Biotech Daily

Wednesday July 13, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALCHEMIA UP 30%; LBT DOWN 18%**

*** FDA CLEARS ALCHEMIA'S FONDAPARINUX TO EARN 'TENS OF MILLIONS'**

*** VICTORIA BIOTECHNOLOGY ADVISORY COUNCIL DEADLINE**

*** CBIO REGISTER CALL TRIGGERS 6m REDUCTION IN 9m SHARE EGM**

*** USCOM EXPECTS 45% INCREASED LOSS FOR INCREASED REVENUES**

*** KARMELSONIX 595.5m SHARE ISSUE; NAME CHANGE EGM**

MARKET REPORT

The Australian stock market climbed 0.43 percent on Wednesday July 13, 2011 with the S&P ASX 200 up 19.4 points to 4514.8 points.

Twelve of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and nine were untraded. All three Big Caps were up.

Alchemia was best, up as much as 39.8 percent to 86 cents, closing up 18.5 cents or 30.1 percent to 80 cents with three million shares traded, followed by Psivida up 31 cents or 7.4 percent to $4.51 with 1,748 shares traded and Resmed up 13 cents or 4.6 percent to $2.96 with 15 million shares traded.

QRX climbed 3.5 percent; Cochlear, CSL and Universal Biosensors rose more than two percent; with Acrux, Biota, Heartware, Living Cell, Mesoblast and Phylogica up more than one percent.

LBT led the falls, down 1.2 cents or 17.9 percent to 5.5 cents with 18,000 shares traded.

Bionomics and Patrys fell four percent or more; Phosphagenics lost 3.6 percent; Sirtex shed 2.4 percent; with Prima and Viralytics down more than one percent.

ALCHEMIA

Alchemia jumped 40 percent on the US Food and Drug Administration approval of its fondaparinux synthetic heparin, partnered with India's Dr Reddy's Laboratories.

Alchemia chief executive officer Dr Pete Smith told Biotech Daily that the approval for the range of four doses of the non-animal based generic version of Glaxosmithkline's Arixtra would deliver "tens of millions of dollars per year" to the company once the sales were "up to speed".

Dr Smith said Alchemia would earn a share of profits with Dr Reddy's with the launch fo the drug "in a matter of days".

"With a generic drug the take up is very quick, so the market share is gained very quickly," Dr Smith said.

"A new drug can take five to six years [to gain market share] but a generic is measured in quarters," Dr Smith said.

Dr Reddy's filed the Alchemia application for fondaparinux to the FDA in 2009 and has long-expected the approval (BD: May 11, 2009).

Alchemia said at that time that the notice of acceptance meant that it would enter a period of formal review of six months from filing and hoped fondaparinux would be approved by the end of 2009.

Last year Alchemia said the facility where syringes were filled with fondaparinux would be inspected by the FDA in November 2010, believing that to be one of the final hurdles to registration (BD: Oct 14, 2010).

Alchemia has said that fondaparinux is an anti-coagulant used for the prevention of deep vein thrombosis and was marketed in injectable form as Arixtra which had been off patent since 2002 but, due to the complexity of its synthesis, there was no approved generic or alternative source of commercial scale active ingredient (BD: Mar 19, 2010).

Alchemia said in 2010 that it had developed a novel, patent-protected, synthesis for the manufacture of fondaparinux at commercial scale.

In 2009, Dr Smith said: "Because we do not foresee the entry of other competitors in the near term, we expect pricing, market share and profitability to remain higher compared to a typical generic product." (BD: Mar 13, 2009)

"Because fondaparinux is a fully synthetic molecule, Alchemia does not believe it will face the regulatory issues of other anticoagulant drugs, such as the low molecular weight heparins, which are complex mixtures derived from animal material," Alchemia said.

In 2007 Alchemia's main competitor for synthetic heparin M-Enoxaparin was rejected by the FDA with Momenta Pharmaceuticals' partner, Sandoz Inc, told the application "was not approvable because the application does not adequately address the potential for immunogenicity of the drug product" (BD: Nov 7, 2007).

Alchemia said M-Enoxaparin was a generic version of the leading low molecular weight heparin, Lovenox, marketed by Sanofi-Aventis.

Alchemia said fondaparinux was a generic copy of Arixtra, which competed directly with Lovenox.

"… any delay in approval of Lovenox generics is positive for Alchemia in terms of pricing, overall market growth and market share of fondaparinux," Alchemia said at that time.

Dr Smith told Biotech Daily at that time that that the Momenta Sandoz drug, like Lovenox, was derived from pig intestines containing many molecules with the biological activity of some unknown.

He said Alchemia's synthetic heparin was entirely laboratory-based and was "completely done with chemistry starting with glucose and glucosamine".

Alchemia climbed as much as 39.8 percent to 86 cents on the news, closing up 18.5 cents or 30.1 percent to 80 cents with three million shares traded.

VICTORIA BIOTECHNOLOGY ADVISORY COUNCIL

The Department of Business and Innovation says applications close for the Victorian Government's Biotechnology Advisory Council on Monday July 25, 2011.

A Departmental officer told Biotech Daily that expressions of interest were sought from applicants from industry sub-sectors, including: discovery and development of drugs as well as biomarkers and other platform technologies; medical devices, including diagnostics; pharmaceuticals and biopharmaceuticals; agricultural biotechnology; industrial; and environmental biotechnology.

The Department said the particular types of organizations that could apply included: small, medium, and large biotechnology companies; domestic, foreign and multinational companies operating in Victoria; companies that export; and companies providing supporting services, such as clinical trials providers.

More details are at www.biotechnology.vic.gov.au/vbac.

The Council was announced by Victoria's Minister for Technology Gordon Rich-Phillips last month (BD: Jun 28, 2011).

Mr Rich-Phillips said at that time that the Victorian Biotechnology Advisory Council would "provide advice to the Victorian Government on current and emerging opportunities and threats to the sector, as well as supporting the implementation of the Government's biotechnology policy" and assist the Government provide a coordinated approach to fostering innovation and promoting growth in Victoria's life sciences industry.

CBIO

CBio has withdrawn four resolutions relating to 6,000,000 free 'performance rights' for directors and executives for its July 15, 2011 extraordinary general meeting.

In June, CBio announced the meeting to issue 9.1 million free performance rights to executives and directors, exercisable, pending conditions, at no charge for seven years (BD: June 14, 2011).

Later in June chairman Stephen Jones said he was concerned that two shareholders requested copies of the shareholders register relating to the meeting (BD: Jun 29, 2011).

Mr Jones said it was "regrettable that the Corporations Act permits one or two shareholders to contact some or all shareholders with potentially unwelcome correspondence, containing personal views on matters relating to the company".

Today, CBio withdrew resolutions to approve 500,000 rights to company secretary Ben Graham, 2,000,000 rights to chairman Stephen Jones, 2,000,000 rights to chief executive officer Jason Yeates and 1,500,000 rights for director James Greig.

CBio was up 1.5 cents or 2.3 percent to 66 cents.

USCOM

Uscom says it expects its loss for the year to June 30, 2011 would be $2,869,000, about 45 percent more than the previous year, despite constant revenue.

Uscom said the loss was due to increased expenditure for the US marketing strategy with new distributors signed to company and the expenditure was "a significant investment for the future and will be a positive impact on revenues".

Uscom said it would incur a large expense related to vested options which accounted for $332,000 or about 40 percent of the increase in expenditure.

The company said it had made distributor appointments in North American, Europe, South Africa, the Middle East and Latin America and enhanced its Asia Pacific distribution.

Uscom was untraded at 22 cents.

KARMELSONIX

Karmelsonix shareholders will vote on the issue of up to 595,550,511 shares including 18,000,000 shares to chairman Ross Haghighat and change the name to Isonea.

The resolutions include approving the prior issue of 3,500,000 shares and 7,000,000 options to Subiaco Capital as well as the prior issue of 72,711,315 shares at 1.6 cents each along with 36,355,657 attaching options to sophisticated and professional investors.

Shareholders will vote to issue 1,339,196 shares at 1.5 cents each to executive chairman Ross Haghighat as well as 18,000,000 shares at one cent each.

Karmelsonix has proposed to issue up to 500,000,000 shares at no less than 90 percent of the five-day volume weighted average price to the date of issue and change the company's name to Isonea.

The meeting will be held at Suite 1, 1233 High Street, Armadale, Victoria on August 10, 2011 at 10.30am (AEST).

Karmelsonix fell 0.1 cents or 9.1 percent to one cent with 6.9 million shares traded.