Biotech Daily

Friday October 7, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: FACTOR THERA UP 18%; LIVING CELL DOWN 8%**

*** REDHILL EXPANDS PHASE III RHB-104 (MYOCONDA) TRIAL, EARLY STOP**

*** TWO SIRTEX LIVER CANCER STUDIES COMBINE FOR META-ANALYSIS**

*** MEDADVISOR, OSTEOPOROSIS AUSTRALIA PARTNER FOR ADHERENCE**

*** ADMEDUS $159,693 DIRECTOR 'IN LIEU' SHARES AGM**

*** MMJ REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** MEDICAL DEVELOPMENTS CHAIR DAVID WILLIAMS 146k DRP SHARES**

*** TISIA, HENDERSON BELOW 5% OF ACTINOGEN**

MARKET REPORT

The Australian stock market fell 0.28 percent on Friday October 7, 2016 with the ASX200 down 15.6 points to 5,467.4 points.

Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and two were untraded.

Factor Therapeutics was the best on no news, up one cent or 18.2 percent to 6.5 cents with 2.7 million shares traded.

Polynovo climbed 8.5 percent; Genetic Signatures was up 6.5 percent; Ellex improved 5.2 percent; Avita and Oncosil were up more than four percent; Orthocell and Uscom rose more than two percent; Atcor, Compumedics and Resmed were up more than one percent; with Cochlear and Medical Developments up by less than one percent.

Living Cell led the falls, down 0.7 cents or 8.2 percent to 7.8 cents, with 352,417 shares traded.

Clinuvel, IDT and Mesoblast lost more than six percent; Opthea fell 4.1 percent; Cellmid, Neuren and Prana were down more than three percent; Actinogen, Psivida and Universal Biosensors shed more than two percent; Airxpanders, Bionomics, Nanosonics, Sirtex, Starpharma and Viralytics were down more than one percent; with CSL, Impedimed and Pro Medicus down by less than one percent.

REDHILL BIOPHARMA

Israel's Redhill says it will increase the number of patients in its phase III trial of RHB-104 (Myoconda) for Crohn's disease and include an early stop success option.

Redhill said that the introduction of an early stop option "for overwhelming efficacy" might significantly shorten the time for study completion, with the expanded patient recruitment expected by the end of 2017 (BD: Jun 23, 2016).

The company said that an independent safety-focused data safety monitoring board (DSMB) meeting was expected by the end of 2016.

Redhill said that RHB-104 was "a potential paradigm-changing treatment for Crohn's disease, targeting a suspected underlying bacterial infectious cause of the disease, Mycobacterium avium subspecies paratuberculosis, with its precursor compound Myoconda originally developed by Prof Tom Borody and acquired from Sydney's Giaconda, with Heliconda (RHB-105) and Picoconda (RHB-106) (BD: Aug 17, 2010).

Today, Redhill said that a companion Mycobacterium avium subspecies paratuberculosis (MAP) diagnostic test has led to the successful identification of MAP DNA in blood samples from Crohn's disease patients, with further development work on the companion diagnostic in progress through a collaboration with the Houston, Texas-based Baylor College of Medicine.

Redhill said it was implementing several improvements to the study's protocol and enhancements to the overall RHB-104 development program, including raising the total number of patients from 270 to 410 to expand the collection of clinical data, including mucosal healing, and to compensate for early terminations.

The company said that the overall 90 percent power had been maintained and sample size calculations modified to reduce the detectable effect from 21 percent to 15 percent, reflecting a more clinically-expected treatment effect, and with the modified sample size, "more precise estimates of the treatment effect can be ascertained"

Redhill said that no changes were planned for the primary endpoint of remission, defined as Crohn's disease activity index of less than 150 at week 26.

The company said that with 219 patients already enrolled in the study, the second DSMB meeting was expected by July 2017, when the first 205 patients will have completed 26 weeks on the study; and the DSMB review would include safety and interim efficacy analysis, with evaluation of an early stop for success under pre-specified efficacy criteria.

Redhill said that if the pre-specified threshold was not met in the interim analysis, the study would continue through randomization of all 410 patients and follow-up at 26 weeks, with final efficacy testing performed using a two-sided p-value of 0.049.

The company said that the increased number of patients would allow for collection of significantly more colonoscopic mucosal healing data, supporting future potential marketing applications and reflecting and adhering to the most recent US Food and Drug Administration and European Medicines Agency guidance.

Redhill said there would be a third DSMB meeting was planned for when 75 percent of the 410 patients will have completed 26 weeks of study participation and to improve patient retention and further expedite recruitment, it was preparing an open-label extension study, offering patients treatment with RHB-104 for a 52-week period.

Redhill advisory board member Prof Borody said he had been treating patients with the anti-MAP combination of antibiotics for more than 20 years and had seen "remarkable results, with many patients achieving complete and lasting remission over time".

"It is very exciting to see Redhill continue to progress RHB-104 through advanced clinical development," Prof Borody said.

Last night on the Nasdaq, Redhill was up 48 US cents or 3.61 percent to $US13.79 ($A18.19) with 75,218 shares traded.

SIRTEX MEDICAL

Sirtex says that French and Singapore researchers intend to combine the data from two major studies of SIR-Spheres for liver cancer in a prospective meta-analysis.

Sirtex said that the two randomized, controlled studies of SIR-Spheres yttrium-90 resin microspheres versus sorafenib had completed patient recruitment and enrolled more than 800 patients with inoperable primary liver cancer, or hepatocellular carcinoma.

The company said that the trials were being conducted at Assistance Publique Hôpitaux de Paris and through the Asia-Pacific Hepatocellular Carcinoma Trials Group and the National Cancer Centre Singapore and Singapore Clinical Research Institute.

Sirtex said that the results of the prospective meta-analysis were expected in 2017.

Sirtex chief executive officer Gilman Wong said the company was "very pleased that the [sorafenib versus radio-embolization in advanced hepatocellular carcinoma] Sarah and [SIR-Spheres Y-90 resin microspheres versus sorafenib] Sirvenib study investigators have decided to collaborate and combine their two studies in a prospective meta-analysis".

"This is a unique opportunity given the individual studies are now both expected to report their results within the same time-frame during the first half of … 2017 and demonstrates considerable foresight by the investigators as most meta-analyses are performed retrospectively," Mr Wong said.

Sirtex chief medical officer Dr David Cade said that by combining the "studies in a prospective manner in a meta-analysis, the clinical data thus generated will be of a higher level of scientific evidence than either of the individual … randomized controlled studies alone".

"This enables the investigators to draw more robust conclusions on overall survival, as well as a number of important pre-planned subgroups including those patients who have received prior trans-arterial chemo-embolization and those with invasion of their disease into the portal vein," Dr Cade said.

"Such an a-priori or prospective analysis is a widely accepted scientific approach in fully appraising the outcomes of similarly designed clinical studies." Dr Cade said.

Sirtex said that further details regarding the methodological and statistical approach to the meta-analysis would be published in a peer-reviewed journal in advance of the meta-analysis findings.

Sirtex fell 37 cents or 1.2 percent to $31.11 with 121,152 shares traded.

MEDADVISOR

Medadvisor says it has a 12-month partnership with Osteoporosis Australia for its mobile telephone technology for drug adherence.

Medadvisor said that the not-for-profit health association Osteoporosis Australia's had more than 150,000 visitors to its website and provided osteoporosis information and services to its patient community and health professionals.

The company said that Osteoporosis Australia promoted improved medication adherence, which could be supported through its platform.

Medadvisor said that osteoporosis affected more than million Australians with more than 155,000 broken bones expected this year from poor bone health.

The company said it had about 5,200 users with osteoporosis using its platform and was running a separate patient engagement program to provide education for patients using a common osteoporosis medication to improve quality use of medicines.

Medadvisor was unchanged at four cents.

ADMEDUS

Admedus will vote to issue directors $159.693 worth of shares in lieu of fees, ratify two placements, re-elect directors and approve the 10 percent placement facility.
The Admedus notice of meeting said the company would issue $105,573 in shares in lieu of director fees to interim executive chairman Wayne Paterson, $54,120 in shares to director Michael Bennett, and $22,000 in shares each to directors John Seaberg and Mathew Ratty, all calculated at the 5-day volume-weighted average price to the date of issue.
The company said it would seek shareholder approval for the prior issue of 11,260,000 placement shares at 66 cents each and 5,630,000 attaching options, and vote on the re-election of directors Mr Seaberg and Mr Ratty.
The meeting will be held at the Rudges Southbank Hotel, 9 Glenelg Street, South Brisbane, Queensland on November 10, 2016 at 11am (AEST).
Admedus was unchanged at 32.5 cents.

MMJ PHYTOTECH

MMJ Phytotech has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on October 11, 2016 or on an earlier announcement.
MMJ last traded at 23 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments chairman David Williams has increased his holding from 17,731,990 shares to 17,877,540 shares and was diluted to 30.37 percent.
Previously Mr Williams sold 12,640,000 shares primarily “to increase liquidity in the company” (BD: May 12, Sep 30, 2015).
Today, Mr Williams said the 145,550 shares were acquired through participation in the company’s dividend reinvestment plan at $5.26 a share and were held by Lawn Views Pty Ltd, Moggs Creek Pty Ltd, Pari Passu Pty Ltd, Kidder Peabody Pty Ltd, Ward Williams and Saul Williams.
Medical Developments was up two cents or 0.4 percent to $5.45.

ACTINOGEN

The Perth, Western Australia-based Tisia Nominees says it has ceased its substantial holding in Actinogen.
Tisia Nominees director Tom Henderson said that Tisia sold 5,750,000 shares for $248,585 or 4.3 cents a share.
In 2015, Mr Henderson said Tisia increased its holding from 20,000,000 shares to 34,717,184 shares but was diluted from 7.91 percent to 5.8 percent (BD: Apr 28, 2015).
The current holding of 27,217,184 shares amounts to 4.49 percent of Actinogen.
Actinogen fell 0.1 cents or 2.1 percent to 4.6 cents with 1.4 million shares traded.