Biotech Daily

Thursday December 8, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 30%, ANTISENSE DOWN 17%**

*** CSL R&D BRIEFING LEADS WITH $30m US NIH CYTOMEGALOVIRUS TRIAL**

*** QUEENSLAND GOVERNMENT, UNIVERSITY, DSM JOIN ON BIOLOGICS**

*** PENNSYLVANIA COMPANY INSURES IMPEDIMED LYMPHOEDEMA TEST**

*** $12m BIDS FOR STARPHARMA $3m CAPPED SHARE PLAN**

*** HEALTHLINX TAKES THREE $3m LA JOLLA COVE CONVERTIBLE NOTES**

*** COGSTATE $711k SCHIZOPHRENIA TRIAL CONTRACT**

*** AVEXA INCREASES, DILUTED TO 16% OF ALLIED HEALTH**

*** CHAIRMAN DR DAVID KING TAKES 5% OF CELLMID**

MARKET REPORT

The Australian stock market fell 0.27 percent on Thursday December 8, 2011 with the S&P ASX 200 down 11.8 points to 4,280.7 points. Ten Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and seven were untraded. All three Big Caps fell.

Neuren was today's best on no news, up 0.7 cents or 30.4 percent to three cents with 46.5 million shares traded, followed by Circadian up 8.05 percent to 47 cents with 35,000 shares traded.

Cellmid and Phosphagenics climbed more than six percent; Bionomics was up four percent; Clinuvel was up 3.1 percent; Anteo and Impedimed rose more than two percent; Alchemia was up 1.75 percent; with Biota up 0.65 percent.

Antisense led the falls, down 0.6 cents or 16.2 percent to 3.1 cents, with 254.4 million shares traded.

Benitec lost 5.9 percent; Avita, Genetic Technologies and Nanosonics fell four percent or more; Phylogica and Prima were down more than three percent; Acrux, Allied Health, Mesoblast and Sunshine Heart shed more than two percent; Heartware and Living Cell were down more than one percent; with Cochlear, CSL, Pharmaxis, QRX, Resmed and Sirtex down by less than one percent.

CSL

CSL will partner with the US National Institutes of Health in a $30 million study to develop a therapy for the prevention of congenital cytomegalovirus.

A CSL spokeswoman told Biotech Daily that congenital cytomegalovirus (CMV) was one of the most common causes of congenital abnormalities in the developed world and the CSL-NIH trial in 800 pregnant women would use an existing registered plasma product targeting CMV antibodies.

CSL research and development director and chief scientist Dr Andrew Cuthbertson led the company's annual research and development briefing in Sydney, providing details of the collaborative project with the US NIH.

CSL said the two organizations would work together to find a preventative treatment for CMV which was a leading cause of disabilities in infants, including deafness, blindness, cerebral palsy, mental and physical disabilities, seizures, and even death.

CSL said cytomegalovirus was present in body fluids, predominantly carried by healthy infants, preschoolers and children who contract the virus from their peers.

The company said that one to two percent of pregnant women were infected with CMV for the first time during pregnancy and one in three would pass the infection to their developing unborn child.

CSL said the risk of infection was reduced by hand washing and general hygiene, but there was currently no proven therapeutic prevention for congenital CMV.

CSL said that starting this month, the NIH would initiate a multi-site clinical trial in the US to test whether CMV immunoglobulin, that is, antibodies collected from human plasma, was an effective preventative of mother to baby transmission of the virus.

The company said that about 160,000 women would be screened over four years to enroll 800 subjects with evidence of primary CMV infection before 23 weeks gestation.

CSL said infants born to those in the study would be followed-up for two years, with primary analysis expected in 2016.

CSL said it was donating product made at its Swiss plant to the NIH for use in this trial.

"This is a very large, complex and long-term trial that requires the resources of a research agency like the NIH," Dr Cuthbertson said.

"CSL is very pleased to be able to support this important research, which could ultimately improve pre-natal care around the world," Dr Cuthbertson said.

CSL said its expenditure on research and development was $325 million in 2010-'11 up 2.7 percent on the previous year.

In its presentation CSL said it continued to develop a range of immunoglobulins, products for haemophilia, breakthrough medicines, vaccines and specialty plasma products, with a pipeline demonstrating programs at every stage of development, from basic research through clinical trials to market development.

CSL said the specialty products included plasma concentrates for the control of major acute bleeding related to complex surgery including cardiac surgery, while immunoglobulins were being developed for the treatment of a chronic inflammatory neuromuscular disorder.

The company said breakthrough medicines included a reconstituted high density lipoprotein for the treatment of acute coronary syndrome and recombinant antibodies for the treatment of acute myeloid leukemia.

CSL said it had licencing deals and/or collaborations with Medimmune on recombinant antibodies for rheumatoid arthritis, with Merck to expand Gardasil indications and with Merck and Pfizer on vaccine development.

CSL fell five cents or 0.15 percent to $32.39 with 1.9 million shares traded.

QUEENSLAND GOVERNMENT

Queensland Premier Anna Bligh says the State Government, the University of Queensland and DSM Biologics will collaborate on a biologics project.

A media release from the University of Queensland said its Australian Institute for Bioengineering and Nanotechnology would collaborate with the Netherlands-based DSM to develop biologics at a $65 million scale-up facility under construction at Brisbane's Princess Alexandra Hospital.

The University of Queensland said that biologics were based on natural proteins made using DNA technology, offering treatment options for a range of diseases including cancer and auto-immune disorders.

The media release said biologics could be used for medical conditions for which there are no other treatments and offered the only known potential treatment for Hendra virus infection.

The announcement said that DSM would operate the scale-up facility, owned by the Queensland Government entity Biopharmaceuticals Australia, under construction next to the Translational Research Institute, to produce clinical and commercial grade biologics.

"DSM Biologics has signed a memorandum of understanding with the University of Queensland's AIBN, completing a vital link in the chain between biopharmaceutical research and manufacturing," Ms Bligh said.

"This announcement represents the final steps in ensuring that Queensland is able to seamlessly take research into new human therapeutics through to human clinical trials and subsequent production," Ms Bligh said.

IMPEDIMED

Impedimed says it has increased US insurance coverage for the use of its L-Dex bioimpedance spectroscopy (BIS) device for the assessment of lymphoedema.

Impedimed said the coverage by an unnamed Pennsylvania insurance company for an unspecified medical centre was for assessing lymphoedema of the arm in women following treatment for breast cancer.

Impedimed chief executive officer Greg Brown told Biotech Daily that until the insurance company published its policy changes he was unable to disclose its identity other than to say it was "a key Pennsylvania-based health plan that had been using the technology in its women's hospital system for more than 12 months".

Last year Impedimed said that the University of Pittsburgh Medical Centre-affiliated Magee Women's Hospital had adopted the L-Dex technology for its lymphoedema screening, early detection and prevention program (BD: Nov 24, 2010).

Impedimed said the health plan provided insurance to more than 1.6 million people in western Pennsylvania, taking the cumulative total of covered lives to 13.8 million.

In a media release Mr Brown said it was "gratifying to see such a prestigious and progressive, academic medical center embrace BIS technology as a part of their breast cancer program".

"The health plan's support of the clinical service demonstrates their confidence in the pre-emptive model and the ability to control the cost of chronic care by covering for L-Dex testing to aid clinicians in their clinical assessment of lymphoedema," Mr Brown said.

Impedimed was up 1.5 cents or 2.7 percent to 57 cents.

STARPHARMA

Starpharma says its share plan at $1.075 a share, capped at $3 million, has attracted bids for more than $12 million in shares.
Starpharma said the applications would be scaled back and monies refunded.
The company said the plan followed the placement of $32 million at the same price.
Starpharma chief executive officer Dr Jackie Fairley said the company was “delighted to see such strong demand shown in the recent financing and we thank our shareholders for their tremendous support”.
“These funds will allow us to significantly accelerate multiple products based on our dendrimer technology platform and position the company very strongly for the future,” Dr Fairley said.
Starpharma said the funds would be used to accelerate and complete both Vivagel bacterial vaginosis phase III programs for treatment as well as prevention of recurrence, support a new drug application filing and commercial licence and advance multiple product opportunities across its drug delivery and agrochemical programs.
Starpharma was unchanged at $1.19.

HEALTHLINX

Healthlinx says it has signed a funding agreement with La Jolla Cove Investors for up to $US9 million ($A8.8 million) over four years.
Healthlinx said the funding would be through the issue of up to three convertible notes with a face value of $US3 million each.
The company said the funds would be used to accelerate the expansion and development of its Ovplex ovarian cancer diagnostic test.
Healthlinx said that along with a “push into North America” the funds would be used to support ongoing market development, strategic alliances and studies required for regulatory purposes.
Healthlinx managing director Nick Gatsios said the “long term, high value funding will provide the company with the best opportunity to meet its milestones over the short to medium term”.
“The company is particularly keen to enter the US market and this funding will assist us to continue to work towards achieving this goal in a timely manner,” Mr Gatsios said.
Healthlinx said the drawdown for each note would be $US165,000 a month until fully drawn, conditional on the satisfaction of certain conditions at the time payment is due, including that the company had the capacity to convert the monthly payment into shares without breaching its obligations under Listing Rule 7.1.
The company said that each note would have a repayment term of four years and 4.75 percent interest per year would be payable monthly in arrears on unconverted drawdown amounts.
Healthlinx said the conversion price would be the lesser of the price calculated as a 15 percent discount to the three lowest daily volume weighted average sale prices of the company’s shares during the 15 days before the conversion date or 10 cents a share.
Healthlinx fell 0.2 cents or 18.2 percent to 0.9 cents with 3.1 million shares traded.

COGSTATE

Cogstate says it has signed a $US730,000 ($A711,039) contract with a pharmaceutical company for a phase II clinical trial for the treatment of schizophrenia negative symptoms.
The US National Institute of Mental Health website says schizophrenia positive symptoms include hallucinations, delusions, thought and movement disorders, while negative symptoms include flat affect or reduced emotion, lack of pleasure, lack of ability to begin and sustain activities and speaking little even when forced to interact.
Cogstate said the schizophrenia study followed previous schizophrenia studies using its technology this year.
The company said it would provide its cognitive testing technology and services to 270 patients in 35 sites in four languages.
Cogstate was up one cent or 4.35 percent to 24 cents.

ALLIED HEALTH, AVEXA

Avexa has increased its substantial holding in Allied Health but has been diluted through a placement.
The change of substantial shareholder notice said that Avexa increased and was diluted from 96,000,000 shares (16.9%) to 103,500,000 shares (15.76%).
The placement was at 2.8 cents a share.
Allied fell 0.1 cents or 2.5 percent to 3.9 cents with 2.4 million shares traded.
Avexa was unchanged at 3.8 cents.

CELLMID

Cellmid chairman Dr David King has become a substantial shareholder in his company with the acquisition of 22,500,000 shares or 5.355 percent.
The initial substantial shareholder notice said that Dr King acquired 9,023,331 shares on December 2, 2011 for $153,397 or 1.7 cents a share.
Last week, Cellmid completed a rights issue raising $480,564 with a $1.2 million shortfall to be placed (BD: Nov 29, 2011).
Cellmid was up 0.1 cents or 6.7 percent to 1.6 cents with 4.8 million shares traded.