Biotech Daily

Tuesday February 14, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: UNIVERSAL BIO UP 12%, CLINUVEL DOWN 8%**

*** COCHLEAR H1 REVENUE UP 9% TO $609m, PROFIT UP 18% TO $111m**

*** REDHILL COMPLETES RHB-102 GUT INFECTION TRIAL TREATMENT**

*** AVIRAGEN (BIOTA) VAPENDAVIR FAILS PHASE IIb HRV TRIAL**

*** WEHI: 'STEM CELL HORMONE RESPONSE LINK TO BREAST CANCER'**

*** ATCOR RECEIVES $472k FEDERAL R&D TAX INCENTIVE**

*** CORRECTION: MESOBLAST**

*** BIOTECH CAPITAL RAISES $1.8M, SHARE PLAN FOR MORE**

*** MGC READY FOR SLOVENIA MEDICINAL CANNABIS EPILEPSY TRIAL**

*** CRESO TO LAUNCH MARIJUANA FOOD ADDITIVE IN 2017**

*** COCHLEAR APPOINTS RAY JARMAN COMPANY SECRETARY**

* **FACTOR APPOINTS JOHN MICHAILIDIS DIRECTOR**

*** BOTANIX APPOINTS DR MICHAEL THURN COO**

MARKET REPORT

The Australian stock market edged up 0.1 percent on Tuesday February 14, 2017 with the ASX200 up 5.5 points to 5,755.2 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and four were untraded.

Universal Biosensors was the best, up four cents or 11.9 percent to 37.5 cents with 266,904 shares traded. Actinogen climbed 6.9 percent; Compumedics was up 5.6 percent; both Living Cell and Mesoblast were up 4.55 percent; Admedus climbed 3.3 percent; Pharmaxis and Sirtex rose more than one percent; with Ellex, Nanosonics, Pro Medicus, Resmed and Viralytics up by less than one percent.

Clinuvel led the falls, down 57 cents or 8.4 percent to $6.20 with 39,595 shares traded. IDT, Neuren and Oncosil lost more than five percent; Uscom fell 4.2 percent; Cellmid, Cochlear, Factor Therapeutics and Polynovo were down more than three percent; Anteo and Starpharma shed more than two percent; Acrux, Airxpanders, Impedimed, Opthea, Orthocell and Prana were down more than one percent; with CSL down 0.35 percent.

COCHLEAR

Cochlear says that revenue for the six months to December 31, 2016 was up 9.15 percent to $609,164,000 with net profit after tax up 18.4 percent to $111,367,000.
Cochlear said that diluted earnings per share climbed 17.9 percent to $1.942 with net tangible assets per share up 51.9 percent to $4.80 compared to December 31, 2015.
The company said that a fully-franked interim dividend of $1.30 a share for shareholders on the record date of March 16 would be paid on April 6, 2017.
Cochlear said research and development expenditure was up 12.7 percent to $72,207,000 compared to the previous period or 11.9 percent of total revenue.
The company said sales revenue was up led by cochlear implants, up 4.0 percent to $377,071,000, and the acoustics division which included bone conduction and acoustic implants up 13.4 percent to $82,481,000, but with the services sector of sound processor upgrades and accessories down 1.0 percent to $144,814,000.
Cochlear said that sales revenue in the Americas was up 8.0 percent to $285,146,000, with Asia Pacific sales up 3.8 percent to $111,308,000 and sales in Europe, Middle East and Africa were down 1.2 percent to $207,912,000.
Cochlear chief executive officer Chris Smith said the company reduced net debt by $24 million between June 30 and December 31, 2016.
Mr Smith said that the company's Kanso off-the-ear sound processor and the Nucleus Profile, the world's slimmest electrode, were launched in Europe and the US with the company "experiencing strong uptake of both products".
Cochlear said it continued to expect net profit to be up 10 to 20 percent to $210 million to $225 million for the full year to June 30, 2017.
Cochlear fell $4.80 or 3.6 percent to $128.95 with 335,004 shares traded.

REDHILL BIOPHARMA

Israel's Redhill says it has completed treatment of 320 adults and children over the age of 12 in its phase III trial of RHB-102 or Bekinda for acute gastroenteritis and gastritis.
Redhill said it expected top-line results from the randomized, double-blind, placebo-controlled 'Guard' study evaluating the safety and efficacy of RHB-102 by July 2017.
The company said that acute gastroenteritis and gastritis were inflammations of the mucus membranes of the gastrointestinal tract which might lead to nausea, vomiting, diarrhoea or abdominal pain, with about 179 million cases a year in the US.
Redhill said that, if approved, Bekinda could become the first 5-HT3 anti-emetic drug in the US indicated for the treatment of acute gastroenteritis and gastritis, targeting a potential worldwide market of more than $US650 million a year.
The company said the study's primary endpoint was the absence of vomiting or the need for rescue medications or intravenous hydration from 30 minutes through 24 hours after the first dose, with secondary endpoints including frequency of vomiting, severity and time to resolution of nausea and time to resumption of normal activities.
Redhill said that, subject to significant positive results, the study might be sufficient to support potential a US marketing application.
The company said that a separate phase II study with Bekinda was underway in the US for the treatment of diarrhoea-predominant irritable bowel syndrome, with top-line results expected "in mid-2017".
In 2010, Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Last night on the Nasdaq, Redhill was up 17 US cents or 1.8 percent to $US9.71 ($A12.64) with 75,660 shares traded.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says its 455 patient, phase IIb trial of vapendavir in moderate to severe asthmatics with a rhinovirus infection failed to meet its endpoints.

Aviragen said the top-line data from the 'Spiritus' multi-center, randomized, double-blind, placebo-controlled, dose-ranging study showed that vapendavir "did not demonstrate a statistically significant reduction in the asthma control questionnaire-6 at day-14, the primary endpoint, for either the 264mg or 528mg cohorts compared to placebo".

In 2015, the then Biota began dosing the patients with laboratory-confirmed human rhinovirus, the cause of most incidents of the common cold, in its phase IIb Spiritus trial of vapendavir and said it expected to report top-line data in mid-2016 (BD: Mar 4, 2015).

The company said at that time that the secondary endpoints were safety and tolerability, with lung function assessments such as forced expiratory volume in one second (FEV1), incidence of asthma exacerbations, assessments of the severity and duration of cold symptoms and virological assessments such as changes in viral load.

Today, Aviragen said the trial at 68 sites in North America and Europe, was in patients aged 18 to 70 years that had an established history of moderate-to-severe asthma and a history of losing asthma control as a result of an upper respiratory tract infection.

The company said that the intent-to-treat patient population consisted of 455 randomized patients and from this group there were 168 laboratory-confirmed human rhinovirus-infected patients.

Aviragen said that the improvement on the asthma control questionnaire for the placebo cohort "was larger than expected for this patient population" and was a great reduction than for either of the vapendavir arms.

The company said the trial "demonstrated statistically significant anti-viral effects for patients that received vapendavir within 24 hours of first symptoms, consistent with previous studies".

Aviragen said that secondary endpoints evaluating the lung function measure FEV1 and reduction in asthma exacerbations did not show significant differences between the treatment groups and placebo, but vapendavir "was shown to be generally well tolerated and the safety profile was consistent with previous clinical studies".

Aviragen chief executive officer Dr Joseph Patti said the company was "disappointed that the Spiritus trial did not meet its primary endpoint in this patient population".

"There was evidence of an antiviral effect in patients that received vapendavir within the first day following the onset of their symptoms and as such we plan to take time to fully analyze the data before making a decision on whether to initiate a study in haematopoietic stem cell transplant patients, where the ability to stop the progression of the [rhinovirus] infection could be beneficial," Dr Patti said.

Prior to Biota departing Australia in a failed attempt to acquire $US54 million in cash held by Nabi Pharmaceuticals and settling for $US27 million, the company was earning multi-million dollar sales royalties from Glaxosmithkline for its Relenza anti-influenza drug, as well as multi-million dollar royalties from Daiichi Sankyo sales of Inavir in Japan (BD: Feb 1, 2011; Apr 23, Oct 30, 2012).

Following its move to the US, Biota lost its $US231 million contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA) to further develop its laninamivir anti-influenza drug with BARDA citing "concerns about the project with regard to the product manufacturing, clinical study enrolment pace, costs, and contractor performance" (BD: Apr 1, 2011; Apr 30, May 1, May 9, 2014).

Last night on the Nasdaq, Aviragen closed down six US cents or 5.26 percent to $US1.08 ($A1.41 - equivalent to 17.6 cents prior to the Nabi merger, when it was trading around $A1.00), with 397,384 shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Walter and Eliza Hall Institute says its researchers have found a breast stem cell responsible for mammary gland growth in pregnancy which may be linked to cancer.
WEHI said the researchers used advanced cellular, bioinformatics and imaging technology to reveal the long-lived stem cells, which responded to the ovarian hormones progesterone and oestrogen, and could be linked to high risk claudin-low breast cancer.
The article, entitled 'Identification of quiescent and spatially restricted mammary stem cells that are hormone responsive' was published in Nature Cell Biology with an abstract at: http://www.nature.com/ncb/journal/vaop/ncurrent/full/ncb3471.html.
WEHI said that the discovery was made by Prof Jane Visvader, Prof Geoff Lindeman Dr Nai Yang Fu and Dr Anne Rios, as part of a 20-year research program into how the breast develops from stem cells and how breast cancers arose from stem cells and developing breast tissue.
Dr Fu said the team had been able to build on their earlier discovery of breast stem cells, by defining subsets of stem cells with different functions, a project that was conducted in collaboration with bioinformatics researchers Dr Matthew Ritchie and Prof Gordon Smyth.
"When we looked at the genes that were switched on in these stem cells, we could distinguish subsets of stem cells that differed in their expression of genes encoding two proteins called tetraspanin8 and Lgr5," Dr Fu said.
"By looking at the levels of tetraspanin8 and Lgr5 protein on the surface of the cells, we could divide the stem cells into three separate groups," Dr Fu said.
Dr Rios said that the research team used advanced technologies including three-dimensional imaging to show that the three groups of stem cells were located in different parts of the breast and function differently.
"We focused particularly on one stem cell sub-type that had the highest levels of tetraspanin8 and Lgr5 protein, which were located in the proximal region of the breast around the nipple," Dr Rios said.
Prof Visvader said the stem cells were normally dormant and remained in the proximal region throughout life.
"However, when they were exposed to the hormones progesterone and oestrogen these cells awakened and could rapidly give rise to new breast cells," Prof Visvander said.
WEHI said that the research showed that the stem cells with high levels of tetraspanin8 and Lgr5 protein had many similarities to a sub-type of triple negative breast cancers known as claudin-low cancers.
"Compared to other types of breast cancer, claudin-low cancers have a high chance of recurrence after treatment, leading to a poor prognosis for patients," Prof Visvader said.
Prof Lindeman, a medical oncologist at the Peter MacCallum Cancer Centre and the Royal Melbourne Hospital, said the research might lead to improved outcomes for people with claudin-low cancers.
"We hope that our discovery can be used to understand how cancers may arise from long-lived stem cells and potentially lead to better outcomes for breast cancer patients in the future," Prof Lindeman said.

ATCOR MEDICAL

Atcor says it has received $472,133 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Atcor chief financial officer Peter Manley told Biotech Daily that the payment related to research and development expenditure in the year to June 30, 2016.
Atcor was unchanged at 6.7 cents.

MESOBLAST

Last night's edition reported that Mesoblast would release 1,277,210 shares from voluntary escrow on February 24, 2017.

While that number was correct, Biotech Daily incorrectly described Mesoblast company secretary Charlie Harrison as the chief financial officer and misreported the number of shares available for trading.

Today, Mr Harrison told Biotech Daily that following the release of the 1,277,210 escrow shares, Mesoblast would have 381,373,137 shares available for trading, with a further 280,911 shares in voluntary escrow until August 19, 2017 and 20,044,771 shares related to the Mallinckrodt Pharmaceuticals collaboration to be held in voluntary escrow until January 6, 2018.

The sub-editor could not cope with the pressure of a busy day and has been dismissed.

Mesoblast was up seven cents or 4.55 percent to $1.61 with 654,413 shares traded.

BIOTECH CAPITAL

Biotech Capital says it has raised $1,791,864 in private placement at 11 cents a share and will offer a share purchase plan to eligible shareholders.

Biotech Capital said that of the 16,289,670 shares issued in the placement, directors intended to take up 2,772,981 shares, subject to shareholder approval.

The company said that the placement and share plan funds would be used "to build greater capabilities for the group in regulatory, quality and clinical services, establish a Melbourne office for Biointelect, promote the group's services to overseas clients and proceed with a number of strategic appointments in coming months".

Biotech Capital said that through wholly-owned subsidiary Bioimpact it was pursuing opportunities to in-licence intellectual property rights to new drugs and medical devices.

The company said that the share plan would allow shareholders to apply for up to $15,000 of shares at 11 cents a share.

Biotech Capital said the share plan's record date was February 13, the plan would open on February 16 and close on March 2, 2017.

Biotech Capital was untraded at 12 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it is ready to begin a 70-volunteer, phase IIa study of its medicinal cannabis for epilepsy at the Ljubljana, Slovenia-based University Children's Hospital.

MGC said that the six-week, crossover study would use "enriched medical cannabis products" in children and adolescents with treatment-resistant epilepsy.

The company said that more than 65 patients had been recruited with more than 150 potential volunteers expressing an interest in participating.

MGC said that the study aimed to assess the efficacy of its medicinal cannabis formulation "a whole plant extract based medicine with high [cannabidiol to tetrahydrocannabinol] ratio, and compare it to pure synthetic cannabidiol.

The company said that the primary end point would be a reduction in the frequency of seizures experienced by individuals suffering from epilepsy.

MGC advisor Prof Uri Kramer said that the cross-over study would investigate the efficacy of a whole plant extract medicinal cannabis formula with a high [cannabidiol to tetrahydrocannabinol] ratio for the treatment of children with refractory epilepsy from different aetiologies".

MGC was up 0.1 cents or 2.6 percent to four cents with 6.3 million shares traded.

CRESO PHARMA

Creso says it hopes to launch its marijuana based food additive by the end of 2017.
Creso said that pilot production would begin by July 2017 “and following stability testing, Creso will move into full-scale production and regulatory submission to health authorities” with a full commercial launch expected by the end of 2017.
The company said it had “achieved significant progress with its first human [cannabinoid] fully plant-based nutraceutical product”.
Creso said that its first product would “provide people with nutritional support to their endo-cannabinoid system to manage situations of everyday anxiety and stress”.
Creso fell 1.5 cents or 6.4 percent to 22 cents.

COCHLEAR

Cochlear says it has appointed Ray Jarman as company secretary replacing Neville Mitchell with effect from February 13, 2017.
Last week, Cochlear said that Brent Cubis would replace Mr Mitchell as chief financial officer from March 13, 2017 (BD: Feb 10, 2017).
Today, the company said that Mr Jarman had been its group general counsel since 2008 and had experience in corporate governance and legal compliance matters and was responsible for its communications with the ASX in relation to the Listing Rules.

FACTOR THERAPEUTICS

Factor Therapeutics says that it has appointed John Michailidis as a non-executive director, effective from February 14, 2017.
Factor Therapeutics said that Mr Michailidis was currently Teva Australia and New Zealand’s managing-director and had about 30 years of commercial pharmaceutical experience.
The company said that Mr Michailidis held executive roles with F Hoffman La Roche, Avipep and Orphan Australia.
Factor Therapeutics said that Mr Michailidis held a Bachelor of Science from LaTrobe University and business qualifications from Harvard Business School and the Paris, France-based Institut Européen d'Administration des Affaires (European Institute for Business Administration, or Insead).
Factor Therapeutics fell 0.2 cents or 3.2 percent to six cents.

BOTANIX PHARMACEUTICALS

Botanix says it has appointed Dr Michael Thurn as chief operating officer.
Botanix said that Dr Thurn had experience in drug development and was formerly Mimetica chief executive officer leading development of a melancortin-5 receptor targeting topical treatment for acne from pre-clinical testing to the completion of a phase II trial.
The company said that previously Dr Thurn worked with the Australian Therapeutic Goods Administration and led Spinifex Pharmaceuticals.
Botanix was unchanged at 4.3 cents.