Biotech Daily

Wednesday July 7, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CIRCADIAN UP 8%; ALCHEMIA DOWN 27%**

*** ALCHEMIA TUMBLES 30% ON COMPETITION FROM APICORE**

*** AVEXA NAMES JOE BAINI CHAIRMAN; CALZADA WANTS BOARD SEAT**

*** ATCOR $2m PHARMACEUTICAL TRIALS DEAL; 2nd MICHIGAN JUDGMENT**

*** HELICON EGM ON SHARES, OPTIONS, LOAN**

MARKET REPORT

The Australian stock market fell 0.5 percent on Wednesday July 7, 2010 with the S&P ASX 200 down 21.5 points to 4254.6 points.

Just four of the Biotech Daily Top 40 stocks were up, 12 fell, 15 traded unchanged and nine were untraded. All three Big Caps fell.

Circadian was best, up four cents or 7.6 percent to 56.5 cents with 11,717 shares traded, followed by Sirtex up 5.7 percent to $5.20 with 29,123 shares traded.

Clinuvel and Viralytics rose more than two percent.

Alchemia led the falls, closing down 13 cents or 26.5 percent at 36 cents with 2.5 million shares traded, followed by Novogen down 2.5 cents or 15.6 percent to 13.5 cents with 119,810 shares traded and Patrys down 11.8 percent to 9.7 cents with 447,668 shares traded.

Cathrx lost 7.1 percent; Living Cell fell 6.5 percent; Heartware and Prima were down more than five percent; Acrux and Prana fell more than three percent; Biota shed 2.8 percent; with CSL, Pharmaxis and Starpharma down more than one percent.

ALCHEMIA

Alchemia fell 29.6 percent to 34.5 cents on news that Apicore LLC has lodged a drug master file for fondaparinux sodium with the US Food and Drug Administration.

Alchemia said the previously unknown competitor lodged the drug master file (DMF) with the FDA on June 28, 2010.

Alchemia said that its manufacturing partner Dr Reddy's Limited filed its DMF for fondaparinux in November 2008, followed by the abbreviated new drug application filing in March 2009 by its North American marketing partner Dr Reddy's Inc.

The company said that because it was a "first to file generic", the application for Alchemia's fondaparinux was receiving priority review and approval was pending.

Alchemia said it had developed a proprietary process for the manufacture of fondaparinux.

Alchemia chief executive officer Dr Peter Smith said the company had been unaware of Apicore's activity in developing a process for the manufacture of fondaparinux sodium.

Alchemia said Apicore had partnered with "a major generic pharmaceutical company" to develop the active pharmaceutical ingredient and pre-filled syringes with the goal of obtaining approval for an abbreviated new drug application to distribute a generic product equivalent to the brand name product Arixtra.

The New Jersey-based Apicore describes itself as "a developer and manufacturer of specialty active pharmaceutical ingredients and cGMP [current good manufacturing practice] advanced intermediates".

Dr Smith told Biotech Daily that it was unknown how much fondaparinux had been made by Apicore for the FDA drug master file and quantities were critical to the development of the drug.

"The game may have changed here, but we don't know to what extent," Dr Smith said.

"We will still get two to three years of the revenues we expected," Dr Smith said.

He said the potential sales of fondaparinux were "still an engine to power us forward for the phase III HA-Irinotecan cancer trial" (BD: Apr 21, 2010).

Dr Smith said that the sole generic in a market should achieve about 80 percent of the branded price, but a third player would reduce prices to about 50 percent.

"The market has reacted correctly if this is a real competitive threat," Dr Smith said.

"What we don't know is how much have they made for their drug master file and how much more work needs to be done," he said.

"It's easy enough to make tiny amounts, but not at a large scale. It's very difficult to work with," Dr Smith said.

"We don't know what quantities they are capable of manufacturing, so we don't have the ability to gauge the competitive threat," Dr Smith said.

In March this year, Alchemia said that fondaparinux was an anti-coagulant used for the prevention of deep vein thrombosis and was marketed in injectable form as Arixtra by Glaxosmithkline (BD: Mar 19, 2010).

The company said at that time that Arixtra 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 pharmaceutical ingredient.

Alchemia said in March 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)

Alchemia said in 2009 that Dr Reddy's manufacturing process for fondaparinux used a novel, synthetic pathway developed by Alchemia.

Alchemia closed down 13 cents or 26.5 percent at 36 cents with 2.5 million shares traded.

AVEXA, CALZADA

Avexa has appointed Joe Baini as non-executive chairman with Bruce Hewett and Steven Crowley as non-executive directors.

Avexa later announced to the ASX that director David Bottomley had also resigned from the company.

Mr Baini told Biotech Daily that the "prime objective is to preserve the $23 million in cash for shareholder value".

"But we will look at all options available to the company for shareholder value," Mr Baini said.

In a media release to the ASX Mr Baini said the board's first priority was to produce a credible plan for the management of Avexa's programs and assets.

"The board will initiate an independent review of all company programs, including the ATC [apricitabine] program and give full consideration to the range of strategic options available to the company," Mr Baini said.

"This will include engaging in discussion with regulatory authorities on the future potential for ATC," Mr Baini said.

"The board has a wealth of commercial and industry experience, extensive international networks and an intimate understanding of the HIV treatment arena," he said.

Avexa said Mr Hewett had more than 25 years experience in the pharmaceutical and healthcare industries and was a director of private pharmaceutical companies Lupin Australia and Equity Pharmaceuticals.

He held senior roles with Janssen-Cilag, Faulding Pharmaceuticals and founded Max Pharma.

Avexa said Mr Crowley had about 30 years experience in healthcare industries and held senior roles with Janssen-Cilag, Merck and Glaxo-Wellcome.

The company said Mr Crowley was the director of S&J Crowley Consulting and a senior lecturer in health economics at the University of Melbourne.

Avexa said Mr Baini had more than 20 years pharmaceutical and commercial experience, predominantly in HIV.

The company said that Mr Baini's most recent appointment was as managing director of Gilead Australia.

Avexa said it had a request for board representation from Calzada, which holds 16.06% of the company and the board was considering the proposal.

Separately Calzada told the ASX it abstained from voting at yesterday's Avexa shareholder meeting "after it became clear that the previous board had lost the support of Avexa shareholders and the proposed new directors decided not to publicly state their intentions for the company".

Calzada said it was "seeking to engage with the new Avexa board to understand the new board members' intentions for the future direction of the company".

"Calzada has also requested board representation commensurate with its position as the largest shareholder in the company," Calzada said.

"As a major shareholder, Calzada's focus is on ensuring that the new board of Avexa is working in the best interests of all shareholders to protect and enhance shareholder value," the company said.

Avexa fell 0.2 cents or 5.6 percent to 3.4 cents with 839,072 shares traded.

Calzada was untraded at three cents.

ATCOR MEDICAL

Atcor says it has signed a $US1.77 million ($A2.09 million) deal to supply systems and trial support services to an unnamed “major international pharmaceutical company”.

Atcor said the contract to supply its Sphygmocor system which measures central blood pressures and arterial stiffness noninvasively was to an existing customer.

Atcor chief executive officer Duncan Ross said the company had “closed new contracts valued at $US2.9 million since March, demonstrating the resurgence of the pharmaceutical trial sector since US healthcare reform legislation was signed”.

“Scientific publications continue to reinforce the importance of using central blood pressure as a measurement [and] this mounting body of evidence helps to drive our sales to pharmaceutical businesses and supports accelerated adoption of Sphygmocor in clinical practice,” Mr Ross said.

“Understanding a drug’s effect on central pressure is vitally important in assessing efficacy and in assuring drug safety. It is equally important in patient care,” he said.

Separately, Atcor said it had “a second positive case ruling by an administrative law judge for the Centers for Medicare and Medicaid Services”.

Atcor said the judge disagreed with the findings of a Medicare health plan assessment in the state of Michigan that the Sphygmocor technology was experimental and ruled that the plan must provide coverage for use of the Sphygmocor system.

Earlier this year Atcor said that an administrative law judge found that the Michigan-based Blue Cross Blue Shield which operated a Medicare health plan “must provide coverage for use of the Sphygmocor system” (BD: May 26, 2010).

Atcor said that a number of private health plans had reimbursed physicians for Sphygmocor assessments using an unlisted cardiovascular services code.

Atcor said it was driving clinical adoption through local reimbursement decisions and the company expected to file for a common procedural terminology (CPT) code specific to central blood pressure assessment in November 2010.

Atcor climbed 3.5 cents or 30.4 percent to 15 cents.

HELICON GROUP

Helicon will vote to ratify a share issue, place 25,000,000 options, hold a rights issue and forgive a $56,000 loan to chief executive officer Peter Abrahamson.

Helicon intended to market medical devices including Avita’s Recell in China but had two products rejected by China’s State Food and Drug Administration and then lost the contract with Avita (BD: May 29, April 1, May 31, 2010).

Last month Helicon placed 13,001,277 shares to clients of CPS Securities at 1.25 cents a share raising $162,516 and said it hoped to raise $1,875,000 in a three-for-two rights issue (BD: Jun 16, 2010).

At that time, Helicon said that a rights issue was “a sensible precursor to a project acquisition” but not necessarily in health care or biotechnology.

The meeting will be held at Suite 3, 257 York Street, Subiaco, Western Australia on August 3, 2010 at 9.30am

Helicon was untraded at 1.5 cents.