Biotech Daily

Thursday November 2, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 16%; LIVING CELL DOWN 5%**

*** DIMERIX ANALYSIS BACKS DMX200 FOR DIABETIC NEPHROPATHY**

*** FEDERAL MTP CONNECT $5m BIOMEDTECH HORIZONS PROGRAM OPEN**

*** MTP CONNECT, MTAA PARTNER FOR INDUSTRY**

*** ADMEDUS: 'NO CHANGE TO VACCINES, IMMUNOTHERAPIES FUNDING'**

*** REDHILL RESUBMITS RIZAPORT FOR MIGRAINE FDA APPLICATION**

*** FACTOR: 'ALL PHASE II VF001 LEG ULCER TRIAL SITES RECRUITING'**

*** IM MEDICAL VOTES TO BECOME BABYLON PUMP & POWER**

*** PARADIGM REQUESTS CAPITAL RAISING TRADING HALT**

*** REGAL FUNDS REDUCES TO 5% OF AVITA**

*** ALLAN GRAY REDUCES TO 6% OF PHOSPHAGENICS**

*** ACTINOGEN APPOINTS DR GEORGE MORSTYN DIRECTOR**

*** CANN MOVES HQ TO LA TROBE UNI TECH ENTERPRISE CENTRE**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Thursday November 2, 2017 with the ASX200 down 6.1 points to 5,937.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and four were untraded.

Dimerix was the best, up three cents or 16.2 percent to 21.5 cents with 1.5 million shares traded. Universal Biosensors climbed 6.15 percent; Polynovo was up 5.8 percent; Clinuvel and Opthea improved more than four percent; Oncosil was up 3.7 percent; Compumedics, Factor Therapeutics, Impedimed, Medical Developments, Mesoblast and Osprey rose more than one percent; with Cochlear, CSL and Volpara up by less than one percent.

Living Cell led the falls, down one cent or five percent to 19 cents with 1.1 million shares traded. Neuren fell four percent; LBT and Prana were down more than three percent; Admedus and Uscom shed more than two percent; Actinogen, Bionomics, Genetic Signatures, Nanosonics, Orthocell, Resmed and Sirtex lost more than one percent; with Airxpanders, Pro Medicus and Starpharma down by less than one percent.

DIMERIX

Dimerix says a sub group analysis of its phase IIa trial of DMX200 for chronic kidney disease shows that diabetic nephropathy patients responded best.

Dimerix said that 27 patients were enrolled in the trial, with 24 completing and three did not complete for reason unrelated to the treatment.

The company said that of the 24 patients completing the trial, 10 had been diagnosed with diabetic nephropathy, the most common cause of chronic kidney disease, with six diagnosed as immunoglobulin A (IgA) nephropathy and the other eight had mixed or unclear aetiologies.

Dimerix said that of the six responders, five had diabetic nephropathy and one had IgA nephropathy and all six had a 50 percent reduction in proteinuria to normal levels.

Dimerix said that the five diabetic nephropathy patients demonstrated average protein creatinine ratio reduction of 31.9 percent ($p = 0.0088$) and an average albumin creatinine ratio mean reduction of 35.6 percent ($p = 0.0063$).

The company said that that 13 of the 24 patients had more than a 30 percent reduction in proteinuria, or blood in urine, as measured by protein creatinine ratio.

Dimerix said the data would be presented in a poster entitled 'A Phase 2a trial of DMX-200: synergistic blockade of AT1R and CCR2 in patients with Chronic Kidney Disease' at the American Society of Nephrology meeting in New Orleans, today.

The poster is available at: http://dimerix.com/wp-content/uploads/ASN-2017-Poster.pdf.

Melbourne Renal Research Group director and co-principal investigator Prof David Packham said the efficacy signal among patients with type 2 diabetic nephropathy was "remarkable as it is seen on top of the maximum recommended dose of existing best therapy".

"Because of the unique study design, it is unlikely that consistent changes of this magnitude could be ascribed to a late effect of standard therapy or could have occurred spontaneously without the administration of DMX-200," Prof Packham said.

Dimerix said it was designing its phase IIb trial of DMX-200 was due to begin recruitment by April 2018 and data from the phase IIa trial was the basis for two patent applications.

Dimerix climbed three cents or 16.2 percent to 21.5 cents with 1.5 million shares traded.

FEDERAL GOVERNMENT, MTP CONNECT

MTP Connect says the Federal Government's $5 million Biomedtech Horizons program will be open for expressions of interest until December 10, 2017.

MTP Connect said the program was part of the Federal $20 billion Medical Research Future Fund and would support "innovative and collaborative health technologies that address key health challenges".

MTP Connect chief executive officer Sue MacLeman said the program would provide support to the sector, particularly for small and middle sized enterprises.

"The Biomedtech Horizons program will provide funding essential to increase the number of biotechnology and medical technology innovations that can reach the proof-of-concept stage and obtain proof-of-concept status, overcoming the key barriers in significant areas of unmet clinical need," Ms MacLeman said. "The program will also assist in increasing investment to progress through pre-clinical and clinical trials, therefore increasing the likelihood of commercialisation.".

MTP Connect said that expressions of interest would be open until December 10, 2017, followed by a targeted application process with eligible proposals that will be open until early 2018.

For more information go to: www.mtpconnect.org.au/biomedtechhorizons.

MTP CONNECT

MTP Connect says it will collaborate with the Medical Technology Association of Australia to boost the medical technologies industry.

The Federal Government-funded MTP Connect, or formally the Medical Technologies, Biotechnologies and Pharmaceuticals Industry Growth Centre, said that the Medical Technology Association represented the industry, which employed more than 19,000 highly skilled workers across 500 companies and was worth more than $10 billion.

Medical Technology Association chief executive officer Ian Burgess said the partnership would help "direct the limited resources to where they will have the greatest outcome for patients through increased clinical trials, research and development, market access and work towards overcoming unnecessary regulations".

ADMEDUS

Admedus says there has been no change to its funding strategy for its 72.2 percent owned vaccines and immunotherapies business.

On Monday, Biotech Daily reported chief executive officer Wayne Paterson saying that he had decided to stop funding the immunotherapies business (BD: Oct 30, 2017).

In an email to Biotech Daily, Mr Paterson said "I mentioned to the market at my mid-year webinar that we are seeking strategic alternatives but the cost of development had been such a drain on our balance sheet (and hence the embarrassing number of cap raises) that I stopped funding it".

"I repeated that again on several other webinars, interviews and non-deal roadshows in London and New York," Mr Paterson said.

Biotech Daily understood that email to mean that the vaccine business, formerly known as Coridon and now Admedus Vaccines led by Prof Ian Frazer, would no longer be funded by Admedus Limited.

Biotech Daily invited Mr Paterson to correct or clarify the article, but at the time of publication had received no response.

Today, Admedus told the ASX that it "notes the recent media speculation about the ongoing funding of Admedus Vaccines Pty Ltd and the Admedus Immunotherapies (AI) business run by it".

"That speculation suggests there has been a change in strategy by Admedus with respect to the ongoing funding of AI," Admedus said.

"In fact, there has been no change in the company's approach to AI to that previously disclosed to ASX," Admedus said.

"As stated in the release to ASX of Admedus' FY2017 financial results on 31 August 2017, AI has funding for the coming financial year," Admedus said.

"In that announcement, Admedus also stated that: 'The board of AI are currently undertaking a review of the potential strategic options available to them to secure the continuing development of AI's technologies in a manner that balances maximising their potential with returns for its shareholders.'," Admedus said.

"That position has not changed," the company said.

"Admedus remains the majority shareholder in Admedus Vaccines and will continue to explore options in respect of AI in order to return value to shareholders," Admedus said.

"The company also notes that AI does not contribute to the company's revenue in a material way and confirms that it is in compliance with ASX Listing Rule 3.1 (Continuous Disclosure)," Admedus said.

Admedus fell half a cent or 2.2 percent to 22.5 cents.

REDHILL BIOPHARMA

Redhill says with its Quebec, Montreal-based partner Intelgenx Corp, it has resubmitted a new drug application for Rizaport for migraine to the US Food and Drug Administration.
Redhill said Rizaport was an oral thin-film formulation of rizatriptan for the treatment of acute migraines and was a therapeutic alternative for patients who suffered from dysphagia or migraine-related nausea.
The company said that after the first submission in 2013, an FDA "complete response letter" had questions primarily related to third party chemistry, manufacturing and controls, packaging and labelling, but with no questions or deficiencies relating to Rizaport's safety and bio-equivalence data and did not require additional clinical trials.
Redhill said that if the resubmission was deemed complete and permitted a full review a Prescription Drug User Fee Act (Pdufa) date was expected to be by July 2018.
The company said Rizaport was approved in Germany and Luxembourg, with an application submitted for Spain.
Redhill said rizatriptan was "one of the most effective oral triptans, a class of molecules that constricts blood vessels in the brain to relieve swelling and other migraine symptoms".
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
On the Nasdaq, Redhill fell two US cents or 0.22 percent to $US8.90 ($A11.53) with 50,498 shares traded.

FACTOR THERAPEUTICS

Factor says all sites in its 168-patient, phase II trial of VF001 for venous leg ulcers have recovered with four new sites recruiting patients.
Last month, Factor said the randomized, double-blinded, placebo-controlled, wound treatment trial had been delayed due to slow recruitment at some sites and the impact of hurricanes on Florida, Texas and Puerto Rico trial centres (BD: Oct 5, 2017).
The company said at that time that it had lost three months due to the delays and expected to complete recruitment by July 2018.
Today, Factor said that October "saw a substantial uplift in site activity, with a total of 26 new patients entered into the screening phase and eight enrolled into the trial at the completion of the two-week standard treatment period".
The company said two Puerto Rico sites became fully operational in late October and delivered the strongest start-up screening activity of any sites in the trial to date.
Factor said all other sites had returned to previous levels of activity, improving on the summer and hurricane season which affected recruitment rates in the previous quarter.
Factor chief executive officer Dr Rosalind Wilson said October was "the strongest month … to date for patients entered into screening and this is very encouraging".
"We're especially pleased that our four new sites have been able to contribute quickly and the sites in Puerto Rico have had such a strong screening performance," Dr Wilson said.
"The progress we've made in October ensures we remain on track to meet our targeted timeframe to complete enrolment and reaffirms the importance of our active management strategy, which has seen us reconfigure our sites, invest in media and advertising and work closely with our clinicians to optimise recruitment," Dr Wilson said.
In October, the company said it expected to complete recruitment by July 2018.
In April, Factor said it expected to complete recruitment by October, last December, the company said it expected an efficacy read-out by the end of 2017 and in July 2016 said it expected results by October 2017 (BD: July 22, 25; Dec 20, 2016; Apr 7, 2017).
Factor was up 0.1 cents or two percent to 5.2 cents.

IM MEDICAL

IM Medical says its annual general meeting voted supported all resolutions including those to merge with the Perth's Babylon Pump & Power (BD: Apr 5, 2017).
IM Medical said the resolutions related to capital raisings and a change in scale and nature of its activities to acquire Babylon, a provider of resources equipment and services.
In 2015, IM said its attempt to acquire data centre service provider Syncom Australia Pty Ltd through a reverse takeover had failed (BD: Jan 18, May 22, Jul 23, 2015).
Previously, IM Medical had been attempting to commercialize cardiac testing.
IM was untraded at 0.1 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested a trading halt "to finalize arrangements around a potential capital raise".
Trading will resume on November 6, 2017 or on an earlier announcement.
Paradigm last traded at 36 cents

AVITA MEDICAL

Regal Funds Management says it has reduced its holding in Avita from 51,966,936 shares 6.71%) to 42,019,615 shares (5.43%).
The Sydney-based Regal Funds said that between October 19 and 30, 2017 it sold 9,947,321 shares for between 5.2 and 5.9 cents a share.
Avita was unchanged at 5.1 cents with 3.5 million shares traded.

PHOSPHAGENICS

Allan Gray Australia says it has reduced its holding in Phosphagenics from 94,853,127 shares (7.52%) to 87,403,902 shares (5.88%)
Allan Gray said that it bought and sold shares between March 11, 2016 and October 5, 2017 with the single largest sale of 8,549,997 shares for $245,280 or 2.9 cents a share.
Phosphagenics was unchanged at 1.5 cents.

ACTINOGEN MEDICAL

Actinogen says it has appointed former Amgen executive Dr George Morstyn as a non-executive director effective from December 1, 2017.
Actinogen said that Dr Morstyn had "extensive drug development experience" and previously was Amgen chief medical officer and head of development, where he "oversaw the marketing approval of many new products and … successful commercial launches".
The company said that Dr Morstyn worked with Prof Don Metcalf at the Walter and Eliza Hall Institute on haemopoietic colony stimulating factors and had been a director of Australian listed biotechnology companies and research organisations, including Bionomics, Chemgenex, Melbourne's Royal Women's Hospital and the Victorian Comprehensive Cancer Centre, as well as the Tokyo-listed Symbio Pharmaceuticals, the Cancer Therapeutics Co-operative Research Centre and Biomedvic.
The company said that Dr Morstyn would be granted 1,500,000 options exercisable at the greater of 10 cents or 170 percent of the five-day volume weighted average market price to the date of granting and within five years and vesting three annual tranches.
Actinogen fell 0.1 cents or 1.8 percent to 5.4 cents.

CANN GROUP

Cann says it has relocated its corporate headquarters to La Trobe University's Technology Enterprise Centre in Bundoora, Victoria.

Cann said the Technology Enterprise Centre was within La Trobe's Research and Development Park and housed innovative businesses and organisations from a variety of sectors and the relocation was part of its production and staff expansion.

La Trobe University pro vice-chancellor for industry engagement Dr Daniel Grant said attracting Cann to the Centre was an example of the University's ability "to establish high quality new business partnerships".

"Over many years we have worked to build strong connections with industry and have created and fostered many mutually beneficial relationships across government, private business and community groups," Dr Grant said.

Cann chief executive officer Peter Crock said the La Trobe Centre "provides us with a base that fits with our aim to be a growing and innovative leader in the Australian medicinal cannabis industry".

Cann said it would continue to operate separate research and development and cultivation facilities at its two undisclosed Victoria locations.

Cann climbed 3.5 cents or 1.9 percent to $1.885 with 529,014 shares traded.