Biotech Daily

Monday July 16, 2018

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: UNIVERSAL BIO UP 8%; PRESCIENT DOWN 8%**

*** AUSCANN SHARE PLAN FOR $8m, TO TAKE TOTAL TO $42.4m**

*** MICROBA 'META-GENOMIC GUT MICROBIOME SEQUENCING KIT' LAUNCH**

*** ANTISENSE BEGINS ATL1102 DUCHENNE PHASE II TRIAL**

*** IMMURON: US ARMY TRAVELAN STUDIES; CSIRO SHIGELLA VACCINES**

*** REVA APPOINTS BIO VASCULAR FOR ITALY, 1st FANTOM ITALY IMPLANT**

*** MEDICAL DEVELOPMENTS: SPAIN APPROVES PENTHROX**

*** FACTOR COMPLETES VF001 LEG ULCER TRIAL RECRUITMENT**

*** MEDIBIO HEART RHYTHM DEPRESSION TEST FDA APPLICATION**

*** FIRB, US FTC APPROVE CDH SIRTEX ACQUISITION**

*** GENETIC TECHNOLOGIES: BREAST, COLORECTAL CANCER TESTS**

*** RACE REQUESTS 'FDA DECISION' TRADING HALT**

*** SUDA TO FOCUS ON US; 12 TERM SHEETS IN NEGOTIATION**

*** MMJ: '$153k FOR 2.5% OF EMBARK FOR MARIJUANA EXTRACTION'**

*** DR RICHARD HOPKINS STARTS AS ZELDA M-D**

MARKET REPORT

The Australian stock market fell 0.43 percent on Monday July 16, 2018 with the ASX200 down 26.9 points to 6,241.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and three were untraded. All three Big Caps fell.

Universal Biosensors was the best, up two cents or 7.7 percent to 28 cents with 35,000 shares traded. Avita was up 7.25 percent; Prana climbed 5.8 percent; Imugene improved four percent; Neuren was up 3.3 percent; Clinuvel and Polynovo rose more than two percent; Impedimed, Medical Developments, Mesoblast, Nanosonics and Pro Medicus were up more than one percent; with Compumedics, Cynata and Starpharma up by less than one percent.

Friday's 10.5 percent best, Prescient, led the falls, down 0.8 cents or 7.6 percent to 9.7 cents with 275,686 shares traded. Bionomics lost 4.6 percent; Optiscan fell 3.2 percent; Benitec, CSL and Immutep shed more than two percent; Airxpanders, Cochlear, Ellex, Telix and Volpara were down more than one percent; with Resmed and Sirtex down by less than one percent.

AUSCANN

Auscann says it hopes to raise up to $8 million through a share plan at $1.05 a share, following last week $33.4 million placement (BD: Jul 5, 2018).
Auscann said that shareholders at the record date of July 13 could apply for parcels of shares up to $15,000, with the offer opening on July 19 and closing on August 2, 2018.
The company said the plan was not underwritten, any shortfall would be placed with professional and sophisticated investors and it reserved the right to scale-back over-subscriptions, as well as increase the total amount.
Auscann fell 3.5 cents or 3.3 percent to $1.04.

MICROBA

The Brisbane-based Microba says that Queensland Energy Minister Dr Anthony Lynham will launch its meta-genomic gut microbiome sequencing Insight kit, tomorrow.
Microba said the direct-to-consumer kit provided “a comprehensive, high-resolution picture of the species of bacteria and micro-organisms residing in the gut [abundance], what they are doing [functional potential] and … information on their known health associations”.
The company said the kit was invented by founders Prof Philip Hugenholtz and Prof Gene Tyson, with Prof Ian Frazer appointed as a director and Blake Wills as its chief executive officer.
Microba said the kit was not a diagnostic, but could sequence which microbe species were in an individual’s gut and the microbial activity, as well as what other micro-organisms might be required for good gut health.
The company said that meta-genomic sequencing was “the most advanced method of DNA testing currently available” and the test was “significantly more accurate and comprehensive than existing methods of DNA testing for gut bacteria or longstanding approaches such as testing live cultures” and offered the potential for better gut health.
Microba said that 10.7 million Australians, about half the population, complained of some form of digestive problem and the causes of the gut health issues were relatively unknown.
Microba said that there were growing links suggesting that the bacteria and micro-organisms living in the gut, or the microbiome, had “a huge influence on our gut health, well-being and even mental health”.
“This technology is crucial for understanding the role that the gut microbiome can play in treating disease and improving patient outcomes,” Mr Wills said.
Mr Wills said the kit was developed in collaboration with the University of Queensland and the Translational Research Centre at the Princess Alexandra Hospital.
The company said that the technology would be made available to consumers, clinicians and researchers with the Microba on-line portal housing patients’ reports safely and securely.
Microba said the Kit was discreet, non-invasive and easy to use with customers swabbing a small amount of faecal matter from their used toilet paper and mailing the sample to Microba in a pre-paid package.
The company said that customers would be able to track progress through the portal.
Microba said that customers would have the option to participate in the Microba future insights program” to build a deeper understanding of the human microbiome to drive innovation in healthcare”.
The company said that customers could choose to share their anonymous health data to make a contribution to discoveries which might help future generations live healthier lives.
Microba is a private company.

ANTISENSE THERAPEUTICS

Antisense says it has begun its 10-patient phase II trial of ATL1102 for Duchenne muscular dystrophy at Melbourne's Royal Children's Hospital (BD: Feb 28, 2018).

Antisense said patient recruitment was underway for the trial, led by principal investigators Dr Ian Woodock and Prof Monique Ryan.

Today, the company said the trial would be conducted on non-ambulant boys aged between 10 year and 18 years with Duchenne muscular dystrophy and would assess the safety and tolerability of ATL1102 as a treatment for inflammation that exacerbates muscle fibre damage, as well as efficacy effects on the blood and imaging markers of inflammation and muscle damage and other disease progression markers.

Antisense said patient dosing was expected to begin in August.

The company said the treatment was the same as that previously used in its phase II multiple sclerosis trial, which showed significant activity in reducing the number of newly formed inflammatory brain lesions (BD: Jun 30, 2008).

Antisense was up 0.1 cents or four percent to 2.6 cents.

IMMURON
COMMONWEALTH SCIENTIFIC & INDUSTRIAL RESEARCH ORGANISATION

Immuron says it has completed two more US Department of Defense-funded Travelan studies and will work with the CSIRO to produce three Shigella vaccines.

Immuron said the two studies added to research reported in January, when a study with the US Armed Forces Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand showed that Travelan was reactive to 180 clinical isolates of Campylobacter, ETEC and Shigella (BD: Jan 30, 2018).

Today, the company said one study was with the Silver Spring, Maryland-based US Naval Medical Research Centre and showed Travelan's ability to bind to and neutralize components used by entero-toxigenic Escherichia coli (ETEC) to attach to host cells and cause disease, with the drug able to react with the major colonization factor antigens to which intestinal bacteria adhere, bind to fimbrial proteins that bacteria use to attach to host cells, inhibit the bacteria binding and cause cell hemagglutination, as well as and react with the heat labile enterotoxin produced by ETEC bacteria.

Immuron said the other study was with the Silver Spring-based Walter Reed Army Institute of Research and had demonstrated that Travelan bound to similar common bacterial antigens present on ETEC and Shigella bacteria.

The company said the research and development program would progress to evaluate the therapeutic potential of Travelan in Shigellosis challenge studies in non-human primates.

Immuron said the studies would be funded by AFRIMS and conducted at its Bangkok-based Department of Enteric Diseases by July 2018.

Immuron said it would work with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to produce three Shigella treatments for pre-clinical assessment by the Walter Reed Institute, with the vaccination program to begin in August and the finished products to be available by the end of 2018.

The company said the Walter Reed Institute would fund the evaluation of anti-Shigella therapeutics, as well as assess their protective capacity in small animal models.

Immuron said it had submitted a grant funding proposal with the Campylobacter research team at the Naval Medical Research Centre for the development of a therapeutic against Campylobacter and other enteric pathogens, with the US Department of Defense to fund clinical development of the product, if approved.

Immuron fell 1.5 cents or 3.9 percent to 37 cents.

REVA MEDICAL

Reva says that Rome's Bio Vascular Group SRL will distribute its Fantom coronary stent in Italy and it has conducted the first Italian commercial implant.
Reva said the implant of the bioresorbable scaffold was conducted by Dr Bernardo Cortese at the Milan-based Clinica San Carlo Casa di Cura Polispecialistica.
The company said Bio Vascular would distribute the Fantom and Fantom Encore scaffolds and would be responsible for sales, marketing, customer training and support, with commercial sales expected to ramp-up by January 2019.
Reva said Italy's market for interventional cardiology devices was $220 million, with about 150,000 coronary intervention procedures performed every year.
Reva chief executive officer Dr Reggie Groves said Bio Vascular's "proven track record with interventional cardiology devices, demonstrated relationships with physicians and commitment to patient care make it an ideal partner for us".
Reva was unchanged at 22 cents with 5.7 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its Penthrox inhaled methoxyflurane analgesic has been approved for sale in Spain.
Last week, Medical Developments said that Penthrox had been approved in more than 20 countries in Europe (BD: Jul 10, 2018).
Today, Medical Developments chief executive officer John Sharman said the approval left "just two further European approvals pending, Luxembourg and Lithuania, with these approvals considered imminent".
Medical Developments was up 10 cents or 1.8 percent to $5.73.

FACTOR THERAPEUTICS

Factor Therapeutics says it has completed recruitment of 156 patients for its phase II trial of VF001 for venous leg ulcers.
In June, Factor said it expected that "top-line" results by October 2018 (BD: Jun 26, 2018).
Today, Factor chief executive officer Dr Ros Wilson said that "thanks to a particularly strong performance in the last two months, we recruited a total of 156 patients, which is at the higher end of the target range set out in the revised trial analysis plan".
Factor was unchanged at six cents with 2.55 million shares traded.

MEDIBIO

Medibio says it has submitted a de novo application to the US Food and Drug Administration for its cardiac rhythm diagnostic for major depressive disorder.
Medibio said that submission for its "clinical decision support system" followed its 230-patient study and a meeting with the FDA (BD: Aug 21, 2017).
The company said its system provided "an infrastructure for physicians to review objective data in the clinical evaluation stages of patient care continuum as an aid in the diagnosis to ongoing monitoring and management of mental illness".
Medibio said the de novo pathway had been used because there was no FDA-cleared predicate product or device for a mental health diagnostic system.
The company said it expected FDA clearance by the end of 2018.
Medibio was up two cents or 11.8 percent to 19 cents.

SIRTEX MEDICAL

Sirtex says the US Federal Trade Commission has granted early termination of a pre-merger notification waiting period relating to the CDH Fund acquisition.
Sirtex said the waiting period came under the US Clayton Act and Premerger Notification and the US Hart Scott-Rodino Antitrust Improvements Act of 1976.
The company said that the approval satisfied a condition for the scheme of arrangement proposed between Sirtex, CDH Genetech and China Grand Pharmaceutical and Healthcare Holdings and followed Australian Foreign Investment Review Board clearance.
Sirtex said it won Australian Foreign Investment Review Board clearance on July 3, 2018.
The FIRB announcement appeared on the ASX platform, but not on the Commsec main website on that day.
In June, Sirtex dropped the previous Varina Medical Systems offer of $28 a share valuing the company at $1.56 billion to accept the $33.60 a share CDH and China Grand offer, valuing the company at $1.87 billion (BD: Jan 31, May 4, Jun 15, 2018).
Sirtex fell two cents or 0.1 percent to $32.03 with 336,579 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it expects to launch genetic risk assessment tests for breast cancer and colorectal cancer in October.
Genetic Technologies said it had begun development of other cancer and disease targets for its predictive technologies, with tests for prostate cancer, melanoma, type 2 diabetes and cardiovascular disease expected to be available over the next 12 months.
Genetic Technologies executive chairman Dr Paul Kasian said “we are now offering an opportunity for doctors to improve their ability to assess a patient’s breast cancer risk.”
“Our new test, when combined with BRCA [gene mutation] testing, will account for almost 100 percent of breast cancers,” Dr Kasian said. “Currently BRCA testing alone only accounts for five to ten percent of breast cancers.”
“Added to this our expanded range of tests will allow doctors to assess a patient’s risk to some of the most common causes of morbidity and mortality,” Dr Kasian said.
Genetic Technologies was unchanged at one cent with 10.2 million shares traded.

RACE ONCOLOGY

Race has requested a trading halt “pending an announcement about an [US Food and Drug Administration] decision in relation to Bisantrene”.
Trading will resume on July 18, 2018 or on an earlier announcement.
Race last traded at 15.5 cents.

SUDA PHARMACEUTICALS

Suda says it will focus its business development strategy on the US, “the world’s largest market … [with] premium valuations and margins”.
Suda said the change of its business strategy followed the appointment of David Phillips as a director earlier this year and the business development refocus aimed to improve deal flow, build a brand and create multiple leads (BD: Apr 9, 2018).
The company said that following the changes it had seen a “significant improvement in target generation and potential new transactions”, with 12 potential transactions at a term sheet stage and more than 30 active leads with discussions at the technical level.
Suda was unchanged at half a cent with four million shares traded.

MMJ PHYTOTECH

MMJ says it has invested $C150,000 ($A153,409) for a 2.5 percent shareholding in marijuana extraction company Embark Health Inc.

MMJ said that the Delta, British Columbia-based privately-held Embark Health was raising $C1 million in a seed-funding round to build an extraction facility for Canada's medical and recreational cannabis markets.

MMJ chief executive officer Jason Conroy said that Embark Health aimed "to capitalize on the legalization of Canada's recreational cannabis market with a focused product development strategy and experienced leadership team".

"The investment in Embark Health fills the space in our portfolio left from the recent divestment of our interest in Dosecann to Cannabis Wheaton," Mr Conroy said.

MMJ was unchanged at 31.5 cents.

ZELDA THERAPEUTICS

Zelda says Dr Richard Hopkins formally began work as its managing-director, effective today, following the announcement of his appointment in May (BD: May 22, 2018).

Zelda said Dr Hopkins brought extensive knowledge and experience with his established track record in drug development of cancer therapies and experience with corporate strategy, business development and intellectual property matters.

Zelda fell 0.2 cents or 2.3 percent to 8.6 cents.