Biotech Daily

Monday October 27, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CLINUVEL UP 75%, ALCHEMIA DOWN 83%**

*** ALCHEMIA FALLS 86% ON HYACT FAILING PHASE III CANCER TRIAL**

*** EUROPEAN COMMITTEE VOTES FOR CLINUVEL SCENESSE FOR EPP**

*** RHINOMED APPOINTS MCM SOUTH AFRICA DISTRIBUTOR**

*** CSL BUYS NOVARTIS 'FLU VACCINE BUSINESS FOR $312m**

*** SCHRODER, ASSOCIATES BELOW 5% IN COCHLEAR**

*** DEUTSCH BANK AG TAKES 12% OF CIRCADIAN**

*** RUSSIAN SPACE AGENCY BUYS USCOM MONITOR**

*** PSIVIDA AGM FOR 375k DIRECTOR STOCK OPTIONS**

*** GENETIC TECHNOLOGIES NAME CHANGE TO 'PHENOGEN' AGM**

*** IMUGENE AGM FOR 25m CEO CHARLES WALKER SHARES**

*** USCOM CHAIRMAN DR ROB PHILLIPS 5m 'INDETERMINATE RIGHTS' AGM**

*** BIOPROSPECT NAME-CHANGE TO 'MEDIBIO', DIRECTOR FEES AGM**

*** BIO-MELBOURNE NETWORK LOOKING FOR MEMBERSHIP MANAGER**

MARKET REPORT

The Australian stock market climbed 0.86 percent on Monday October 27, 2014 with the ASX 200 up 46.8 points to 5,459.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and two were untraded. All three Big Caps rose.

Clinuvel was the best, up $1.97 or 75.2 percent to $4.59 with 514,028 shares traded. Optiscan climbed 10 percent; IDT and Living Cell rose more than nine percent; Anteo was up 7.7 percent; Universal Biosensors climbed 6.9 percent; Benitec and Sirtex were up more than four percent; Analytica was up 3.1 percent; both Prana and Resmed rose 2.3 percent; Mesoblast climbed 1.05 percent; followed by Cochlear, CSL and Psivida.

Alchemia led the falls (see below), down 51.5 cents or 83.1 percent to 10.5 cents with 64.0 million shares traded, followed by Genetic Technologies down 17.65 percent to 1.4 cents. Neuren fell 7.2 percent; Ellex lost 6.45 percent; Phosphagenics fell 5.9 percent; Acrux, Bionomics and Oncosil fell more than four percent; Cellmid, GI Dynamics and Impedimed were down more than three percent; Starpharma shed 2.3 percent; with Nanosonics, Tissue Therapies and Viralytics down more than one percent.

ALCHEMIA

Alchemia fell as much as 86 percent on news that HA-irinotecan for metastatic colorectal cancer failed to meet is phase III primary endpoint.

Alchemia said that the randomized, double-blinded, active-controlled study compared its Hyact hyaluronic acid-formulated irinotecan, HA-irinotecan, to irinotecan as compnonets of the standard combination of folinic acid, fluorouracil and irinotecan (Folfiri) to second or third-line metastatic colorectal cancer patients.

The company said that the primary objective of the trial was to demonstrate superiority in progression-free survival of HA-irinotecan over irinotecan.

Alchemia said that the trial demonstrated a median progression-free survival of 5.5 months for patients treated with HA-irinotecan as part of the Folfiri regimen and patients treated with standard irinotecan as part of the Folfiri regimen also achieved a median progression-free survival of 5.5 months.

The company said that a planned interim analysis of overall survival was performed and the Folfiri and HA-irinotecan arms demonstrated an equivalent overall survival of about 14 months.

Alchemia said that the safety profile was equivalent between both arms of the study.

In 2007, an 80-patient phase II trial showed median progression free survival for the HA-irinotecan patients of 5.2 months, compared to 2.4 months for the irinotecan arm (p=0.014) (BD: Apr 26, May 29, 2007).

Today, Alchemia chief scientific officer Prof Tracey Brown told a teleconference that treatment in the phase III trial was completely different to the phase II monotherapy trial, but the company was expecting similarly clear differences in the results.

Alchemia chief executive officer Thomas Liquard said that the company would review all the data and specified “geographical differences”.

Prof Brown said at all locations patients were randomized to the two treatment groups, HA-irinotecan was well-tolerated and the company would undertake more data analysis.

“We are extremely disappointed in the outcome of this trial and extend our appreciation to trial investigators, the clinical sites and the hundreds of patients who participated in this study,” Mr Liquard said in a media release.

“We expect to report back to the scientific community and the market with further details on our data reviews and corporate strategy early in 2015,” Mr Liquard said.

Alchemia said its oncology pipeline included investigator-sponsored phase II trials with HA-irinotecan in metastatic colorectal cancer patients and a small cell lung cancer trial to obtain safety and efficacy data and demonstrate that HA-irinotecan could safely be combined with the chemotherapeutic drug, carboplatin.

The company said that the Chime study collaboration with Merck Serono was investigating HA-irinotecan as a component of the Folfiri regime when used with the biological therapy cetuximab (Erbitux) in patients with metastatic colorectal cancer.

Alchemia said it had two focal adhesion kinase inhibitor pre-clinical candidates and was evaluating small molecule drug discovery targets from its Vast discovery platform.

The company said that Fondaparinux was provided a revenue stream, it had $8.9 million in cash, it expected a $6.5 million R&D Tax Incentive payment in November 2014 and would assess all of its programs.

On October 22, 2014 in an unusual single large transaction, 887,980 shares were sold driving the company’s price to a low of 55 cents.

Mr Liquard told the teleconference: “To the company’s knowledge there has been no leakage in information to the market.”

Alchemia fell as much as 53.4 cents to 8.6 cents, before closing down 51.5 cents or 83.1 percent to 10.5 cents with 64.0 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Committee for Medicinal Products for Human Use has voted for marketing authorization for Scenesse for erythropoietic protoporphyria (EPP).
Clinuvel said that the European Medicines Agency's Committee voted in favor of Scenesse (afamelanotide 16mg) for adult patients with erythropoietic protoporphyria, which it said was a debilitating, rare genetic disorder clinically regarded as extreme intolerance to light and ultra-violet light, or phototoxicity.
The company said that about 10,000 patients were affected worldwide, with 45 percent in Europe.
Clinuvel said it had conducted five trials testing Scenesse in about 350 adult patients with erythropoietic protoporphyria, in Australia, Europe and the US.
The company said it treated the first patient in 2006 and submitted its dossier for EMA evaluation on February 6, 2012.
Clinuvel said that in September 2014 the EMA announced that for the first time it would incorporate patients and physicians clinical experiences with Scenesse in the Committee's decision process.
The company said that the decision in favor took into account the challenges and limitations of conducting clinical trials in rare and severe disorders and allowed access to treatment for patients without alternative medicine.
The company said that marketing authorization was given for distribution of Scenesse across 31 European states and the Committee decision would be sent to the European Commission for formal ratification, expected within 67 days.
Clinuvel said it agreed with the EMA to a post-authorization pharmaco-vigilance plan to monitor patients safety long term.
The company said that Scenesse would be distributed through academic and specialized centres.
Clinuvel chair Stan McLiesh said he congratulated "shareholders and patients, experts in the field and Clinuvel's teams around the world" on the decision.
"I have witnessed from our staff a decade long dedication and an enormous zeal which has come together for patients and all stakeholders in a marvellous outcome, one rarely accomplished in pharmaceutical development and which is now unique to Australia," Mr McLiesh said.
Clinuvel chief executive officer Dr Philippe Wolgen said that medical innovation required "an exceptional focus with a consistent strategy, passionate team and long term trust from patients, expert physicians and regulatory authorities worldwide".
"Today I am excited but mostly proud that Clinuvel overcame a number of hurdles from having identified an unmet clinical need and taken a molecule from discovery to final commercial product," Dr Wolgen said. "This outcome greatly impacts Clinuvel, our further operations and intrinsic value."
"The immediate goal is to distribute the drug to European patients in the coming months, while we owe it to our American and Asia-Pacific patient community to accelerate the regulatory process for them to gain access to Scenesse," Dr Wolgen said.
Clinuvel climbed $1.97 or 75.2 percent to $4.59 with 514,028 shares traded.

RHINOMED

Rhinomed says it has appointed MCM Solutions its wholesale distributor for the Turbine range of nasal plugs to the South Africa cycling and triathlon retail sector.
Rhinomed said that the deal with the Cape Town-based MCM Solutions was confidential.
Rhinomed was unchanged at 2.9 cents with 2.5 million shares traded.

CSL

CSL says it has acquire the loss-making Novartis' global influenza vaccine business for US$275 million ($A312.4 million) and combine it with Bio-CSL.

In a teleconference CSL chief executive officer Paul Perreault and chief financial officer Gordon Naylor confirmed that despite $US2 billion having been invested by Novartis in both the influenza vaccine plant and the research and development within it over a period of time, the plant was currently worth $US700 million.

The CSL executives confirmed that despite revenue of $US527 million in the year to December 31, 2013, CSL was able to acquire the loss-making business for $US275 million.

Mr Perreault said that the acquisition would "transform the Bio-CSL business ... and will triple capacity" as well as complement the company's existing products.

In a media release CSL said that combining subsidiary Bio-CSL's existing influenza vaccine operations with the Novartis business would "create the number two global player [after Sanofi] in the $US4 billion global influenza vaccine industry, with manufacturing plants in the US, UK, Germany and Australia, a diversified product portfolio and strong pre-pandemic and pandemic franchises in its major centres of operation.

CSL said that the combined business would have a strong growth profile and was expected to achieve sales approaching $US1 billion a year in three to five years.

The company said the Novartis influenza vaccine business was "one of the largest in the world" with state-of-the-art manufacturing and a diversified, late stage product pipeline.

Mr Perreault said the Novartis influenza vaccine business "provides Bio-CSL with a global leadership position in an attractive sector we understand intimately".

"It will transform Bio-CSL by giving it first class facilities and global scale as well as product and geographic diversity," Mr Perreault said.

"CSL has demonstrated its ability to make the most of specialist pharmaceutical acquisitions in areas we know well and this transaction has the potential to create a global platform for Bio-CSL that is comparable in many aspects to our global protein science business," Mr Perreault said.

CSL said that final settlement was expected by the end of 2015, subject to regulatory approval.

The company said that acquisition synergies were estimated to reach $US75 million a year by 2020, with integration costs estimated at $US100 million, accruing predominantly in fiscal year 2016.

The acquisition is expected to be funded through surplus cash and was not expected to impact the share buy-back program.

CSL was up 70 cents or 0.9 percent to $76.36 with 1.4 million shares traded.

COCHLEAR

Schroder Investment Management has reduced its substantial shareholding in Cochlear from 2,973,337 shares (5.21%) to 2,578,041 shares (4.52%).

Schroder said that between October 3 and 24, 2014, it bought 4,430 shares for $302,944 or $68.38 per share and sold 399,726 shares for $28,348,594 or $70.92 per share.

Last year, the Pitt Street, Sydney and Gresham Street, London-based Schroder said it acquired shares and the then registered shareholders included BNP Paribas, Citicorp Nominees, HSBC Custody Nominees, JP Morgan Custodial Services, National Nominees, State Street Australia, Brown Brothers Harriman, Sommerzank, JP Morgan Chase Bournemouth and NT London (BD: Sep 20, Oct 24, 2013).

Cochlear fell 34 cents or 0.5 percent to $72.57 with 156,266 shares traded.

CIRCADIAN

The Frankfurt, Germany-based Deutsche Bank AG and related bodies, says they have become a substantial shareholder in Circadian with 6,857,143 shares (12.36%).
Deutsche Bank said it acquired the shares at 17.5 cents a share in the recent placement (BD: Oct 6, 2014).
Deutsche Bank said that the holder was Deutsche Asset and Wealth Management Investment GmbH which had the “power to dispose of, or control the exercise of a power to dispose of, the securities” with the registered holder the State Street Bank GmbH.
Circadian was unchanged at 18 cents.

USCOM

Uscom says the Russian Federal Space Agency has bought one of its Uscom 1A ultra-sonic cardiac output monitors.
Uscom said that the monitor has been commissioned “for high level research of cardiovascular physiology in astronauts before, during and after space travel”.
The company said that the influence of weightlessness on circulation was not well understood, “in part because there has previously not been available an accurate, non-invasive method to monitor the circulation”.
Uscom said that the use of the device would provide an improved understanding of the circulation of astronauts in space.
Uscom executive chairman Dr Rob Phillips said that the “high accuracy and sensitivity of the Uscom device results in many unique applications in which Uscom can improve our understanding of physiology and contribute to the global body of cardiovascular knowledge”.
“The results of the [monitor] in space physiology research may be translated into improved clinical care in heart failure, hypertension, sepsis and the guidance of fluid therapy,” Dr Phillips said.
Uscom was untraded at 24 cents.

PSIVIDA

Psivida will vote to grant chief executive officer Dr Paul Ashton and five directors stock options and ratify the issue of 1,700,000 shares of common stock.
Psivida said that it proposed to grant Dr Ashton 245,000 options , vesting in four equal tranches from July 15, 2015 and exercisable at $US4.47 a share, within 10 years of grant.
The company said that David Mazzo would receive, pending shareholder approval 30,000 options, with 20,000 each for Douglas Godshall, Michael Rogers and Peter Savas, all exercisable at $US4.47 vesting on July 15, 2015 and within 10 years of grant.
Psivida said that options for director Dr James Barry to purchase 40,000 shares at $US4.77 a share vest in three equal tranches from September 8, 2015 and expire in 10 years from grant.
The company said that shareholders would vote on the election of directors Dr Ashton, Mr Mazzo, Mr Godshall, Dr Barry, Mr Rogers and Mr Savas.
The meeting will be held at the Cambridge Room, Waltham Westin Hotel, 70 Third Avenue, Waltham, Massachusetts on December 11, 2014 at 10am (US EST).
Psivida was up two cents or 0.4 percent to $4.72.

GENETIC TECHNOLOGIES

Genetic Technologies shareholders will vote to change the company's name to 'Phenogen Sciences' the name of it US Brevagen sales subsidiary.
In 2010, Genetic Technologies established the Charlotte North Carolina Phenogen Sciences to market the breast cancer test (BD: Oct 26, 2010).
The company said that shareholders would be asked to approve the issue of options to debt note subscribers, approve the debt notes becoming convertible and vote to elect directors Dr Lindsay Wakefield, David Carter, Dr Paul Kasian and Grahame Leonard.
The meeting will be held at Treetops, Melbourne Museum, 11 Nicholson Street, Carlton, Melbourne, on November 25, 2014, at 10.30am (AEDT).
Genetic Technologies fell 0.3 cents or 17.65 percent to 1.4 cents.

IMUGENE

Imugene will vote to issue chief executive officer Charles Walker 25,000,000 shares at 1.2 cents each under a company loan for a share purchase plan.
Imugene said that Mr Walker, who was appointed chief executive officer in August, had "achieved the necessary hurdles" for the first two tranches of a total of four tranches of 12,500,000 shares each in the loan and purchase plan (BD: Aug 27, 2014).
The company said it proposed to issue $5 million in shares in a placement at no less than 80 percent of the five-day volume weighted average price to the issue, as well as 2,500,000 options exercisable at 2.5 cents each by July 14, 2019 to the Switzerland-based Mymetics SA for "exclusive supply rights" under a virosome services agreement.
Imugene's notice of meeting said it would also seek shareholder approval to re-elect directors Paul Hopper and Otto Buttula and issue up to $150,000 in shares to Mr Buttula as part of a capital raising.
The meeting will be held in Marble Room 1, Radisson Blu Hotel, 27 O'Connell Street, Sydney on November 25, 2014 at 10.30am (AEDT).
Imugene fell 0.1 cents or 9.1 percent to one cent.

USCOM

Uscom will vote to grant executive chairman Dr Robert Phillips 5,409,902 'indeterminate rights' in three tranches pending increasing revenue targets.
Uscom's notice of meeting said that the rights to be issued at no cost and converted to shares at no cost would vest on July 1, 2018, 2019 and 2020, pending revenue increases from a minimum of $1,330,833 by September 30, 2015 to at least $1,863,166 by September 30, 2017.
The company's notice of meeting said shareholders would vote on the ratification of a private placement of 5,783,337 shares at 24 cents a share, the Uscom equity incentive plan, an additional 10 percent share placement capacity and the re-election of director Sheena Jack.
The meeting will be held at Suite 1, Level 7, 10 Loftus Street, Sydney on November 26, 2014 at 11am (AEDT).

BIOPROSPECT

Bioprospect shareholders will vote to change the company's name to 'Medibio' and increase the directors' fee pool 25 percent to $500,000 a year.
Bioprospect said that the annual general meeting would vote on the prior issue of 333,333,331 shares at 0.3 cents a share.
The company said it would vote to re-elect directors Dr James Campbell, Kris Knauer and Vincent John Fayad.
The meeting will be held at PKF Lawler, Level 8, 1 O'Connell Street, Sydney, on November 24, 2014, at 10.30am (AEDT).
Bioprospect was unchanged at 0.3 cents with 9.2 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it wants to find the right person to fill the role of membership engagement manager.
The Network said it was looking for "a forward-thinking, enthusiastic communicator with diverse skills who understands the vital contributions made by the biotechnology and medical technology industries".
The industry association for the biotechnology and medical technology industries of Victoria said the position required working closely with the chief executive officer Dr Krystal Evans and the successful candidate would be design and implement the events programs.
The Bio-Melbourne Network said that the candidate would be expected to create marketing and communications strategies to support and inform members.
For more details go to: http://www.seek.com.au/job/27530332.