Biotech Daily

Friday September 26, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 6%, CLINUVEL DOWN 21%**

*** CLINUVEL EXPECTS EUROPEAN SCENESSE RESULT NEXT MONTH**

*** REVA NOTES, OPTIONS TO RAISE $55m**

*** PSIVIDA SALES OF ILUVIEN FOR DME IN FRANCE IN DOUBT**

*** ANTISENSE: 'PATERSONS UNDERWRITES $1m OF $1.5m PLAN'**

*** RHINOMED APPOINTS INTERFUSION TURBINE COLOMBIA DISTRIBUTOR**

*** QRX 2nd STRIKE BOARD SPILL AGM**

*** SIRTEX AGM FOR 73k, $1.6m CEO RIGHTS, DIRECTORS PAY UP 60%**

MARKET REPORT

The Australian stock market fell 1.28 percent on Friday September 26, 2014 with the S&P ASX 200 down 68.8 points to 5,313.4 points.

Nine of the Biotech Daily Top 40 stocks were up, 20 fell, six traded unchanged and five were untraded.

Optiscan was the best, up 0.2 cents or 5.7 percent to 3.7 cents with 25,000 shares traded.

Psivida and Viralytics climbed more than five percent; Benitec was up 4.1 percent; Universal Biosensors was up 3.2 percent; Acrux rose 2.2 percent; with Avita, Cochlear, Medical Developments and Tissue Therapies up by less than one percent.

Clinuvel led the falls, down 70 cents or 21.2 percent to $2.60 with 212,253 shares traded, followed by Genetic Technologies down 12 percent to 2.2 cents with 192,366 shares traded and Compumedics down 10.7 percent to 12.5 cents with 345,082 shares traded.

Cellmid lost 6.7 percent; Analytica, Anteo, Impedimed, Neuren and Phosphagenics fell four percent or more; Admedus, Osprey and Pharmaxis were down more than three percent; GI Dynamics, Mesoblast and Prima shed more than two percent; Alchemia, CSL, Nanosonics and Resmed were down more than one percent; with Bionomics, Sirtex and Starpharma down by less that one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says it attended a European Medicines Agency Committee for Human Medicinal Products meeting in London and an outcome was expected in October.
Clinuvel said that the meeting was held as part of the scientific review of the marketing authorization application for Scenesse, or afamelanotide 16mg, as a potential therapy for adult patients diagnosed with the orphan disease erythropoietic protoporphyria.
The company filed the application to the European Medicines Agency in February 2012 and answered follow-up questions in October, and in April 2013 expected the procedure to continue to the end of June 2013 (BD: Feb 7, Oct 1, 2012; Apr 5, 2013).
In August 2013, Clinuvel said that the EMA centralized procedure application for Scenesse would be delayed to January 2014 to "enable further investigation into the benefits of Scenesse by the EMA and patients and physicians may be contributing their experience to the EMA" (BD: Aug 1, 2013).
Earlier this year, the EMA requested additional time to review data from the US phase III erythropoietic protoporphyria study which was submitted last year (BD: Jan 30, 2014).
In 2013, Clinuvel said the study failed to meet its primary endpoint, but treated patients showed "a strong trend" for sunlight exposure compared to placebo (BD: Nov 11, 2013). "
Clinuvel's application is believed to be one of the longest reviews by the EMA.
Clinuvel fell 70 cents or 21.2 percent to $2.60.

REVA MEDICAL

Reva says it expects to raise up to $US48.2 million ($A54.9 million) through the issue of convertible notes and options to Goldman Sachs International and Senrigan Master Fund.
A spokesperson for Reva told Biotech Daily that Goldman Sachs and Senrigan would each take half of the $US25 million in convertible notes with the 8,750,000 in attaching options raising up to $US23.2 million.
Reva said that if the issue was approved by stockholders, it would provide funding for ongoing operating, clinical and capital needs including the clinical testing and planned Conformité Européenne (CE) mark application for its Fantom bioresorbable scaffold.
The company said that each of the 8,750,000 options allowed the purchase of one share of Reva's common stock and if the options were exercised in full at their maximum exercise price of $A3.00 a share, they would generate about $US23.2 million of additional capital, based on current exchange rates.
Reva said the exercise price of each option was $A2.50 per US share or the equivalent of 25 cents per Chess depositary interest (CDI) until such time as Reva completed full patient enrollment in its CE mark clinical trial of Fantom, at which time the exercise price would increase to $A3.00 a US share or 30 cents per CDI.
Reva said that the convertible notes had a five-year term, at 7.54 percent interest and allowed for cash redemption options by the holder at 26 months, at maturity, and on a change of control or following an event of default under the convertible note deed.
The company said that note holders would be allowed to convert some or all of the convertible notes into securities at any time at an initial conversion price of 25 cents per CDI and would automatically convert to CDIs in the event the company received CE mark approval for Fantom and the market price of CDIs was more than 60 cents for 20 consecutive trading days.
Reva said it expected to begin a human clinical trial of Fantom before the end of 2014, designed to enroll up to 125 patients and provide the data needed to apply for the CE mark by mid-2016.
Reva was up 10.5 cents or 70 percent to 25.5 cents.

PSIVIDA

Psivida says it does not expect to market Iluvien for diabetic macular oedema in France until next year, if at all.
Psivida said that licencee Alimera Sciences had been negotiating with regulatory authorities in France regarding the pricing of Iluvien.
The company said that the negotiations had taken longer than expected, and Alimera did not plan to commercially launch Iluvien in France prior to reaching a satisfactory agreement with regulatory authorities, which Alimera did not expect to occur in 2014.
Psivida said that the earliest that Iluvien could be launched in France would be 2015, although there was no assurance that Alimera "would reach a satisfactory agreement with such regulatory authorities in 2015, if at all".
Psivida was up 25 cents or 5.4 percent to $4.85.

ANTISENSE THERAPEUTICS

Antisense says that Patersons Securities has agreed to underwrite $1 million of its proposed $1.5 million share purchase plan.
Yesterday, Antisense said it had raised $1 million in a placement at 11.5 cents a share (BD: Sep 25, 2014).
Today the company said the share plan was available for holders at the record date of September 24, would open on October 7 and close on October 31, 2014.
Antisense was unchanged at 11.5 cents.

RHINOMED

Rhinomed says it has appointed the Bogota-based Interfusion as its Breatheassist Turbine nasal plugs distributor in Colombia.
Rhinomed said that Interfusion was a wholesaler to the sporting goods industry.
The company said that the terms of the distribution deal were confidential.
Rhinomed fell 0.2 cents or 5.9 percent to 3.2 cents with 1.1 million shares traded.

QRX PHARMA

QRX annual general meeting will vote on a potential second strike board spill, along with the election of director Bruce Hancox.
Last year, the QRX remuneration report was opposed by 14,310,456 votes or 33.9 percent, providing the first trigger for a potential board spill at this year's annual general meeting (BD: Nov 13, 2013).
The Corporations Act (Section 250U) provides for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting and if passed by more than 50 percent of votes the directors must stand for reelection at a subsequent meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
The meeting will be held at the offices of Dibbs Barker Lawyers, Level 8, 123 Pitt Street, Sydney on October 29, 2014 at 10am (AEDT).
QRX fell 0.1 cents or 3.7 percent to 2.6 cents.

SIRTEX MEDICAL

Sirtex will vote to grant chief executive officer Gilman Wong 73,000 performance shares worth $1.6 million and increase directors' remuneration 60 percent to $1,000,000.
Sirtex said that it proposed that the maximum aggregate remuneration for non-executive directors be increased by $375,000 from $625,000 to $1,000,000.
The company said that it would ask shareholders to approve the issue of 73,000 'performance rights' at no cost and exercisable at no cost to Mr Wong.
Sirtex share price has increased from $11.98 at the close on June 28, 2013 to $16.88 on June 30, 2014, and from $13.74 on September 27, 2013 to $21.94 today.
The Sirtex notice of meeting said it would also seek shareholder approval for the remuneration report and the re-elect of director Richard Hill.
The meeting will be held at the Christie Conference Centre, Level 4, 100 Walker Street, North Sydney, on October 28, 2014 at 10.30am (AEDT).
Sirtex fell 16 cents or 0.7 percent to $21.94 with 185,946 shares traded.