

Biotech Daily

Wednesday September 7, 2011

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: CLINUVEL UP 12%; LBT DOWN 7%
- * AVITA'S MIDDLE EAST NORTH AFRICA JOINT VENTURE
- * HEALTHLINX APPOINTS BRANDWOOD FOR REGULATORY UPGRADE
- * CBIO ACTION GROUP CALLS FOR THREE DIRECTORS; DILUTION ISSUE
- * GI FALLS 20c ON FIRST TRADING DAY
- * CAPITAL GROUP SELLS 3m CSL SHARES, BELOW SUBSTANTIAL
- * LANG WALKER TAKES 5.5% OF QRX
- * ROSS HAGHIGHAT'S TRITON TAKES 6% OF ISONEA

MARKET REPORT

The Australian stock market climbed 2.65 percent on Wednesday September 7, 2011 with the S&P ASX200 up 107.9 points to 4,183.4 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and six were untraded. All three Big Caps were up.

Clinuvel was the best, up 18 cents or 12.2 percent to \$1.65 with 18,700 shares traded, followed by Reva up 12.1 percent to 78.5 cents with 49,471 shares traded and Phosphagenics up 11.1 percent to 15 cents with 1.5 million shares traded.

Allied Health climbed 6.4 percent; Genetic Technologies and Prima were up more than five percent; Alchemia, Anteo and Benitec rose more than four percent; CSL, Mesoblast, Psivida and Starpharma were up three percent or more; Acrux rose 2.7 percent with Viralytics up one percent.

LBT led the falls, down 0.4 cents or 7.1 percent to 5.2 cents, with 316,668 shares traded, followed by Sunshine Heart down 6.7 percent to 4.2 cents with 1.1 million shares traded.

Cellmid and Circadian lost five percent or more; Pharmaxis and Prana were down more than three percent; Bionomics shed two percent; with Biota, Impedimed, Nanosonics, Phylogica and Tissue Therapies down more than one percent.

AVITA MEDICAL

Avita says it has a joint venture with the Kuwait-based Mena United for sales and marketing of the Recell wound treatment in the Middle East and North Africa (MENA). Avita said the joint venture would be registered in Kuwait as Avita Medical Mena and Avita would hold 70 percent control.

The company said the venture would be governed by a board of directors consisting of two Avita medical appointees, chief executive officer Dr William Dolphin and Tiziano Caldera and one Mena United appointee Yousef Al- Sultan.

Avita said Dr Khaled Alkandari would be the initial general manager, based in Kuwait City, Kuwait.

Avita said that Avita Mena would be responsible for sales and marketing in Egypt, Iraq, Jordan, Kuwait, Lebanon, Iran, Syria, Saudi Arabia, Bahrain, Oman, Yemen, United Arab Emirates and Qatar, with more than 180 million people.

The company said the Avita Mena launch was scheduled for September 24, 2011 with regional press coverage and live workshops to be held at Al Babtain Burn Center in Kuwait.

Dr Dolphin said the joint venture "helps diversify our operations geographically while opening the door to growth for the company's products in a large, affluent and important global marketplace".

"This agreement combines the power of the Avita Recell brand with Mena United's deep regional knowledge, clinical expertise and connections within this complex and significant market," Dr Dolphon said.

Mr Al-Sultan said the "revolutionary Recell technology represents an excellent match with our goals of introducing new and innovative healthcare products to the Middle Eastern markets".

"With its wide range of medical and aesthetic applications there is a tremendous market need and opportunity for Recell in the region," Mr Al-Sultan said.

"We hope to greatly enhance physicians' ability to treat burns, wounds and other skin conditions throughout the region," Mr Al-Sultan said.

Avita was up one cent or 10 percent to 11 cents.

HEALTHLINX

Healthlinx says it has appointed Brandwood Biomedical to help prepare the Australian regulatory application for manufacturer certification and Ovplex device approval. Healthlinx said that although Ovplex ovarian cancer diagnostic had been on sale in Australia since 2009, under new regulations introduced on July 1, 2010 most in vitro diagnostic devices were required to undergo pre-market assessment, approval and listing on the Australian Register of Therapeutic Goods by the Therapeutic Goods Administration.

Healthlinx managing director Nick Gatsios said that Brandwood was "highly respected in the industry and experienced in regulatory approvals processes worldwide".

Mr Gatsios said that David Harrison had more than 25 years experience in the industry, would lead the project.

Healthlinx said TGA approval would secure ongoing access to the Australian market and facilitate approvals in Asian jurisdictions such as South Korea and China which required country-of-origin approval as a prerequisite to market access.

Healthlinx said the technical file developed in the application could be used in support of concurrent and subsequent regulatory submissions including in the US.

Healthlinx was unchanged at two cents with 1.5 million shares traded.

CBIO

The shareholder action group calling for a CBio meeting says it wants to replace chairman Stephen Jones and directors Prof John Funder and James Greig (BD: Sep 5, 2011). In a media release, the action group said it proposed the appointment of former Amrad director and Avexa chair Helen Cameron, Dr Ralph Craven and Warren Brown. The media release said Ms Cameron was formerly the head of healthcare research at Citigroup and Dr Craven is the chairman of Queensland Government electricity distributor Ergon Energy.

The action group said it would move within two months to consider resolutions to restructure the board.

The group's spokesman Alan Baker said the group wanted "to provide shareholders with an opportunity to rejuvenate the board with a view to improving CBio's record of communication with shareholders and the market, [and improve] capital management and corporate governance.

Mr Baker is an associate director of the Brisbane-based Retirewell Financial Planning and a certified financial planner.

The media release was signed by Alan and Julie Baker, Tony and Marie Gillett, Warren and Roslyn Brown, Morten Weaver, Jane Duncan and Pella Comino, most of whom were named as substantial shareholders in a notice to the ASX on Monday (BD: Sep 5, 2011). The media release said that the University of Queensland through its commercial arm, Uniquest was a major shareholder in CBio, which was formed in 2000 to develop the XToll drug for rheumatoid arthritis, developed at the University.

"We believe CBio will prove to be a Queensland success story and a triumph of Australian science," Mr Baker said. "We expect CBio will enter into a licencing and royalty deal with a global pharmaceutical company next year to bring its drug XToll to market."

"Because of its strong safety profile and efficacy at the right dose, we believe XToll will benefit millions of people throughout the world who suffer from rheumatoid arthritis and other auto-immune diseases," Mr Baker said.

Mr Baker said the presence on the CBio board of distinguished and eminent directors such as Novo-Nordisk's vice-chairman Dr Goran Ando, retired Pfizer senior vice-president of science and technology Dr Peter Corr and retired European Medicines Agency executive director Dr Thomas Lonngren supported the predicted success of the company. "We consider that the market is significantly undervaluing CBio at present because of an inadequate announcement on July 31, 2011 by CBio regarding the interim results of the recently completed phase IIa trial," Mr Baker said (BD: Aug 1, 2011).

"The announcement did not provide investors with full and complete information regarding the trial and led to the misconception that the trial was not a success, which consequently drove down the share price by around 60 percent," Mr Baker said.

Mr Baker said that missing the primary endpoint was the result of under-dosing. "We question whether the company has fulfilled its continuous disclosure obligations by neglecting to clarify the meaning of the July 31, announcement before this week and then only partly and failing to specifically inform the market of recent presentations the company has made to ... European pharmaceutical companies," Mr Baker said. Mr Baker said that best practice in corporate governance was having an independent chairman and separating the roles of chief executive and chairman.

"The removal of Mr Jones, who has chaired the company since its inception more than 10 years ago, will achieve this," Mr Baker said. "While we believe that major shareholders will support the rights issue ... we are dismayed at the board's actions in diluting shareholders unnecessarily by raising more capital than is essential at such a low price." CBio was up 1.05 cents or 5.4 percent to 20.5 cents.

GI DYNAMICS

GI Dynamics opened down 2.7 percent from its initial public offer price of \$1.10 to \$1.07, falling as much as 18.2 percent to 90 cents in its first day on the ASX.

GI closed down 17 cents or 15.5 percent at 93 cents with 331,515 shares traded.

CSL

Capital Group Companies has ceased their substantial shareholding in CSL reducing from 28,713,899 shares (5.47%) to 25,671,870 shares (4.89%).

Capital Group said it sold the 3,042,029 shares for an average price of \$28.63 per share. Capital Group sold 6,113,796 shares for an average of \$32.8175 in July (BD: Jul 6, 2011) and in March sold 7,026,383 shares for an average of \$33.7785 (BD: Mar 23, 2011). Last year Capital Group acquired 4,063,035 shares for an average \$33.4027 per share between October 19, 2009 and March 8, 2010 (BD: Mar 10, 2011).

The Capital Group said it did not own shares in CSL but held them on behalf of "one or more of the investment management companies that make up the Capital Group Companies".

CSL climbed \$1.05 or 3.9 percent to \$27.84 with four million shares traded.

QRX PHARMA

Companies associated with Sydney property developer Langley Alexander Walker have become substantial shareholders in QRX with 7,866,472 shares or 5.46 percent. The initial substantial holder notice named Auckland Trust Co as Trustee for the Second Pacific Master Superannuation Fund as a shareholder, along with Tesroff as trustee for the Leighton Place Unit Trust, Werft as trustee for the Walker Group of Companies Retirement Fund and Langley Alexander Walker.

The notice said the shares were bought between October 8, 2010 and August 30, 2011 for \$8,119,809 or an average price of \$1.032 a share.

In May, Mr Walker became a substantial shareholder in Neuren with the acquisition of 13.04 percent and in June increased to 19 percent (BD: May 5, Jun 20, 2011).

QRX chief executive officer Dr John Holaday is a director of Neuren.

QRX fell half a cent or 0.4 percent to \$1.28.

ISONEA

Triton Systems has become a substantial shareholder in Isonea (formerly Karmelsonix) with the acquisition of 61,172,529 shares or 5.66 percent of the company.

The initial substantial shareholder notice said that Triton was based in Chelmsford Massachusetts and held 27,730,319 shares and that the Hong Kong-based Maple Management was an associated company holding 33,442,210 shares.

The notice was signed by Isonea chairman Ross Haghighat as a director of Triton and said the shares were acquired between December 17, 2010 and September 2, 2011 for \$500,000 in cash and \$406,088 in non-cash or an average price of 1.48 cents per share. Isonea was up 0.3 cents or 16.7 percent to 2.1 cents with 16.6 million shares traded.