Biotech Daily

Thursday May 26, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 11%, ADMEDUS DOWN 4%**

*** FDA APPROVES CSL AFSTYLA FOR HAEMOPHILIA A**

*** GI DYNAMICS SCOTT SCHORER: ENDOBARRIER RESTART OR NEW TRIAL**

*** CLOVER, PREMNEO DHA FAILS PHASE III BPD TRIAL; BRIAN MCNAMEE**

*** TBG WINS $60k CHINA GRANT FOR HLA TYPING KIT**

*** UP TO 18% OF REVA OPPOSE 50% DIRECTORS POOL HIKE**

*** M&G QUITS GI DYNAMICS, TAKES $45m LOSS**

*** PAUL HOPPER, ASSOCIATES INCREASE, DILUTED TO 8% OF PRESCIENT**

*** AIRXPANDERS TO RELEASE 99m ESCROW CDIs**

MARKET REPORT

The Australian stock market climbed 0.29 percent on Thursday May 26, 2016 with the ASX200 up 15.6 points to 5,388.1 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and three were untraded.

Avita was the best, up 1.1 cents or 11.1 percent to 11 cents with 1.9 million shares traded.

Cellmid climbed 9.1 percent; Anteo, Ellex and Prima were up more than four percent; Actinogen, Bionomics, Pharmaxis and Polynovo were up three percent or more; Compumedics, Factor, Sirtex and Viralytics rose more than two percent; Biotron, CSL, Impedimed, Orthocell and Pro Medicus were up more than one percent; with Airxpanders up 0.6 percent.

Admedus led the falls, down 1.5 cents or 4.2 percent to 34 cents, with 292,977 shares traded.

Antisense Neuren and Osprey shed two percent or more; Mesoblast, Prana and Starpharma were down more than one percent; with Clinuvel, Medical Developments, Resmed and Reva down by less than one percent.

CSL

CSL says the US Food and Drug Administration has approved subsidiary CSL Behring's Afstyla long-lasting recombinant factor VIII single-chain therapy for haemophilia A.
CSL said that Afstyla was its anti-haemophilic, recombinant factor VIII single-chain therapy for adults and children, indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, on-demand treatment and control of bleeding episodes and the peri-operative management of bleeding, with twice weekly dosing.
CSL said that Afstyla was expected to be available by September 2016.
CSL chief scientific officer Dr Andrew Cuthbertson said the approval showed CSL's "dedication to developing and delivering novel therapies that have the potential to improve patients' lives".
The company said that haemophilia A was a congenital bleeding disorder affecting about one in 6,000 male births and was characterized by deficient or defective factor VIII.
CSL said that Afstyla was designed for greater molecular stability and longer duration of action, using a covalent bond that formed one structural entity, a single polypeptide-chain, to improve the stability of factor VIII and provide longer-lasting factor VIII activity.
CSL said that it had filed regulatory applications in Europe, Switzerland and Australia.
CSL climbed $1.27 or 1.1 percent to $115.82 with 855,781 shares traded.

GI DYNAMICS

GI Dynamics chief executive officer Scott Schorer says the company did not need to end its US Endobarrier trial and it could either restart the trial or begin a new one.
Last year, the company terminated its 500 patient pivotal trial of the Endobarrier duodenum insert for obesity and type II diabetes following what it said was an unexpected high rate of hepatic abscesses or liver infections (BD: Jul 30, 31, 2015).
GI Dynamics had previously halted European exports of the Endobarrier over regulator issues, "separated" chief financial officer Bob Crane and sacked chief medical officer Dr David Maggs (BD: Oct 6, 7, Dec 1, 9, 2014; Jun 19, 2015).
This year, the company replaced chief executive officer Michael Dale, who was appointed in 2014 to replace Stuart Randle and the company later replaced chairman Jack Meyer (BD: Aug 19, 2014; Feb 24, May 3, 2016).
Today, Mr Schorer told Biotech Daily that the previous management had not responded in a timely fashion to communications from the US Food and Drug Administration and he had specifically appointed Brian Callahan, who had "an excellent working relationship" with FDA officials, to renew the relationship with the regulator.
Mr Schorer said that the total rate of non US hepatic abscesses was less than one percent with 32 cases recorded in 3,400 procedures, and he would need to fully understand all the data to be definitive, but he believed that the Endobarrier barb attachment might not be the cause of the increased abscesses and the trial termination.
"I don't think the barbs are a problem that needs to be solved," Mr Schorer said.
"The high volume sites don't understand what the fuss is all about," Mr Schorer said. "We didn't need to end the trial."
Mr Schorer said that there had been an inadequate response to the liver infections and the next trial would focus on early detection.
He said that there was evidence form a 9,040 patient study of a relationship between proton pump inhibitors and hepatic abscesses unrelated to the Endobarrier and the increased use of proton pump inhibitors in the trial protocol could have been a mistake.
Mr Schorer said that a trial restart or new trial would depend on FDA discussions.
GI Dynamics was unchanged at two cents with 4.9 million shares traded.

CLOVER CORP, PREMNEO PHARMACEUTICALS

Clover Corp says its 1,273 paediatric patient phase III trial of DHA emulsion for broncho-pulmonary dysplasia has failed to meet its primary endpoint.

Clover chief executive officer Peter Davey told Biotech Daily that although the trial failed to meet its primary endpoint of a 10 percent reduction in the incidence of broncho-pulmonary dysplasia (BPD) there would be a great deal of data to interpret and there were no treatments approved for BPD.

Last year, Clover Corp said that it had a licence agreement with Premneo Pharmaceuticals, whose executive chairman was former CSL chief executive officer Dr Brian McNamee, to accelerate development its docosahexaenoic acid (DHA) emulsion for premature babies (BD: Oct 12, 2015).

Dr McNamee told Biotech Daily at that time that Premneo Pharmaceuticals Pty Ltd and Premneo Pty Ltd were “family owned companies” with his daughter Natalie McNamee also a director of the company.

Clover said last year that Premneo would “gain an exclusive worldwide licence to develop and commercialise the emulsion product for use in premature babies” and Clover would earn milestone payments as product development advances and royalties on future sales.

Today, Clover said that the Premneo licence “was taken in anticipation of a positive outcome from the clinical research study, in order to accelerate the market launch of the DHA emulsion product”.

“On the basis of the top line result Premneo Pharmaceuticals Pty Ltd has decided to terminate the licence agreement with Clover Corporation,” the company said.

According to the Australian New Zealand Clinical Trials Registry the trial, entitled ‘Docosahexaenoic acid for the reduction of bronchopulomonary dysplasia in preterm infants born at less than 29 weeks gestational age: a randomised controlled trial’ would compare tuna oil emulsion containing 120mg/mL of DHA to provide 60mg/kg/day of DHA (0.17ml/kg three times a day) against the placebo of soy oil emulsion with no additional DHA given at 0.17mL/kg three times a day.

The Registry said that primary sponsor was the Adelaide, South Australia-based Women's and Children's Health Research Institute with Dr Carmel Collins the principal investigator.

Today, Clover said that South Australian Health and Medical Research Institute (SAHMRI) reported that the study had “not met its primary endpoint of a statistically significant 10 percent reduction in the incidence of broncho-pulmonary dysplasia (BPD) a lung condition common in premature babies, when the high DHA treatment was compared with a placebo emulsion”.

The company said that a previous phase II trial showed improved cognitive development in girls at 18 months, reduced oxygen requirement at 36 weeks in boys and reduced incidence of hay fever later in their development.

Clover Corp said it invested $1.235 million in the DHA program.

Mr Davey said the company was “clearly disappointed in this early report of the top-line results from the … study , however, we remain committed to better understanding the full data set as we consider potential paths forward for the DHA emulsion product”.

“With strong clinical results from the previous … study and high tolerability of the DHA formulation we will continue to seek a viable path forward for the development of DHA emulsions in this and wider clinical applications,” Mr Davey said.

Clover Corp said that its core business was the manufacture and sale of encapsulated omega 3 and 6 oils supplied as ingredients into food, pharmaceutical and infant formula products, with increased demand in China and changing regulations in Europe and China providing opportunities for additional growth in the future.

Clover Corp fell 16 cents or 28.6 percent to 40 cents with 3.7 million shares traded.

TBG DIAGNOSTICS (FORMERLY PROGEN PHARMACEUTICALS)

TBG says that China's Xiamen Municipal Bureau of Science and Technology will provide CNY300,000 ($A64,000) for development of its HLA Typing Kit.

TBG said the first payment of RMB180,000 was paid after review and approval of the proposal and the second and final payment of CNY120,000 would be paid by October 2017, after development of the human leukocyte antigen (HLA) Typing Kit, completion of production lines and production trials, successful third party inspection, and application for patent approval.

In March TBG said the kits were designed to match the gene on the surface of white blood cells for transplantations (BD: Mar 23, 2016).

The company said that the Xiamen Municipal Bureau of Science and Technology was the administrative department in Xiamen responsible for coordinating the development of science and technology in the municipality.

TBG said the grant "ensures that TBG Diagnostics strengthens its portal into the Chinese market for its products and services and validates the strategy of the company as it pursues distribution of its innovation and products into greater Asian markets".

TBG fell two cents or 8.3 percent to 22 cents.

REVA MEDICAL

Reva shareholders voted modest dissent at the annual general meeting against a 50 percent increase in the directors remuneration pool to $US450,000 ($A625,157).

Reva said that all other resolutions passed easily, with 2.76 percent of votes opposing the grant of shares and options worth about $1.3 million to directors (BD: April 20, 2016).

The company said that directors pool resolution was supported by 20,724,199 votes (81.7%), with one vote equivalent to one US share or 10 Chess depository instruments (CDIs) and opposed by 4,653,588 votes (18.3%).

The company's most recent Appendix 3B new issue announcement said that Reva had 425,364,860 CDIs on issue, equivalent to 42,536,486 US shares, meaning that the votes against the increase to the directors remuneration pool amounted to 10.9 percent of the company, sufficient to requisition extraordinary general meetings.

Reva fell one cent or 0.9 percent to $1.145.

GI DYNAMICS

M&G Investment Funds says it has sold its 46,030,187 GI Dynamics Chess depository instruments(CDIs) for $781,572 or an average price of 1.7 cents a share.

The London-based M&G group participated in the GI Dynamics initial public offer at $1.10 a share acquiring 13,250,000 shares and then buying a further 14,500,000 shares for $12,640,230 along with participation in a later capital raising at 53 cents per CDI (BD: Aug 30, 2011; Mar 27, 2012; May 2, 12, 2014).

Biotech Daily calculates that M&G invested a total of about $46,055,139 for its total of 63,190,038 CDIs.

M&G began reducing its GI Dynamics holding in April, selling all the shares for a total of $1,112,174, a loss of about $44,942,964 (BD: Apr 7, 19; May 11, 2016).

PRESCIENT THERAPEUTICS

Executive director Paul Hopper and associates have increased their holdings but have been diluted in Prescient from 8,976,472 shares (9.58%) to 9,026,472 shares (7.97%).
Mr Hopper said the group acquired 50,000 shares for $4,650 or 9.3 cents a share on-market but was diluted following a share issue.
Prescient fell one cent or 10 percent to nine cents.

AIRXPANDERS

Airxpanders says it will release US shares and Chess depository instruments (CDIs) equivalent to 99,051,633 CDIs on June 18, 2016.
Airxpanders said that voluntary and ASX-imposed escrow agreements related to last years initial public offer (BD: May, 25, Jun 10, 23, 2015).
The company said that it would release from escrow 32,324,172 shares in class A common stock, equivalent to 96,972,516 CDIs, 2,079,117 CDIs equivalent to 693,039 US shares, 343,324 options to subscribe for shares equivalent to 1,029,971 CDIs and 111,117 warrants to subscribe for shares equivalent to 333,351 CDIs.
Airxpanders was up half a cent or 0.6 percent to 84.5 cents.