



Biotech Daily

Tuesday October 21, 2008

Daily news on ASX-listed biotechnology companies

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- * **LIVING CELL JUMPS 64% ON NZ XENOTRANSPLANT TRIAL APPROVAL**
- * **US PATENT ALLOWANCE FOR ALCHEMIA'S SYNTHETIC HEPARIN**
- * **NOVOGEN'S GLYCOTEX COLLABORATES WITH ADVANCED MEDICAL**
- * **KARMELSONIX APPARATUS GRANTED AUSTRALIAN PATENT**
- * **AVANTOGEN CEO DR WILLIAM ARDREY JOINS HAWAII BIOTECH BOARD**
- * **CHEMGENEX VOTES ON DIRECTORS, FEES, \$17.9m REDUCTION**
- * **BONE VOTES ON \$75m 'ACCOUNTING ENTRY', DIRECTORS' SHARES**
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MARKET REPORT

The Australian stock market climbed 3.7 percent on Tuesday October 21, 2008 with the All Ordinaries up 152.7 points to 4,251.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and eight were untraded.

Living Cell was best, climbing as much as 64 percent before closing up six cents or 42.86 percent at 20 cents with 362,700 shares traded, followed by Alchemia up 10.26 percent to 21.5 cents and Pharmaxis up 8.39 percent to \$1.68. Chemgenex and Psivida climbed more than seven percent; Mesoblast and Starpharma were up more than five percent; Avexa, Progen, Ventracor and Viralytics rose more than four percent; Bionomics was up 3.57 percent; Clinovel and Optiscan were up two percent or more; with Novogen, Peplin and Proteome up more than one percent.

Cytopia led the falls, down one cent or 7.69 percent to 12 cents, followed by Cochlear and Stem Cell down more than six percent; Cellestis fell 5.34 percent; Acrux, Antisense, Biota and Sirtex were down more than two percent; with Circadian and CSL down more than one percent.

LIVING CELL TECHNOLOGIES

New Zealand Health Minister, David Cunliffe, has approved Living Cell's application for a phase I/IIa trial of its Diabecell porcine islets of Langerhans for type 1 diabetes.

Living Cell jumped 64.3 percent to 23 cents on the announcement.

Living Cell founder and medical director Prof Bob Elliott told Biotech Daily the recruitment process effectively had begun and the company expected to dose the first patient early in 2009.

Living Cell's chief executive officer Dr Robert Caspari said the approval to begin the clinical trial was "a major milestone for the company and also makes it easier ... to obtain approvals in other countries".

"Porcine insulin has been used therapeutically for 80 years to treat type 1 diabetes," Dr Caspari said.

"Early data shows that utilizing our proprietary encapsulation technology with islet cells may significantly reduce daily insulin requirements in type 1 diabetics," Dr Caspari said.

"The Minister's approval is the culmination of a thorough regulatory process under the Medicines Act 1981, involving detailed consideration of clinical and ethical issues by a wide range of expert bodies over a two year period, and public consultation," he said.

"Approval is subject to extensive conditions designed to safeguard the health and safety of the trial's participants and the wider public and will be monitored on an ongoing basis by the Ministry of Health," Dr Caspari said.

Living Cell's chief operating officer Dr Paul Tan said the company was "delighted to be able to get this clinical trial underway in New Zealand, the place where the Diabecell concept was initially conceived by Prof Bob Elliott".

"The conditions of the Minister's approval allow us to proceed with commencing the trial and work with an independent international expert to assure the Minister that the world's first safety procedures set up by LCT are adequate," he said.

Living Cell began a phase I/IIa clinical trial of Diabecell in Russia in June 2007 and continues to enroll patients into the program.

The Russian component of phase I/IIa development was designed to include only the lowest dose, 5,000 islet equivalents (IEQ/kg) of Diabecell, but as a result of positive preliminary results, it was expanded to include a higher dose of 10,000 IEQ/kg, which is now being studied.

Living Cell said in July that the six participants who received Diabecell in the Russian trial all derived clinical benefit with no significant adverse events (see Biotech Daily July 22, 2008). The company said the approval allowed it to extend its phase I/IIa clinical data.

The New Zealand trial will enroll eight patients, four of whom are to receive the dose of 10,000 IEQ/kg followed by four patients to receive the high dose of 15,000 IEQ/kg.

The trial will be conducted by the clinical director and diabetes physician at Auckland's Middlemore Hospital, Dr John Baker.

Prof Elliott said the company was "now able to formally access volunteers and intend to start work on this with Middlemore Hospital immediately".

Diabecell is an encapsulated porcine insulin-producing cell product, in development for the treatment of type 1 diabetes without the use of immunosuppressive drugs.

Five to 10 percent of the more than 200 million diabetics worldwide have insulin-dependent type 1 diabetes with 30,000 cases of diabetes diagnosed each year in the US, of whom approximately 40 percent are children.

Type 1 diabetes is associated with kidney failure, blindness, nerve damage, cardiovascular disease and amputations. Treatment options include multiple daily injections of insulin.

Living Cell closed up six cents or 42.86 percent to 20 cents with 362,700 shares traded.

ALCHEMIA

Alchemia says it has received a notice of allowance for the US patent application titled 'Synthetic Heparin Pentasaccharides'.

Alchemia chief executive officer Dr Pete Smith said the patent allowance provided significant protection for the company's "improved synthetic process and a further barrier to entry for other generic manufacturers".

"Our preparations for filing for approval are advancing well and today's announcement strengthens our belief that our product will be the first and, potentially, only generic version of Arixtra," Dr Smith said.

Alchemia said the application was the first in a series of patent applications in the US covering the compounds and processes for Alchemia's generic fondaparinux program. The company said the patent protected "important intermediates in Alchemia's synthetic process and provides Alchemia with the legal means to prevent other companies from using these intermediates, or selling product derived from these intermediates, in the US". Alchemia was up two cents or 10.26 percent to 21.5 cents.

NOVOGEN

Novogen's 81 percent subsidiary Glycotex Inc has finalized an agreement with UK-based Advanced Medical Solutions to study GLYC-101 with wound dressings.

Novogen said Glycotex and Advanced Medical agreed to an initial phase of testing of the use of GLYC-101 with Advanced Medical's wound dressings.

Should the first phase of testing give rise to favorable results, or generates data that suggest further research may be warranted, Glycotex and Advanced Medical will have an opportunity to extend their collaboration for the purposes of continued research.

Novogen said GLYC-101 was intended to stimulate and modulate the natural cascade of wound healing activities of several cell populations.

The company said the product candidate under development is a topical gel to be applied directly on the wound surface.

The strategic priorities for GLYC-101 include wound healing following laser ablation, burn wounds, surgical wounds, venous ulcers and diabetic ulcers, Novogen said.

In May 2006, Glycotex completed a phase II clinical trial of GLYC-101 in Australia, which produced a statistically significant rate of wound area reduction versus combined placebo and standard care in patients with chronic venous ulcers. Novogen said the results provided proof-of-concept and dose-ranging information for GLYC-101.

In US clinical trials, GLYC-101 was being assessed for safety and effectiveness on wound closure in patients undergoing carbon dioxide laser skin resurfacing.

Novogen was up one cent or 1.01 percent to \$1.00.

KARMELSONIX

Karmelsonix says the Australian Patent Office has granted it a patent entitled 'Method and apparatus for determining conditions of biological tissues'.

Karmelsonix said the patent, with previously granted patents, provided additional protection to its range of core technologies using active acoustic technology.

The company said the technologies protected by the patent determined characteristics of the lung such as lung density and airway patency and could be applied to the monitoring, diagnosis and/or treatment of various lung and airway conditions such as obstructive sleep apnoea and emphysema.

Karmelsonix was unchanged at 2.4 cents.

AVANTOGEN

Avantogen says chief executive officer Dr William Ardrey has been appointed a director of Hawaii Biotech effective from today.

Avantogen owns 33 percent of Hawaii Biotech.

Avantogen said it was “focused on commercial licencing and revenue outcomes throughout the group” and that Dr Ardrey’s appointment would advance these goals.

The company said it intended to purchase additional shares in Hawaii Biotech based on proceeds received from Avantogen’s recent \$1 million capital raising.

Avantogen chairman Patrick Elliott said the company was “firmly convinced that Hawaii Biotech’s recombinant DNA manufacturing platform is an excellent investment opportunity, and Avantogen actively seeks to increase its stake in this promising vaccine development company”.

Hawaii Biotech has begun a phase I West Nile virus vaccine clinical trial, development of partnerships with the Bill & Melinda Gates Foundation and the Walter Reed Army Institute of Research and recruitment of Prof Ian Frazer to its scientific advisory board.

Avantogen was untraded at four cents.

CHEMGENEX

Chemgenex shareholders will vote on an increase in director’s remuneration pool from \$500,000 to \$650,000 along with a \$17.9 million capital reduction.

Chemgenex said the proposed \$17.9 million capital reduction followed the demerger of Autogen Research and was a requirement of the Australian Taxation Office class ruling (see Biotech Daily; May 12, 2008).

Chemgenex said the proposed issued capital reduction would be offset by an equal reduction in the value of losses carried forward.

“Accordingly, if approved by shareholders, this transaction will have no real effect on the total net equity,” Chemgenex said.

The meeting will also consider the issue of 250,000 options to director Jean-Luc Tétard as well as the reelection of directors Donald Santel, Dr Julie Cherrington, Mr Tétard, Brett Heading and Dr Dennis Brown.

The meeting will be held at ABN Amro Morgans, Level 27, 367 Collins Street, Melbourne on November 26, 2008 at 12pm.

Chemgenex climbed 4.5 cents or 7.5 percent to 64.5 cents.

BONE MEDICAL

Bone Medical shareholders will vote on a \$74.7 million capital reduction along with the issue of shares and options to directors Leif Jensen and Leon Ivory.

Bone said that under the capital reduction the company would not be returning any capital to shareholders or cancelling any shares.

“It will essentially be an accounting entry,” Bone Medical said.

The meeting will also consider the issue of 200,000 shares and 900,000 unquoted options exercisable at 40 cents each to Mr Jensen and 450,000 unquoted options exercisable at 40 cents each to Mr Ivory, the prior issue of 2,960,000 placement shares along with the issue of parcels of 563,875 shares and 436,125 shares to Proxima Laboratory

Bone shareholders will also consider the reelection of directors Mr Ivory and Barry Walker.

The meeting will be held at Seminar Room 5, Technology Park Function Centre, 2 Brodie Hall Drive, Bentley, Western Australia on November 19, 2008 at 4.30pm.

Bone Medical was untraded at 30 cents.

VIRALYTICS

Viralytics shareholders will vote on the issue of 3,000,000 options each to directors Paul Hopper and Peter Molloy.

Viralytics chief executive officer Bryan Dulhunty told Biotech Daily that the grant of options was required as “part of the need to attract highly-respected US-based directors”.

Mr Dulhunty said the directors would be “hands-on” and would earn their pay.

The options will be exercisable at the higher of five cents or the 30 day volume-weighted average price, plus 50 percent, vest over three years and expire after five years.

The meeting will vote on the prior issue of shares and the proposed issue of 60,000,000 placement shares and the re-election of directors Dr Phillip Altman, Mr Hopper and Mr Molloy.

The meeting will be held in the Promenade Room, Noah's on the Beach, Corner of Shortland Esplanade and Zara Street, Newcastle, New South Wales on November 18, 2008 at 11am.

Viralytics was up 0.2 cents or 4.08 percent to 5.1 cents.

NANOSONICS

Nanosonics shareholders will vote on the issue of 1,500,000 options to chief executive officer David Radford and allow Mr Radford and Dr Ron Weinberger to acquire up to 500,000 shares each in lieu of pay.

Nanosonics said the resolutions, if passed, would permit the two executive directors, Mr Radford and Dr Weinberger, to acquire shares as part of their total remuneration packages.

Nanosonics said it was able “to incentivise all other employees through the company's three share-based payment schemes”.

The Nanosonics's annual general meeting will also vote on the re-election of directors Dr David Fisher, Dr Weinberger and Mr Radford.

The meeting will be held at the NSW Trade & Investment Centre, Level 47, MLC Centre, 19 Martin Place, Sydney on November 18, 2008 at 4pm.

Nanosonics climbed four cents or 22.22 percent to 22 cents.

NORWOOD ABBEY

Norwood Abbey shareholders will vote on the issue of shares, options and convertible notes to employees and for a prior placement.

The meeting will vote on the prior issue of 7,000,000 shares at one cent a share and the approval of 7,000,000 free options to Lettered Management Pty Ltd exercisable at 1.5 cents and 43,000,000 convertible notes, convertible into shares at one cent each, as well as 43,000,000 options exercisable at 1.5 cents.

Norwood Abbey shareholders will consider the “conversion of J Bell employee entitlements” to 19,000,000 shares at one cent a share and 19,000,000 free attaching options exercisable at 1.5 cents to company secretary Jeff Bell; and 3,000,000 shares and options under the same terms to IT manager and office administrator Ray Close.

A further resolution provides for 8,000,000 shares and options under the same terms be issued to Lewis Trende.

Norwood Abbey' will also vote on the re-election of director Ron Lewis.

The meeting will be held at Minter Ellison, Level 23, Rialto Towers, 525 Collins Street, Melbourne on November 20, 2008 at 10am.

Norwood Abbey was unchanged at 0.6 cents.

CORRECTION: GBS VENTURE PARTNERS

In yesterday's edition the appointment of former Amgen senior vice-president Dr George Morstyn as a director of GBS Venture Partners contained an error.

At the end of the article instead of Dr Moyston, a different name was transposed.

Dr Moyston's correct biography is below.

We apologize for the error.

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 Moyston has been a director Neuprotect, Chemgenex and New Zealand's Proacta .

Dr Moyston 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.