Biotech Daily

Monday April 18, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP; BIOTECH EVEN: PATRYS UP 12%; CELLMID DOWN 9%**

*** CELLESTIS BOARD RESPONDS TO SHAREHOLDERS**

*** HEARTWARE 250-PATIENT DATA: 94% REACH 180-DAY SURVIVAL**

*** MESOBLAST JOINS AUSTRALIA'S TOP 200**

*** MEDICAL DEVELOPMENTS SAYS PENTHRANE SAFE AS ANALGESIC**

*** STIRLING NOVA SCOTIA PLANT OPERATIONAL**

*** CYCLOPHARM AGM VOTES ON M-D LOAN, DIVIDEND CHANGES**

*** FOUNDER CHAIRMAN SALIBA SASSINE QUITS HELICON**

*** MEDIGARD DIRECTOR DR PETER CLARK GOES NON-EXECUTIVE**

MARKET REPORT

The Australian stock market climbed 0.2 percent on Monday April 18, 2011 with the S&P ASX 200 up 9.8 points to 4861.9 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and two were untraded. All three Big Caps were up.

Patrys was best, up 1.5 cents or 11.5 percent to 14.5 cents with 1.6 million shares traded, followed by Living Cell up 8.7 percent to 12.5 cents with 1.2 million shares traded.

Mesoblast and Starpharma climbed more than five percent; Sunshine Heart and Viralytics were up four percent or more; Psivida was up 3.6 percent; Circadian and Impedimed rose more than two percent; with Cochlear, CSL, Heartware, LBT, Phylogica and Resmed up more than one percent.

Cellmid led the falls, down 0.3 cents or 9.1 percent to three cents with 7.6 million shares traded.

Bionomics and Cathrx lost more than seven percent; Benitec fell 6.7 percent; Prana was down 4.35 percent; Clinuvel and Prima were down more that three percent; Tissue Therapies shed 2.6 percent; with Alchemia, Pharmaxis, QRX and Sirtex down more than one percent.

CELLESTIS

The Cellestis board has responded to criticism from shareholders who say they have the numbers to prevent the Qiagen takeover (BD: Apr 14, 2011).

The shareholders group said they had more than 30 percent of Cellestis shares on offer and the scheme of arrangement would require 75 percent of shares to be approved.

Today, in a 'Chairman's letter to shareholders', chairman Ron Pitcher said the terms of the scheme were heavily negotiated with Qiagen and the board "only resolved to recommend the scheme and provide shareholders with the opportunity to vote on the scheme after conducting appropriate analysis of the fairness of the Qiagen offer price, including an assessment of relevant valuation methodologies completed by Cellestis with the assistance of the company's financial advisors".

Cellestis noted that the consideration of $3.55 per share, implied a market capitalization of $341.3 million which was a premium of 24.3 percent to the one-month five-day volume weighted average price and 31.5 percent to the three-month five-day volume weighted average price to April 1, 2011.

In the chairman's letter, Mr Pitcher said the board "actively canvassed potential alternative bidders for Cellestis" which did not result in Cellestis receiving a superior offer.

He said the board's recommendation and intention to vote the shares that they control in favor of the Scheme were "subject to both the absence of a superior proposal and the independent expert confirming that the scheme is fair and reasonable and in the best interests of Cellestis shareholders".

"In the event that either a superior proposal is received by Cellestis or the independent expert opines that the scheme is anything other than fair and reasonable and in the best interests of Cellestis shareholders, the Cellestis directors are able to change their recommendation of the scheme," Mr Pitcher said.

He said the scheme implementation deed was negotiated "to provide the Cellestis board with reasonable flexibility to respond to any unsolicited superior proposal that may be received".

Mr Pitcher said that substantial shareholders chief executive officer Dr Anthony Radford and chief scientific officer Dr James Rothel had published their option arrangements with Qiagen to the ASX.

He said the agreements permitted Qiagen to exercise the options to acquire up to 19.9 percent of Cellestis shares if Dr Radford and Dr Rothel deal in their Cellestis shares in breach of the option arrangements, but Qiagen's right to acquire up to 19.9 percent was subject to approval for the acquisition from the Foreign Investment Review Board.

Until this approval is obtained, Qiagen can only acquire up to 14.9 percent of Cellestis shares by exercising the options, Mr Pitcher said.

He said the legal agreements specify that the only other circumstances in which Qiagen could exercise the options were where a competing transaction had been announced and Qiagen elected to match or better the terms of that competing transaction or Qiagen had elected not to match or better the competing transaction and formed the view that the competing transaction was likely to be successful if the Cellestis shares that are the subject of the option arrangements participate in the competing transaction.

Mr Pitcher said if Dr Radford and Dr Rothel had "not entered into a binding arrangement with Qiagen to vote in favor of the scheme".

He said that the "provisions in the option arrangements were negotiated in this manner to mitigate the risk that the option arrangements could dissuade any interested third party from proposing a competing transaction".

Cellestis was unchanged at $3.46.

HEARTWARE INTERNATIONAL

Heartware says updated data from its Advance pivotal bridge to heart transplantation study, shows 94 percent survival at 180-days for 250 patients.

Heartware said that data presented at the International Society of Heart and Lung Transplantation meeting in San Diego, California using a Kaplan-Meier analysis for the combined 140 patients in Advance clinical trial and an additional 110 patients from continued access protocol investigational device patients was 94 percent.

The co-principal investigator and chief of the Division of Thoracic and Cardiovascular Surgery at the University of Louisville Prof Mark Slaughter said that data generated from the continued access protocol patient population "confirmed that implantation of the investigational device was associated with a consistently high probability of survival at 180 days, just as we have observed in the Advance study".

"The adverse event profile from the [continued access protocol] data was consistent with the very positive rates demonstrated in the Advance trial, with particularly low observed rates of bleeding and infection," Prof Slaughter said.

Heartware chief executive officer Doug Godshall said the continued access protocol data had "added to our understanding of implantation techniques and post-operative care that appear to impact patient outcomes".

The company previously published results from the Advance study showing that it achieved its primary endpoint of non-inferiority between the investigational device and comparator arm of the study ($p<0.0001$), which was derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support (BD: Nov 15, 2010).

Heartware said it completed its submission to the US Food and Drug Administration of a pre-market approval application for the Heartware System for the bridge-to-transplant indication on December 28, 2011.

Heartware was up four cents or 1.85 percent to $2.20.

MESOBLAST

Standard & Poor's say that Mesoblast will be promoted to the S&P ASX200 replacing Tower Australia Group from the close of business on April 27, 2011.

In an announcement to the ASX Standard & Poor's said Tower was expected to be acquired by Dai-ichi Life Insurance, subject to shareholder and final court approval of the proposed scheme of arrangement.

At March 31, 2011, Mesoblast had the largest market capitalization of all biotechnology companies (excluding Cochlear CSL and Resmed) at $2,023 million.

Heartware was the next biggest at $1,179 million, including the majority of its shares traded on the Nasdaq.

Mesoblast chief executive Prof Silviu Itescu said inclusion in the S&P/ASX 200 was "a major achievement for Mesoblast".

"This important milestone serves to further underscore the company's strong financial performance and global leadership in the field of regenerative medicine," Prof Itescu said.

Mesoblast was up 40 cents or 5.2 percent to $8.05 with 2.6 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its methoxyflurane marketed as Penthrane is safe for analgesia despite a case of hepatitis from its use as an anaesthetic.

Medical Developments managing director John Sharman told Biotech Daily that the case reported in the Medical Journal of Australia was reported to the Australian Therapeutic Goods Administration in 2010 and there were "no ongoing issues" from the case.

The article is at: http://www.mja.com.au/public/issues/194_08_180411/oro10992_fm.html.

The article entitled 'A case of hepatitis attributable to repeated exposure to methoxyflurane during its use for procedural analgesia' under the heading 'Lessons from Practice' said that a 33-year-old woman was admitted for investigation and management of acute hepatitis having reported symptoms of nausea, fatigue, pruritus and right upper abdominal discomfort.

The patient had undergone three varicose vein sclerosing procedures over three weeks and in each procedure, was given methoxyflurane as an inhaled analgesic.

The article said there were no other risk factors and clinical examination revealed jaundice and mild tender hepatomegaly only.

The article said the pathological diagnosis was of an idiosyncratic drug reaction, with the implicated drug being methoxyflurane. The patient's condition continued to improve, with resolution of symptoms over four weeks and associated normalization of liver enzyme and bilirubin levels.

She has remained well and has been advised to avoid future exposure to methoxyflurane.

The article concluded that in the pre-hospital setting, where methoxyflurane is being widely used, the side effect profile is minimal.

"It seems the exposure to methoxyflurane in our patient was the likely cause of acute hepatitis and it may be that repeated exposure was a contributing factor," the article said.

"This observation has implications for the way methoxyflurane is prescribed, including its use for procedural analgesia in cases in which several procedures (and hence, repeated dosing) are required," the article said.

Mr Sharman said a recent Western Australian study of more than 13,000 uses of Penthrane for analgesia said the drug was safe.

"There's a pile of literature on its use as an analgesic, but it shouldn't be used as an anaesthetic," Mr Sharman said.

Penthrane, in the form of 3mL methoxyflurane, inhaled through Medical Developments' Penthrox inhaler is widely used for pain relief in ambulance services.

Victoria's Metropolitan Ambulance Service clinical guidelines say it is contraindicated for people with severe renal disease or with tetracycline use and no more than 6ml should be given in any 24 hour period.

A spokesman for the Metropolitan Ambulance Service said the matter reported in the Medical Journal of Australia appeared to be an isolated case and the Service would not be changing its use of the pain relief drug.

The guidelines say that exceeding 6mL in 24 hours could lead to renal impairment.

Medical Developments fell four cents or 8.2 percent to 45 cents.

STIRLING PRODUCTS

Stirling says its first contract manufacturing operations have begun at its Cape Breton, Nova Scotia pharmaceutical plant.

Stirling said the plant's operation was delay one year while it was required to re-validate all plant and equipment as well as processes and procedures.

Stirling was unchanged at 0.4 cents with 6.1 million shares traded.

CYCLOPHARM

Cyclopharm's annual general meeting will vote to lend managing director James McBrayer $504,638 to buy 5,046,378 shares in the company.
Cyclopharm said shareholders would vote to approve the buy-back of up to 25 percent of the company's issued shares.
The company said shareholders would vote on a series on constitutional changes relating to the payment of dividends.
Cyclopharm investors will also vote on the reelection of director David Heaney.
The meeting will be held at the level 1 Seminar room, Australian School of Advanced Medicine, 2 Technology Park Drive, Macquarie University Hospital North Ryde, New South Wales on May 26, 2011 at 11.30am (AEST).
Cyclopharm fell 0.1 cents or 2.2 percent to 4.5 cents.

HELICON GROUP

Founding chairman and former major shareholder Saliba Sassine has resigned as a director of Helicon.
Last week Helicon said Rod Tomlinson had replaced Mr Sassine as non-executive chairman and that Mr Sassine would continue "as a consultant to Helicon and be integral in assisting us in our commercial decisions" (BD: Apr 12, 2011).
The announcement did not say that Mr Sassine had resigned from the board.
Today, Helicon filed an Appendix 3Z final director's interest notice saying that Mr Sassine directly held 4,400,000 shares in the company and had an indirect interest in 26,901,000 shares.
Helicon fell 0.1 cents or three percent to 3.2 cents.

MEDIGARD

Medigard said director Dr Peter Clark has resigned from his executive role, effective from April 29, 2011, but will remain as a director.
Medigard said Dr Clark had accepted a role as manager of research development at a higher education institution.
Medigard was untraded at four cents.