



Biotech Daily

Tuesday December 8, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: SUNSHINE HEART UP 5%; NANOSONICS DOWN 8%**
- * **EASTLAND REVIEWING POTENTIAL ASIC, ASX BREACHES**
- * **CATHRX CHANGES GERMAN-SPEAKING SECTOR DISTRIBUTOR**
- * **FDA APPROVES AVITA'S US RECELL TRIAL**
- * **PHYLOGICA RAISES \$2m**
- * **SOPHIE MIRABELLA APPOINTED SHADOW INNOVATION MINISTER**
- * **CSL LOSES CFO TONY CIPA; CHANGES SENIOR EXECUTIVE GROUP**
- * **ASIA UNION TAKES 8.6% OF ANTEO**
- * **XCEED RIGHTS ISSUE TO RAISE \$1m; GEORGE CAMERON-DOW M-D**

MARKET REPORT

The Australian stock market slipped 0.13 percent on Tuesday December 8, 2009 with the S&P ASX 200 down 5.9 points to 4670.6 points.

Eight of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and seven were untraded. All three Big Caps were down.

Sunshine Heart was best, up 0.2 cents or 5.3 percent to four cents with 323,500 shares traded, followed by Heartware up four cents or 4.1 percent to \$1.01.

Novogen climbed 3.2 percent; Bionomics and Chemgenex rose more than two percent; with Biota, Cellestis and Starpharma up by less than one percent.

Nanosonics led the falls, down five cents or eight percent to 57.5 cents with 971,389 shares traded, followed by Universal Biosensors down 6.8 percent to \$1.77.

Avexa and Psivida lost more than five percent; Alchemia, LBT and QRX fell four percent or more; Clinuvel and Optiscan were down more than three percent; Cochlear, Pharmaxis, Prana and Viralytics shed more than two percent; with Acrux, Genera, Living Cell and Phosphagenics down more than one percent.

EASTLAND MEDICAL SYSTEMS

Eastland says a review of its operations has revealed a range of potential breaches of the Australian Securities and Investments Commission regulations and ASX guidelines.

Eastland said that since the restructure of its board and management team, it had begun "a complete review of all past relevant contractual and financial transactions in line with our corporate governance and risk management processes".

In September Eastland said chief financial officer Peter Tiede and company secretary Trevor Strahan had resigned effective immediately (BD Sep 2, 2009).

Eastland said at that time that chief executive officer Dermot Patterson had been appointed company secretary and a replacement chief financial officer would be announced "shortly".

Mr Patterson told Biotech Daily in September that Eastland would review and upgrade its financial reporting systems.

Last night, Eastland said the review focused on matters covered under Sections 3.0, 4.0 and 7.0 of ASX Corporate Governance Principles and Recommendations.

The ASX Corporate Governance Principles and Recommendations document says the areas covered are designed to (3) Promote ethical and responsible decision-making; (4) Safeguard integrity in financial reporting; and (7) Recognize and manage risk.

Eastland said that "a number of past related-party transactions have been identified which do not appear to comply with the Corporations Act and ASX Listing Rules, particularly where shareholder approvals would be required in the ordinary and normal course".

The company said the review highlighted "a number of matters relating to the fulfillment, or otherwise, of directors and officers' statutory and common law duties".

Eastland said that in mid 2008 it granted HC Berlin Pharma AG manufacturing rights for Artimist in exchange for eight million (controlling) HC Berlin shares, all of which Eastland should have, but did not, receive.

Eastland said it began action in the Western Australia Supreme Court which, if successful, would recover nearly two million of those shares from parties including related parties. The shares have a current market value of about EUR2 million (\$A3.25 million).

Eastland said a writ had been issued to protect the interests of all its secured convertible note-holders and shareholders.

The company said that a past director Douglas Sims has begun legal action to recover unpaid expenses and disbursements made on behalf of Eastland.

Eastland said that "without prejudice" negotiations failed to resolve the issues and Mr Sims action had to be defended by Eastland.

Eastland said it had "investigated certain payments made and financial entries in its books as at June 30, 2009 which appear to not have been properly authorized" and if irregularities were demonstrated, it would be reported to ASIC.

Eastland fell 0.3 cents or 4.9 percent to 5.8 cents.

CATHRX

Cathrx says Germany's Pioneer Medical Devices will distribute the company's cardiac catheter range in Germany, Austria and Switzerland.

Cathrx president Ged Wallace said the German, Swiss and Austrian markets were "key pillars of our European sales strategy".

Mr Wallace said the previous distributor Corizon had "a fundamental change" in its business operations and Cathrx's German sales program had been delayed.

The company said it and Corizon agreed to end the business relationship.

Cathrx was unchanged at 68 cents.

AVITA MEDICAL

Avita says the US Food and Drug Administration has approved its US clinical trial for its Recell device to treat burns, wounds and skin defects using the patient's own cells. Avita said the company (then Clinical Cell Culture) previously began US trials in 2006 under a conditional approval but "due to excessively restrictive inclusion criteria patient recruitment was very low".

Avita said that Clinical Cell "had not successfully addressed concerns of the FDA regarding study endpoints, patient follow-up and statistical analysis of collected data". Avita said it suspended the trial in July 2008.

The company said it recently submitted a modified study protocol with substantial changes including inclusion criteria allowing for an expanded wound size and body region; decrease in the number of patients required to 106 patients; decrease in the patient follow-up period from 52 to 16 weeks; a change in the study endpoint from "time to 100 percent epithelialization" to a binomial assessment of "healed versus non-healed" at four weeks of follow-up; and inclusion of superiority as well as non-inferiority outcomes, significantly expanding post-study marketing claims.

Avita said the study would yield a randomized, controlled, clinical comparison with the current standard of care in treating burn wounds.

The company said it had appointed 10 clinical sites to participate in the trials, patient enrolment was expected to begin in early 2010.

Avita chief executive officer Dr William Dolphin said Avita was "on-track for its US regulatory approval process for Recell".

"With the FDA protocol approval in place, our next steps are to obtain ... approval at each site and train investigators in the use of Recell," Dr Dolphin said.

"We now have a pragmatic and clinically feasible trial protocol in place and we are confident of successfully achieving the trial endpoints," Dr Dolphin said.

Avita said part of the funding for the trial comes from a \$US1.45 million grant from the US Army to help develop regenerative medicine through the recently initiated Armed Forces Institute for Regenerative Medicine.

The Wake Forest Institute for Regenerative Medicine's Dr James Holmes and principle investigator for the trial said Recell was "a transformational technology that will fundamentally change the way we treat burns and other wounds".

"When Recell is approved for use in the United States there is no doubt that it will save the lives of burn victims," Dr Holmes said.

"What's available today is the same technology that was available 30 years ago," Dr Holmes said.

"In a burn, one is always working against time," Dr Holmes said.

"Recell will allow us to turn back the clock on all kinds of burns," he said.

"We are very anxious to complete administrative details and commence enrolment for this important study," Dr Holmes said.

Avita was unchanged at 16 cents with 2.2 million shares traded.

PHYLOGICA

Phylogica says it has raised \$2 million through the placement of 20 million shares at 10 cents a share. The lead broker was CPS Securities.

Phylogica said it was in advanced negotiations with a pharmaceutical and biotechnology group on a partnership using its library of phylomer protein fragments.

Phylogica said it expected to complete the negotiations shortly.

Phylogica was untraded at 12 cents.

FEDERAL OPPOSITION

Opposition leader Tony Abbott has appointed Sophie Mirabella as spokesperson on Innovation, Industry, Science and Research.

Ms Mirabella is the Member of the House of Representatives for the seat of Indi, in North Eastern Victoria and was formerly shadow minister for Early Childhood Development, Childcare, Women and Youth.

The former shadow minister, Senator Eric Abetz, has been appointed as spokesperson on Employment and Workplace Relations.

CSL

CSL says chief financial officer and director Tony Cipa will retire from both roles in October 2010 but will be available as an advisor until March 2011.

CSL said Gordon Naylor would be CFO-designate from January 2010, returning to Australia from the US where he is CSL Behring's executive vice-president of plasma, supply chain and chief information officer.

The company said Mr Naylor had 22 years service with CSL in Australia, Europe and the US and has held specialist, operations and general management roles.

CSL said Mr Naylor had experience in mergers and acquisitions and risk management, and was instrumental in the transformation of CSL Plasma. He graduated from the University of Melbourne and holds an MBA from Melbourne Business School.

Mr Naylor will be replaced in his current role by Dr Karen Etchberger, who was CSL Behring's head of quality.

The company said chief executive officer Dr Brian McNamee would continue in that role and as managing director "for at least a further three to four years".

CSL said CSL Behring president Peter Turner would continue in that role based in Pennsylvania and would become CSL group chief operating officer from January 1, 2010 and would join the board as an executive director, immediately.

The company said Mr Turner had been with CSL for more than 40 years, in Australia, Switzerland and the US.

He led the construction and operation of the Melbourne manufacturing facility, played a key role in the integration of the ZLB, NABI and Aventis Behring acquisitions and since 2004 led CSL Behring, through an era of expansion and revenue growth.

The company announced further appointments supporting the executive appointments.

Dr McNamee said the changes "signal increased alignment of our international operations which have grown through a number of successful acquisitions"

"We are strengthening the future of the Australian businesses as well as supporting our continuous drive for operational excellence," Dr McNamee said.

"The merging of the Australian businesses in particular provides a platform for future sustainability and the opportunity for a greater contribution to the growth of the global company from Australia," Dr McNamee said.

"The senior executive moves are part of our long term approach to succession," he said.

CSL fell four cents or 0.13 percent to \$31.22 with 1.4 million shares traded.

ANTEO DIAGNOSTICS

Asia Union Investments has become a substantial shareholder in Anteo with a holding of 35,844,350 shares or 8.56 percent.

Anteo was untraded at 0.7 cents.

XCEED CAPITAL

Xceed hopes expects to raise \$1.0 million through a partly underwritten one-for-one non-renounceable share rights offer at one cent a share.

Xceed said the rights issue was underwritten to \$300,000 by St George Capital, a related party.

The company said the funds would enable it “to realize value from its existing assets and actively identify and assess new opportunities”.

Xceed has appointed George Cameron-Dow as managing director.

Xceed fell 0.4 cents or 14.8 percent to 2.3 cents.