

Biotech Daily

Wednesday February 9, 2011

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: VIRALYTICS UP 32%; GENERA DOWN 6%
- * CLINUVEL COMPLETES US PHASE II SCENESSE FOR EPP STUDY
- * MESOBLAST EGM VOTES FOR CEPHALON AND ITS \$30m
- * RELEVARE RESCHEDULES ASX IPO FOR MARCH 2011
- * NSW POLICE EXTENDS GENETIC TECHNOLOGIES FORENSICS TESTING
- * STARPHARMA SAYS REPORTS MAY HAVE PUSHED PRICE ABOVE \$1
- * ACUVAX LOSES CEO DR WILLIAM ARDREY; ALL CHANGED, AGAIN
- * XCEED VOTES TO DIVEST BORON MOLECULAR
- * PHARMAUST REQUESTS 'SIGNIFICANT TRANSACTION' TRADING HALT

MARKET REPORT

The Australian stock market was up 0.29 percent on Wednesday February 9, 2011 with the S&P ASX 200 up 14.4 points to 4904.8 points.

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

Viralytics was the best for the second day in a row, up 1.4 cents or 31.8 percent to 5.8 cents, with 23.9 million shares traded, followed by Optiscan up 7.1 percent to six cents with 148,865 shares traded.

QRX climbed 6.6 percent; Bionomics was up 5.3 percent; LBT was up 4.2 percent; Benitec was up 3.1 percent; Chemgenex, Starpharma and Sunshine Heart rose more than two percent; with Cellestis, Cochlear and Patrys up more than one percent.

Genera led the falls, down 0.5 cents or six percent to 47 cents with 49,600 shares traded.

Genetic Technologies lost 4.35 percent, Cellmid, Circadian, Nanosonics and Prana fell more than three percent; Alchemia, Prima and Tissue Therapies shed more than two percent; with CSL down one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says all 70 patient visits for its first US phase II study of afamelanotide or Scenesse have been completed and analysis of the results was underway.

Clinuvel said the six-month, randomized, placebo-controlled study was designed to further evaluate the safety and efficacy of Scenesse in reducing the number and severity of phototoxic skin reactions in patients with the rare light intolerance disorder erythropoietic protoporphyria (EPP).

Clinuvel said patients were administered either the afamelanotide implant or a placebo, in two parallel groups, every two months and asked to record the number and severity of reactions experienced as well as the duration of time they spent outside, exposing their skin to sunlight.

The company said that three of the study sites conducted photo-provocation testing in which an artificial light source was used to clinically measure the time required to elicit a photo-toxic response in patients' skin under standardized laboratory conditions.

Clinuvel said that no drug-related serious adverse events had been identified to date. The company said that phase II and III studies evaluating Scenesse for erythropoietic protoporphyria had been completed in Europe and Australia, a confirmatory phase III study was underway in Europe and Scenesse had orphan drug status in Europe and the US for erythropoietic protoporphyria.

Clinuvel said that erythropoietic protoporphyria was characterized by severe photo-toxicity of the skin resulting in intolerable pain, swelling, and scarring, usually of the exposed areas such as the face, hands and feet, with patients often forced to lead an indoors existence, severely affecting their quality of life.

The company said that about 10,000 people were affected by the illness worldwide, with an estimated 4,000 patients in the US.

Clinuvel's chief scientific officer Dr Hank Agersborg said that although the study was conducted in the US "we will evaluate these results and if they add to the body of evidence that afamelanotide is safe and effective in EPP, include them ... in the European dossier to obtain marketing authorization".

Clinuvel chief executive officer Dr Philippe Wolgen said that due to the lack of effective treatments in erythropoietic protoporphyria and a strong demand from patients in the study, the company was in discussion with the US Food and Drug Administration to facilitate further drug access for the patients.

Clinuvel fell one cent or 0.45 percent to \$2.22.

MESOBLAST

Mesoblast shareholders overwhelmingly supported the issue of shares to US partner Cephalon, triggering a further \$US30 million in upfront fees.

The resolution on the issue of shares to Cephalon was passed with 153,493,277 proxy votes in favor and 57,798 proxy votes against.

The ratification of a prior share issue and the election of Cephalon's Kevin Buchi as a director were supported by more than 153 million votes and opposed by 37,994 and 351,819 votes, respectively.

A resolution to increase directors' fees was passed with 76,641,457 votes in favor and 8,765,882 votes against.

A presentation for the meeting said that following the meeting the company would have 279 million shares on issue, \$280 million in cash and a market capitalization of \$1,575 million.

Mesoblast fell four cents or 0.7 percent to \$5.54.

RELEVARE PHARMACEUTICALS

Relevare is hoping to raise up to \$25 million for a March 2011 listing on the ASX and conduct a pivotal phase IIb/III trial of its pain drug flupirtine or CNB015.

Relevare chief executive officer Mark Blumling told Biotech Daily his company hoped to list on the ASX last year, but the process had been delayed (BD: May 10, 2010).

Mr Blumling said that Relevare, formerly CNSBio, wanted to raise \$20 million with up to \$5 million in oversubscriptions, with Lodge Partners as brokers for the initial public offer.

Mr Blumling said that the company had conducted two phase IIa trials of flupirtine in combination with opioids for neuropathic cancer pain and HIV neuropathic pain, with results published from the first trial and the second awaiting publication.

He said the next step was a 300-patient European phase IIb/III pivotal trial for neuropathic cancer pain comparing 300mg flupirtine with existing opioid treatment against 600mg flupirtine and opioid as well as a third arm of opioid alone.

Mr Blumling said Relevare had received "a very good response from the investor community".

Flupirtine is a non-opioid, non-steroidal, non-NSAID analgesic which has been available in Europe since 1984, described as having muscle relaxant qualities, with "many potential uses" and few if any side effects.

Relevare is a private company.

GENETIC TECHNOLOGIES

Genetic Technologies says the New South Wales Police Force has extended its forensic DNA testing agreement for a further year.

Genetic Technologies said it would conduct forensic DNA analysis on "complex volume crime" samples which include, but are not limited to, materials relating to crimes such as breaking and entering, motor vehicle theft, theft of items from motor vehicles and malicious damage offences.

The company said this was higher value-add work compared to the types of tests conducted during the first three years of its forensics testing for the NSW Police. Genetic Technologies chief executive officer Dr Paul MacLeman said his company was "the only non-government, NATA-accredited forensics testing laboratory in Australia". "Contracts such as this provide stable revenue underpinnings that enable us to develop our healthcare related business, including our emerging suite of cancer diagnostics," Dr MacLeman said.

Genetic Technologies fell half a cent or 4.35 percent to 11 cents.

STARPHARMA

Starpharma has told the ASX that analysts and media reports may have pushed its share price 60 percent to its highest close ever.

The ASX said the company's share price rose from 88.5 cents on January 31, 2011 to \$1.03, a 16.4 percent increase, on January 20, 2011, and noted an increase in trading volumes.

Starpharma hit \$1.00 in intra-day trading in March 2002 and 99 cents in September 2004 before falling to an intraday low of 16 cents in February 2009.

Starpharma said that apart from the two positive stockbroker analysts' reports and media reports, it was not aware of any information it has not announced which, if known, could explain recent trading in its securities.

Starpharma was up two cents or two percent to \$1 with 2.1 million shares traded.

ACUVAX

Acuvax has completely changed its ownership, board and management with the resignation of chief executive officer Dr William Ardrey today.

Following the Merck Sharp and Dohme acquisition of the biotechnology assets of the Acuvax 26 percent subsidiary Hawaii Biotech (BD: Jul 23, 2010) and failure of the cancer drug RP101 (BD: Oct 6, 2009), the company saw the departure of majority shareholder Dr Richard Opara (BD: Nov 16, 2010) and the introduction of new shareholders.

Dr Opara held up to 86 percent of Acuvax.

Acuvax was formerly known as Avantogen and before that Australian Cancer Technology with Katherine Woodthorpe, Dr Roger Aston and Paul Hopper as directors.

Dr Opara invested in the company and eventually became a director and chairman. Acuvax was unchanged at 0.3 cents.

XCEED CAPITAL

Xceed says that shareholders overwhelmingly voted to divest Boron Molecular to the Melbourne-based Welvic Australia for \$1.5 million (BD: Jan 16, 2011). Xceed is no longer involved in biotechnology.

PHARMAUST

Pharmaust has requested a trading halt pending an announcement relating to "a significant transaction".

Trading will resume on February 11, 2011 or on an earlier announcement.

Pharmaust last traded at 2.4 cents.