

Biotech Daily

Monday February 22, 2016

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: MESOBLAST UP 10%, OSPREY DOWN 12%
- * COMPUMEDICS KOREA DEAL OPENS \$4b BRAIN IMAGING MARKET
- * OPTISCAN REQUESTS FUNDRAISING TRADING HALT
- * MESOBLAST CLAIMS GvHD 'RESPONSES, EXTENDED SURVIVAL'
- * IMMURON, PROF GERHARD ROGLER TO STUDY IMM-124E FOR COLITIS
- * ITL EXPANDS MYHEALTH TEST, TIGHTENS HEALTH CARE BELT
- * PIPPA MANN DRIVES GENETIC TECHNOLOGIES BREVAGENPLUS SALES
- * UBS AG BUYS, SELLS, BORROWS, RETURNS TO 5% OF MAYNE
- * HUNTER HALL TAKES 5% OF MEDICAL DEVELOPMENTS
- * MTPCONNECT: SUE MACLEMAN, BRONWYN EVANS, ASHLEY BATES
- * RESAPP APPOINTS CO-FOUNDER BRIAN LEEDMAN DIRECTOR

MARKET REPORT

The Australian stock market climbed 0.98 percent on Monday February 22, 2016 with the ASX200 up 48.4 points to 5,001.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and five were untraded.

Mesoblast was the best, up 15.5 cents or 10.3 percent to \$1.66 with 1.1 million shares traded. Genetic Technologies climbed 9.5 percent; Acrux, Cellmid, Compumedics, Neuren, Prima and Starpharma rose five percent or more; Biotron was up 4.8 percent or more; Benitec, Polynovo and Pro Medicus were up one percent or more; with Cochlear, CSL, Medical Developments and Sirtex up by less than one percent.

Osprey led the falls, down 3.5 cents or 12.1 percent to 25.5 cents with 50,038 shares traded, followed by Antisense down 11.8 percent to 4.5 cents with 706,622 shares traded. Ellex lost 5.4 percent; Nanosonics fell 4.6 percent; Atcor, Clinuvel, Orthocell, Pharmaxis and Universal Biosensors were down more than three percent; Admedus and Viralytics shed more than two percent; Opthea was down 1.3 percent; with Impedimed and Resmed down by less than one percent.

COMPUMEDICS

Compumedics says a licence and technology transfer deal with the Korean Research Institute of Standards and Science, will open "significant imaging market opportunities". Compumedics said that combining the Korean Institute's technology with its 'Curry' multimodal brain analysis software had the potential to generate more than \$US20 million in annual revenues within two years.

The company said that the new magneto-encephalograph (MEG) incorporated its superconducting quantum interference device (Squid), enabling "superior temporal resolution, for the improved measurement of brain function and cognition".

Compumedics executive chairman Dr David Burton told Biotech Daily that the Squid technology was "ten-times faster than magnetic resonance imaging" and would be incorporated into the products available to its clients including the Stockholm, Swedenbased Elekta in Europe and Japan's Yokogawa Electric Corporation.

"We have been providing MEG for more than a decade and we'd be very disappointed if we didn't take [significant] market share within three years," Dr Burton said.

"The execution of this deal achieves a key initial milestone in our strategy to transition the Compumedics Neuroscan business from a technology leader in the \$50 million specialist brain research market, to the much larger \$4 billion multi-modal brain imaging market," Dr Burton said.

Compumedics said that the licence and technology transfer deal would enable the release of its MEG brain imaging systems.

The company said that the global magneto-encephalograph market was \$US270 million a year and expected to grow to \$350 million by 2020.

Compumedics said that the new magneto-encephalograph system was "the first of its kind ... [a] fully-integrated, brain imaging system with superior brain function sensitivity,

applicable to diagnosis and management of some of the most prevalent and debilitating neurological disorders including Alzheimer's, epilepsy, Parkinson's, autism and other neuro-functional disorders".

The company said that strengthening market demand was underpinned by an increasing aged population and longer life expectancy, coupled with growing prevalence and awareness of neurological disorders, particularly in the Asia Pacific regions.

Compumedics said its Neuroscan MEG system provided 50 percent greater spatial resolution and sensitivity than the traditional market leader and at least four to five orders of magnitude temporal resolution, or speed of brain functional or cognitive measures, of traditional functional magnetic resonance imaging (MRI), positron emission tomography (PET) or other structural brain imaging systems, improving patient outcomes and reducing healthcare costs.

The company said that the development of its multi-modality MEG electro-encephalogram electro-encephalogram (EEG) brain imaging system was important as it had become "the leading supplier of premier sleep and neuro-diagnostic systems to China and Asia Pacific, the region of greatest demand and growth for these systems".

Compumedics was up two cents or five percent to 42 cents.

<u>OPTISCAN</u>

Optiscan has requested a trading halt "pending an announcement to the market concerning fundraising".

Trading will resume on February 24, 2016 or on an earlier announcement. Optiscan last traded at two cents.

MESOBLAST

Mesoblast says that data from 241 children with graft versus host disease treated with its stem cells had "clinically meaningful responses and significantly increased survival". Mesoblast said that the 241 children with steroid-refractory acute graft versus host (GvHD) disease were treated with the mesenchymal stem cell product candidate remestemcel-L, or MSC-100-IV, under its expanded access program at 50 sites.

The company said the data showed an overall response rate of 65 percent at day 28 after treatment with MSC-100-IV.

Mesoblast said that children who achieved overall response at day 28 had significantly improved survival of 82 percent compared to 39 percent (p = 0.0001).

The company said that extending therapy beyond day 28 in children who had not achieved an overall response, but had some improvement at day 28, resulted in significantly improved survival, with 72 percent compared to 18 percent (p = 0.003). Mesoblast said that a response rate of 81 percent was achieved when MSC-100-IV was used as front-line therapy following steroid failure.

The company said that in patients with gastrointestinal and liver disease, who had the highest mortality risk, overall response rates were 65 percent and 62 percent, respectively.

Mesoblast said that the data was presented at the scientific meetings of the Center for International Blood and Marrow Transplant Research and the American Society of Blood and Marrow Transplantation in Hawaii on February 20, 2016.

The company said the presentation was given by the lead investigator, Duke University Medical Centre's Dr Joanne Kurtzberg who said that "historically there is a high mortality rate associated with this complication, [but] we are now seeing the majority of children who receive Mesoblast's cell therapy respond and survive".

Mesoblast said it was conducting a 60-patient, open-label phase III trial of MSC- 100-IV as front-line therapy in children with steroid-refractory acute graft versus host disease. Mesoblast was up 15.5 cents or 10.3 percent to \$1.66 with 1.1 million shares traded.

IMMURON

Immuron says it will begin a colitis pre-clinical development program with University of Zurich inflammatory bowel disease researcher, Prof Gerhard Rogler, this year. Immuron said that a study of IMM-124E for autoimmune colitis in mice showed amelioration of disease on all histological parameters, decreased weight loss and an immunological effect related to treatment with IMM-124E.

The company said the article, 'The gut microbiome as a target for regulatory T cell-based immunotherapy: induction of regulatory lymphocytes by oral administration of anti-LPS enriched colostrum alleviates immune mediated colitis' was published in Biomed Central Gastroenterology and is at: <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4628342/</u>. Immuron said that with Prof Rogler it had developed a pre-clinical program to evaluate the efficacy of IMM-124E for the treatment of colitis.

Immuron has previously reported on its 120-patient phase IIb trial of IMM-124E for nonalcoholic steato-hepatitis, or fatty liver disease (BD: Nov 18, 2015).

Prof Rogler said the proposed mechanism of action of IMM-124E was "extremely interesting" and with its reported level of safety, he was eager to assess the compound. Immuron said that colitis was the result of interactions between multiple factors including the environment, genetic predisposition, immune response and the gut microbiome in the colon or intestines and could cause pain, fever, weight loss and chronic, bloody diarrhoea. Immuron was up two cents or 5.3 percent to 40 cents.

<u>ITL</u>

ITL says it will expand its financial commitment to its recently-acquired subsidiary Myhealthtest, while maintaining its commitment to its existing divisions.

ITL said that it developed and manufactured medical devices for operating theatres, blood-banks and laboratories, sold in more than 50 countries, while Myhealthtest developed and marketed direct-to-consumer pathology testing for major chronic diseases. The company said that combining the profitable core businesses with the potential of Myhealthtest was" a good mix of stability and future accelerated growth potential". ITL said that its bio-medical division would continue to seek growth through patent-driven opportunities, with 18 international families of patents filed in the last four years, of which seven were filed in the last 12 months, as well as eight new products launched. ITL said its health care division had faced "extremely competitive pricing and low margins in its packing business" and the company had reduced purchasing costs, manufactured

more components itself and transferred some assembly to its Malaysia facility. The company said it would develop new products for the operating theatre that would be progressively introduced into its health care division.

ITL said that Myhealthtest had been awarded a \$1 million grant from the Federal Government, established a new pathology laboratory, launched its HbA1c test for diabetes and begun commercial online sales of the test, and identified additional tests for development with a focus on cardiac, thyroid and prostate conditions.

The company said that Myhealthtest's commercial and developmental goals in 2016 were to establish partnerships with the retail pharmacy market for the sale of tests, establishing partnerships with major companies through its "corporate wellness" program, establish partnerships with the Victoria, Western Australia and Queensland diabetes associations, and launch a secure portal to make test results available to customers and doctors online. ITL executive chairman Bill Mobbs said the increased investment would "enable [Myhealthtest] to maintain and increase the momentum it has already built".

"ITL is well placed as a funded stable business that via its ownership of [Myhealthtest] has put itself in a position to see growth accelerate significantly, and the decision to increase the investment enhances this position," Mr Mobbs said.

ITL was unchanged at 20 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says race-car driver Pippa Mann will promote its Brevagenplus risk assessment for breast cancer, starting at the 100th Indianapolis 500 race. The company said its first marketing program promoting Brevagenplus in the US, reflected Ms Mann's "commitment to working with research organisations and corporations who

share her passion for reducing the impact that breast cancer has on women".

The company said that the Indianapolis 500 was "the largest single-day sporting event in the world" and offered promotional opportunities during the month-long lead-up to the race, including 12 days of on-track activities and hospitality events.

Genetic Technologies said that Ms Mann was one of nine women drivers to compete in the race, the only female driver to start in the past three races, and the agreement included the Brevagenplus logo appearing on Ms Mann's car at the May 29, 2016 race, along with promotional apparel and Ms Mann would participate at promotional activities. The company said that Ms Mann had a partnership with Susan G Komen, the world's largest breast cancer organization, which funded breast cancer research, while providing screening, education, treatment and psychosocial support programs.

Genetic Technologies was up 0.2 cents or 9.5 percent to 2.3 cents.

MAYNE PHARMA

The Singapore-based UBS AG and related bodies corporate say they have become substantial shareholders in Mayne Pharma with 42,409,612 shares (5.25%).

UBS AG said that between October 19, 2015 and February 17, 2016 it bought, sold, borrowed and returned shares in more than 800 separate trades

Last year, UBS AG and related bodies corporate became and ceased their substantial holding in Mayne Pharma borrowing and lending shares in more than 60 individual over a six-day period (BD: Dec 7, 14, 2015).

Mayne fell three cents or 2.4 percent to \$1.21 with one million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Hunter Hall Investment Management says it has become a substantial shareholder in Medical Developments with 2,932,737 shares or 5.07 percent.

The Sydney-based Hunter Hall said that it bought shares between February 5 and 18, 2016 with the largest transaction, the acquisition of 852,689 shares for \$3,341,660 or \$3.92 a share.

Medical Developments was up one cent or 0.2 percent to \$4.21.

MEDICAL TECHNOLOGIES & PHARMACEUTICALS INDUSTRY INNOVATION GROWTH CENTRE

The Medical Technologies and Pharmaceuticals Industry Innovation Growth Centre says it has appointed Sue MacLeman as chief executive officer effective from April 2016. The Medical Technologies and Pharmaceuticals Industry Innovation Growth Centre, or MTPConnect, said it had been established under the Australian Government's Industry Growth Centres Initiative as part of the National Innovation and Science Agenda announced by Prime Minister Malcolm Turnbull last year "to promote and accelerate innovation and entrepreneurship, to identify and remove barriers to success and to deliver sectoral competitiveness, collaboration and productivity" (BD: Dec 7, 8, 2015). MTPConnect said that Ms MacLeman had more than 25 years as a pharmaceutical, biotechnology and medical technology executive with roles in corporate, medical, commercial and business development at Schering-Plough Corporation (now Merck),

Amgen and Bristol-Myers Squibb and had been employed as chief executive officer and a director of companies including Eqitx, Progen, Benitec and was currently a non-executive director at Reproductive Health Sciences and Oventus Medical.

Ms MacLeman holds a University of Queensland Bachelor of Pharmacy, a Masters of Laws from Deakin University and a Melbourne Business School Masters of Marketing. MTPConnect said that Ms MacLeman was currently Mesoblast's head of commercial MTPConnect chair Dr Bronwyn Evans said Ms MacLeman would bring "vast experience and leadership to the role and will work closely with our [medical technologies and pharmaceutical] industries, researchers, agencies and associations".

MTP previously appointed Dr Ashley Bates as a director and Elizabeth Stares as chief operating officer.

RESAPP HEALTH

Resapp says that it has appointed co-founder and corporate affairs vice-president Brian Leedman as a director.

Resapp said that Mr Leedman was a marketing and investor relations professional with over 10 years' experience in the biotechnology and healthcare industry.

The company said that previously Mr Leedman co-founded Enigma Therapeutics which back-doored into Neurodiscovery to create Oncosil Medical (BD: Feb 7, 2013).

Resapp said that Mr Leedman was a founding director of Biolife Science which backdoored into Imugene (BD: Oct 23, 2013).

The company said that Mr Leedman had been employed for 10 years as Psivida's head of investor relations and was currently the chair of the Western Australian state division of industry organization Ausbiotech.

Resapp was up half a cent or 3.6 percent to 14.5 cents with 3.1 million shares traded.