

Biotech Daily

Monday April 29, 2019

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: OPTISCAN UP 11%; PRESCIENT DOWN 6%
- * MCRI TRIALS MARIJUANA FOR BEHAVIOR PROBLEMS
- * FEDERAL \$5m FOR PAINCHEK ROLL-OUT
- * POLYNOVO APPOINTS POLYMED NOVOSORB DISTRIBUTOR
- * RESPIRI TO START WHEEZO CLINICAL STUDY
- * SOMNOMED 'HAS TWO QUARTERS CASH'
- * ADMEDUS HAS LESS THAN ONE QUARTER CASH
- * DR CHIPLIN, DR DUNTON REPLACE REGENEUS DR ASTON, JOHN MARTIN

MARKET REPORT

The Australian stock market fell 0.41 percent on Monday April 29, 2019, with the ASX200 down 26.1 points to 6,359.5 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and six were untraded. All three Big Caps were up.

Optiscan was the best, up 0.4 cents or 11.1 percent to four cents, with 862,212 shares traded, followed by Antisense up 10.9 percent to 5.1 cents with 4.5 million shares traded.

Volpara climbed 8.1 percent; LBT was up 6.7 percent; Clinuvel, Impedimed, Imugene, Neuren and Polynovo improved more than five percent; Immutep was up 3.7 percent; Mesoblast and Nanosonics rose more than two percent; Osprey and Resmed were up more than one percent; with Cochlear, CSL, Cynata and Starpharma up by less than one percent.

Prescient led the falls, down 0.3 cents or 6.25 percent to 4.5 cents, with 1.5 million shares traded.

Actinogen, Dimerix and Kazia lost more than three percent; Medical Developments and Paradigm shed more than two percent; Avita, Ellex, Pro Medicus and Telix were down more than one percent; with Genetic Signatures and Opthea down by less than one percent.

MURDOCH CHILDREN'S RESEARCH INSTITUTE

The Murdoch Children's Research Institute says a 10-patient pilot trial will investigate medical marijuana for severe behavior problems in intellectually disabled children. MCRI professor of paediatrics Prof Daryl Efron said the first pilot study was not testing the effectiveness of medicinal cannabis, but was a placebo-controlled, small-scale, preliminary study exploring the practicalities, feasibility, time and cost of a large-scale trial. The Institute said the trial would use the Nanaimo, British Columbia-based Tilray's C100 oral solution.

Prof Efron said the 10 participants, aged eight to 16 years would be divided into placebo and control groups.

The MCRI said Prof Efron would apply to the National Health Medical Research Council for funding for a larger trial into the effectiveness of medicinal cannabis.

Prof Efron said more than 50,000 Australian children had an intellectual disability and a percentage suffered dangerous behavioral problems, including physical aggression and self-harm.

"The medications most often prescribed for these children are stimulants, anti-depressants and anti-psychotics, which all carry a risk of serious side-effects," Prof Efron said.

"There is little research into new drugs to help these children, but medicinal cannabis has been shown to be effective to treat other medical conditions, including some severe epilepsies in children, and chemotherapy side effects and multiple sclerosis in adults," Prof Efron said.

Prof Efron said he heard anecdotal evidence from parents that their children were "less physically aggressive and did not self-harm after taking unregulated medicinal cannabis but there had never been a medical, peer-reviewed trial investigating this claim".

"As a paediatrician, parents often ask me if medicinal cannabis would help their children, but I am unable to advise on the effectiveness of medicinal cannabis for children with severe behavioral problems, as there has been no research in the field," Prof Efron said. "We hope to fill that void with some quality research," Prof Efron said.

The Institute said the cannabis plant produced between 80 and 100 cannabinoid chemicals, the two main cannabinoids with therapeutic benefits were tetrahydrocannabinol (THC) which had strong psychoactive effects and cannabidiol (CBD) which had no psychoactive effects and CBD was being used in the trial.

PAINCHEK

Painchek says the Federal Government has provided a \$5 million grant to support the rollout of its pain recognition computer application.

Painchek said the grant through the Federal Medical Research Future Fund would allow it to licence the application to more than 1,000 residential aged care providers and their 100,000 residents living for dementia for one year.

The company said the application software automatically detected pain through artificial intelligence and facial recognition technology.

Painchek chief executive officer Philip Daffas said the investment would "trigger widespread and long-term use of the Painchek [application]".

"From a business perspective we have been focused on how best to facilitate national uptake," Mr Daffas said.

"We have been making good progress by approaching aged care providers individually but this takes the implementation to a whole new level in double-quick time," Mr Daffas said.

Painchek was untraded at 3.4 cents.

POLYNOVO

Polynovo says it has appointed Polymedics Innovations as its Novosorb wound treatment distributor for Germany, Austria, Switzerland and Luxembourg.

Polynovo said it expected Conformité Européenne (CE) regulatory clearance for Novosorb biodegradable temporizing matrix (BTM) "shortly" and the appointment of the Denkendorf, near Stuttgart, Germany-based Polymed would "enable immediate market entry" for Novosorb BTM in the four countries.

The company said Polymed was the manufacturer of Suprathel, a synthetic topical cover for partial thickness burns and donor sites.

Polynovo said Polymed had a direct sales force in the four countries with sales in the majority of burn units.

The company said Suprathel was not a competitor to Novosorb BTM and was often used as a temporary cover before Novosorb BTM was applied.

Polynovo said that "with their established channel to market and surgeon relationships [it sees Polymed] as an innovative, dynamic partner that can facilitate timely market entry". Polynovo chief executive officer Paul Brennan said the partnership "should bear fruit quickly in a pivotal European market for Novosorb BTM".

"We have been in discussion with [Polymed] for some time and we are confident we will be very successful in the ... region," Mr Brennan said.

Polymed chief operating officer Christian Planck said the company was "excited to be able to offer the BTM dermal skin substitute to our customers".

"BTM is a perfectly complementary technology to our synthetic epidermal skin substitute Suprathel because our more than 250 customers have been looking for a cost effective, easy-to-use dermal wound matrix for a long time," Mr Planck said.

Polynovo was up five cents or 5.2 percent to \$1.005 with 6.3 million shares traded.

RESPIRI

Respiri says it is preparing for the first clinical study of its Wheezo diagnostic to detect asthma and chronic obstructive pulmonary disease wheeze.

Respiri said did not disclose the number of patients, but said the study would be a collaboration with Melbourne's Eastern Health at Box Hill Hospital and Swinburne University, recruiting patients with asthma or chronic obstructive pulmonary disease (COPD) causing wheezing.

The company said the successful launch of its Wheezo depended on the clinical acceptance of Respiri's technology.

Respiri said the study intended to compare and correlate Wheezo's acoustic respiratory monitoring of wheeze severity in patients with clinical assessment of wheeze severity. The company said that patients admitted to hospital with an exacerbation of airway

disease would have Wheezo held to their trachea in their throats and their breath sounds recorded to return a wheeze rate calculated over 30 second of recording.

The company said the study was expected to take six weeks.

Respiri has been attempting to commercialize its wheeze test for asthma since 2006, saying it would be available in Europe and the US in February 2007 (BD: Nov 24, 2006). In 2015, the then Isonea said it had lost its fourth chief executive officer in 12 months and later said one of the issues with its asthma diagnostic was that it did not detect breath sounds (BD: Jan 23, Aug 6, 2015).

The company changed its name to Respiri at the end of 2015.

Respiri was unchanged at 9.7 cents.

SOMNOMED

Somnomed says that despite an estimated cash burn for the coming three months to June 30, 2019 of \$17,300,000 it will maintain a positive cash balance.

The company's Appendix 4C for the three months to March 31 said it had receipts from customers of \$15,889,000, a cash burn for the three months of \$2,711,000, cash and cash equivalents of \$7,063,000 at March 31, along with a credit standby facility of \$3 million. Somnomed chief executive officer Neil Verdal-Austin told Biotech Daily that he expected to have "much higher revenue in the fourth quarter, allowing us to keep the current balance".

Mr Verdal-Austin said that in the longer-term closure of the US-based Renew Sleep Solutions would reduce expenditure.

Somnomed was untraded at \$1.85.

ADMEDUS

Admedus says it had receipts of \$5,973,000 for the three months to March 31, 2019, cash of \$4,626,000 and an expected three months burn to June 30 of \$12,591,000.

In an Appendix 4C filed after the market closed on Friday April 26, Admedus said it had a cash burn of \$6,351,000 to March 31, comprising \$788,000 on research and development, \$6,948,000 on staff costs, \$2,380,000 on administration and corporate costs and \$2,014,000 on product manufacturing and operating costs.

Combining the revenue for the quarter to March 31, with cash and cash equivalents implies \$10,599,000 compared to projected spend of \$12,591,000 for the coming quarter. Earlier this month, the company said it had an agreement to sell Admedus Vaccines, formerly Coridon, to Hong Kong's Star Bright and Constellation but last week said the sale had been terminated and it remained suspended for funding (BD: Apr 10, 23, 2019). Last year, Admedus said the Hong Kong-based Star Bright Holding intended to take 60 percent of Admedus Vaccines for \$18 million, with Admedus to retain 29.1 percent of the vaccines business and chief executive officer Wayne Paterson would be chairman of the venture for five years (BD: Apr 27, Jun 27, 2018).

In January, Admedus said it expected a net operating cash burn for the three months to March 31, 2019 of \$15,494,000 with cash at the end of the quarter of \$12,036,000, in the three months to December 31, 2018, the company earned \$6,439,000 in customer receipts, and had a cash burn of \$5,844,000 (BD: Jan 21, 2019).

In December, the company said that it had raised \$18,964,198 of a hoped-for \$20 million with applications for \$5,374,530 shares at eight cents a share and underwriters taking \$13,589,668 of the shortfall shares (BD: Dec 14, 2018).

In November, Admedus said it hoped to raise a minimum of \$12 million after the payment of underwriter fees and repayment of a \$5 million loan to major shareholder Star Bright through the rights issue (BD: Nov 28, 2018).

The company said at that time that the New York hedge fund SIO Partners LP would underwrite up to \$6 million with Star Bright underwriting \$1 million and taking its full entitlement of about \$4 million.

Admedus said that SIO would provide "up to a further \$6.3 million in underwriting" if the offer did not raise a minimum net cash amount after underwriting fees and repayment of the Star Bright loan of about \$12 million, with SIO to be paid 3.0 percent for the initial \$6 million underwriting, but if SIO was required to provide more than \$6 million because the offer did not raise a net \$12 million, it would be paid 12.5 percent on the initial underwriting instead of the 3.0 percent and 25 percent on any amount SIO takes up over \$6 million. Admedus was in a suspension and last traded at six cents.

REGENEUS

Regeneus says Dr John Chiplin and Dr Alan Dunton will replace chairman Dr Roger Aston and director John Martin effective from today, April 29, 2019.

Regeneus said Dr Aston would resign after six years on the board and previous chairman Mr Martin would leave after 10 years with the company.

The company said that Dr Chiplin and Dr Dunton had been appointed as independent, non-executive directors, with director Barry Sechos appointed as non-executive chairman. Regeneus said Dr Chiplin had experience in sourcing capital and Dr Dunton had experience in drug development, commercialization and pain management.

The company said the London-based Dr Chiplin was Newstar Ventures managing-director and had operational, investment and transaction experience in the life science and technology industries.

Regeneus said that between 1995 and 2014, Dr Chiplin was chief executive officer of software, biotechnology and cancer immunotherapy companies including Calzada, now Polynovo, was the executive director of Benitec and currently is a director of Adalta, Batu Biologics, Cynata, Scancell and Sciencemedia.

Regeneus said that the Florida-based Dr Dunton had more than 35 years' experience in pharmaceutical research and development, and was previously a director of Palatin Technologies, Oragenics, Cormedix and Cytogel Pharma.

Regeneus was untraded at 11 cents.