Biotech Daily

Friday April 5, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRIMA UP 5%, BENITEC DOWN 13%**

*** PHOSPHAGENICS READY FOR PHASE I TPM-OXYCODONE TRIAL**

*** SIRTEX 6% Q3 DOSE SALES GROWTH**

*** CORRECTION: STARPHARMA**

*** PSIVIDA EVALUATION AGREEMENT WITH UNNAMED COMPANY**

*** EMA CONTINUES LENGTHY REVIEW OF CLINUVEL'S SCENESSE**

MARKET REPORT

The Australian stock market fell 0.45 percent on Friday April 5, 2013 with the S&P ASX 200 down 22.1 points to 4,891.4 points.

Eight of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and five were untraded.

Prima was the best, up 0.5 cents or 5.4 percent to 9.8 cents with 2.3 million shares traded.

Phosphagenics climbed 4.2 percent; Allied Health and Anteo were up more than three percent; Living Cell and Osprey rose more than two percent; Acrux and Circadian were up more than one percent; with Resmed up 0.9 percent.

Benitec led the falls, down 0.2 cents or 13.3 percent to 1.3 cents with 4.3 million shares traded.

Sirtex lost 7.6 percent; Genetic Technologies and Viralytics were down more than six percent; Medical Developments was down 5.2 percent; Avita and Clinuvel fell more than four percent; Cellmid was down 3.2 percent; Nanosonics shed 2.1 percent; Bionomics, Cochlear, CSL, Mesoblast, Optiscan and Pharmaxis were down more than one percent; with Heartware, QRX and Starpharma down by less than one percent.

PHOSPHAGENICS

Phosphagenics says it will take tocopheryl phosphate mixture (TPM) oxycodone into a further phase I clinical trial at the CMAX facility at Royal Adelaide Hospital, this month.
Phosphagenics said the trial was designed to assess the profile of the new patch and form an integral part of the clinical program for 2013 with results due by October 2013.
The company said that the final design specifications of the transdermal patch technology were completed in collaboration with Germany's Tesa Labtec GmbH.
In February, Phosphagenics said the patch had been refined with Tesa Labtec and crystallization issues relating to the original TPM-oxycodone patch with 3M for pivotal phase II/III trials had been resolved (BD: May 23, 2011; May 23, 2012; Feb 11, 2013).
Today, Phosphagenics said that oxycodone was one of the lead candidates in its opioid transdermal delivery portfolio, which included a range of opioid patch products targeting all levels of chronic pain.
The company said that its transdermal delivery system had application for systemic delivery as well as potential for use in topical application.
Phosphagenics said that a phase I study of TPM-oxymorphone patch met the primary endpoints of safety and delivery of oxymorphone into the bloodstream for 72 hours.
Phosphagenics chief executive officer Dr Esra Ogru said that "returning to the clinic with our oxycodone patch technology is an important milestone in progressing our pain patch clinical programs during 2013".
The company said that market research indicated demand for a TPM-oxycodone patch was expected to be more than $1 billion a year, with the current global oxycodone market exceeding $3 billion a year.
Phosphagenics was up half a cent or 4.2 percent to 12.5 cents.

SIRTEX MEDICAL

Sirtex says that sales of its SIR-Spheres microspheres for liver cancer grew 6.3 percent for the three months to March 31, 2013 compared to the previous corresponding period.
Sirtex said it had recorded 35 consecutive quarters of positive growth and the three months to March 31 was "the highest quarterly dose sales achieved to date".
In February, Sirtex said that revenue for the six months to December 31, 2012 was up 25.1 percent to $46,042,000 primarily on dose sales up 30.5 percent to 3,522 SIR-Spheres, implying about $13,073 per dose and an average of about 1,761 doses per quarter (BD: Feb 14, 2013).
In January, Sirtex reported dose sales for the three months to December 31, 2012 up 25 percent (Jan 20, 2013); in October last year the company reported dose sales for the three months to September 2012 up 37 percent; with dose sales up 26 percent for the three months to June 30, 2012; and up 34 percent for the three months to March 31, 2012 (BD: Apr 11, Jul 4, Oct 4, 2012).
For the 12 months to June 30, 2012, Sirtex reported revenue up 18.7 percent to $86,575,000 with dose sales for the year up 23 percent.
Today, Sirtex said that sales for the three months to March 31, 2013 in the Americas were up 4.1 percent, Europe, Middle East and Africa sales were up 3.8 percent respectively, with Asia-Pacific sales up 30.1 percent.
Sirtex chief executive officer Gilman Wong said the company expected "fluctuations in quarter on quarter dose sales growth".
"We remain confident that dose sales growth for the full year will be at a healthy level, bearing in mind that we are also coming off a much higher base," Mr Wong said.
Sirtex fell 85 cents or 7.6 percent to $10.33 with 2.6 million shares traded.

STARPHARMA

Last night's edition wrongly reported Starpharma's phase II trial of Vivagel for recurrence of bacterial vaginosis missing statistical significance with p = 0.588.
The significance value of one percent Vivagel compared to placebo was p = 0.0588.
Biotech Daily apologizes unreservedly for the error, which was made by the Easter sub-editor, who has suffered the same fate as the bunny of the same name.
Starpharma was down one cent or 0.9 percent to $1.125 with 1.5 million shares traded.

PSIVIDA

Psivida says it has signed a funded technology evaluation agreement with an unnamed pharmaceutical company.
The company did not disclose the commercial details of the agreement.
Psivida said the agreement was to evaluate its Durasert and Tethadur drug delivery insert technologies for the pharmaceutical company's ophthalmology products.
Psivida said the Durasert system delivered specific quantities of drugs directly to a target site in the body at controlled rates for predetermined periods of time ranging from weeks to months.
The company said that Tethadur was its technology for the delivery of proteins, peptides and antibodies.
Psivida chief executive officer Dr Paul Ashton said his company was "extremely pleased to be working with another global pharmaceutical company to apply our unique technologies to develop transformational products in ophthalmology".
The company said that it had developed three of the four sustained release devices for retinal diseases that have been approved in either the US or Europe.
Psivida was unchanged at $2.15.

CLINUVEL PHARMACEUTICALS

Clinuvel says that the European Medicines Agency will take more time to complete the review of its marketing authorization application under the centralized procedure.
Clinuvel said the Agency procedure, led by the Committee for Medicinal Products for Human Use would "continue at the end of June 2013".
Clinuvel said that it filed its application for Scenesse (afamelanotide 16mg implant) for the preventative treatment of the rare light intolerance disorder erythropoietic protoporphyria in February 2012 (BD: Feb 7, 2012).
Last October, Clinuvel said that it was in a question and answer period with the European Medicines Agency and before a recommendation on the clinical use of Scenesse was made by the Agency's Committee for Medicinal Products for Human Use two further question periods could be imposed (BD: Oct 1, 2012).
Earlier this year, the European Medicines Agency completed a good manufacturing practice audit of the manufacturing facilities for Scenesse at Birmingham Laboratories, part of the Evonik Corp, in Birmingham, Alabama (BD: Feb 28, 2013).
Clinuvel acting chief scientific officer Dr Dennis Wright said that it was "not unusual for a first-in-class drug and first-line therapy to be subject to a lengthy review".
Clinuvel fell 10 cents or 4.3 percent to $2.25.