair test would be used by medical staff in a clinical setting.

The company said an individual patient's test results could be compared directly to their imaging including mammography and/or ultrasound results.

Fermiscan said it would assist it and the medical community "to position the test within current clinical practice".

The Fermiscan test will be provided free to patients taking part in the study as part of the company's program to make the test widely available to Australian women.

Fermiscan said it was undertaking focused studies in other clinical settings and a study of patients in Italy with identified symptoms of breast cancer was "progressing well" and was expected to be completed by the end of the year.

Fermiscan fell half a cent or two percent to 24.5 cents.

## GIACONDA

Giaconda says its chairman Richard Woods has resigned "for personal reasons".

Giaconda chief executive officer Patrick McLean will take on the role of acting chairman while a replacement is sought.

In July Giaconda said it hoped to raise up to \$40 million through the issue of 100,000,000 shares to Australian Medical Therapy Investments (see Biotech Daily; July 18, 2008) but the deal has been entangled in the divorce proceedings of chief scientist, director and major shareholder Dr Tom Borody.

Giaconda was untraded at 13 cents.

## PRANA BIOTECHNOLOGY

Prana's annual general meeting will vote on a 50 percent increase in the share pool for directors, employees and consultants to 45,000,000 shares.

The meeting will also consider the prior issue of 18,125,000 shares which raised \$7.25 million, the adoption of a new constitution and the re-election of directors Peter Marks and Brian Meltzer.

On Friday October 17, 2008 after the market closed Prana requested the issue of 2,000,000 unlisted options exercisable at 50 cents "in lieu of cash payment to consultants for services rendered".

Prana's chief executive officer Geoffrey Kempler told Biotech Daily today that the company had a variety of consultants including, but not limited to, scientific, medical and management consultants.

Mr Kempler said these options and the shares in the company share pool were not for directors, but for the company's employees and consultants.

Mr Kempler said that directors would require separate shareholder approval to be granted any shares under the schemes.

Prana said it had 27,101,127 unlisted options and 3,700,000 unlisted warrants over American depository receipts equivalent to 10 shares per warrant (or a total of options and warrants over 64,101,127 shares) not quoted on the ASX with exercise prices ranging from no cost to \$US8 per warrant.

Exercise dates range from December 17, 2008 to August 7, 2014.

Prana's annual general meeting will be held in the Peppin Merino Room, Ground Floor, 369 Royal Parade, Parkville, Victoria on November 28, 2008 at 1030am.

Prana climbed one cent or 2.56 percent to 40 cents.

## GBS VENTURE PARTNERS

GBS Venture Partners has appointed former Amgen Inc senior vice-president Dr George Morstyn as a director.

GBS managing director Brigitte Smith said the company was "delighted to have someone of the calibre of Dr Morstyn join our board".

"Dr Morstyn has had a significant career in biotechnology and oncology, both internationally and within Australia, with his skill set spanning discovery, development, licensing, commercialization and manufacturing," Ms Smith said.

GBS said Dr Morstyn spent 11 years at Amgen, becoming senior vice-president of development and chief medical officer in 1999.

The position involved dealing with the US Food and Drug Administration, medical centres, media and the investment community.

Since returning to Australia about six years ago Dr Morstyn has a director Neuprotect, Chemgenex and New Zealand's Proacta.

Dr Morstyn is also chair of the scientific advisory board at Symbio Pharmaceuticals and has an honorary appointment at the Walter and Eliza Hall Institute of Medical Research, GBS said.

He is a board member of the Cancer Therapeutics Cooperative Research Centre and previously was the director of medical oncology at Melbourne's Austin Hospital and was head of the clinical program at the Ludwig Institute for Cancer Research in Melbourne.

GBS is a private company.



## ELLEX MEDICAL LASERS

Ellex Medical Lasers has appointed Giuseppe Canala and Malcolm Plunkett as directors and Warwick Kitt as an adviser.

Ellex said Mr Canala was an experienced company director with an engineering and economics background.

He is the managing director of Seghetti Estates, a private investment company and is a major shareholder in, and co-founder of, Ellex.

Ellex said Mr Canala had worked for the company in a range of management roles, including as director of engineering, director of operations and managing director.

He was company chairman from 1990 to 2001.

Mr Canala has a Bachelor of Technology in Electrical Engineering from the University of Adelaide and a BA in Sociology and Economics from Melbourne's La Trobe University.

Mr Plunkett has worked at Ellex for 12 years and is the managing director of Ellex R&D Pty Ltd and the head of Ellex's advanced research group.

Ellex said Mr Plunkett had nearly 40 years experience in the fields of electronics and engineering, including consumer electronics, mineral exploration, mineral analysis, electronic security systems and scientific instrumentation.

The company said Mr Plunkett was "instrumental in the establishment of design control and regulatory frameworks and is the author of five Ellex patents".

Ellex said Mr Kitt was "an experienced and well respected manager with a wealth of experience in the ophthalmic industry, both globally and locally".

The company said Mr Kitt retired as managing director of Alcon Laboratories Australia in 2006 and has been a director of Australian sales subsidiary, Ellex Australia for nearly two years.

Ellex chairman Victor Previn said the expansion of the board had been on the company's agenda for some time and the appointments "brought together the experience and skills needed to guide Ellex through the current challenging economic landscape".

Ellex fell two cents or 8.7 percent to 21 cents.

## BIOSCEPTRE INTERNATIONAL

Biosceptre International has appointed Dr Paul Kelly as a director.

Biosceptre chairman Alan Bootes said Dr Kelly had more than 15 years experience in commercializing life science-related technologies "and impeccable credentials in assisting mid-stage companies attract funding by transforming ideas and technologies into successful commercial products".

Biosceptre said Dr Kelly was a general partner and executive director at investment management firm Andover Venture Partners.

Prior to his position at Andover Dr Kelly was chief executive officer of Medcenter Holdings, a Latin America-based on-line pharmaceutical marketing company, developing and implementing an operational and strategic restructure of the company.

Previously, he served as chief executive officer of Orchid Cellmark, described by Biosceptre as "the world's leading provider of genetic testing services".

Biosceptre said it had identified a target that exists on all solid tumor cells.

The company said it had identified a specific structural change in the P2X7 receptor that rendered it non-functional on cancer cells and the non-functional P2X7 receptor was not found on normal cells.

Biosceptre said its discoveries meant it was "well-positioned to unlock the significant commercial potential of being able to identify and treat cancerous cells more effectively".

Biosceptre is a public, unlisted biotechnology company.

## AUSBIOTECH

Ausbiotech's 2008 'Building a Bioeconomy' Conference will be held in Melbourne from Sunday October 26 to Wednesday October 29, 2008.

Ausbiotech said the conference and a bio-industry exhibition and business matching program would "create a world leading event".

The industry organization said that more than 1,400 participants would attend the conference.

Ausbiotech said the plenary speakers included the president of the California Institute for Regenerative Medicine Dr Alan Trounson; National Australia Bank chief executive officer Ahmed Fahour; Commonwealth Scientific and Industrial Research Organisation's deputy chief executive for science strategy and investment Dr Alastair Robertson; the Africa Harvest Biotech Foundation International chief executive officer Dr Florence Wambugu; Burrill & Co managing director Benjamin Chen.

Ausbiotech said the business matching program would give delegates "the opportunity to update their company profile in the bio-partnering system and request appointments with other delegates/company representatives attending the event in a meeting room atmosphere on a half hour or hourly basis".

The conference will be at the Melbourne Convention Centre, Clarendon Street, Melbourne.

The Ausbiotech October Bio-Beers will be held at Treasury at the Sebel Hotel, 394 Collins Street, Melbourne, on October 23, between 6pm and 9pm.