Biotech Daily

Wednesday February 13, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CLINUVEL UP 10%, ANTISENSE DOWN 7%**

*** FDA ALLOWS MINIMAL TRIAL DATA FOR 'BREAKTHROUGH THERAPIES'**

*** FDA APPROVES MESOBLAST SINGAPORE STEM CELL PLANT**

*** CSL RECORD H1 REVENUE UP 6% TO $2.5b, PROFIT UP 24% TO $608m**

*** BIOTA H1 REVENUE UP 90% TO $11m, LOSS DOWN 79% TO $2.3m**

*** ALLIED EARNS ISO CERTIFICATE FOR CARDIOCEL MANAGEMENT SYSTEM**

*** AVITA PASSES ISO AUDIT**

*** CSL CEO-ELECT PAUL PERREAULT APPOINTED EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market climbed 0.9 percent on Wednesday February 13, 2013 with the S&P ASX 200 up 44.7 points to 5,003.7 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded. All three Big Caps fell.

Clinuvel was the best, up 22 cents or 9.9 percent to $2.44 with 2,900 shares traded.

Phylogica climbed eight percent; Benitec and Reva were up more than seven percent; Circadian was up 5.1 percent; Living Cell and Optiscan were up more than four percent; Alchemia was up 3.1 percent; Bionomics, Neuren and Prana rose more than two percent; Heartware, Tissue Therapies and Universal Biosensors were up more than one percent; with GI Dynamics and Starpharma up by less than one percent.

Antisense led the falls, down 0.1 cents or 7.1 percent to 1.3 cents with 649,000 shares traded.

Patrys lost 5.9 percent; Genetic Technologies and Impedimed fell more than four percent; Avita and Medical Developments were down more than three percent; Acrux, Nanosonics, Phosphagenics and QRX shed more than two percent; Mesoblast, Resmed and Sirtex were down more than one percent; with Cochlear, CSL and Pharmaxis down by less than one percent.

US FOOD AND DRUG ADMINISTRATION

The US Food and Drug Administration has approved a provision for 'Breakthrough Therapies' potentially reducing drug trial data to a single trial.

An FDA fact sheet said that the Food and Drug Administration Safety and Innovation Act "included a provision that allows sponsors to request that their drug be designated as a Breakthrough Therapy".

"FDA is in the process of developing guidance related to this designation," the US regulator said.

While the legislation does not specify what sort of safety and efficacy trials would be sufficient for approval, there have been reports that three drugs have been approved under the protocol.

The fact sheet refers to amendment to the Federal Food, Drug, and Cosmetic Act, which is at: http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf.

The FDA said that until guidance was developed, requests for Breakthrough Therapy designation should follow the criteria outlined below and a request for Breakthrough Therapy designation should be submitted with, or as an amendment to an investigational new drug application with a cover letter, a completed form 1571, and specified documentation including "a brief, but comprehensive, summary of information that justifies why your product qualifies for a Breakthrough Therapy designation for the indication being studied, including: evidence that the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition".

The FDA said data provided should include "preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development".

The FDA said that in total the supporting documentation could be captured in an approximately 10-20 page document.

The FDA said that no later than 60 days after receipt of the submission, a determination would be made to either grant or deny the request for Breakthrough Therapy designation.

A separate FDA document dated January 15, 2103, said the regulator had "identified the first therapy to receive this special designation".

There have been unconfirmed reports that Vertex had two cystic fibrosis drugs approved as 'Breakthrough Therapies' and a third drug may have been given the designation.

Several industry experts were skeptical of reported claims that a single expanded phase I trial would satisfy the FDA in order to allow market approval for any drug.

MESOBLAST

Mesoblast says the US Food and Drug Administration has approved Lonza's contract manufacturing facility in Singapore to supply mesenchymal precursor cells for trials.

Mesoblast said the Singapore facility was in addition to its US facility.

The company said that as its clinical indications continued to broaden, particularly using intravenous delivery of mesenchymal precursor cells for inflammatory and immune disease, the Singapore facility would support strategies for new product delineation.

Mesoblast said that the FDA had agreed that its manufacturing process was acceptable for phase III clinical supplies and the company planned to use product manufactured in the Singapore plant in global phase III trials.

Mesoblast chief executive Prof Silviu Itescu said that multiple geographic sites was integral for product delineation and offset risks of single site dependence.

Mesoblast fell 10 cents or 1.5 percent to $6.75 with 300,618 shares traded.

CSL

CSL's net profit after tax for the six months to December 31, 2012 was up 24.4 percent to a record $US627 million ($A608 million) on revenue up 6.3 percent to $A2,489 million.
CSL chief executive officer Dr Brian McNamee told a telephone conference that there was growth across all products and stronger margins from greater efficiency in blood collection and processing.
In what was expected to be Dr McNamee's last results teleconference before retiring in June, he said that CSL had again posted record revenue and profit figures.
Dr McNamee said that the immunoglobulin business was "clearly a driver" for the business along with increasing albumin sales, particularly in China.
Research and development expenditure increased 12 percent to $184.4 million for the six months to December 31, 2012 and as a percentage of total revenue, research and development expenditure was up from 7.0 percent for the half year to December 31, 2011 to 7.4 percent for the six months to December 31, 2012.
CSL said that diluted earnings per share was up 29.4 percent to $US1.243, reflecting the capital management share buy-back programs.
The company said that the interim unfranked dividend of 50 US cents, compared to the previous corresponding period's 37.57 US cents, would be paid on April 5, 2013 for shareholders at the record date of March 12, 2013.
CSL said it had cash and cash equivalents of $US757 million at December 31, 2012 and net debt of $US371 million.
Dr McNamee said the company intended to raise $US300 million in a US placement to repay existing debt, fund an ongoing share buyback and for general corporate purposes.
"We continue to anticipate fiscal year 2013 net profit after tax to grow by approximately 20 percent at constant currency," Dr McNamee said in a media release. "We anticipate earnings per share growth of approximately 24 percent."
CSL fell three cents or 0.05 percent to $57.21 with 1.4 million shares traded.

BIOTA PHARMACEUTICALS

Biota says revenue for the six months to December 31, 2012 was up 89.9 percent to $US11,850,000, ($A11,467,010) with net loss after tax down 78.6 percent to $US2,413,000.
Including an Australian research and development tax payment of $US4,428,000, Biota posted a net profit after tax for the three months to December 31, 2012 of $US4,829,000.
Biota said that royalty and milestone revenue, primarily from Glaxosmithkline sales of Relenza and Daiichi Sankyo sales of Inavir was up 32.0 percent to $US1,927,000 for the six months to December 31, 2012.
Biota chief financial officer Damian Lismore told Biotech Daily that the company received $US1 million in Relenza royalties and $US900,000 from Inavir royalties, compared to $US700,000 each in the previous corresponding period..
The company said that revenue from services, primarily from the five-year $231 million ($A223.7 million) US Office of Biomedical Advanced Research and Development Authority (BARDA) contract, to develop its laninamivir anti-influenza drug, was up 104.6 percent to $US9,681,000.
Biota said that research and development costs were down 28.3 percent to $US8,647,000 or 73.0 percent of revenue.
The company said its diluted loss per share fell 82.0 percent from 50 US cents to 0.09 US cents, with cash and cash equivalents of $US74,111,000 at December 31, 2012.
Last night on the Nasdaq, Biota closed up 10 cents or 2.6 percent at $US4.00.

ALLIED HEALTHCARE GROUP

Allied Health says it has received its ISO 13485 certification as part of the Cardiocel Conformité Européenne (CE) mark approval process, expected to “by mid-2013”.
Allied managing director Lee Rodne said that ISO 13485 approval was “a critical step along the path to obtaining a CE Mark, which opens up the European Union market as well as many other markets around the world to grow significant revenue from our lead regenerative tissue product starting in 2013”.
Mr Rodne said the approval would assist Allied in obtaining its Health Canada Medical Device Licence for the bovine cardiac patch.
The company said that ISO 13485 certification meant the company had implemented a quality management system conforming to the International Organization for Standardisation standards for medical devices.
Allied said it had also undergone a quality management system audit by the Australian Therapeutic Goods Administration for Cardiocel.
The company said that as well as Cardiocel and the initial cardiovascular suite of products, it was also evaluating other applications for its Adapt tissue engineering platform technology, such as its use in pelvic floor reconstructions, hernia repairs, orthopaedics and as a biological scaffold to grow and deliver stem cells.
Allied was unchanged at 2.6 cents with 5.4 million shares traded.

AVITA MEDICAL

Avita says it has successfully completed the annual ISO quality recertification audit conducted January 8 and 9, 2013.
Avita said that the quality audit, conducted by an independent, external auditor of the European Notified Body, covered all applicable elements of ISO 9001:2008 quality management system certification, ISO 13485:2003 medical devices certification, Medical Devices Directive 93/42/EEC and Canadian Medical Devices Regulations for Avita’s class III medical devices.
The company said that no major or minor non-conformances were identified in the audit.
Avita said that the ISO audit under the auspices of the International Organization for Standardisation was a rigorous recertification audit and was required to maintain Conformité Européenne (CE) mark registration.
Avita said the audit addressed quality, manufacturing and management systems as well as a comprehensive review and verification of controls on its portfolio including Recell spray-on skin and the respiratory products Funhaler and Breath-A-Tech.
Avita fell half a cent or 3.45 percent to 14 cents.

CSL

CSL has appointed chief executive officer-elect Paul Perreault an executive director.
CSL said that Mr Perreault was the president of CSL Behring and on July 1, 2013 would succeed Dr Brian McNamee as CSL chief executive officer and managing director.