Biotech Daily

Thursday July 15, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN:**
- SUNSHINE HEART UP 10%; OPTISCAN DOWN 14%

*** FDA APPROVES STARPHARMA PHASE II VIVAGEL VAGINOSIS TRIAL**

*** ALCHEMIA, DR REDDY'S EXPAND FONDAPARINUX DEAL**

*** AVEXA REFUSES BOARD SEAT FOR 16% CALZADA**

*** JM FINANCIAL CEASES SUBSTANTIAL IN HALCYGEN**

*** AVITA APPOINTS ANDREW QUICK V-P RESEARCH, TECHNOLOGY**

*** STIRLING CLAIMS AUSTRALIAN PATENT FOR SALBUTAMOL FAT-BUSTER**

MARKET REPORT

The Australian stock market fell 0.44 percent on Thursday July 15, 2010 with the S&P ASX 200 down 19.8 points to 4442.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and nine were untraded.

Sunshine Heart was best, up 0.3 cents or 10 percent to 3.3 cents with 345,994 shares traded, followed by Patrys up one cent or 9.5 percent to 11.5 cents with 105,071 shares traded.

Cellmid climbed five percent; Alchemia and Clinuvel were up four percent or more; Circadian and Starpharma were up more than three percent; Living Cell and Tissue Therapies rose more than two percent; with Pharmaxis and Virax up more than one percent.

Optiscan led the falls, down 0.8 cents or 13.8 percent to five cents with 400 shares traded, followed by Phylogica down 6.7 percent to seven cents with 165,000 shares traded.

Impedimed lost 5.4 percent; Biota and Heartware fell more than four percent; Benitec and Chemgenex were down more than three percent; CSL and Viralytics shed more than two percent; with Bionomics, Sirtex and Universal Biosensors down more than one percent.

STARPHARMA

Starpharma says the US Food and Drug Administration has approved a randomized, placebo-controlled, 132-patient, phase II trial of Vivagel for bacterial vaginosis.

Starpharma said Vivagel (SPL7013) was under investigation for both the short term treatment and longer term suppression of recurrence of bacterial vaginosis in women.

The company said the initial phase of the clinical program would investigate the treatment of bacterial vaginosis with a once daily for seven days treatment of Vivagel and its findings would guide further investigation of suppression of recurrence.

Starpharma said the trial would be conducted under an investigational new drug application (IND) in the US and was expected to begin within a month.

Starpharma said the primary objective was to identify the efficacy and optimal dosing of Vivagel for bacterial vaginosis with three strengths (0.5%, 1% and 3%) compared with a placebo gel.

Subjects will be assessed at the end of treatment and then two to three weeks after the end of treatment.

Starpharma said the primary endpoint was a clinical cure as defined by no abnormal discharge, as described by the (Dr Richard) Amsel's criterion for vaginal discharge and fulfilling no more than one of the other three Amsel's criteria, which according to the US National Institutes of Health include vaginal pH of more than 4.5; the presence of clue cells and a positive whiff (fish smell) test.

The company said that secondary objectives were to explore the microbiological and overall efficacy of 0.5 percent, 1 percent and 3 percent SPL7013 gel compared to the placebo gel; determine the safety and tolerability of SPL7013 gel and determine patient perceived symptom resolution and acceptability of SPL7013 gel in the study population

Starpharma said that bacterial vaginosis was the most common vaginal infection worldwide and the most common cause of vaginal irritation, discharge and malodor.

The company said it was particularly prevalent in the US, where it affects an estimated one-third of the adult female population.

Starpharma said the condition was implicated in pelvic inflammatory disease and might be associated with an increased risk of sexually transmitted infections, including HIV, and pre-term birth.

The company said the global market for topical bacterial vaginosis treatments was estimated at $US350 million ($A397 million).

Starpharma said the current treatment for bacterial vaginosis with conventional antibiotics (orally or topically) was acknowledged to be inadequate by clinicians with high recurrence rates and common side effects and could lead to the development of drug resistance, increased susceptibility to thrush or candidiasis and drug interactions and topical treatments were often incompatible with condoms.

Starpharma said that earlier trials of Vivagel for bacterial vaginosis showed no signs of these issues and Vivagel was designed to be used with condoms.

Starpharma chief executive officer Dr Jackie Fairley said the start of the bacterial vaginosis program was "an important milestone in Vivagel's development".

"The treatment and suppression of recurrence of [bacterial vaginosis] opens up a whole new application for the product in an attractive, established market," Dr Fairley said.

"Feedback we've received suggests that a product without the drawbacks of conventional antibiotics and designed for use during sex, is likely to be very well received indeed," Dr Fairley said.

Starpharma said Vivagel was being developed as a topical microbicide for the prevention of HIV and genital herpes and as a condom coating.

Starpharma was up 1.5 cents or three percent to 51 cents.

ALCHEMIA

Alchemia says it has agreed terms with India's Dr Reddy's for marketing fondaparinux sodium for injection in all territories outside of North America.

Alchemia said the agreement did not alter the existing arrangements between the companies for the manufacture and North American marketing of fondaparinux, the generic version of Glaxosmithkline's Arixtra.

Alchemia said Dr Reddy's would pay Alchemia a royalty on sales and have the option to market the drug itself or enter into agreements with third parties.

Alchemia chief executive officer Dr Pete Smith said the agreement made "a great deal of sense for Alchemia".

"Dr Reddy's has the experience of directly marketing generic drugs in a large number of countries and supplying [active pharmaceutical ingredient] to numerous other pharmaceutical and generic companies across the globe," Dr Smith said.

"Whilst Alchemia has been approached by a number of companies interested in marketing fondaparinux, it would be inefficient for us to identify and enter into multiple agreements in the markets where we have no experience," Dr Smith said.

Alchemia said that fondparinux was used for the treatment and prevention of deep vein thrombosis.

In 2009, global sales of Glaxosmithkline's Arixtra were $US400 million ($A454 million) an increase of 25 percent over the prior year, with $US180 million in sales outside the US.

Alchemia said an abbreviated new drug application was filed to the US Food and Drug Administration by Dr Reddy's in March 2009 with approval expected "in the near term".

Alchemia said that Arixtra was protected by data exclusivity in the European Union which expires in 2012.

Alchemia was up 1.5 cents or four percent to 39 cents.

AVEXA, CALZADA

Avexa has refused 16.06 percent shareholder Calzada a seat on its new board.

Last week, following the investor dismissal of chairman Nathan Drona and director Uri Ratner and the election of Steven Crowley and Bruce Hewett as directors, Calzada formally requested a seat on the board (BD: Jul 6, 2010).

Avexa reappointed Joe Baini as a director and chairman and appointed Dr Jonathan Coates as interim chief executive officer and chief scientific officer (BD: Jul 13,2010) .

Dr Coates is the inventor of apricitabine or ATC which was dropped by the previous board which included Mr Baini, following the failure of a phase III trial to show a statistically significantly difference over 3TC, also invented by Dr Coates (BD: May 10, 2010).

Dr Coates has said he would oversee an independent review of Avexa's assets.

Under the Corporations Act shareholders with five percent or more of a company can requisition meetings, as did the supporters of directors Mr Crowley and Mr Hewett.

Calzada chairman David Franklyn told Biotech Daily that he was "mystified by their unwillingness to engage with us, being their largest shareholder – particularly given the current board holds no shares".

No one from Avexa was available for comment.

Avexa fell 0.3 cents or 8.1 percent to 3.4 cents with 2.2 million shares traded.

Calzada was up 0.1 cents or 3.3 percent to 3.1 cents.

HALCYGEN PHARMACEUTICALS

JM Financial Group has ceased its substantial shareholding in Halcygen.
In March JM Financial reduced its holding from 9,621,609 shares (6.68%) to 8,105,896 shares (5.63%) (BD: Mar 9, 2010).
Halcygen fell half a cent or 0.9 percent to 53.5 cents.

AVITA MEDICAL

Avita says it has appointed Andrew Quick as vice-president of research and technology, based in the company's Boston, Massachusetts office.
Avita said Mr Quick would have primary responsibility for the implementation and conduct of the company's clinical studies, to include regulatory trials underway with the US Food and Drug Administration, as well as clinical marketing studies outside the US.
The company said Mr Quick would oversee research and development efforts related to its regenerative medicine products and expansion of the company's product lines.
Avita said Mr Quick held a Masters of Science in biomedical engineering from Boston University.
The company said Mr Quick had more than 20 years experience in the medical industry and had held senior management positions in the areas of product development and clinical research.
Avita said Mr Quick's teams had "designed and developed medical products that have won numerous international engineering awards".
Most recently, he headed clinical research for US-based medical device company Advanced Bionics where he managed large multi-centre phase III and phase IV trials.
Avita fell one cent or 8.7 percent to 10.5 cents.

STIRLING PRODUCTS

Stirling says the Australian Patents Office has granted a patent for the pharmacologically active component of the common asthma drug salbutamol as an obesity drug candidate.
Stirling said the patent was for 'The Use of R-Salbutamol as a Method of Decreasing Fat Deposits' and was valid until November 12, 2024.
The company said that an early proof-of-concept study in beagle dogs achieved weight loss results of two percent per week.
Stirling said salbutamol had been safely used in humans in the treatment of respiratory disease for more than 30 years "and in its purified form, r-salbutamol for over 15 years".
Stirling said that its application to obesity did "not require any drug discovery work but rather the re-purposing of an existing approved drug, which is a common practice within the pharmaceutical industry".
Stirling said further development of the obesity drug candidate was intended to be pursued with a major industry partner.
Stirling climbed 0.1 cents or 11.1 percent to one cent with 3.3 million shares traded.