Biotech Daily

Friday September 9, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: DIMERIX UP 13%, GENETIC SIGNA DOWN 8%**

*** REDHILL YELIVA MULTIPLE MYELOMA TRIAL; MORE INDICATIONS**

*** UAE APPROVES MEDICAL DEVELOPMENTS PENTHROX PAIN-KILLER**

*** FACTOR CLOSER TO VENOUS LEG ULCER TRIAL START**

*** ANTEO RECEIVES $2m FEDERAL R&D TAX INCENTIVE**

*** ADMEDUS, DR LANE, DR WOOLLARD SETTLE CARDIOCEL FIGHT**

*** CSL $6.6m CEO 'RIGHTS', DIRECTORS 33% FEE HIKE AGM**

*** BRANDON, MRCF, AUSTRALIAN SUPER TAKE 24% OF OSPREY**

*** PROF MARSHALL'S ONDEK QUITS BIOXYNE, TAKES $159k PROFIT**

*** FIL TAKES 6% OF RESAPP**

*** NOVOGEN APPOINTS KATE HILL INTERIM CO SEC, LIONEL MATEO GOES**

MARKET REPORT

The Australian stock market fell 0.87 percent on Friday September 9, 2016 with the ASX200 down 46.6 points to 5,339.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Dimerix was the best for the third day this week, up 0.2 cents or 13.3 percent to 1.7 cents with 12.7 million shares traded. Opthea climbed 12.0 percent; Medical Developments and Neuren were up more than 10 percent; Actinogen and Cyclopharm improved more than five percent; Factor Therapeutics was up 4.3 percent; Bionomics was up 3.45 percent; Reva rose 2.3 percent; Admedus, Clinuvel, Compumedics and Living Cell were up more than one percent; with Nanosonics up 0.3 percent.

Genetic Signatures led the falls, down four cents or 7.8 percent to 47 cents with 50,305 shares traded. Cellmid lost 6.45 percent; Atcor fell 4.55 percent; Mesoblast, Prana and Uscom were down three percent or more; Acrux, CSL, Ellex, IDT, Impedimed and Sirtex shed more than two percent; Cochlear, Pharmaxis, Polynovo and Starpharma were down more than one percent; with Pro Medicus and Resmed down by less than one percent.

REDHILL BIOPHARMA

Redhill says it has begun a 77-patient, open-label, dose-escalation, phase Ib/II study of Yeliva in patients with refractory or relapsed multiple myeloma.

Redhill said that the study at Duke University Medical Center would enrol patients who had previously been treated with proteasome inhibitors and immune-modulatory drugs, with Prof Yubin Kang as lead investigator.

The company said that Yeliva, or ABC294640 was licenced from the Hummelstown, Pennsylvania-based Apogee Biotechnology Corp in 2015 and the study was supported by a $US2 million grant from the National Cancer Institute, to Apogee in conjunction with Duke University, with additional support from Redhill.

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

Today, Redhill said that Yeliva was a first-in-class, oral, sphingosine kinase-2 (SK2) selective inhibitor with anti-cancer and anti-inflammatory activities and by inhibiting the SK2 enzyme, Yeliva blocked the synthesis of sphingosine 1-phosphate (S1P), a lipid signalling molecule that promoted cancer growth and pathological inflammation.

Redhill medical director Dr Terry Plasse said the study followed a "pre-clinical study demonstrating that sphingosine kinase-2 is overexpressed in multiple myeloma cell lines and in human specimens and that its inhibition may fight the disease".

"This is the second phase I/II study initiated with Yeliva," Dr Plasse said.

"We expect to initiate additional clinical studies in the coming months, including studies in advanced hepatocellular carcinoma and prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy," Dr Plasse said.

"Given Yeliva's unique mechanism of action, we continue to evaluate its therapeutic potential for multiple oncology, inflammatory and gastrointestinal indications, as a single agent and in combination with other oncology drugs," Dr Plasse said.

Redhill said that the primary objectives were to assess safety and determine the maximum tolerated dose in refractory or relapsed multiple myeloma patients, with secondary objectives the assessment of anti-tumor activity and determination of the pharmaco-kinetic and pharmaco-dynamic properties of Yeliva in the patients.

The company said the phase II primary objectives were to assess the overall treatment response rate and overall survival, with secondary objectives evaluating the treatment response in patients with refractory or relapsed multiple myeloma after three cycles of treatment and evaluation of pharmaco-dynamic markers.

Redhill said that a phase I study of Yeliva in patients with advanced solid tumors at the Medical University of South Carolina met its primary and secondary endpoints, showing the drug was well-tolerated and could be safely administered to cancer patients at doses predicted to have therapeutic activity.

The company said that of 16 assessable subjects, one had a partial response with a progression-free survival of 16.9 months and six subjects had stable disease with a progression-free survival of between 3.5 and 17.6 months, and of the three patients with cholangio-carcinoma, one had a partial response and the other two had stable disease, one for more than a year and Yeliva was well-tolerated.

Redhill said that a phase I/II study of Yeliva for refractory and/or relapsed diffuse large B-cell lymphoma began at the Louisiana State University Health Sciences Center in New Orleans in June 2015 and was expected to resume this year following an administrative hold and pending a protocol amendment.

Last night on the Nasdaq, Redhill fell 21 US cents or 1.38 percent to $US15.03 ($A19.68) with 22,073 shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has regulatory approval and marketing authorization for its inhaled analgesic Penthrox in the United Arab Emirates.

Medical Developments chief executive officer John Sharman said that Penthrox had been supplied in the UAE on a named patient basis and was used in many of the major private and public hospitals as well as the major ambulance services.

Penthrox is generally used for emergency pain relief.

“All of these organisations have gone out of their way to make special purchase orders and comply with complex importation rules so they can access Penthrox,” Mr Sharman said.

Mr Sharman said that its UAE distribution partner Pharma Solutions expected the approval to “significantly open up the market and improve sales in the UAE and other regions”.

Mr Sharman said that the UAE authorisation was the first of several being pursued in the Middle East including in Jordan, Iran, Iraq and Saudi Arabia.

Medical Developments chairman David Williams said the Middle East was “a very lucrative market”.

“We have been working on regulatory approvals in this region for many years and the UAE approval is a significant breakthrough,” Mr Williams said.

“Because of the non-narcotic, fast acting characteristics of Penthrox, it is an ideal trauma analgesic for the entire region, which is non-narcotic in its approach to treating pain,” Mr Williams said.

Medical Developments climbed 52 cents or 10.2 percent to $5.60.

FACTOR THERAPEUTICS

Factor Therapeutics says it has manufactured placebo, standard-dose VF-001 and high-dose VF-001 for its US phase II venous leg ulcers clinical trial.

Factor Therapeutics said the manufacturing was a “milestone” which marked the completion of work that involved moving operations to the US and manufacturing packaged drug product in conformity with the US Food and Drug Administration requirements for a biologic drug.

The company said that drug and placebo were in the process of being released and the investigational new drug application amendments were being finalized for publication and submission to the FDA, including a significantly revised and improved clinical protocol based on feedback from its medical advisory board, which was expected to take about two weeks to complete.

Factor Therapeutics chief executive officer Nigel Johnson said that the company had completed “two years of major effort and a major push in the US the past six months”.

Factor Therapeutics was up 0.2 cents or 4.3 percent to 4.9 cents with 1.1 million shares traded.

ANTEO DIAGNOSTICS

Anteo says it has received $2,061,301 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anteo said the rebate related to research and development expenditure for the year to June 30, 2016 and the funds will be used to advance its nanochemistry coating programs.

Anteo was unchanged at 5.8 cents.

ADMEDUS

Admedus says that Federal Court legal action begun Dr Geoffrey Lane and Dr Keith Woollard relating to its Cardiocel product has been settled for an undisclosed amount.
In 2014, Admedus said that co-investors in its Cardiocel subsidiary Admedus Regen Dr Geoffrey Lane, Dr Keith Woollard and associated entities, Palkingston Pty Ltd and K V Woollard Pty Ltd issued legal proceedings against it, Admedus Australia and Admedus Regen (BD: Nov 12, 2014).
Admedus said at that time that Dr Lane, Dr Woollard, Palkingston and K V Woollard collectively owned about 20 percent of Admedus Regen, with Admedus holding about 80 percent and the proceedings would have “no material impact on ... ongoing activities”.
Today, Admedus executive chairman Wayne Paterson said he wanted “to thank the parties for resolving the proceedings” which had resulted in Admedus owning 100 percent of the regenerative technology “in full and final resolution of the proceedings and is without admission of liability of Admedus”.
Admedus said that the terms and conditions of the settlement were “confidential; however settlement will have a minimal impact on the financial position of the company”.
Admedus was up half a cent or 1.6 percent to 32.5 cents.

CSL

CSL will vote to issue chief executive officer Paul Perreault performance shares and options worth $6,636,637 and increase directors’ fees 33.3 percent to $4,000,000.
The CSL notice of motion said that shareholders would vote to issue Mr Perreault ‘performance options’ worth up to $US2,013,650, and ‘performance rights’ worth up to $US3,053,306.
The notice said that investors would vote to increase the directors’ remuneration pool from $3,000,000 a year to $4,000,000 a year.
CSL said that shareholders would also vote on the remuneration report and the election of directors Marie McDonald, Dr Megan Clark and Dr Tadataka Yamada.
The company said that Mr Perreault’s performance options would be exercisable at the 5-day volume-weighted average price to September 30, 2016.
In previous years, resolutions to issue ‘performance’ stock to Mr Perreault have been passed but the resolutions have faced opposed from up to 19.5 percent of voting shareholders (BD: Oct 16, 2013; Oct 15, 2014; Oct 15, 2015).
The meeting will be held at the Function Centre, National Tennis Centre, Melbourne Park, Batman Avenue, Melbourne on October 12, 2016 at 10am (AEDT).
CSL fell $2.33 or 2.25 percent to $101.39 with one million shares traded.

OSPREY MEDICAL

Brandon Capital says it has increased its holding in Osprey from 24,791,272 shares (12.9%) to 60,505,552 shares (23.8%).
The substantial shareholder notice, signed by directors Dr Chris Nave said that the shares were acquired in the recent $28 million placement and $1 million share purchase plan at 28 cents a share (BD: Aug 4, Sep 7, 2016).
Dr Nave said that the shares were held by Brandon Capital, the Medical Research and Commercialization Fund Pty Ltd for the MRCF Trust, BBF1 Trustco Pty Ltd for the Brandon Biosciences Fund No 1 Trust, BBF1 IIF Partnership LP, Australian Super Pty Ltd for Australian Super, and three MRCF Services entities.
Osprey was unchanged at 40 cents.

BIOXYNE, ONDEK

The Sydney-based Ondek Pty Ltd says it has sold its entire 19.9 percent holding in Bioxyne.

Last year, Ondek said it acquired 39,868,277 shares (19.9%) in Bioxyne from Fleming SG Capital for $518,288 or 1.3 cents a share (BD: May 20, 2015).

The Sydney-based Ondek was created in 2009 to develop work by Nobel prize-winning scientist Prof Barry Marshall on a Helicobacter pylori-based anti-influenza virus oral vaccine (BD: Jul 30, 2009).

In 2013, Ondek appointed former Tyrian Diagnostics chief executive officer Dr Jenny Harry as its chief executive officer (BD: Mar 18, 2013).

Today, Ondek said it sold its 39,868,277 shareholding for $677,761 or 1.7 cents a share.

Bioxyne was untraded at 2.1 cents.

Ondek is a private company.

RESAPP

FIL Limited says it has increased its substantial holding in Resapp from 32,842,028 shares (5.06%) to 39,977,684 shares (6.15%)

The Hong Kong, London and Sydney-based FIL said it bought 7,135,656 shares between July 18 and September 6, 2016, at prices ranging from 30 cents and 40 cents.

Resapp was up two cents or 5.4 percent to 39 cents with 3.8 million shares traded.

NOVOGEN

Novogen says that Kate Hill has been appointed interim company secretary replacing Lionel Mateo, effective immediately.

Novogen fell half a cent or 4.8 percent to 10 cents.