Biotech Daily

Tuesday May 8, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CYNATA UP 14%; GENETIC SIGNATURES DOWN 8%**

*** REDHILL COMPLETES PHASE III RHB-104 CROHN'S DISEASE DOSING**

*** BOTANIX: US FDA APPROVES PHASE II BTX1503 ACNE TRIAL**

*** IMMURON: IMM-124E 'SIGNIFICANT ALLEVIATION OF COLITIS' IN MICE**

*** ORTHOCELL APPOINTS KOMAK POLAND DISTRIBUTOR**

*** GENERA, BECKMAN COULTER MOVE TO DISTRIBUTION DEAL**

*** ADMEDUS REQUESTS CAPITAL RAISING TRADING HALT**

*** BIOTRON REQUESTS CAPITAL RAISING TRADING HALT**

*** AUSTRALIAN ETHICAL TAKES 19% OF ANTISENSE**

*** FIL TAKES 5% OF CYNATA**

*** BRAIN APPOINTS AJAY ARORA DIRECTOR**

*** CORRECTION: DIMERIX**

MARKET REPORT

The Australian stock market was up 0.12 percent on Tuesday May 8, 2018 with the ASX200 up 7.4 points to 6,091.9 points. Nineteen of the Biotech Daily Top 40 stocks were up, nine fell, 11 traded unchanged and one was untraded.

Cynata was the best, up 16 cents or 13.7 percent to $1.33 with 345,843 shares traded. Osprey climbed 11.8 percent; Airxpanders was up 8.3 percent; Oncosil improved 6.45 percent; Uscom was up 5.4 percent; Medical Developments and Prescient climbed more than four percent; Neuren, Optiscan and Volpara were up more than three percent; Clinuvel, Immutep and Prana rose two percent or more; Avita, Bionomics, CSL and Ellex were up more than one percent with Nanosonics, Pro Medicus, Resmed and Viralytics up by less than one percent.

Genetic Signatures led the falls, down 2.5 cents or 7.7 percent to 30 cents with 90,398 shares traded. Actinogen, Opthea and Starpharma lost two percent or more; Cochlear and Orthocell were down more than one percent; with Cyclopharm, Mesoblast, Sirtex and Telix down by less than one percent.

REDHILL BIOPHARMA

Redhill says that the last of 331 patients has been treated in its first phase III study of RHB-104 for Crohn's disease.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, the company said that top-line results were expected in about three months.

Redhill said that the US, Canada, Europe, Israel, Australia and New Zealand study was a randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of RHB-104 in subjects with moderately to severely active Crohn's disease a defined as Crohn's disease active index (CDAI) between 220 and 450.

The company said that the primary endpoint was disease remission, defined as a CDAI value of less than 150 at week 26.

Redhill said that "a review of the blended efficacy rate of the current blinded data suggests that the total number of treatment successes at this point in the study is consistent with the predefined expected treatment outcome and protocol-defined 15 percent treatment effect" with the RHB-104 arm at 36 percent compared to the placebo arm at 21 percent.

The company said that the blended remission rate of the blinded data was "consistently within or superior to our pre-specified protocol defined assumptions, indicating potential study success assuming the placebo and RHB-104 remission rates in the study are in line with trial assumptions".

Redhill said that placebo remission rates in similar, but not identical, pivotal studies ranged from about seven percent to 25 percent with the two most-recently approved therapies at seven percent for Entyvio and 20 percent for Stelara.

Redhill said that RHB-104 was "a potentially ground-breaking, proprietary, orally-administered antibiotic combination therapy, with potent intracellular, antimycobacterial and anti-inflammatory properties … based on the hypothesis that Crohn's disease is caused by Mycobacterium avium subspecies paratuberculosis (MAP) infection in susceptible patients".

The company said that an open-label extension phase III study was ongoing to evaluate the safety and efficacy of RHB-104 in subjects who had active Crohn's disease after 26 weeks of blinded study therapy in the ongoing phase III study.

Redhill said that additional studies were likely to be required to support a US new drug application.

On the Nasdaq, Redhill was up 15 US cents or 3.01 percent to $US5.13 ($A6.84) with 173,157 shares traded.

BOTANIX PHARMACEUTICALS

Botanix says the US Food and Drug Administration has approved its 360-patient, phase II trial of its synthetic cannabidol BTX1503 for acne.

Botanix said the FDA had approved the investigational new drug application allowing the start of enrolment for the 12-month study at more than 30 dermatology clinics in the US and Australia.

In January, the company said its 21-patient, phase Ib trial showed that BTX1503 was safe and effective at reducing acne lesions by 47 percent, after four weeks of treatment (BD: Jan 29, 2018).

Botanix executive director Matt Callahan said the company was "pleased to clear this important hurdle with the FDA and now have a clear and rapid path completing the phase II program in the US following the recent success of our phase Ib study".

Botanix fell half a cent or 3.6 percent to 13.5 cents with 6.8 million shares traded.

IMMURON

Immuron says oral IMM-124E shows “significant alleviation of colitis symptoms” in mice.
Immuron said the study at Switzerland’s University of Zürich showed that IMM-124E resulted in reduced weight loss and disease activity, reduction of macroscopically-detectable colitis, less shortening of the colon, and the histology of the terminal and proximal colon showed reduced colitis in the drug treatment arms.
The company said the results were obtained by using mice with immune systems deficient in B and T-lymphocytes, which meant chronic colitis was induced immunologically and not chemically, in contrast to positive results last year that treated chemically-induced colitis (BD: Apr 18, 2017).
The study’s lead principle investigator and the University of Zürich’s professor of gastroenterology and hepatology Prof Gerhard Rogler said the study “concludes our comprehensive preclinical program to evaluate the therapeutic potential of IMM-124E in our established colitis animal models”.
"Our results clearly demonstrate that treatment with IMM-124E significantly reduces intestinal inflammation via reducing the accumulation and differentiation of pathogenic T cells, while concomitantly enhancing the induction of regulatory cells,” Prof Rogler said.
“This indicates that IMM-124E inhibits lipo-polysaccharide-mediated effects on the mucosal immune system, resulting in reduced intestinal inflammation,” Prof Rogler said.
“Summarized, our findings indicate that IMM-124E administration represents a novel therapeutic strategy to induce or maintain remission in [irritable bowel disease] patients,” Prof Rogler said.
Immuron interim chief executive officer Dr Jerry Kanellos said the results “added to our published preclinical and clinical data which has repeatedly shown that IMM-124E delivers a significant reduction in liver and mucosal inflammation”.
“[Lipo-polysaccharide] endotoxins have been widely implicated as a major driver of inflammation in colitis, inflammatory bowel disease, [non-alcoholic steato hepatitis] as well as numerous auto-immune diseases,” Dr Kanellos said.
Immuron fell half a cent or 1.7 percent to 29.5 cents.

ORTHOCELL

Orthocell says it has appointed the Ruszowice, Poland-based Komak Sp as the Poland distributor of its Celgro dental bone and soft tissue repair collagen medical device.
Orthocell said the distribution agreement would last for five years and followed the appointment of Bimar Ortho in Italy, as part of the company’s plans for expansion in Europe.
Orthocell fell half a cent or 1.45 percent to 34 cents.

GENERA BIOSYSTEMS

Genera says it has a distribution agreement with Indianapolis-based Beckman Coulter, replacing last year’s proposed co-marketing deal (BD: Dec 6, 2017).
Genera said it would hire two regional sales application specialists for the initial launch of its Ampasand molecular diagnostic in Australia and New Zealand, and it would “support focussed strategic sales to facilitate an expanding global presence”.
Last year, the company said it had a “co-marketing partnership” with Beckman Coulter to combine Ampasand technology with Beckman Coulter’s Cytoflex flow cytometry system.
Genera fell half a cent or 2.9 percent to 16.5 cents.

ADMEDUS

Admedus has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on May 10, 2018 or on an earlier announcement.
Admedus last traded at 36 cents.

BIOTRON

Biotron has requested a trading halt pending “an announcement regarding a proposed capital raising”.
Trading will resume on May 10, 2018 or on an earlier announcement.
Biotron last traded up 0.1 cents or 3.3 percent to 3.1 cents with 1.8 million shares traded.

ANTISENSE THERAPEUTICS

Australian Ethical Investment says it has increased its substantial holding in Antisense from 24,233,911 shares (13.04%) to 70,833,333 shares (19.31%).
The Australian Ethical substantial shareholder notice said it acquired the 46,599,422 shares on May 7, 2018 but failed to disclose the price paid as required by the Corporations Act 2001.
Last week, Antisense said it had raised $4,459,040 in a rights issue at 2.4 cents a share following a $581,614 placement to Australian Ethical (BD: Apr 11, May 3, 2018).
Antisense was up 0.1 cents or four percent to 2.6 cents.

CYNATA THERAPEUTICS

FIL Limited says it has become a substantial shareholder in Cynata with 4,607,153 shares or 5.07 percent.
The Hong Kong-based FIL said it bought the shares between January 24 and on May 3, 2018 at prices ranging from 70 cents to $1.53.
Cynata was up 16 cents or 13.7 percent to $1.33.

BRAIN RESOURCE

Brain Resource says it has appointed Ajay Arora as a non-executive director, effective immediately.
Brain said Mr Arora was currently a director of product innovation at television entertainment company Netflix and spent the last 20 years in management roles with digital subscription businesses including photo-sharing company Imgur’s head of product management and led product management for the on-line retailer Amazon-owned Audible.
The company said Mr Arora held a Bachelor’s degree from the Hamilton, Ontario-based McMaster University, a Master of Electrical Engineering from the University of Southern California and a Master of Business Administration from Harvard University.
Brain Resource was unchanged at 3.8 cents.

DIMERIX

Last night's edition quoted Dimerix saying that principal investigator Prof Simon Roger held the combined Bachelor of Medicine and Bachelor of Surgery degrees (MBBS) from the University of New South Wales, as well as a Doctor of Medicine from the University.
Prof Roger has told Biotech Daily that following two years clinical and laboratory research in London and completion of a thesis he was awarded a Doctorate of Medicine, superseding the MBBS.
Dimerix was unchanged at 11 cents.