Biotech Daily

Wednesday July 9, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS DOWN: LABTECH UP 11%, NEUREN DOWN 10%**

*** TISSUE THERAPIES TO START PERTH TRIAL; SEEK FUNDS**

*** STARPHARMA TRIALS VIVAGEL AS BACTERIAL VAGINOSIS TREATMENT**

*** BIONOMICS MANUFACTURES 'NO SIDE EFFECTS' ANTI-ANXIETY DRUG**

*** UK PATENT FOR STEM CELL'S ENZYME INHIBITOR**

*** XCEED MAY INVEST $5m IN SUBSIDIARY POLYNOVO**

*** IDT DIRECTOR GEOFFREY LORD'S 8% HELD BY PRIMEBROKER**

MARKET REPORT

The Australian stock market rebounded 1.3 percent on Wednesday July 9, 2008 with the All Ordinaries up 67.0 points to 5,089.4 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and five were untraded.

Labtech was best, up two cents or 11.43 percent to 19.5 cents on small volumes followed by Psivida up 9.72 percent to $2.71 and Clinuvel up 7.94 percent to 34 cents.

Cathrx climbed 5.63 percent; Starpharma and Ventracor were up more than four percent; CSL was up 3.1 percent; Antisense rose 2.99 percent; with Alchemia, Avexa, Bionomics, Heartware and Resmed up more than one percent.

Neuren led the falls, down 0.9 cents or 10.0 percent to 8.1 cents, followed by Peplin down 9.09 percent to 35 cents following a valuation downgrade by ABN Amro Morgans and Living Cell down 8.0 percent to 23 cents.

Optiscan lost six percent; Acrux, Genetic Technologies and Polartechnics fell four percent or more; Novogen was down 3.33 percent; Progen and Universal Biosensors shed more than two percent; with Chemgenex, Pharmaxis, Prana and Viralytics down more than one percent.

TISSUE THERAPIES

Tissue Therapies expects to begin a Vitrogro clinical trial for venous ulcers in Perth in August 2008.

The company has been attempting to start a separate trial in Toronto but regulatory hurdles have delayed that trial by more than six months.

Tissue Therapies' chief executive Dr Steven Mercer said the Perth trial would complement the Toronto trial.

Dr Mercer said approval for the Perth trial followed agreement between Tissue Therapies' chief clinical investigators, Prof Michael Stacey from the University of Western Australia and Prof Gary Sibbald, who is the director of dermatology and wound healing at the Womens' College Hospital in Toronto.

"The human trial of Vitrogro at Prof Stacey's wound care centre in Perth will focus on the treatment of venous ulcers, while the Toronto study will also include diabetic and pressure ulcers," Dr Mercer said.

"The Perth trial will start after a short period of patient recruitment," Dr Mercer said.

"Interim results will be released progressively and final results are expected in early 2009, within six months of first patient treatment," he said.

Dr Mercer said preparation for both trials was complete and the Toronto trial would commence as soon as final approval was granted.

He said Tissue Therapies had responded to technical queries from Health Canada as part of the regulatory approval process and the company was "keenly awaiting the response from Health Canada".

Dr Mercer said that the two trials were highly complementary and that data from both trials would be used to validate the performance of the Vitrogro wound care process.

Tissue Therapies said Vitrogro was a synthetic, animal product-free technology delivering growth-enhancing factors to cells, tissue and patients, based on the protein vitronectin.

"The Canadian clinical trial monitor Dr Douglas Queen will review the data from both studies and these results will be used in ongoing commercial negotiations with the international wound and healthcare companies that have expressed commercial interest in Vitrogro," Dr Mercer said.

"A number of major wound care and healthcare companies have expressed commercial interest in Vitrogro and are now awaiting initial clinical trial results," he said.

Dr Mercer said Tissue Therapies had the scientific and preclinical evidence that Vitrogro would be a transforming technology in a wound care market estimated at $US4 billion.

"We have great confidence in the clinical results of Vitrogro based on more than six years of research using live human skin cells in the laboratory," Dr Mercer said.

"The scientific development and refinement of Vitrogro has provided a potentially fast and cost-effective cure for diabetic, venous and pressure ulcers," Dr Mercer said.

"This would relieve the clinical, personal, emotional, economic and social devastation of a pandemic that is currently causing an amputation every 30 seconds," Dr Mercer said.

Tissue Therapies said that among its other benefits, the approval of the Perth-based clinical trial allowed "improved certainty" for Tissue Therapies' commercial planning purposes.

Tissue Therapies said it would consider further fund-raising options for large scale manufacturing of new formulation Vitrogro to maximize sales and enhance margins and to provide additional working capital and fund product development.

Tissue Therapies climbed 1.7 cents or 17.35 percent to 11.5 cents.

STARPHARMA

Starpharma will add the treatment of bacterial vaginosis to the development program for its vaginal microbicide Vivagel.
Starpharma said it was the first application of Vivagel as a treatment.
The existing applications are for prevention of infection by the sexually transmitted viruses that cause AIDS (HIV), genital herpes and genital warts, or for contraception.
Starpharma said bacterial vaginosis is characterized by an imbalance between the naturally occurring vaginal lactobacilli and disease-causing bacteria.
It is a major cause of vaginal infection and is particularly prevalent in the US, where it is reported to affect 29 percent of women.
The condition is implicated in pelvic inflammatory disease and may also be associated with an increased risk of sexually transmitted infections and abortion.
Preliminary findings from Starpharma's recent clinical trials suggest that Vivagel treatment tends to restore the normal balance of bacteria in women who had asymptomatic bacterial vaginosis when they were enrolled in the trial. Women with bacterial vaginosis symptoms were excluded from the studies.
Starpharma chief executive officer Dr Jackie Fairley said the application had “potential to open up a new, possibly rapid, path to market for Vivagel”.
Dr Fairley said clinical trials would examine Vivagel’s efficacy for bacterial vaginosis.
The global market for topical vaginal treatments for bacterial vaginosis is estimated at $300 million with four million prescriptions a year for bacterial vaginosis in the US alone.
Treatment with conventional antibiotics may lead to the development of drug resistance, increased susceptibility to thrush, drug interactions and are incompatible with condoms.
Starpharma said that if proven effective against bacterial vaginosis, Vivagel may offer advantages over current conventional antibiotic treatments.
The company said Vivagel was compatible with condoms and was not absorbed by the body, so it was less likely to cause drug interactions or lead to drug resistance.
Many women experience recurrent bacterial vaginosis and were unhappy about the need for continued administration of conventional antibiotics creating a need for alternative therapeutic approaches, Starpharma said.
Starpharma climbed 1.5 cents or 4.84 percent to 32.5 cents.

BIONOMICS

Bionomics says it has completed the good manufacturing practice synthesis of its anti-anxiety drug candidate, BNC210, putting it on-track to file an investigational new drug application with the US Food and Drug Administration.
The India-based Sai Advantium completed Bionomics’ synthesis on time and on budget.
Bionomics will use the material for formal toxicology studies as well as for the clinical trials.
The company said anxiety affected 19 million patients in the US alone and had an estimated market value $5-$12 billion worldwide. Many blockbuster drugs are for anxiety.
Bionomics said most of the anxiety drugs were not ideal and had a range of side effects, including sedation and loss of memory.
BNC210 is a novel chemical compound generated from Bionomics’ medicinal chemistry platform technology Multicore.
It was the best performing anxiety drug candidate in a focused library of compounds that were synthesized, evaluated and tested in a range of animal models for anxiety and related side-effects (see Biotech Daily; May 29, 2007).
Bionomics was up half a cent or 1.56 percent to 32.5 cents.

STEM CELL SCIENCES

The UK Patent Office has granted Stem Cell Sciences a patent covering a new range of stem cell culture media.
Stem Cell Sciences said the Culticell Istem range used the inhibitor-based technology discovered by Prof Austin Smith and recently published in Nature (vol. 453, pp.519-523).
The culture media covered by the patent contain the key combination of two or three types of enzyme inhibitor.
Prof Smith discovered that by inhibiting certain key enzymes in specific combinations, pluripotent or embryonic mouse stem cells could be grown reliably without feeder cells, growth factors, leukaemia inhibitory factor or serum.
The UK patent covers any use of the media and the use of the media for culturing stem cells, especially pluripotent stem cells.
Stem cell said this gave the company the exclusive right to market cell culture media containing these inhibitor combinations.
Stem Cell's chief scientific officer Dr Tim Allsopp said the breakthrough would "change the way authentic embryonic stem cells are isolated and grown in the laboratory".
"These new inhibitor-based media offer pharmaceutical companies and university researchers a simple and elegant way to minimize variability in their stem cell cultures," Dr Allsopp said.
Stem Cell's chief executive officer Dr Alastair Riddell said the discovery was "an important scientific breakthrough and an excellent market opportunity for Stem Cell Sciences".
"As the stem cell reagents market approaches $US100 million annually growing at 20-25 percent per year, we believe that this product will make a significant impact on the sector that focuses on the study of basic stem cell biology and new strain isolation," he said.
Dr Riddell said patent applications were filed in all the major markets via the Patent Co-operation Treaty (PCT) procedure and in several non-PCT markets.
Stem Cell was untraded at 30 cents.

XCEED CAPITAL

Xceed Capital says that pending existing negotiations, it will invest up to $5 million in subsidiary Polynovo Biomaterials to assist it meet the terms of three international deals.
Polynovo has agreements with Medtronic to develop Novosorb for biodegradable stents; Biomet to develop Novosorb for the use in cartilage repair and cranial repair; and Smith & Nephew to develop Novosorb for the use in bone void filler and fracture fixation.
Polynovo needs further working capital to expand in order to meet the requirements of these current deals and to develop applications of Novosorb polymer in other markets including cosmetic surgery.
Polynovo has been pursuing alternative funding for its next phase of growth including direct investment of private equity. The previous proposal of a demerger and initial public offering is no longer being pursued due to the changes in equity markets.
Xceed said a number of incomplete proposals were being considered by Polynovo but none were binding.
The proposed equity subscription by Xceed allows these negotiations to continue, but given there is no certainty of a timely successful conclusion, this subscription agreement will enable the appropriate funding and continued growth of Polynovo.
Xceed will await the outcome of current negotiations before proceeding with any further investment in Polynovo.

Xceed said the material terms of the subscription agreement with Polynovo included investing up to $5,000,000 taking its shareholding in Polynovo from 64 percent to a maximum of 76 percent.
The three directors of Polynovo chief executive officer Dr Ian Griffiths, chairman Bruce Rathie and non-executive director Peter Francis would remain on the board and Xceed would appoint two non-executive directors, George Cameron-Dow and Dr Stewart Washer.
A condition to the investment is that the agreement between the two current shareholders, the Commonwealth Scientific and Industrial Research Organisation and Xceed Capital, will be terminated and replaced.
The CSIRO must waive any rights it holds that would prevent or qualify the issue of shares and options under the agreement.
Xceed would initially subscribe for 3,458,333 new shares in Polynovo for a total of $2.5 million and Xceed has the right to procure third party subscribers to take up the subscription of Polynovo shares and options.
Subject to settlement Xceed would be granted 2,500,000 unlisted options exercisable at $1.00 and 2,083,333 unlisted options exercisable at $1.20.
Xceed would also have the right to subscribe for an additional 3,458,333 new shares in Polynovo for $2.5 million exercisable within 60 days of the initial $2.5 million investment being made and will be granted a second tranche of options on the same terms as the first tranche.
Xceed was untraded at 5.6 cents.

IDT AUSTRALIA

IDT Australia has told the ASX that 3,471,899 shares or eight percent of the company held by companies associated with director Geoffrey Lord are affected by margin lending agreements.
IDT (formerly the Institute of Drug Technology) said the eight percent of the company held by Mr Lord's companies Keygrowth and Belgravia Strategic Equities were subject to margin lending agreements with Primebrokers Securities and were held by the receivers of the failed stock-broking house.
IDT said it had not been advised about the current status of the margin lending facilities and was unable to comment on the effect of the facilities on the ownership and control of the securities.
In the Federal Court Judge Raymond Finkelstein ruled on May 2, 2008 that shares loaned to Opes Prime under an Australian Master Securities Lending Arrangement were the investor's liability and they were subsequently legitimately acquired by the ANZ when Opes Prime collapsed.
IDT fell 25 cents or 13.51 percent to $1.60.