Biotech Daily

Monday February 21, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ADVANCED SURGICAL UP 20%; LBT DOWN 12%**

*** FDA APPROVES UNIVERSAL BIOSENSORS, J&J BLOOD GLUCOSE TEST**

*** PHYLOGICA DEVELOPS PYCAG5 FOR TRAUMATIC BRAIN INJURY**

*** EMEA APPROVES PRIMA PHASE III CVAC OVARIAN CANCER TRIAL**

*** MORE MOXDUO BETTER THAN LESS, TAKES QRX TO PRE-NDA MEETING**

*** ANTEO OPTIONS EXERCISE RAISES $5.1m; TRANSOCEAN SUBSTANTIAL**

*** ANTISENSE PREPARES ATL1103 GROWTH HORMONE SAFETY TRIAL**

*** BENITEC INVESTIGATORS GROUP REPLACES SCIENTIFIC ADVISORS**

*** ACUVAX EGM TO ROLL DIRECTORS, AGAIN**

*** GENERA REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.74 percent on Monday February 21, 2011 with the S&P ASX 200 down 36.7 points to 4900.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, three traded unchanged and five were untraded.

Advanced Surgical was best, up six cents or 20 percent to 36 cents with 8,280 shares traded, followed by Optiscan up 12.9 percent to seven cents with 198,925 shares traded and Antisense closing up 12.5 percent to 0.9 cents with 127.8 million shares traded.

Universal Biosensors climbed 12 percent; Tissue Therapies was up 7.7 percent; Alchemia rose 6.4 percent; Benitec and Bionomics were up more than five percent; Circadian and QRX rose more than two percent; with Immuron up 1.2 percent.

LBT led the falls, down 0.9 cents or 12.3 percent to 6.4 cents with 10,000 shares traded.

Prana, Viralytics and Virax lost more than five percent; Living Cell fell 4.2 percent; Biota was down 3.5 percent; Cellestis, Clinuvel, Psivida and Sunshine Heart shed more than two percent; with Chemgenex, Genetic Technologies, Impedimed, Mesoblast, Nanosonics and Phylogica down more than one percent.

UNIVERSAL BIOSENSORS

Universal Biosensors says that the US Food and Drug Administration has granted regulatory clearance for the Onetouch Verio blood glucose test.

The Onetouch Verio diagnostic was developed with Johnson & Johnson's Lifescan and has regulatory clearance in Australia, the Netherlands, France and Italy.

Universal Biosensors chairman and interim chief executive officer Andrew Denver said the company was "pleased that the FDA has approved the Verio system".

"It is another step in the commercialization of the UBI developed product," Mr Denver said.

"However it must be noted that Lifescan have not disclosed their plans for a US launch, a decision which is solely within their control," Mr denver said.

Mr Denver told Biotech Daily that Lifescan had indicated last year that they plan to launch in the US pending regulatory approval.

Mr Denver said there were about 30 million diabetes patients in the US, which had about 30 percent to 40 percent of the world's diabetes patients.

Universal Biosensors receives payments both for the manufacture and use of the meter testing strips.

In November last year Universal Biosensors said its second point-of-care technology would be a strip and meter system for blood clotting (BD: Nov 29, 2010).

Universal Biosensors was up 16 cents or 11.9 percent to $1.50.

PHYLOGICA

Phylogica says it has demonstrated preclinical proof-of-concept with a Phylomer-peptide drug candidate for traumatic brain injury.

Phylogica said that in a three-year collaborative study with the Australian Neuromuscular Research Institute and the University of Tasmania funded by the Neurotrauma Research Program of the Western Australia Institute of Medical Research, the group had shown that in a preclinical mouse model that PYCAG5 was able to protect neural tissue at lesion sites and significantly reduce inflammation.

Phylogica chief executive officer Dr Paul Watt said he was "particularly encouraged" by these results, which could eventually pave the way for better outcomes in head injury patients around the world.

"While several Phylomer peptides showed neuro-protective activity in this brain trauma model, this particular peptide, PYCAG5, showed outcomes most consistent with therapeutic potential," Dr Watt said. "This Phylomer significantly protected neural issue in the vicinity of the lesion at four days after the induced head injury and decreased the extent of inflammation, increasing the potential for healing at seven days post-injury."

Dr Watt said the average loss of neurons from the injured region treated with PYCAG5 was less than one third of the average loss observed for control animals, or animals treated with a non-Phylomer peptide.

"Furthermore this particular Phylomer was associated with the largest increase in axonal sprouting relative to neuronal loss at four and seven days post-injury, which could increase the likelihood of brain tissue recovery in the damaged area," Dr Watt said.

Dr Watt said the Phylomer drug was only administered upon injury, but its protective effects appeared to be ongoing.

"With controlled release delivery approaches, even better results could be expected, through maintaining concentrations of Phylomers at the site of injury," Dr Watt said.

Phylogica said it was pursuing partnering opportunities for further development of lead candidate PYCAG5 and other neuro-protective Phylomers.

Phylogica fell 0.1 cents or 1.3 percent to 7.6 cents with 1.8 million shares traded.

PRIMA BIOMED

Prima says the European Medicines Agency (EMEA) has approved a phase III clinical registration trial of CVac for ovarian cancer pending country and hospital approvals.
Prima chief executive officer Martin Rogers told Biotech Daily that similarly to a special protocol assessment with the US Food and Drug Administration the company had approved endpoints for registration purposes from the EMEA.
Prima said the EMEA advised that scientific advice for the phase III trial had been granted and that receiving scientific advice approval was “a significant milestone in the timeline progression for CVac’s global registration”.
The company said it could begin preparations for enrolling the 750 patients in a double-blind, placebo-controlled study at sites in Europe, the US and Australia.
Prima said enrollment was expected to begin in “mid-2011” and be completed by the end of 2012, with interim data expected in late 2012 or early 2013.
Prima recently began a phase IIb trial of CVac in the US (BD: Feb 1, 2011).
Prima said the European phase III trial and the US phase IIb trial would seek to add to the positive efficacy results from its 2007 phase IIa trial on 28 patients in Australia.
The company said that if statistical endpoints were reached in the phase III trial, CVac could become “the world’s first ovarian cancer immunotherapy treatment”.
Prima was unchanged at 23.5 cents with 10.9 million shares traded.

QRX PHARMA

QRX expects to meet with the US Food and Drug Administration for a pre-new drug application meeting for immediate release Moxduo on March 22, 2011.
The company said the meeting followed completion of its third pivotal phase III registration trial (study 009) for immediate-release Moxduo, which demonstrated that a range of doses of up to 24mg morphine with 16mg of oxycodone were more effective following total knee replacement surgery than a fixed dose of 3mg morphine and 2mg oxycodone after an initial 6mg morphine with 4mg oxycodone loading dose of Moxduo.
The company said the 142-patient study was designed to evaluate the analgesic efficacy and safety of Moxduo comparing a flexible dose against a fixed low-dose regimen.
QRX said the data indicated that patients in the flexible dose treatment group achieved statistically superior pain reduction ($p<0.02$) compared to those receiving the lower dose.
The company said the side effects were similar to those observed in earlier studies.
QRX said that at the pre-new drug application meeting the company and the FDA would review the adequacy of its planned submission including efficacy and safety findings and statistical analyses from the study and earlier trials, as well as technical organization and proposed data summarization methods.
QRX chief executive officer Dr John Holaday said the meeting was “a major milestone”.
“We not only achieved the primary analgesic endpoint, but also believe the basic clinical requirements for NDA filing have been satisfied,” Dr Holaday said.
“We can see the goal line.” Dr Holaday said.
The company said that reductions in pain intensity scores following surgery relative to baseline in patients receiving the flexible Moxduo dose regimen (12 mg/8 mg was the most common dose) were significantly greater than those in the low dose group.
QRX said that additional data from the recently initiated phase III trial (Study 022) comparing the tolerability and safety profile of Moxduo to equi-analgesic doses of either morphine or oxycodone given alone should further reinforce its regulatory filings in Europe and the US.
QRX was up three cents or 2.3 percent to $1.36.

ANTEO DIAGNOSTICS

Anteo says it has raised $5.1 million through the exercise of 78,845,313 options at 6.5 cents per option.
Anteo said that with 81,943,291 options available, the company had a 96 percent take-up.
Anteo said that with $7 million in cash it had funds for about three years activity.
Transocean Securities said it had become substantial in Anteo with 66,261,369 shares or 8.86 percent of the company.
Anteo fell half a cent or 6.85 percent to 6.8 cents with 8.6 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says planning is underway to begin its first human safety trial of ATL1103 by October 2011.
Antisense said ATL1103 was designed to block growth hormone receptor expression and was a potential treatment for particular growth and sight disorders and some cancers.
Following the manufacture of the drug compound by technology partner Isis Pharmaceuticals, Antisense said it had begun formulation of the raw material into injectible product for the phase I safety clinical trial.
The company said the drug formulation work should be completed in April 2011 when an application would be made to conduct the clinical trial planned to begin by October 2011.
The company said the first stage of the trial to demonstrate the safety and tolerability of ATL1103 in healthy volunteers was expected to be completed by the end of 2011.
Antisense chief executive officer Mark Diamond said the company was “very excited to be moving toward the first clinical trial of ATL1103 following the successful pre-clinical pharmacology and toxicology stages of its development”.
“ATL1103 has a number of potential disease applications where we believe this second generation antisense drug should have significant competitive advantages over existing treatments,” Mr Diamond said.
Antisense climbed as much as 37.5 percent to 1.1 cents before closing up 0.1 cents or 12.5 percent to 0.9 cents with 127.8 million shares traded.

BENITEC

Benitec says it has created a chief investigators’ group, bringing its scientific founders together with its collaborative partners.
Benitec said the group replaced its scientific advisory board, which “reflects both the collaborative approach to its [research and development] and the clinical focus of its programs”.
The company said the group comprised the discoverer of RNAi technology Dr Michael Graham, Benitec founder Dr Ken Reed, California City of Hope Cancer Centre’s Prof John Rossi, China’s Biomics Biotechnologies’ Dr Yorke Zhu, University of New South Wales Children’s Cancer Institute’s Prof Maria Kavallaris and the group would be chaired by chief executive officer Dr Peter French.
Benitec said the group’s members would not be remunerated.
Dr French said the aim of the group was “to bring together internationally renowned scientists in the field of RNAi to review the progress of Benitec’s R&D programs and to ensure that Benitec’s science remains at the cutting edge of the technology”.
The company said the group was expected to meet twice a year with the first meeting planned for Melbourne in May 2011.
Benitec was up 0.2 cents or 5.7 percent to 3.7 cents with 1.7 million shares traded.

ACUVAX

Acuvax shareholders will vote to replace director Keong Chan with Rocco Tassone.
Last month, Acuvax received a meeting requisition to replace Mr Chan with Mr Tassone.
The company said at that time the notice did not contain a requesting shareholder statement that was "normally required to be circulated to all members of the company with the notice of meeting" (BD: Jan 31, 2011).
The notice lodged with the ASX after the close of business on February 17, 2011 did not contain any statement from the requisitioning shareholders.
Acuvax recently had a significant change in ownership (BD: Nov 16, 19; Dec 3, 13, 2010).
Acuvax chairman Ian Murie and director Lloyd Flint said shareholders should vote against the resolutions.
They said Mr Tassone was nominated by shareholders with more than five percent of the company but his Syracuse Capital became substantial in November and then ceased its substantial shareholding in January.
The directors said the other shareholder requesting the meeting similarly sold down their shareholding at the same time.
In November last year Acuvax received a notice under section 249D of the Corporations Act 2001 requesting a general meeting to remove chairman Patrick Elliott and director Dr Yvonne Foong and elect Lloyd Flint and Keong Chan as directors (BD: Nov 16, 2010).
Mr Elliott and Dr Foong resigned on November 24, 2010 while Mr Flint and Mr Chan were appointed on the same day.
The meeting will be held at Suite 2, 16 Ord Street, West Perth on March 25, 2011 at 10am (AWST).
Acuvax was unchanged at 0.2 cents.

GENERA BIOSYSTEMS

Genera has requested a trading halt pending an announcement "regarding the outcome of … capital raising discussions".
Trading will resume on February 23, 2011 or on an earlier announcement.
Genera last traded at 41 cents.