Biotech Daily

Monday June 26, 2017

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: NEUREN UP 6%, COMPUMEDICS DOWN 10%**

*** AUSTRALIAN ETHICAL BACKS ANTISENSE ATL1102 TRIAL FOR DMD**

*** PSIVIDA APPLIES FOR EU DURASERT UVEITIS APPROVAL**

*** VIRALYTICS: 'RAISED TRAIL BACKS CAVATAK FOR BLADDER CANCER'**

*** FLINDERS UNI, SAHMRI RESEARCH GLUCOSE, GLP-1, DIABETES**

*** MACH7 SIGNS $1.8m RADIOLOGY ASSOCIATES CONTRACT**

*** FDA APPROVES MICRO-X NANO-X-RAY**

*** MEDIBIO: RESEARCH SUPPORTS HEART RATE FOR PTSD DIAGNOSES**

*** NEUROTECH RENEWS ESE PAZARLAMA MENTE AUTISM CONTRACT**

*** JM FINANCIAL TAKES 7% OF MACH7**

*** PHYLOGICA CEO STEPHANIE UNWIN $500k, CSO DR HAYES $550k**

MARKET REPORT

The Australian stock market edged up 0.08 percent on Monday June 26, 2017 with the ASX200 up 4.3 points to 5,720.2 points. Nine of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and one was untraded.

Neuren was the best, up 0.4 cents or 6.1 percent to seven cents with 2.5 million shares traded. Uscom climbed five percent; Living Cell was up 4.8 percent; Ellex, Oncosil and Psivida rose two percent or more; Actinogen and Cyclopharm were up more than one percent; with Medical Developments and Resmed up by less than one percent.

Last week's best, Compumedics, led the falls, retreating seven cents or 10 percent to 62.5 cents with 310,343 shares traded. Benitec lost 7.7 percent; ITL and LBT were down more than six percent; Mesoblast was down 5.2 percent; Atcor, Polynovo, Prana and Starpharma fell four percent or more; Cellmid, Impedimed, Osprey and Prima were down more than three percent; Factor Therapeutics and Opthea shed more than two percent; Avita, Bionomics, Pro Medicus and Universal Biosensors were down more than one percent; with Airxpanders, Cochlear, CSL, Nanosonics and Sirtex down by less than one percent.

ANTISENSE THERAPEUTICS, AUSTRALIAN ETHICAL INVESTMENT

Antisense says Australian Ethical will provide $775,485 to fund a phase II trial of ATL1102 for Duchenne muscular dystrophy at Melbourne's Royal Children's Hospital.

Antisense previously said that ATL1102 had shown efficacy for multiple sclerosis as well as potential as a stem cell mobilization agent in stem cell transplantation, and separately, today, Antisense said it had applied for a 195-patient phase IIb trial of ATL-1102 for both remitting relapsing multiple sclerosis and secondary progressive multiple sclerosis (BD: Jun 30, 2008; Mar 24, 2010; Sep 20, 2011; May 24, 2017).

The company said it would place 24,233,911 shares at 3.2 cents each to Australian Ethical to raise $775,485, the maximum number under the 15 percent placement capacity limit, pending hospital approval for the trial by September 30, 2017.

Antisense said that it would undertake a rights issue at the same price to raise up to $2,000,000, with Australian Ethical intending to take up its entitlement and acquire shortfall shares to increase its holding to 19.99 percent.

Antisense managing director Mark Diamond told Biotech Daily that the funds raised, along with cash on hand, would fund the trial, the company's other programs and be used for working capital.

Mr Diamond said the trial of ATL1102 for Duchenne muscular dystrophy (DMD) was assisted by the pre-clinical and clinical experience with ATL1102's development in multiple sclerosis and the phase II trial would assess the drug's effects on the inflammation associated with the rare and incurable muscle wasting disease in boys.

Mr Diamond said that Duchenne muscular dystrophy was "a rare disease with a high unmet medical need" affecting about one in 3,500 to 5,000 males and was caused by a mutation in the muscle dystrophin gene leading to severe progressive muscle loss and premature death.

"ATL1102 is expected to benefit materially from development incentives, including orphan drug designation, that are provided to support rare disease drug development," Mr Diamond said.

Antisense said that one challenge in the management of Duchenne muscular dystrophy patients was to reduce the inflammation that exacerbated the muscle fibre damage.

The company said that cortico-steroids were the only approved treatment for muscle inflammation, but they did not sufficiently suppress muscle inflammation, were not well tolerated and had serious side effects including adversely affecting growth rate.

Antisense said that clinical research on Duchenne muscular dystrophy patients had shown that patients who had a greater number of T immune cells in the blood that express high levels of CD49d, known as the CD49dhiT-cell, were associated with both more severe and rapid disease progression, with an increase in the number of CD49dhi T-cells associated with reduced walking capacity, but cortico-steroids did not reduce CD49dhi T-cells.

The company said that ATL1102 had been shown to block CD49d, or VLA-4, expression on lymphocytes, including T-cells, reduce immune cell numbers, including T-cells, and to be effective in reducing inflammatory brain lesions in multiple sclerosis patients after eight weeks of dosing.

Antisense said that an advisory board had been appointed to be chaired by former Sarepta Therapeutics chair and Antisense director William Goolsbee, with eteplirsen inventors Prof Steve Wilton, Prof Sue Fletcher, as well as the Paris-based Sorbonne University's Dr Gillian Butler-Browne.

The company said that Sarepta was the marketer of the antisense drug eteplirsen the first and only drug approved for the restoration of muscle dystrophin.

The company said XEC Partners had been appointed lead manager for the raising.

Antisense was up 0.1 cents or three percent to 3.4 cents.

PSIVIDA

Psivida says it has filed a marketing authorization application to the European Medicines Agency for its Durasert three-year treatment for posterior segment uveitis.

Earlier this month, Psivida said its 153-patient, second phase III trial of Durasert for posterior segment uveitis achieved its primary endpoint of prevention of recurrence at six months, with the Durasert three-year insert showing “a significant reduction in the recurrence of posterior segment uveitis through six months” (BD: Jun 14, 2017).

Last month, the company said its first 129-patient, phase III trial of Medidur for posterior uveitis met its primary endpoint of prevention of recurrence of disease with a high statistical significance at 12 months follow-up (BD: Jul 28, 2016; May 9, 2017).

Psivida previously referred to the technology as Medidur.

Today, Psivida chief executive officer Nancy Lurker said that the European submission was “another significant milestone delivered on time by the Psivida team”.

“Durasert three-year uveitis treatment … has now proven to be highly effective in reducing the recurrence of uveitis in two phase III studies,” Ms Lurker said.

“Both studies illustrate the benefits Durasert brings to those patients suffering from this disease, which is a leading cause of blindness,” Mr Lurker said.

Ms Lurker said the company was in discussions with potential partners to licence Durasert in the EU.

Psivida was up five cents or two percent to $2.55.

VIRALYTICS

Viralytics says raised levels of TNF-related apoptosis-inducing ligand were detected in urine samples of 10 of 12 patients in its phase I/II Cavatak for bladder cancer trial.

Viralytics said that the notable levels of tumor necrosis factor (TNF) related apoptosis-inducing ligand (Trail) in the Cavatak in non-muscular bladder cancer (Canon) study suggested that intra-vesically-delivered Cavatak induced secretion of Trail.

The company said data was presented in a poster entitled ‘Phase I/II Canon study: Oncolytic immunotherapy for Non-Muscle Invasive Bladder Cancer (NMIBC) using Intravesical Coxsackievirus A21’ at the European Association for Cancer Research (EACR), the American Association for Cancer Research (AACR), and the Italian Cancer Society (SIC) special conference in Florence, Italy from June 24 to 27, 2017.

Viralytics said the Canon trial evaluated intra-vesical, or directly injected into the bladder, Cavatak in 16 patients with non-muscle invasive bladder cancer to evaluate the safety and tolerability of Cavatak, first as monotherapy, and then in combination with sub-therapeutic doses of mitomycin C, in patients scheduled for trans-urethral resection for clinical treatment and disease staging.

Viralytics principal investigator Prof Hardev Pandha said that Trail was “a cytokine that acts in inducing apoptotic cell death primarily in tumor cells”.

“The increasing levels of Trail appear in general to correlate with the kinetics of increasing Cavatak replication,” Prof Pandha said. “This finding is potentially exciting, as detection of elevated levels of functional Trail in urine are believed to be one of the predictors of a beneficial immune response to bacillus Calmette–Guerin (BCG) therapy mediating potential clinical benefit and our preliminary data suggest intra-vesicular administration of Cavatak similarly induces secretion of Trail in the urine,” Prof Pandha said.

Viralytics managing director Dr Malcolm McColl said the data supported observations that Cavatak replication “up-regulates target molecules for combination strategies with immune-checkpoint blockade therapies in [non-muscular bladder cancer] patients”.

Viralytics was unchanged at 94 cents.

FLINDERS UNIVERSITY, SA HEALTH AND MEDICAL RESEARCH INSTITUTE

Flinders University says its research has shown how glucagon-like peptide 1 (GLP-1) is released from the human gut in response to the food we eat.

A media release from Flinders University and the South Australian Health and Medical Research Institute said the research focused on the secretion of GLP-1 from the lining of the gut and when it was released after a meal GLP-1 triggered insulin secretion from the pancreas, signalling fullness, to limit further food intake.

Flinders University said that the hormone has been the focus of significant new drug development for type 2 diabetes and obesity.

The research, entitled 'Mechanisms Controlling Glucose-Induced GLP-1 Secretion in Human Small Intestine' was published in the journal Diabetes and an abstract is at: http://diabetes.diabetesjournals.org/content/early/2017/04/04/db17-0058.

Flinders University lead researcher Prof Damien Keating said that "we knew that GLP-1 was important in diabetes and obesity treatment, [but] we still knew little about how the release of this hormone was controlled in humans".

"We have now recorded how the arrival of glucose in the upper intestine triggers the release of this important hormone, which has been a chief therapeutic target for a number of diabetes and new anti-obesity drugs," Prof Keating said.

"By learning more about the gut's mechanism to process glucose and produce this hormone, we can begin to develop potential new therapies which may be much more targeted and effective," Prof Keating said.

Co-author, the University of Adelaide's Prof Richard Young said the findings showed that the secretion of GLP-1 in humans was triggered by the precise movement of glucose across the gut and into the blood.

"This has revealed new ways that we may be able to control GLP-1 release and in turn further improve the outlook for people with obesity and/or type 2 diabetes," Prof Young said.

MACH7 TECHNOLOGIES

Mach7 says it has a $1.8 million, three-year software licence agreement with the Little Rock Arkansas-based Radiology Associates PA for its enterprise imaging products.

Mach7 said that its Enterprise Imaging Platform would provide image distribution, diagnostic reading and enable patient electronic medical records.

The company said that Radiology Associates employed 35 radiologists performing more than 750,000 examinations a year and it would earn recurring fees for at least three years.

Mach7 was up eight cents or 66.7 percent to 20 cents with 1.3 million shares traded.

MICRO-X

Micro-X says the US Food and Drug Administration has approved its DRX Revolution Nano carbon nano-tube-powered x-ray technology.

Micro-X said the FDA determined the substantial equivalence of the DRX Revolution Nano to the predicate device and it could be marketed in the US.

The company said the decision was "an historic first regulatory approval for a product and marks the culmination of an intensive development program by Micro-X in close collaboration with distributor Carestream Health.

Micro-X managing-director Peter Rowland said that the company was "pleased and proud to have achieved this highly significant milestone".

Micro-X was up 4.5 cents or 10.6 percent to 47 cents.

MEDIBIO

Medibio says that research at the Atlanta, Georgia-based Emory University shows its heart rate technology can accurately diagnose post-traumatic stress disorder.
Medibio said that the heart rate algorithm technology was developed at Emory University and licenced to the company.
The company said the research entitled 'Classification of post-traumatic stress disorder from heart rate variability metrics with heart rate-based window segmentation' was published in the journal Physiological Measurement.
An article abstract entitled 'Heart rate-based window segmentation improves accuracy of classifying posttraumatic stress disorder using heart rate variability measures' is available at: http://iopscience.iop.org/article/10.1088/1361-6579/aa6e9c.
Medibio said that Emory researchers Dr Gari Clifford and Dr Amit Shah achieved an accuracy of 80 percent for objectively diagnosing subjects with post-traumatic stress disorder (PTSD) and differentiating them from those without PTSD using 24-hour heart rate data and machine learning algorithms.
The company quoted the researchers saying: "Our results suggest the potential for a non-invasive tool to objectively track PTSD status".
The published abstract said the results "demonstrate our segmentation approach improves the classification of PTSD from [heart rate] and [heart rate variability] measures and suggest the potential for tracking PTSD illness severity via objective physiological monitoring".
"Future studies should prospectively evaluate if classifier output changes significantly with worsening or effective treatment of PTSD," the abstract said.
Medibio said the Emory collaboration aimed at expanding indications beyond depression to post-traumatic stress disorder and the company had the rights to commercialize discoveries based on the PTSD technology developed by Dr Clifford and Dr Shah.
The company said that the research was conducted in collaboration with the Department of Veterans Affairs, using its twins database.
Medibio said that more than 22 US veterans committed suicide each day due to PTSD and mental illness and PTSD had a prevalence of 3.5 percent in the general US population and up to 30 percent among returning US service personnel.
Medibio was up 2.5 cents or 7.5 percent to 36 cents.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says distributor ESE Pazarlama has signed a new three year agreement to distribute Mente Autism in Turkey.
Neurotech said that ESE Pazarlama, previously known as MBM Medikal, had bought 50 Mente 2 devices, the predecessor to its Mente Autism and was the first partner to renew its contract.
Neurotech fell one cent or 3.7 percent to 26 cents.

MACH7 TECHNOLOGIES

JM Financial Group says it has become a substantial shareholder in Mach7 with the acquisition of 7,970,368 shares (6.74%).
The Melbourne-based JM Financial said it held the shares with No Plan B Pty Ltd, buying and selling shares between March 3 and June 16, 2017 with the largest purchase 3,903,795 shares for $428,744 or 10.99 cents a share.

PHYLOGICA

Phylogica says chief executive officer Stephanie Unwin will start on $500,000 a year and chief scientific officer Dr Robert Hayes will be paid a base rate of $550,000 a year.

Last week, Phylogica said it had raised $5 million and appointed chair Stephanie Unwin as its chief executive officer with Dr Robert Hayes appointed as chief scientific officer (BD: Jun 20, 2017).

Phylogica said that Australian Land Pty Ltd invested $5 million at four cents a share which would be used for the pre-clinical development of Phylomer lead candidates.

The company said that Ms Unwin's base salary would be $500,000 a year, including superannuation and director fees.

Phylogica said that should the share price improve by 150 percent in 12 months, Ms Unwin would be entitled to 40 percent of her base salary as a bonus and if it improved by 200 percent, she would be entitled to 80 percent of her base salary as a bonus, with a sliding scale between the two targets.

The company said that the share price would be the 30-day volume-weighted average price on the date of the agreement, June 17, 2017, with Phylogica trading at prices between 3.9 cents and 4.6 cents in the 30 day period.

Phylogica said the same bonus rate would apply in the second year determined on the 30-day volume-weighted average price to the June 17, 2018.

The company said that 10,000,000 options exercisable at 50 percent above the 3.9 cents closing price on June 16, 2017, or 5.85 cents, vesting in two equal tranches 12 months and 24 months from the date of issue and expiring on June 30, 2019.

Phylogica said that the second year base share price was intended to be no less than five cents and no more than 10 cent.

The company said that in each 12 month period of the two year term it could pay Ms Unwin up to 20 percent of the bonus.

Phylogica said that Dr Hayes would receive a base salary of $550,000 in his first year, with $150,000 paid up-front and an additional $50,000 reimbursement for medical health care and $600,000 in his second year, including superannuation and director fees.

The company said that Dr Hayes would entitled to $300,000 including superannuation as a performance bonus for agreed scientific and corporate milestones to be determined within one month of the agreement.

Phylogica said that Dr Hayes would be granted 10,000,000 incentive option under the same terms as Ms Unwin's options, or as an alternative, it could issue 10,000,000 shares under a loan funded share scheme.

Phylogica was untraded at 4.2 cents.