Biotech Daily

Monday November 10, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS EVEN: NOVOGEN UP 22.5%, BIONOMICS DOWN 11%**

*** PROGEN INVESTORS NARROWLY MISS COUP REQUISITION**

*** SUNSHINE HEART LOSES COO VICTOR WINDEYER**

*** ELLEX LASER 'SAFE, EFFECTIVE FOR DIABETIC MACULAR OEDEMA'**

*** NSW GOVERNMENT $1m PROOF OF CONCEPT GRANTS**

*** STEM CELL HELPS CHDI MOUSE CELLS FOR HUNTINGDON'S RESEARCH**

*** NEUREN EXPECTS PIVOTAL GLYPROMATE DATA NEXT MONTH**

MARKET REPORT

The Australian stock market climbed 1.3 percent on Monday November 10, 2008 with the All Ordinaries up 53.4 points to 4,060.0 points.

Nine of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and 11 were untraded. All three Big Caps: Cochlear, CSL and Resmed were up.

Novogen was best, up 16.5 cents or 22.45 percent to 90 cents with 1,000 shares traded, followed by Mesoblast up 9.5 cents or 9.6 percent to $1.085, with Neuren and Universal Biosensors up 9.09 percent to six cents and 60 cents, respectively.

Circadian climbed 6.06 percent; Living Cell, Resmed and Sirtex were up five percent or more; Arana climbed 4.52 percent; with Acrux, Cochlear and CSL up more than one percent.

Bionomics led the falls, down three cents or 10.71 percent to 25 cents with 17,000 shares traded, followed by Progen down 5.47 percent to 60.5 cents and Starpharma down 5.45 percent to 26 cents.

Alchemia, Polartechnics, Stem Cell and Ventracor fell four percent or more; Avexa was down 3.23 percent with 1.95 million shares traded having climbed strongly in early trade; with Viralytics shedding two percent.

PROGEN

Progen says a requisition for a general meeting of the shareholders to spill the board was 0.13 percent short of the five percent required under the Corporations Act.

The spill resolutions are proposed by a group if investors who have nominated replacement directors including Antisense chairman Robert (Bob) Moses, former Progen director Dr Stanley Chang and former EG Capital executive Alison Coutts, now with Martin Place Securities and Dr Woei-jia Jiang.

Mr Moses told Biotech Daily that the primary role of the proposed directors would be to "cause change".

Following the closure of its phase III trial of PI-88 for liver cancer, Progen had about $66 million in cash (see Biotech Daily; July 23, 2008).

Mr Moses, who is a former managing director of commercial law firm Freehills and a former vice president at CSL, said the shareholder group had set out a plan and submitted it to the board of Progen expecting it would be in a statement to shareholders and made available to the ASX.

"Substantial changes are required in this document," Mr Moses said.

He said it was a fair assumption that the proposed directors would use Progen's cash position of about $66 million, but said the company retained other assets that could realize value for shareholders.

"The board is responsible to shareholders," Mr Moses said.

"The results are there and the board has to wear it," he said.

Progen said it was unable to identify one of the shareholders on its share register and those that could be identified held 4.87 percent of the votes that could be cast at a general meeting.

The company said it was in the process of formerly advising those shareholders of this deficiency.

Until the deficiency has been rectified Progen said it would not call and arrange a general meeting of shareholders.

Mr Moses said the shareholders held significantly more shares than five percent, but one of the nominees held their shares through a different name.

He said that they did not intend to take control of the company themselves but change the board to effect change at Progen.

The shareholders calling for the meeting were Shu-Hui Hu, Fu-Ying Wang, Fu Mei Wang, and the Lambert Super Fund.

They called for the removal of directors Dr Malvin Eutick, Robert Williamson, Stephen Jun Chi Chang, Patrick Owen Burns and Justus Homburg.

Progen fell 3.5 cents or 5.47 percent to 60.5 cents.

SUNSHINE HEART

Sunshine Heart says that as part of its US focus the position of chief operating officer held by Victor Windeyer has been "eliminated" and Mr Windeyer will leave the company.

The company said the US focus included the 20-patient US clinical trial.

Sunshine Heart's chief executive officer Don Rohrbaugh said the company was "greatly appreciative of the efforts of Victor in developing the C-Pulse heart assist device and his role in obtaining US Food and Drug Administration approval to conduct a US clinical trial".

The company's chief technical officer Dr William Peters will resume management of development activities.

Sunshine Heart was untraded at 6.5 cents.

ELLEX MEDICAL LASERS

Ellex says a six-month study has shown that the Ellex 2RT is “clinically safe and effective in the treatment of macular oedema secondary to diabetic retinopathy”.

Ellex said the clinical study results for the retina regeneration therapy (Ellex 2RT) were presented at the annual meeting of the American Academy of Ophthalmology by Prof John Marshall of London’s St Thomas’s Hospital who conducted the study.

“This is a revolutionary treatment because, for the first time, we can obtain all the therapeutic benefits seen with earlier laser treatments, but without the collateral damage,” Prof Marshall said.

“This is the mildest laser therapy to be tested in a clinical setting which has demonstrated a selective and therapeutic effect on the retinal pigment epithelium,” Prof Marshall said.

Ellex 2RT uses a custom designed, Q-switched green YAG laser that produces very precise, three nanosecond pulses of 532nm light energy.

Ellex’s managing director of advanced research Malcolm Plunkett told Biotech Daily the YAG laser, or Nd:YAG laser, was a neodymium-doped yttrium aluminium garnet infrared laser generally used to perform capsulotomy or iridotomy.

Mr Plunkett said the Q-switched (quality-switched) green YAG laser was developed for Ellex 2RT by the advanced research team to double the fundamental frequency to produce 532nm green nanosecond pulses. The pulses are produced by the Q-switching.

The trial at St Thomas’ Hospital in London investigated 38 eyes in 23 patients with newly diagnosed diabetic maculopathy, treated with Ellex 2RT.

Seventeen patients (28 eyes) completed the six-month follow-up examination.

Patients underwent treatment using the Ellex 2RT laser to deliver a modified macular grid pattern, guided by fluorescein angiography.

Ellex said that six months after laser treatment, 46 percent of patients had a decrease in their central macular thickness by more than 5.0 percent from baseline.

The company said central macular thickness remained stable in 39 percent of patients and increased by more than 5.0 percent in 15 percent of patients.

The amount of hard exudates also decreased in more than half of the treated eyes.

In terms of visual acuity, at six months, 43 percent of eyes had an improvement of two or more lines of Logmar visual acuity, while 28 percent showed an improvement of one to two lines of visual acuity.

Visual acuity remained stable in 15 percent of eyes and deteriorated in 14 percent of eyes.

Ellex chief executive officer Simon Luscombe said the six-month results confirmed the company’s belief that there was a way to successfully treat diabetic macular oedema safely and effectively “without a significant visual trade-off”.

“Our next step is to expand clinical studies to investigate the therapeutic role of Ellex 2RT in other diseases that impact the retinal pigment epithelium, including early age-related macular degeneration, drusen and central serous retinopathy,” Mr Luscombe said.

Ellex said it had begun Australian trials to further validate the effectiveness of Ellex 2RT.

The company said this included double blind randomized control studies for treating diabetic macula oedema and diabetic retinopathy in conjunction with the South Australian Institute of Ophthalmology and the Royal Adelaide Hospital.

An early age-related macular degeneration trial is also planned with the Royal Victorian Eye and Ear Hospital.

Results from these trials are expected to be available by June 30, 2009. Further trials are also planned for London.

Ellex was up one cent or 5.26 percent to 20 cents.

NEW SOUTH WALES

New South Wales' Minister for State Development Ian Macdonald has approved $950,700 in grants to develop and commercialize new research projects.

Mr Macdonald said 10 grants had been awarded from the Department of State and Regional Development's Bio-Business Proof of Concept program.

"This program helps life science companies develop their research to early stage commercialization while at the same time stimulating innovation and productivity in the State's life science industry," Mr Macdonald said.

Minomic International has received $100,000 to develop a urine test for prostate cancer, improving the ability to accurately diagnose prostate cancer without the need for more invasive examinations.

Dosimetry and Imaging has received $100,000 to develop an x-ray system potentially 100 times more sensitive than current technologies, providing less radiation exposure to patients.

The digital radiography system comprises an analyzing plate coated with a chemical compound called optically excited luminescence which is highly sensitive to ionizing radiation.

Neustent was awarded $100,000 to test the effectiveness of two devices to prevent and treat strokes. The devices clear clots and other blockages in the blood vessels of the brain without impeding blood flow.

Vetphage will receive $95,150 to produce a biopharmaceutical to help control salmonella bacteria contamination in chickens bred for human consumption, reducing the risk of gastroenteritis. The product has been developed from bacteria-eating viruses known as bacteriophages, which destroy target bacteria before disappearing.

E-Nose has been awarded $100,000 for the combining and testing of electronic nose sensors and software in a prototype air pollution and emissions monitor to assist companies with their environmental management.

Ulco Medical will receive $100,000 to develop an electronic simulation system to train medical professionals in a procedure where medical equipment performs the role of the heart and lungs in circulating and oxygenating blood. Training for the procedure, known as veno-arterial extra corporeal membrane oxygenation, is performed in emergencies but the simulation system will provide for safer training.

Human Genetic Signatures has been awarded $100,000 to develop technology to allow doctors and small hospital laboratories to conduct rapid tests to detect infectious diseases, including methicillin-resistant staphylococcus aureus. The technology will allow cost-effective swab or blood analysis to be done in a machine the size of a microwave oven within two hours, replacing traditional methods that can take up to two days and allow physicians to prescribe antibiotics faster and more accurately.

Protech Research was awarded $74,700 to develop enzyme technology that can alter the structure of wheat gluten to produce ingredients for use in nutrition-enhanced foods, beverages, snacks and breakfast cereals. The enzyme system will be targeted at flour and starch markets and will aim to capture gluten that is currently lost during processing.

Cellixe will receive $80,850 for the prototype design, development and testing of an injection device called the Regun which will be used to inject a patented protein preparation to help regenerate damaged spinal disc tissue in patients.

Elastagen has been awarded $100,000 to produce a synthetic version of tropoelastin which provides human tissues such as skin with its stretchy characteristic. The synthetic injectable elastin will be used for a range of cosmetic and surgical applications.

STEM CELL SCIENCES

Stem Cell Sciences will support the standardization of mouse embryonic stem cell lines for the US-based CHDI Foundation for Huntington's disease research.

Stem Cell said the cell lines had been produced over several years under varying conditions and conversion to a standard methodology was expected to facilitate their use in research towards the development of new drugs and diagnostics.

CHDI and its collaborators have developed a series of 20 embryonic stem cell lines from genetically modified mouse models that mimic aspects of Huntington's disease.

The cell lines and mouse models are a tool for medical researchers to use in a wide variety of research programs in HD, a genetic neurological disorder affecting seven in 100,000 people.

Stem Cell said high-quality mouse embryonic stem cells were expected to be important and valuable for drug target validation and drug screening efforts.

Under the service agreement Stem Cell Sciences would create standard culture conditions for CHDI's mouse embryonic stem cell lines using its serum-free and feeder-free Esgro Complete media.

Financial terms were not been disclosed.

Stem Cell said it would convert three cell lines to the standardized culture conditions and monitor their viability and stability during the process.

If successful, Stem Cell "may have the opportunity to apply its proprietary technologies across the entire range of CHDI's mouse [embryonic stem] cell lines, as well as providing the Foundation and researchers with media and reagents for future programs".

Stem Cell's senior vice-president George Murphy said that switching the cell lines to his company's Esgro Complete media would allow researchers "to apply uniform media and growth conditions for easy maintenance of CHDI's mouse model [embryonic stem] cell lines, removing a substantial source of experimental variability".

Mr Murphy said the deal was further validation of the quality of the company's media and repeat use of CHDI's cell lines was expected to generate further revenue growth from Esgro Complete.

Stem Cell Sciences fell one cent or 4.76 percent to 20 cents.

NEUREN

Neuren has completed patient follow-up in the pivotal trial of its lead product, Glypromate.

In June, Neuren announced that efficacy could be established with 320 patients rather than 606 as initially planned and in July completed recruitment and dosing (see Biotech Daily; July 16, 2008) with patients followed-up at six weeks and 12 weeks after treatment.

Follow-up data has been received and is undergoing final review for quality and completeness, with top level efficacy results expected in December 2008.

Neuren said Glypromate was being developed to reduce cognitive impairment following cardiac surgery with cardiopulmonary bypass.

Neuren climbed half a cent or 9.09 percent to six cents.