

Biotech Daily

Tuesday December 7, 2010

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: SUNSHINE HEART UP 17%; LBT DOWN 11%
- * CSL DETAILS R&D PROGRAM, INCREASED SPENDING
- * AUSTRALIAN PHENOMICS NETWORK LAUNCHES MICRO-RNA PLATFORM
- * PHARMAXIS STARTS ASM8 PHASE II TRIAL FOR ALLERGIC ASTHMA
- * ANTEO PLEADS SCHULTZ TO 37% SHARE PRICE RISE; ASX MISTAKEN
- * COMPUMEDICS SYSTEM IN \$303k ATHEROSCLEROSIS SLEEP STUDY
- * ANTISENSE RIGHTS ISSUE RAISES \$2.4m

MARKET REPORT

The Australian stock market climbed 0.82 percent on Tuesday December 7, 2010 with the S&P ASX 200 up 38.2 points to 4726.8 points.

Nineteen of the Biotech Daily Top 40 stocks were up, six fell, seven traded unchanged and eight were untraded.

Sunshine Heart was best, up 0.4 cents or 17.4 percent to 2.7 cents with 561,092 shares traded, followed by Antisense up 12.5 percent to 0.9 cents with 60,000 shares traded.

Optiscan climbed six percent; Benitec was up four percent; Alchemia, Clinuvel, Psivida and QRX were up more than three percent; Acrux, Impedimed, Nanosonics, Patrys and Uscom rose more than two percent; with Chemgenex, Starpharma, Tissue Therapies and Universal Biosensors up more than one percent.

LBT led the falls, down one cent or 11.1 percent to eight cents with 156,845 shares traded, followed by Living Cell down 6.9 percent to 13.5 cents with 554,266 shares traded.

Phosphagenics lost 4.2 percent; Viralytics was down three percent; Circadian shed 2.4 percent; with Cellestis, Cochlear and Resmed down by less than one percent.

CSL

CSL's chief scientist Dr Andrew Cuthbertson says the company will continue increasing its research and development budget, with a greater focus on new product development. Speaking to a research and development teleconference, Dr Cuthbertson detailed the four major segments of the CSL pipeline as immunoglobins, specialty products, haemophilia products and breakthrough medicines.

Dr Cuthbertson said that much work was being done to improve the yield, purity and formulation of immunoglobin products to make them more convenient for patients.

He said that patient convenience was not a trivial issue when people were on drugs for the long term.

The highly concentrated Hizentra for primary immunodeficiency could be self-administered as a sub-cutaneous injection instead of intra-venous, requiring a formal medical setting. Dr Cuthbertson gave Fibrinogen as an example of development in specialty products to reduce the need for blood transfusions during aorta surgery.

He said Fibrinogen was currently in phase II trials and was undergoing pre-clinical development for other indications.

Dr Cuthbertson said CSL was working on lengthening the half life of haemophilia products by combining the short half-life coagulant factor with the long half-life albumin.

Dr Cuthbertson said the hope was to extend the coagulant life to five to eseven days in order to change dosing from daily to weekly.

In breakthrough medicines, he cited work on reconstituted high density lipoproteins (HDL), CSL112, as infusions post cardiac arrest to prevent death or repeated arrests.

Dr Cuthbertson said the results of a phase I trial were "a few months away" with a phase II trial expected within the next 12 months.

He said that CSL362 was a second generation monoclonal antibody for acute myeloid leukemia, targeting the CD123 receptor on the leukemia stem cells.

Dr Cuthbertson said CSL362 was expected to latch onto the cell and aid the body's natural killer cells destroy the tumor, with clinical trials expected to begin in 2012.

"We can't develop all the things we have in our portfolio ourselves," Dr Cuthbertson said.

He cited work with Medimmune Astrazeneca on rheumatoid arthritis as wells as periodontal disease research with Sanofi Pasteur as examples of licenced work.

He said that Merck was expanding the uses of Gardasil and there was "a lot of intense excitement" about the product.

Dr Cuthbertson said CSL employed 800 scientists with about half in Australia and half in the Northern Hemisphere including Switzerland, Germany, the US and Japan.

The company increased total research and development spending from \$312 million in 2009 to \$317 million 2010, with decreasing shares to market development and life cycle management of existing products and an increasing share of funds to new product development.

Dr Cuthbertson said CSL expected to increase spending on research and development by five to seven percent [per annum].

Dr Cuthbertson said the formulation facility at Parkville which received Victorian Government funds had been used by academic researchers and smaller biotechnology companies as per the agreement with the Government, but said he was not at liberty to disclose which companies had used the facility.

Dr Cuthbertson said the CSL pipeline had shown "a lot of movement" over the past year with a bunching of compounds from pre-clinical to clinical development.

"We are going into a very exciting period over the next 12 months and it is very data driven," Dr Cuthbertson said.

CSL was up 21 cents or 0.6 percent to \$36.36 with two million shares traded.

AUSTRALIAN PHENOMICS NETWORK

The Australian Phenomics Network, with the Victorian Centre for Functional Genomics at the Peter MacCallum Cancer Centre, will launch a micro-RNA screening platform. The Victorian Centre for Functional Genomics' Dr Kaylene Simpson said that micro-RNA consisted of small pieces of RNA that bind to messenger RNA and reduce gene expression.

Dr Simpson said that micro-RNAs provided a new layer of gene regulation complexity, with more than 1,000 of them in the human genome and a single micro-RNA could target many genes.

Dr Simpson said that researchers were beginning to identify micro-RNA signatures that may in the future be able to classify different cancers and lead to more targeted therapies. "This is another mechanism of gene regulation which is getting exciting attention because we are finding a lot of diseases, such as breast cancer, can be regulated by micro-RNA," Dr Simpson said. "We provide researchers with the opportunity to identify novel genes which, after characterization, can ultimately provide new mouse models." "This fits well with the goal of the APN to discover new genes via mouse models," Dr Simpson said.

Dr Simpson said the micro-RNA platform would be fully functional by March 2011. A media release from Australian Phenomics Network said the micro-RNA screening platform was an extension of its RNA-interference capabilities and the platform would encompass all the known micro-RNAs currently identified in the human genome. The Network's media release said that the Australian Phenome Bank was a joint project involving the Australian National University and Monash University.

The Bank's curator Dr Stuart Read said "the fact that a large number, if not most, of the medical advances in recent years are thanks to the humble mouse, is an untold story". "What's also news is that the mouse isn't so humble anymore," Dr Read said. "Our ability to switch mouse genes on and off, to regulate their function and so on, has allowed scientists to breed mice specifically designed to help solve problems like obesity, find the cause of allergies, find an effective malaria vaccine, or understand why certain babies develop birth abnormalities," Dr Read said..

"The mouse has become a huge part of our medical research infrastructure; huge because there are now approximately 5,000 variants of mice in Australia that scientists can call upon to answer important questions for the health of us all," Dr Read said. "But these mice are expensive to develop and take time and effort to breed and maintain." "Australian scientists were spending time and money reproducing or importing strains already in existence in Australia, but the APB is working to address this issue," Dr Read said. "What we're doing is bringing together infrastructure and expertise to reduce the cost and time to current researchers who use mice as models to study human disease." "But you never know when a new idea emerges which needs a type of mouse that hasn't been used in research for many years," Dr Read said.

"That's where the APB comes in," Dr Read said. "It's also a bank for posterity - for Australian researchers, and human health issues, in generations to come."

Twelve Australian facilities and institutions constitute the APN. These are: the Australian National University, Monash University, the Walter and Eliza Hall Institute, the University of Melbourne, the University of Tasmania, the Centenary Institute of Cancer Medicine and Cell Biology, the Animal Resources Centre, the Institute of Medical and Veterinary Science, Western Australia Institute of Medical Research, the Peter MacCallum Cancer Centre, the Queensland Institute of Medical Research and the University of Queensland. The Network said its core expertise and infrastructure was extended by partnerships with the Garvan Institute, the Wellcome Trust and the University of Manitoba.

PHARMAXIS

Pharmaxis says it has enrolled the first subjects in its 16-patient, randomized, three-way crossover, phase II clinical trial evaluating ASM8 in patients with allergic asthma. Pharmaxis chief executive officer Dr Alan Robertson said ASM8 was "one of the next generation drugs designed to tackle the airway inflammation that underpins asthma". "We have previously shown in a short term study that ASM8 is effective in reducing the signs and symptoms of asthma," Dr Robertson said.

"Now we will assess how effective it is over a longer treatment period," he said.
"The moderate to severe sector of the asthma market, which is the target of ASM8, represents a significant commercial opportunity and is under-served by current therapies," Dr Robertson said.

Pharmaxis acquired ASM8 along with other respiratory technologies from Canada's Topigen Pharmaceuticals earlier this year (BD: Jan 17; Feb 9, 2010).

Pharmaxis said the trial was a crossover design and would evaluate the efficacy and safety of two doses of inhaled ASM8 compared to placebo when administered over 14 days.

The company said the trial was being conducted in four hospitals in Canada and would recruit 16 asthmatic adults.

Pharmaxis said ASM8 was a combination product of two RNA-silencing oligonucleotides targeted at a number of receptors for mediators of inflammation in asthma.

The company said the prevalence of asthma was estimated at 60 million in the US, Europe and Japan of which about three million were classified as having severe, persistent asthma.

Pharmaxis was up one cent or 0.3 percent to \$2.91.

ANTEO DIAGNOSTICS

Anteo has told the ASX that the Exchange had misinterpreted a sentence in a paid-for interview in asking about a share price rise of 37.0 percent to 7.4 cents.

Anteo told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 5.4 cents on November 29, 2010 to 7.4 cents on December 6, 2010 and noted an increase in trading volume.

"In answering this question, please address comments by the [chief executive officer] of the company, Dr Geoffrey Cumming, in a Boardroom Radio Interview on December 1, 2010 that the company is 'perilously close' to having many signatures for its new Mix & Go technology," the ASX asked.

Anteo said that Dr Cumming did not say in the December 1, 2010 interview that the company was "perilously close" to having many signatures for its Mix & Go technology, but that a large number of companies were assessing the technology and "some are now perilously close to making a decision".

The recent trading chart for Anteo also suggests the company has been the subject of day-trader activity, with volumes of more that 23 million shares traded on November 25, compared to the more than 15 million traded on December 6, 2010.

Anteo fell 0.3 cents or 4.3 percent to 6.7 cents with 9.8 million shares traded.

COMPUMEDICS

Compumedics says its Somté PSG portable sleep-testing systems will be used in the NIH funded Multi-Ethnic Study of Atherosclerosis (MESA) sleep study.

Compumedics quoted the senior investigator Harvard Medical School Prof Susan Redline saying that the Somté PSG was chosen to further investigate the link between sleep disorders and cardio-vascular disease in various ethnic and racial populations "because of its ability to record complex sleep studies in the home environment with acceptable participant burden".

Compumedics said the contract was worth about \$US300,000 (\$A302,538).

The company said patients enrolled in the study would be monitored from the Reading Center located at Brigham and Women's Hospital in Boston, Massachusetts.

"The Compumedics Somté PSG systems allow us to record all of the parameters of sleep and breathing that we need to evaluate and quantify abnormal sleep patterns but in the more natural environment of the patients' homes," said Prof Redline.

Compumedics chairman Dr David Burton said the Somté PSG systems had "the ability to capture and analyze heart rhythm data related to the sleep and breathing patterns, which is very important in studying this population".

Compumedics chairman Dr Burton said the NIH MESA sleep study holds special significance to the company.

"It was Prof Redline's team who led the original sleep heart health study, during their important investigation into the cardiovascular consequences of sleep-disordered breathing," Dr Burton said.

"It is once again an honor to be working with Prof Redline and her team," Dr Burton said.

"Somté PSG systems uniquely deliver uncompromised data recording with integrated waveform displays, but at the same time incorporates the user friendliness and trouble-free patient operation essential for reliable home sleep testing," Dr Burton.

"These factors will enable Prof Redline's team to collect high quality and meaningful data from these patients with a minimum of inconvenience," Dr Burton said.

"In addition, this project comes at an opportune time for Compumedics when the company is focusing its growth on its core product lines, including Somté PSG, with the expansion of its global sales force," Dr Burton said.

Compumedics said that over the last 15 years it had been selected to supply sleep recorders for several NIH-funded studies, including a multi-center study involving more than 6,000 subjects.

Compumedics was untraded at 10.5 cents.

ANTISENSE THERAPEUTICS

Antisense says it has raised \$2.4 million through its fully underwritten one –for-two renounceable rights Issue.

Antisense said there were applications for 126,256,962 share with the one-for-five attaching options and Patersons Securities would place the 169,907,174 shortfall shares. The company said the proceeds would help take ATL1103 for growth and sight disorders into clinical development, as well as implement the strategy "to realize value from its other project assets in the form of licencing or partnering agreements".

Antisense was up 0.1 cents 12.5 percent to 0.9 cents.