Biotech Daily

Tuesday July 12, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 17%, COMPUMEDICS DOWN 5%**

*** VICTORIA $20m HEALTH, MEDICAL RESEARCH PLAN**

*** ORTHOCELL READY FOR ORTHO-ATI TENNIS ELBOW TRIAL**

*** PRIMA, GERMAN COLLABORATION ON IMP321 FOR SOLID TUMORS**

*** PRESCIENT SHORTFALL SHARES RAISE $1.3m, TOTAL $10.4m**

*** IMPEDIMED US L-DEX 2017 REIMBURSEMENT $168 PER TEST**

*** US APPROVES OVER-THE-COUNTER ANALYTICA PERICOACH**

*** INVITROCUE DEVELOPING PANCREATIC TOXICITY ASSAY**

*** BLUECHIIP HAS ONE QUARTER CASH**

*** RESPIRI (ISONEA) PLEADS SCHULTZ TO ASX 83% QUERY**

*** TONY WALKER TAKES 16% OF BARD1**

*** AVEXA LOSES DIRECTOR BRUCE HEWETT TO THE UK'S CLINIGEN**

MARKET REPORT

The Australian stock market was up 0.3 percent on Tuesday July 12, 2016 with the ASX200 up 16.1 points to 5,353.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and one was untraded.

Antisense was the best, up half a cent or 16.7 percent to 3.5 cents with 363,916 shares traded. Atcor, Ellex, IDT and Impedimed climbed eight percent or more; Orthocell was up 6.35 percent; Nanosonics and Sirtex were up more than three percent; Factor Therapeutics rose 2.5 percent; Bionomics, Clinuvel, Cochlear, Mesoblast, Osprey, Reva and Starpharma were up more than one percent; with Airxpanders, CSL and Medical Developments up by less than one percent.

Compumedics led the falls, down two cents or five percent to 38 cents, with 147,159 shares traded. Prana fell 4.8 percent; Biotron, Oncosil and Viralytics lost more than three percent; Acrux, Actinogen, Admedus, Opthea and Prima shed more than two percent; Avita and Resmed lost more than one percent; with Pro Medicus down 0.75 percent.

VICTORIA GOVERNMENT

The Victoria Government says it has a $20 million plan to ensure the State continues to be a world leader in health and medical research.
The State Government said that the 'Healthier Lives, Stronger Economy: Victoria's Health and Medical Research Strategy 2016-2020' outlined the Government's priorities over the next four years to support new and evolving fields of medical research such as genomics, precision medicine, health services research and big data.
The Government said it was the first time in 10 years that Victoria had developed a health and medical research strategy.
The Government said that the strategy would deliver better health outcomes by translating health and medical research into clinical practice and would create jobs and drive economic growth by investing in areas where Victoria could lead the world.
The State Government said that the strategy had six priority areas to develop the workforce of the future, integrate research, education and health, develop advanced convergence science, stimulate more industry engagement, attract more clinical trials and optimise big data and informatics.
The Government said that in its first year, the strategy would invest in the coordination of clinical trials, with $3 million through the Medical Research Acceleration Fund and $600,000 for postdoctoral research fellowships.
The Victoria Government said it was delivering $150 million to build Australia's first cardiac hospital and $60 million to rebuild Orygen Youth Mental Health's clinical and research facility in Parkville, as well as $52 million to develop a national centre for proton beam therapy, $25 million for a state-wide genomic sequencing program and $60 million for the Aikenhead Centre for Medical Discovery at St Vincent's Hospital.

ORTHOCELL

Orthocell says it has ethics approval for a 50-patient study comparing surgery for severe tennis elbow to its minimally invasive cell therapy Ortho-ATI injection.
Orthocell said that the study would be conducted by two elbow surgeons at the Ramsey Health Care group's The Avenue private hospital in Melbourne.
The company said that patient recruitment would begin by October 2016 and the study was designed to show that a single non-invasive treatment of Ortho autologous tenocyte implantation (ATI) was superior or equivalent to surgical intervention for the repair of severe, treatment resistant lateral epicondylitis, or tennis elbow.
Orthocell managing-director Paul Anderson told Biotech Daily the Ortho-ATI injections would be conducted at the Melbourne Radiology Clinic, in East Melbourne.
The company said the program would support "the continued demonstration of clinical efficacy and the cost effectiveness of Ortho-ATI as a minimally invasive injectable treatment for resistant tendon injuries of the elbow".
In a media release Mr Anderson said that "demonstrating equivalence or superiority of Ortho-ATI to the standard surgical approach which, for tennis elbow, has a mixed success rates, is an important element of our growth strategy".
"We expect a repeat of the results that showed Ortho-ATI was a durable, curative and cost effective treatment for degenerate tennis elbow injuries," Mr Anderson said.
Trial co-investigator and Orthocell chief scientific officer Prof Ming Hao Zheng said that "as the population ages and degenerate tendon conditions become much more prevalent, doctors and patients are seeking cost effective, minimally invasive and evidenced based treatments to alleviate symptoms that affect their mobility and quality of life".
Orthocell was up two cents or 6.35 percent to 33.5 cents.

PRIMA BIOMED

Prima says it will collaborate on a 40-patient German study of IMP321 as an activator of dendritic cells in solid cancer tumors.

Prima, said that the 'Insight' trial, entitled 'An explorative, single centre, open-label, phase I study to evaluate the feasibility and safety of intra-tumoral, intra-peritoneal, and subcutaneous injections with IMP321 (LAG-3Ig fusion protein) for advanced stage solid tumour entities' would be conducted by the Institute of Clinical Cancer Research, Krankenhaus Nordwest GmbH in Frankfurt, Germany.

The company said that the open-label study would examine the potential for IMP321 as an activator of dendritic cells in solid cancer tumors, with objectives including feasibility, safety and toxicity, immune response in whole blood and tumor tissue and the identification of biomarkers that correlated with clinical response and/or clinical outcomes.

Prima said that the lead investigator would be the Institute's director Prof Salah-Eddin Al-Batran and it would begin subject to approvals.

Prof Al-Batran said that the "promising results from previous studies and favorable safety profile of IMP321 have led us to conduct a phase I trial investigating a potential enhancement of the immune-activating effects of IMP321 by new routes of administration".

"We will explore the possibility to extend the positive results obtained by subcutaneous injections of IMP321 in metastatic renal cell and breast carcinomas to further solid tumor entities," Prof Al-Batran said.

Prime chief executive officer Marc Voigt said it was the first investigation into whether direct injection of IMP321 into a solid tumour could activate the antigen presenting cells located inside the tumor to boost the body's immune response.

Mr Voigt said that the investigator initiated trial would "not require any significant near-term resource commitment from Prima".

Prima fell 0.1 cents or 2.3 percent to 4.2 cents with 1.9 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says its entitlement offer shortfall was "heavily over-subscribed" and has raising a further $1.3 million, taking the total raised to $10.4 million.

Prescient said that shortfall placement of 15 million shares at nine cents a share, included one attaching option for every two shares subscribed, exercisable at 18 cents; by June 30, 2018.

In May, Prescient raised $7.0 million in a two-tranche placement at nine cents a share which was followed by a rights issue which raised $2,040,846 of a hoped for $3.4 million (BD: May 18, Jun 29, 2016).

Prescient was unchanged at 10.5 cents.

IMPEDIMED

Impedimed says the US Centers for Medicare and Medicaid Services has increased the L-Dex test for lymphoedema payment by 13.1 percent to $US127.42 ($A167.69).

In 2014, the Centers approved the $US112.67 payment, then worth $A129.26, for the lymphoedema assessment which had the current procedural terminology (CPT) category I code of 93702 (BD: Nov 3, 2014).

Today, Impedimed said that the new rate would be effective from January 1, 2017.

Impedimed climbed nine cents or 8.6 percent to $1.14 with 1.65 million shares traded.

ANALYTICA

Analytica says the US Food and Drug Administration has granted over-the-counter clearance for its intra-vaginal Pericoach pelvic floor strength training system.
Analytica said that until now the Pericoach device, to assist pelvic floor exercise to reduce or eliminate stress urinary incontinence, was only available by prescription.
Analytica chief executive officer Geoff Daly said the approval was “a terrific achievement” opening market opportunities and positioning the company for potential partners.
“Achieving [over-the-counter] clearance in such a short time means the device is more easily accessible by women in the US who will no longer need a referral from their health professional to purchase the product,” Mr Daly said.
Mr Daly said the approval would help raise awareness among physical therapists and health care professionals and assurance to customers and clinicians that the product has been designed, developed, tested and manufactured to recognized standards.
Analytica was unchanged at 0.6 cents.

INVITROCUE

Invitrocue says it has progressed its technology in modelling multi-organ toxicity by developing a novel assay to detect pancreatic toxicity.
Invitrocue said that the assay was being developed throuhg its collaboration with the Zurich, Switzerland-based Insphero AG, which provided assay-ready, three-dimensional micro-tissues for predictive drug discovery and development, and built on earlier work for an in-vitro cell-based hepato-toxicity assay.
Invitrocue executive director Dr Steven Fang said the company intended “to offer a convenient assay solution for our bio-pharmaceutical customers to accelerate pre-clinical drug development and assessment of potential pancreatic toxicity associated with the drugs liver metabolites”.
The company said it had introduced disease-specific drug screening services related to non-alcoholic steatohepatitis, leishmaniasis and malaria.
Invitrocue was untraded at 6.5 cents.

BLUECHIIP

Bluechiip says its net operating cash burn for the three months to June 30, 2016 was $446,000 with cash at the end of the quarter of $488,000.
Bluechiip said that “in reviewing the company’s liquidity and cash flow, the directors note that the company is considering, amongst others, sales and licencing income anticipated to be generated over the next 12 months, loans from third party and/or directors and assessing alternatives for capital raising in the near term”.
Bluechiip was up 0.1 cents or 4.55 percent to 2.3 cents.

RESPIRI (FORMERLY ISONEA)

Respiri has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 83.3 percent from 3.6 cents on June 30 to 6.6 cents on July 11, 2016 but did not note an increase in trading volume.
Respiri said that its $4.3 million rights offer at three cents a share was 92.4 percent subscribed (BD: Jun 17, 2016).
Respiri fell 0.9 cents or 13.0 percent to six cents with 1.4 million shares traded.

BARD1 (FORMERLY EUROGOLD)

The Geneva, Switzerland-based Tony Walker says he has become substantial in Bard 1 with 88,501,626 shares or 16.03 percent.
Mr Walker said that the Bard1 shares were in payment for 1,062,062 Bard1AG shares and he held a further 88,501,626 unquoted performance shares.
Bard1 conducted a backdoor listing into Eurogold (BD: Jun 20, 2016).
Bard1 was up 0.2 cents or 10 percent to 2.2 cents.

AVEXA

Avexa says that non-executive director Bruce Hewett has resigned "following his appointment as global commercial director with [the UK's] Clinigen Group PLC".
Avexa executive chairman Iain Kirkwood said that Mr Hewett had "made a significant contribution, in particular bringing his wealth of healthcare business experience to bear on a broad range of matters … [and] we congratulate him on his new appointment".
Mr Kirkwood said the company would appoint a new director as soon as practicable.
Avexa was up 0.1 cents or 3.3 percent to 3.1 cents.