Biotech Daily

Thursday November 21, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHYLOGICA UP 11%, ALLIED HEALTH DOWN 9%**

*** CSL HEART THERAPY CSL112 'REVERSES CHOLESTEROL TRANSPORT'**

*** ANTISENSE $550k 1-FOR-3 'LOYALTY' OPTIONS, CONSOLIDATION**

*** THAI GREEN LIGHT OF BIOTRON BIT225 HEPATITIS C TRIAL**

*** UNILIFE, HIKMA DEAL $40m UPFRONT, MILESTONES**

*** EDITORIAL: REPORTING UBS AG IN BIOTECHNOLOGY COMPANIES**

*** UBS AG CEASES SUBSTANTIAL IN COCHLEAR, NEUREN**

*** ALLIED HEALTH BECOMES ADMEDUS, 8% OPPOSE DIRECTORS' STOCK**

MARKET REPORT

The Australian stock market fell 0.37 percent on Thursday November 21, 2013 with the S&P ASX 200 down 19.4 points to 5,288.3 points.

Ten of the Biotech Daily Top 40 stocks were up, 20 fell, eight traded unchanged and two were untraded.

Phylogica was the best, up 0.2 cents or 11.1 percent to two cents with 30,000 shares traded.

Neuren climbed 8.3 percent; Phosphagenics was up 4.55 percent; Cellmid rose 2.4 percent; Clinuvel, Prana, Starpharma and Universal Biosensors were up more than one percent; with CSL, Osprey, Psivida and Resmed up by less than one percent.

Allied led the falls, down 1.5 cents or 9.1 percent to 15 cents with 20.6 million shares traded.

Compumedics lost 7.5 percent; Patrys fell 6.7 percent; Impedimed, Medical Developments and Prima were down five percent or more; Avita fell 4.8 percent; Antisense, Bionomics, Living Cell and Reva were down more than three percent; Acrux, Atcor, Benitec, IDT and Tissue Therapies shed two percent or more; with Cochlear, Genetic Technologies, Mesoblast, QRX and Sirtex down one percent or more.

CSL

CSL says its phase IIa trial of CSL112 in patients with stable cardiovascular disease has shown a dramatic and rapid increase in key indicators of reverse cholesterol transport.
CSL said reverse cholesterol transport was a process by which cholesterol was removed from arteries and transported to the liver for clearance.
The company said that rapid removal of cholesterol following a cardiac arrest might be a new mechanism for stabilizing vulnerable plaque lesions and lowering the high risk of subsequent events.
CSL said that CSL112 was a novel formulation of apolipoprotein A-I, the active component of high-density lipoprotein or 'good cholesterol' purified from human plasma and reconstituted to form particles suitable for intravenous infusion.
CSL said the randomized, multi-center, double-blind, placebo-controlled trial evaluated the effects of a single-dose administration of CSL112 in 44 patients over a 90 day period and in addition to positive results for key biological indicators, the data also showed favorable safety and tolerability and the company would proceed to a phase IIb study.
CSL chief scientist Dr Andrew Cuthbertson said that patients who had an acute coronary event had a high risk of suffering another heart attack, stroke or other cardiovascular event, particularly within the first 30 days.
"The results of this clinical study of CSL112 support our continued enthusiasm for its development as a novel approach to address this important treatment void," Dr Cuthbertson said.
CSL said the global phase IIb trial would assess multiple dose administration of CSL112 compared with placebo in about 1,200 cardiac arrest patients.
CSL said that South Australian Health and Medical Research Institute cardiologist Prof Philip Aylward would lead the Australian arm of the study.
"CSL112 is a promising treatment targeting the unstable coronary plaques causing these events and deserves further investigation," Professor Aylward said.
CSL said that CSL112 was developed by CSL scientists and benefitted from collaborations with a number of medical research institutions including Melbourne's Baker IDI Heart and Diabetes Institute.
Baker head of metabolic and vascular physiology Prof Bronwyn Kingwell said that there was "good reason to believe that this therapeutic approach will support both cholesterol removal from plaques and their stabilization".
"Such actions would likely reduce the risk of plaque rupture and heart attack," Prof Kingwell said.
CSL said that there were no available therapies to reduce the incidence of early recurrent events by directly acting on coronary plaque before it ruptures.
CSL was up 12 cents or 0.2 percent to $67.67 with 947,751 shares traded.

ANTISENSE THERAPEUTICS

Antisense has completed its 10-for-one consolidation and filed its prospectus for a one-for-three 'loyalty' options issue to raise $570,000 (BD: Sep 27, 2013).
Today, Antisense said the one-for-three, non-renounceable, entitlement offer was for one new option costing 1.2 cents each, for every three existing shares held on November 28, 2013, and exercisable at a post consolidation 27 cents by January 31, 2017.
The company said the offer would open on December 3 and close on December 17, 2013 and it expected to raise up to $549,700 to progress its pipeline and for working capital.
Antisense fell 0.5 cents or 3.0 percent to 16 cents.

BIOTRON

Biotron says Bangkok's Siriraj Hospital has given ethics approval for a 60-patient, three-month, dosing study of BIT225 in patients with hepatitis C.

Biotron said that the trial would be conducted at up to six trial sites in Thailand with the first patients expected to begin dosing by the end of November.

The company said that the trial was expected to be fully recruited by mid-2014, with preliminary data available by November 2014.

Biotron managing director Dr Michelle Miller said the study was designed to generate safety and efficacy data for BIT225 when administered in a capsule formulation over three months in patients with hepatitis C virus genotypes 1 or 3.

The company said the capsules were expected to have an improved safety profile and ease of use compared to the previous powder formulation.

Biotron said that subjects would receive 200mg of BIT225 twice daily for three months in combination with current standard of care therapies, pegylated interferon alfa 2b and ribavarin, before continuing to receive standard of care to 24 weeks for genotype 3 patients or 48 weeks for genotype 1 patients.

The company said the previous phase IIa BIT225 study in hepatitis C patients was a four week dosing regimen and demonstrated that all subjects who received 400mg BIT225 for four weeks had undetectable levels of virus in the blood at the 48 week follow up, compared to 75 percent of patients who received standard of care alone.

Dr Miller said that "indications to date demonstrate that BIT225 has potential to be an adjunctive agent in the future treatment of [hepatitis C] alongside other new classes of direct-acting antiviral drugs".

Biotron was unchanged at eight cents.

UNILIFE CORP

Unilife says it will supply the London-based Hikma Pharmaceuticals Plc its prefilled syringes with a range of generic injectable drugs.

Unilife said that under the 15-year agreement, in addition to product sales Hikma, would pay Unilife $US40 million ($A43.0 million) in upfront and milestone payments with an initial upfront payment of $US5 million immediately and an additional $US15 million in payments expected during 2014 with the final $US20 million milestone payments in 2015.

Hikma's website said the company was founded in the Amman, Jordan in 1978 and listed on the London Stock Exchange in 2005.

Hikma said it developed, manufactured and marketed generic and in-licenced pharmaceutical products, primarily in oncology, diabetes, cardiovascular and central nervous system.

Unilife said Hikma had selected an initial list of 20 of its generic injectable products to be used with Unifill products and additional injectable drugs might be added.

Unilife said it would begin product sales to Hikma in early 2014, supplying a minimum volume of 175 million units a year.

The company said that its Unifill Nexus product addressed problems that conventional prefilled devices had of preventing universal attachment with any standard needle hub or intra-venous connector and associated patient safety risks, including spontaneous disconnection and the leakage or occlusion of medication.

Hikma chief executive officer Said Darwazah said the agreement "supports our strategy of developing higher value products and we are extremely pleased to be partnering with Unilife to develop our generic injectables capabilities".

Unilife climbed 20.5 cents or 40.2 percent to 71.5 cents with 9.2 million shares traded.

EDITORIAL: UBS AG

UBS AG and related companies have filed numerous holding notices on several biotechnology companies, frequently becoming and ceasing their substantial holdings.
Today, the group, which files its notices from Singapore, ceased its substantial holding in both Cochlear and Neuren.
UBS AG has previously filed substantial shareholder notices in Acrux, Atcor, CBio (now Invion), Pharmaxis and in 2010, Acuvax and Cathrx.
The UBS notices do not disclose who buys and sells the shares but has cited UBS AG, Australia Branch, UBS AG London Branch, Australian Leaders and others as the beneficial owners of shares.
UBS AG has said the shares were acquired in its role as a 'prime broker' and held as a "borrowing right in respect of shares pursuant to a prime broking agreement".
Biotech Daily understands these holdings are being borrowed and returned as part of short-selling arrangements in which traders 'borrow' shares for a fee and sell them in the hope or expectation that the price will fall and they can be bought back at a lower price and returned for a profit.
If the expectation of a share price fall is met, the trader makes a profit, but if the share price rises, the trader can face heavy losses.
While there is nothing illegal about such activity, Biotech Daily is concerned that the public does not know the true identity of the ultimate share traders in defiance of the spirit, but not the letter, of the Corporations Act.
Biotech Daily is also concerned with the frequency of the becoming and ceasing substantial shareholder notices and the meaninglessness of these filings other than acknowledging that person or persons unknown are playing with Australian biotechnology companies for their own purposes.

NEUREN PHARMACEUTICALS

UBS AG and related companies has ceased its substantial shareholding in Neuren, reducing to 70,082,774 shares (4.76%).
Between October 31 and November 15, 2013, UBS AG and related companies reduced their substantial shareholding in Neuren from 90,539,390 shares (6.24%) to 76,928,129 shares (5.23%) (BD: Oct 31, Nov 15, 2013).
The UBS substantial shareholder notices filed from Singapore said that UBS Securities Australia was a beneficial owner and UBS AG, Australia Branch had an interest in the shares held as "borrowing right in respect of shares pursuant to a prime broking agreement", with UBS AG London Branch also holding shares as a "borrowing right".
Neuren was up one cent or 8.3 percent to 13 cents with 12.7 million shares traded.

COCHLEAR

UBS AG and related companies said it had ceased its substantial shareholding in Cochlear.
On November 12, UBS AG filed a becoming substantial shareholder notice for Cochlear, which said the shares were held as a beneficial owner, fund manager, broker or prime broker.
Today's announcement detailed a large number of trades, primarily sales of small parcels of shares.
Cochlear fell 58 cents or 0.97 percent to $59.12 with 155,796 shares traded.

ALLIED HEALTHCARE GROUP

Allied Health's annual general meeting passed all resolutions including the name change to Admedus, but with up to 7.95 percent opposition to directors shares and options.

In October, Allied proposed the grant of shares in lieu of pay to three directors and issue 7,000,000 options to directors (BD: Oct 21, 2013).

Resolutions on the name change, remuneration report and the re-election director Graeme Rowley were passed overwhelmingly, with 8.3 million votes opposing the re-election of chairman Christopher Catlow and 311.4 million votes in favor.

The issue of shares and options to directors, as well as the ratification of the prior issue of securities to employees and approval of the 10 percent placement facility faced greater dissent.

The strongest opposition was to the issue of 900,000 options to Mr Catlow with 24,351,800 votes (7.9%) against and 282,009,253 votes (92.1%) in favor.

The company's most recent Appendix 3B said that Allied had 1,255,509,211 shares on issue meaning that the opposition to Mr Catlow's options amounted to 1.9 percent of the company's total shares on issue, not sufficient to requisition extraordinary general meetings.

Allied fell 1.5 cents or 9.1 percent to 15 cents with 20.6 million shares traded.