Biotech Daily

Thursday June 27, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GI DYNAMICS UP 7%, AVITA DOWN 10%**

*** INNOVATION MINISTER GREG COMBET RESIGNS**

*** QRX DATA ERROR DELAYS FDA PDUFA DATE 3 MONTHS**

*** CHIEF SCIENTIST'S SCIENCE STRATEGY**

*** PHYLOGICA PATENTS CELL-PENETRATING TECHNOLOGY**

*** ACRUX SIGNS GEDEON RICHTER FOR NON-US ESTRADIOL**

*** JAPAN PATENT FOR BONE'S AXCESS IV**

*** ISONEA REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market climbed 1.68 percent on Thursday June 27, 2013 with the S&P ASX 200 up 79.6 points to 4,811.3 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and three were untraded.

GI Dynamics was the best, up four cents or 7.1 percent to 60 cents with 20,535 shares traded.

Phylogica climbed 5.6 percent; Cellmid and Phosphagenics were up four percent or more; Psivida was up three percent; Allied Health, Nanosonics, Prima, Reva and Viralytics rose more than two percent; both Cochlear and CSL were up 1.7 percent; with Heartware, Mesoblast, Sirtex and Universal Biosensors up by less than one percent.

Avita led the falls, down 1.5 cents or 10 percent to 13.5 cents with 1.4 million shares traded.

Antisense lost 9.1 percent; both Circadian and Patrys fell eight percent; Benitec was down 7.1 percent; Uscom was down five percent; Bionomics and Optiscan fell more than four percent; QRX and Pharmaxis were down more than three percent; Living Cell, Neuren, Prana and Starpharma shed more than one percent; Acrux and Alchemia were down more than one percent; with Clinuvel and Resmed down by less than one percent.

FEDERAL GOVERNMENT

Following the election of Kevin Rudd as Prime Minister, the Minister for Climate Change Industry and Innovation Greg Combet has resigned from the Ministry.
At the time of publication a replacement had not been announced.

QRX PHARMA

QRX says it will take several weeks to resubmit corrected oxygen saturation data from its phase III study of the dual opioid Moxdua compared to morphine and oxycodone.
In a telephone conference QRX chief executive officer Dr John Holaday said that data for 64 of the 375 subjects at a single trial site had incorrect time codings and that needed to be corrected.
Dr Holaday said that there were 28 million individual data points collected and the company discovered an anomaly with the 64 subjects.
Dr Holaday said that QRX found that the oxygen saturation machines had incorrectly set time zones and allowances for daylight savings.
Dr Holaday said the data was inaccurate by one hour or two hours over the 48 hour period.
Dr Holaday said that adjusting the times made no significant difference to the results and the US Food and Drug Administration had worked closely with the company to resolve the issue.
In a media release, QRX said that while reviewing Study 022 data in preparation for its proposed July 17, 2013 FDA advisory committee meeting it found that for 64 of the 375 patients, the timing of electronically collected oxygen desaturation information at one site did not accurately reflect the local time zone or changes relating to daylight savings time, resulting in a displacement of electronic oxygen desaturation data relative to nurse-reported events for those patients by one or two hours in the 48-hour study.
QRX said that its initial analysis showed that adjustments for timing should have no significant effect on the conclusion that Moxduo demonstrated a respiratory safety advantage over equi-analgesic doses of morphine or oxycodone.
“I don’t know how long the delay will be but the FDA extensions of time are typically three months,” Dr Holaday said.
Dr Holaday said QRX expected to file the adjusted data “in the next several weeks” and said the Prescription Drug User Fee Act date would be delayed from August 26 to November 2013.
QRX fell four cents or 3.6 percent to $1.08.

AUSTRALIA CHIEF SCIENTIST

The office of Australia’s Chief Scientist Prof Ian Chubb says it is developing an overarching strategy for science, technology, engineering and mathematics (Stem).
A media release from the Chief Scientist said a brief outline of the strategy had been release to encourage discussion.
The discussion paper is available at: http://www.chiefscientist.gov.au.
The media release said the focus of the strategy would be on science, technology, engineering and mathematics, but it is about Australia’s enterprise operating with a social licence that was built on a compact with society.
“When fully developed and implemented, this strategy will lead Australia into the future,” Prof Chubb said.

PHYLOGICA

Phylogica says it has developed and patented an enhancement to its Phylomer peptide platform to discover more sophisticated cell-penetrating drugs to help tackle disease.

Phylogica said the Endosomal Escape Trap would enable “more efficient screening of its library of billions of naturally occurring peptides to identify and capture those with greatest potential to target disease proteins inside of cells”.

The company said there was a demand for novel peptides that delivered biologic drugs to cells where most targets reside and the peptides needed to penetrate natural cell membrane barriers, target particular parts of the cell such as nuclei, and ensure that drug cargos were not trapped in endosomes.

Phylogica said that its technology identified effective cell-penetrating peptides that could deliver targeted therapeutic drug cargos to a desired location.

Phylogica chief executive officer Dr Paul Watt said he was not aware of any other peptide discovery company that had overcome the challenge of identifying effective cell-penetrating peptides”.

“We are already applying this technology in collaboration with a pharmaceutical company to discover novel Phylomer-drug conjugates and anticipate new partnerships in this field to further realize the value of this exquisitely sensitive technology,” Dr Watt said.

“The opportunity for developing peptide-drug conjugates targeting abnormal processes that manifest within the cell is substantial, with the potential to treat an enormous variety of diseases more effectively,” Dr Watt said.

“This new technology is game changing and we look forward to the opportunity to present data to the global scientific and pharmaceutical community,” Dr Watt said.

“The vast majority of known disease targets reside inside of cells, yet we can’t reach them with the next generation of molecular therapies, because of the barriers presented by cell membranes,” Dr Watt said.

Phylogica said its chief scientific officer Dr Richard Hopkins had and would present the ‘Endosomal Escape Trap’ technology at the American Peptide Symposium in Honolulu, Hawaii on June 25, 2013 and the Next Generation Protein Therapeutics Summit in San Diego, California on June 27, 2013.

Phylogica said it had filed an international patent application on the new technology with claims covering techniques for the specific capture of the rare class of cell-penetrating peptides that escape from endosomes from its library of over 400 billion peptides, assays for detecting efficient delivery of therapeutic cargoes or toxic payloads to particular locations within the cells, such as cytoplasm or nucleus and specific functional assays for detecting the therapeutically relevant activities of Phylomer peptide drug conjugates.

Phylogica said that there was a significant requirement for technologies that improved the efficiency of the delivery of large therapeutic molecules such as proteins into cells and more specifically into the cytoplasm and nucleus.

Phylogica said that cell membranes were the major impediments to the delivery of therapeutic macromolecules into cells.

The company said that although conventional cell-penetrating peptides could be used to inefficiently deliver cell-impermeable therapeutic cargos into cells via peptide-drug conjugates, these conjugates often remained trapped inside endosomes and failed to reach the disease target within the cell from which they remain isolated.

Phylogica said its Endosomal Escape Trap enabled the efficient identification of Phylomer cell-penetrating peptide drug conjugates both delivered the therapeutic payload across the cell membrane and efficiently escaped from the endosome so that the drug could have a therapeutic effect.

Phylogica was up 0.1 cents or 5.6 percent to 1.9 cents with 1.3 million shares traded.

ACRUX

Acrux says the Budapest, Hungary-based Gedeon Richter Plc will commercialize its Estradiol skin spray therapy for female menopause symptoms in markets outside the US.
Acrux chief financial officer Jon Pilcher told Biotech Daily that the total European market for estrogen therapy, including Western Europe, Eastern Europe and Russia was EUR180 million ($A252 million) and Gedeon Richter expected Estradiol could take about EUR20 million ($A28 million) of that market.
Estradiol has been approved in Sweden and Switzerland and has been marketed in the US as Evamist since 2008 (BD: Aug 12, 2008; May 27, 2011; Jan 30, 2012).
In 2009, the Australian Therapeutic Goods Administration refused registration of Ellavie, despite US approval and sales, requiring a further trial (BD: Nov 12, 2009).
Acrux made the decision at that time that Australian registration was not cost effective.
The US distributor, KV Pharmaceutical, is in Chapter II bankruptcy proceedings and has been selling about 200,000 prescriptions of Evamist a year (BD: Aug 10, 2010).
Today, Acrux said that Richter had licenced manufacturing and marketing rights for all territories excluding the US, South Korea, Southern Africa, Switzerland and Australasia, where Acrux had previously appointed distributors.
Acrux chairman Ross Dobinson told Biotech Daily that the agreement was “a great result for us”.
“Gedeon is paying for everything – manufacturing, regulatory and commercials and any further clinical data the European regulators require,” Mr Dobinson said.
Acrux said that it would receive an up-front payment of $US1 million and then further payments of $US2.6 million subject to European Union regulatory milestones, as well as royalties on sales, with the first royalties expected in 2015.
Gedeon Richter managing director Erik Bogsch said the agreement was “a further step to enhance our existing female healthcare franchise, being a paramount strategic initiative for our company”.
Acrux fell six cents or 1.7 percent to $3.54 with two million shares traded.

BONE MEDICAL

Bone says Japan has allowed its Axcess IV patent application relating to oral peptides for musculoskeletal diseases.
Bone said that peptide and protein-based medicines were generally broken down by enzymes and were poorly absorbed in the gut and needed to be given by injection or non-oral routes of administration, a limitation of their clinical utility.
The company said that the Axcess platform inhibited enzymatic breakdown and enhances intestinal absorption, in its oral parathyroid hormone product Capthymone for osteoporosis and in its oral calcitonin product that it is targeting for the relief of osteoarthritis pain.
Bone was untraded at 0.1 cents.

ISONEA

Isonea has requested a trading halt pending an announcement “in relation to a proposed capital raising”.
Trading will resume on July 1, 2013 or on an earlier announcement.
Isonea last traded at 36 cents.