Biotech Daily

Wednesday March 7, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AVITA UP 5%; IMMUTEP DOWN 8%**

*** MESOBLAST TAKES $96m LOAN**

*** PROTEOMICS DOMINICAN REPUBLIC PROMARKERD LAUNCH**

*** ADMEDUS: CANADA APPROVES CARDIOCEL, CARDIOCEL 3D, VASCUCEL**

*** VICTORIA, ST VINCENT'S LAUNCH CLINICAL TRIALS GATEWAY**

*** PRANA: 'PBT434 PREVENTS MSA NEURON, FUNCTION LOSS IN MICE'**

*** SHARP HEALTHCARE TAKES IMPEDIMED SOZO, L-DEX**

*** ADHERIUM: 'TRIAL SHOWS 81% ASTHMA ADHERENCE'**

*** IMMURON REQUESTS 'NASH TRIAL RESULTS' TRADING HALT**

*** IMMURON CORRECTS NASDAQ CODE, 'FALSE, MISLEADING NEWS'**

*** CORRECTION: NOXOPHARM**

*** MICHAEL ABOLAKIAN, HISHENK TAKE 11.2% OF KAZIA**

*** HARVEST LANE TAKES 5.25% OF RHS (REPRODUCTIVE HEALTH)**

*** ALLEGRA APPOINTS DR NICHOLAS HARTNELL DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.01 percent on Wednesday March 7, 2018 with the ASX200 down 60.4 points to 5,902.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Avita was the best, up 0.3 cents or 5.3 percent to six cents with 464,721 shares traded. Admedus and Mesoblast improved four percent or more; Acrux, Dimerix and Polynovo were up more than three percent; Optiscan rose 2.5 percent; Ellex and Pharmaxis were up more than one percent; with Clinuvel and Viralytics up by less than one percent.

Yesterday's 8.7 percent best, Immutep, led the falls, down 0.2 cents or eight percent to 2.3 cents with 4.97 million shares traded. Osprey shed 6.9 percent; Orthocell lost five percent; Bionomics and Neuren fell more than four percent; Nanosonics, Oncosil and Uscom were down more than three percent; Cochlear, Factor Therapeutics, Opthea and Volpara shed more than two percent; with CSL, Resmed, Reva, Starpharma and Telix down one percent or more.

MESOBLAST

Mesoblast says it has a $US75 million ($A96.1 million) “non-dilutive, four-year credit facility” with the Palo Alto, California based Hercules Capital at 9.45 percent per annum.
Mesoblast said it drew the first tranche of $US35 million ($A44.8 million) on closing and that an additional $US15 million could be drawn by the end of 2018, with a further $US25 million available to be drawn by October 2019, pending milestones.
The company said interest on the facility would accrue at 9.45 percent per annum, with the interest only period lasting up to 30 months, pending conditions.
Mesoblast chief executive Prof Silviu Itescu said the credit facility would enable the company “to progress our commercial plans for MSC-100-IV as it moves towards filing for regulatory approval in the United States for acute graft versus host disease”.
“A stronger balance sheet will allow Mesoblast to focus on further business opportunities involving all of its tier 1 product candidates,” Prof Itescu said.
Mesoblast was up nine cents or 4.95 percent to $1.91 with 3.9 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has formally launched its Promarkerd predictive diagnostic for diabetic kidney disease in the Dominican Republic.
Proteomics said the diagnostic was launched by Puerto Rico-based Omics Global Solutions, through its Dominican Republic distributor Macrotech Farmacéutica, which was “the exclusive provider of dialysis services in the country”.
Last year, the company said Promarkerd would be launched in February but Proteomics managing-director Dr Richard Lipscombe told Biotech Daily said that the formal paperwork took longer than expected (BD: Nov 27. 2017).
Dr Lipscombe said the world was “recognizing the growing burden of diabetes and the importance of kidney health … and we see Promarkerd as transforming the diagnosis and treatment of diabetic kidney disease and saving healthcare systems … millions of dollars”.
“The test is being provided using the published mass spectrometry technology platform, known as a laboratory developed test and the company expects to conclude its next licencing deal for this version of Promarkerd with a certified laboratory within weeks,” Dr Lipscombe said.
Dr Lipscombe said the company was finalizing development of the in-vitro diagnostic immunoassay version of Promarkerd, for clinical laboratories.
Proteomics said the Promarkerd test had predicted 86 percent of previously disease-free patients who went on to develop chronic kidney disease within four years.
Proteomics was unchanged at 23.5 cents.

ADMEDUS

Admedus says Canada is the second jurisdiction to approve its Adapt bovine patch products, Cardiocel, Cardiocel 3D and Vascucel.
Admedus said Cardiocel 3D was launched in the US on February 1, 2018 and was a “disruptive technology in the high-complexity congenital defect repair space”.
Admedus said the product’s pre-shaped curve provided an arch reconstruction product that did not trigger an immune response and was resistant to calcification.
Admedus chief executive officer Wayne Paterson said the approval was a “valuable opportunity to move up the value chain and increase our presence and market share in North America”.
Admedus was up one cent or four percent to 26 cents.

VICTORIA GOVERNMENT, ST VINCENT'S HOSPITAL

The Victoria Government says the launch of the St Vincent's Hospital-developed Clinical Trials Gateway will strengthen the State "as a global destination for clinical trials".

A media release from the Victoria Minister for Innovation and the Digital Economy Philip Dalidakis said the Gateway, developed by Melbourne's St Vincent's Hospital would make it easier for companies to access service providers, trial-ready infrastructure and talent, providing "a single point of entry for international companies to connect with Victorian clinical trial sites, contract research organisations and professional services".

The Government said the Gateway would "help local companies, particularly start-ups and small to medium enterprizes, find the support and services they need to grow".

The media release said that global health care spending was projected to grow by more than four percent a year, with about 1,000 new clinical trials in Australia each year and more than a third in Victoria.

"More clinical trials in Victoria means greater access to cutting edge medications and a growing health sector that creates more local jobs," Mr Dalidakis said.

The portal is at: https://victrials.com.au/

PRANA BIOTECHNOLOGY

Prana says mouse data shows further evidence for PBT434 to prevent the loss of neurons and improved function for multiple system atrophy (MSA).

Prana said the pre-clinical data was presented in a poster at the International Multiple System Atrophy Conference held in New York on March 1 and 2, 2018.

The company said that multiple system atrophy was "a devastating neurological disease with no established treatments and is one of the potential indications for PBT434".

Prana said that PBT434 was "the first of a new generation of small molecules from the quinazolinone class of drugs that was specifically designed to block the accumulation and aggregation of alpha-synuclein, an abundant brain protein widely believed to be involved in the pathogenesis of Parkinson's disease and related disorders.

The company said that prior non-clinical characterization of PBT434, including in-vitro and animal models of Parkinson's disease, was published last year in Acta Neuropathologica Communications and an abstract of the research was available at: https://actaneurocomms.biomedcentral.com/articles/10.1186/s40478-017-0456-2.

Today, the company said that the new experimental data showed that PBT434 prevented alpha-synuclein accumulation, preserved neurons and decreased the number of glial cell inclusions in the brains of treated animals.

Prana said that glial cell inclusions were the key pathological finding in multiple system atrophy and contained abundant aggregated alpha-synuclein associated with neurodegeneration.

The company said that "these benefits led to improved motor function in treated animals".

Prana said that alpha-synuclein was of great interest because aggregated forms of the protein were considered a pathological hallmark of Parkinsonian conditions and were a recognised therapeutic target by basic and clinical neuroscientists.

Prana chief medical officer and head of clinical development Dr David Stamler said the data was "robust and [indicated] that PBT434 has excellent potential to treat this progressive neurodegenerative disease".

"We expect to begin dosing in healthy volunteers mid-year and are actively planning our first patient study", Dr Stamler said.

Prana was untraded at 5.4 cents.

IMPEDIMED

Impedimed says it that the San Diego, California-based Sharp Healthcare will use its Sozo body composition diagnostic with its L-Dex lymphoedema diagnostic.

Impedimed said the multi-year agreement with Sharp would allow multiple Sozo systems to be used to establish best practices and calculate the economic impact of Sozo.

The company said that the agreement allowed for the expansion of the program which included the L-Dex assessment for post-breast cancer lymphoedema, to all cancer patients within the Sharp system.

Impedimed said that Sharp was a not-for-profit, regional health care system that included four acute-care hospitals, three specialty hospitals, two affiliated medical groups and a health plan.

The company said that installation and training had been completed for the first four sites.

Sharp head of oncology Nancy Harris said that “as one of the first integrated health systems to use Sozo, Sharp is excited to bring this innovative technology for measuring tissue composition to cancer care across diverse care settings and to all types of cancer”.

“The opportunity to demonstrate simultaneous improvements in patient experience, care management and a reduction in the cost of care is expected to go well beyond the early detection and management of lymphedema,” Ms Harris said.

Impedimed was unchanged at 77 cents.

ADHERIUM

Adherium says a 40-patient, randomized trial shows physicians implementing an Asthma Adherence Pathway with its Smartinhaler device achieved 81 percent adherence.

Adherium said the Asthma Adherence Pathway was successful in promoting adherence to the recommended use of a long-acting beta agonist and an inhaled corticosteroid.

The company said the 40-patient study examined how objective monitoring, identification of barriers, delivery of barrier-specific adherence strategies could promote adherence to asthma treatments for patients with “poor asthma control”.

Adherium was up 0.4 cents or 4.2 percent to 10 cents.

IMMURON

Immuron has requested a trading halt pending an announcement “in respect to the release of its phase II non-alcoholic steato-hepatitis clinical trial results”.

Trading will resume on March 9, 2018 or on an earlier announcement.

Immuron last traded at 28.5 cents.

IMMURON

Immuron says an incorrect Nasdaq code led to a “false and misleading” newswire statement saying that Immuron had a trading halt “due to regulatory concern”.

Immuron said the trading halt was requested due to the pending release of its phase II non-alcoholic steato-hepatitis clinical trial results.

The company said it appeared that the Nasdaq assigned an inaccurate trading halt reason code of “H11 Halt Regulatory Concern”, instead of the correct “T1 Halt - News Pending - Trading is halted pending the release of material news”.

Immuron said it was not aware of any regulatory issues at this time and was “concerned about the inaccurate news being reported to the market and by this statement makes an immediate correction”.

CORRECTION: NOXOPHARM

Last night's headline incorrectly said Noxopharm: '12 of 14 NOX66 patients response' when there was one partial response and 11 patients with stable disease.
The original headline said Noxopharm: '12 of 14 NOX66 patients stable disease, partial response' but was truncated for space, changing the meaning (BD: Mar 6, 2018).
The report was correct that of 15 patients with evaluable disease, one withdrew due to carboplatin toxicity, one had a partial response, 11 had stable disease and two showed disease progression.
Noxopharm fell 14 cents or 10.5 percent to $1.195.

KAZIA THERAPEUTICS

Michael Abolakian says that through Hishenk Pty Ltd he has increased his substantial holding in Kazia from 4,583,111 (9.5%) to 5,437,787 (11.2%).
The Artarmon, Sydney-based Mr Abolakian said the shares were held by Hishenk Pty Ltd and Hishenk Super Fund, which acquired 855,676 shares for $528,739 or 61.8 cents a share, between January 15 and 29, 2018.
Kazia fell 1.5 cents or two percent to 73 cents.

RHS (FORMERLY REPRODUCTIVE HEALTH SCIENCE)

Harvest Lane Asset Management says it has become a substantial shareholder in RHS with the acquisition of 4,724,623 shares (5.25%).
The Sydney-based Harvest Lane said that it acquired the shares between February 26 and March 6, 2018 with the single largest purchase 1,134,381 shares for $305,257 or 26.9 cents a share
Last week, RHS said the Waltham, Massachusetts Perkinelmer Inc would acquire it for $25,177,735 or 28 cents a share (BD: Feb 26, 2018).
RHS was up half a cent or 1.9 percent to 27 cents with 2.1 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it has appointed consultant advisor and orthopaedic surgeon Dr Nicholas Hartnell as a non-executive director.
Allegra said that Dr Hartnell had focused on orthopaedic training and specialization and had experience in all facets of orthopaedic care.
The company said that Dr Hartnell established a practice in Bowral, New South Wales and had expanded to the Goulburn, Camden and Campbelltown areas of the state.
Allegra said that Dr Hartnell held a Bachelor of Medicine and Bachelor of Surgery from the University of Sydney.
Allegra was untraded at 14 cents.