



Biotech Daily

Monday May 31, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH FLAT: CELLMID UP 10%; CATHRX DOWN 13%**
- * **AVITA DELIVERS THIRD STRIKE TO HELICON**
- * **FEDERAL \$21m FOR STEM CELL RESEARCH**
- * **FLUOROTECHNICS RIGHTS ISSUE RAISES \$1.6m**
- * **NOVOGEN REQUESTS PHASE III TRIAL RESULTS TRADING HALT**
- * **SMALL DISSENT AT PHOSPHAGENICS AGM**
- * **BENITEC VOTES ON SHARE ISSUES**

MARKET REPORT

The Australian stock market fell 0.6 percent on Monday May 31, 2010 with the S&P ASX 200 down 27.8 points to 4429.7 points.

Eleven of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and seven were untraded.

Cellmid was best, up 0.2 cents or 9.52 percent to 2.3 cents with 332,717 shares traded.

Clinuvel and Patrys climbed more than four percent; Heartware and Nanosonics were up more than three percent; Circadian, Sunshine Heart and Tissue Therapies rose more than two percent; with Cellestis and Resmed up more than one percent.

Cathrx led the falls, down 2.5 cents or 13.2 percent to 16.5 cents with 16,260 shares traded, followed by Antisense down 6.7 percent to 1.4 cents with 751,500 shares traded.

Viralytics lost 4.2 percent; Living Cell and Prana were down more than three percent; Genetic Technologies, Impedimed, LBT, Mesoblast and QRX shed more than two percent.

AVITA MEDICAL. HELICON

Avita Medical and Helicon say they have “mutually agreed not to renew a distribution agreement” for the People’s Republic of China and Taiwan.

Avita said it was in discussions “with a leading Chinese medical device distributor” and was negotiating the establishment of a joint venture which would include the appointment of a regional manager.

Helicon has had two if its three products for distribution in China rejected by the State Food and Drug Administration.

In April the SFDA rejected an application to market the plasma substitute Volplex citing potential quality issues with the gelatine used in the manufacturing process (BD: Apr 1, 2010).

Helicon said at that time that Volplex was a sterile solution of chemically-modified gelatine in normal saline, widely used as an intravenous infusion to replace the plasma component of blood lost as a result of trauma or surgery and had been available in the UK for many years.

Helicon chief executive officer Peter Abrahamson said last month the decision was “very disappointing” and reflected “the growing conservatism of this regulatory agency following a number of decisions that had disastrous consequences in China”.

Mr Abrahamson said the SFDA was rejecting more than 60 percent of applications.

A few days earlier the SFDA rejected Helicon’s application to market Medwrap’s Island Wound Dressing with Microban (tricolosan) (BD: Mar 29, 2010).

Helicon said the SFDA cited the risk associated with potentially extended exposure to the antibacterial Microban as the main reason for its decision.

Helicon said Medwrap’s Island Wound Dressing with Microban was approved by the US Food and Drug Administration “and has been marketed in the US for many years”.

Avita’s Recell was the third product Helicon was hoping to distribute in China.

Mr Abrahamson told Biotech Daily that the company’s future would be decided by the end of the month.

“We have been actively looking for other projects, not necessarily in health care or biotechnology,” Mr Abrahamson said.

“We hope to make an announcement by the end of June,” Mr Abrahamson said.

Avita said chief executive officer Dr William Dolphin and Asia-Pacific general manager Lorraine Glover held meetings with surgeons, regulatory representatives and distributors in China and Taiwan to advance sales and marketing efforts for its Recell spray-on-skin technology.

The company said Recell was the first regenerative medicine or tissue therapy product cleared by the Chinese State Food and Drug Administration.

Avita said that to obtain a listing on the Chinese Ministry of Health formulary and thereby establish reimbursement for Recell, a series of limited clinical evaluations was being scheduled with surgeons in military and public hospitals.

Avita said the Recell technology had “strong sales potential in China with the cosmetics and [plastic surgery] markets growing exponentially” with estimates of \$US2.4 billion a year and more than 50,000 cosmetic surgery clinics in China’s major hospitals.

The company said the approval and distribution process in Taiwan was “much more straightforward than in China”.

The company said Dr Dolphin and Ms Glover met with plastic and reconstructive surgeons, the regulatory representative and the company’s distributor Shaw Han in Taipei and “a well-defined rollout plan” had been developed.

Avita was up half a cent or 4.35 percent to 12 cents.

Helicon was untraded at 2.5 cents.

FEDERAL GOVERNMENT, AUSTRALIAN RESEARCH COUNCIL

The Federal Government will provide \$21 million for a stem cell research fund to be administered by the Australian Research Council.

A media release from Innovation Minister Senator Kim Carr said the Special Research Initiative in Stem Cell Science would “further build Australia’s capacity to conduct stem cell research”.

“This fund will keep our scientists at the forefront of this rapidly developing field, giving them the best chance to make life-changing breakthroughs,” Senator Carr said.

“It will help stem cell researchers and institutes develop and maintain key national and international collaborations that are important for the advancement of stem cell science,” Senator Carr said.

“Not only will successful recipients be conducting valuable research; they will also help inform the community about stem cell science and technologies,” Senator Carr said.

The media release said the National Health and Medical Research Council would also invite applications for Centres for Research Excellence in Regenerative Medicine, encouraging researchers to undertake stem cell research with clinical applications.

The media release said the ARC Special Research Initiative was open for proposals. Funding will commence in July 2011 and be offered for up to seven years.

For more information, visit www.arc.gov.au.

The NHMRC expects to seek proposals for Centres for Research Excellence, including those in regenerative medicine, in July.

Funding will commence in 2011 and be offered for five years.

Applications for funding must be through an eligible Australian research institution.

FLUOROTECHNICS

Fluorotechnics says its non-renounceable rights issue at 15 cents raised \$1,625,044 of the hoped for \$2.2 million.

Fluorotechnics received acceptances and applications for additional shares, including from the underwriter, totaling 10,833,624 shares, leaving a shortfall of 3,720,864 shares. The company said it would seek to place the shortfall shares.

Fluorotechnics was untraded at 15 cents.

NOVOGEN

Novogen has requested a trading halt “pending the release of a price sensitive announcement relating to the phase III clinical trial known as the overture trial”.

In Novogen closed the trial early to conserve funds, having enrolled 142 patients of the planned 340 patients (BD: Apr 15, 2009).

The trial was a multi-centre phase III clinical trial of orally-administered phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs, to determine its safety and effectiveness when used in combination with carboplatin.

Late last year, Novogen chief executive officer Christopher Naughton resigned and was replaced by chief financial officer David Seaton as interim chief executive officer (BD: Dec 1, 2009).

Last month Novogen’s 71.3 percent US subsidiary Marshall Edwards appointed Dr Daniel Gold as its US-based chief executive (BD: Apr 27, 2010).

Trading will resume on June 2, 2010 or on an earlier announcement.

Novogen last traded at 39.5 cents.

PHOSPHAGENICS

The Phosphagenics annual general meeting passed resolutions on the reelection of director Prof John Mills, the remuneration report and new constitution.

A total of 15,782,546 proxy votes were cast against Prof Mills, with 137,695,930 proxy votes in favor.

The other two resolutions were passed by wider margins.

Phosphagenics was unchanged at 15.5 cents.

BENITEC

Benitec will vote on the issue and the prior issue of shares to a range of organizations and people.

Benitec proposes to issue 40,097,026 shares to the Commonwealth Scientific and Industrial Research Organisation; issue 134,596 shares to Newstar Ventures; issue 12,000,000 shares and 12,000,000 options to Dr Christopher Bremner, approve the conversion of 12,000,000 options to shares by Dr Bremner; issue shares for convertible notes to La Jolla Cove Investors; issue 1,500,000 options to director Peter Francis; issue 1,500,000 options to director Mel Bridges.

The meeting will be held on June 30, 2010 at RSM Bird Cameron, Level 8, Rialto South Tower, 525 Collins Street, Melbourne at 11.30pm.

Benitec was unchanged at 3.5 cents.