

Biotech Daily

Tuesday February 26, 2019

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: BENITEC UP 8%; OSPREY DOWN 13%
- * ARAVAX PVX108 'SAFE' FOR PEANUT ALLERGY
- * IMUGENE B-CELL VACCINE 'ANTI-TUMOR ACTIVITY'
- * OPTISCAN MICROSCOPE AT SLOAN KETTERING
- * OPTISCAN, SUMMIT WORK ON MICROSCOPES, IMAGING
- * ELIXINOL FIRST H1 REVENUE \$37.1m, LOSS \$860k
- * PROBIOTEC H1 REVENUE UP 35% TO \$37m, PROFIT UP 258% TO \$1.1m
- * BENITEC H1 REVENUE UP 3392% TO \$14.6m, LOSS TO PROFIT OF \$9.1m
- * CLINUVEL H1 REVENUE UP 27% TO \$9m, PROFIT UP 189% TO \$4.1m
- * OSPREY REVENUE UP 54% TO \$3.5m, LOSS UP 22% TO \$24.5m
- * LBT H1 REVENUE DOWN 49% TO \$1.8m, LOSS UP 59% TO \$1.7m
- * BOTANIX BTX1503 '5 TIMES OTHERS CBD'
- * MGC MARIJUANA 'MORE THAN 35% THC'
- * CARDIEX APPOINTS HARRY KIM ADVISOR

MARKET REPORT

The Australian stock market fell 0.94 percent on Tuesday February 26, 2019, with the ASX200 down 57.9 points to 6,128.4 points. Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, 10 traded unchanged and two were untraded. All three Big Caps fell.

Benitec was the best, up one cent or 8.3 percent to 13 cents with 336,682 shares traded. Medical Developments climbed 4.2 percent; Avita and Nanosonics improved more than three percent; Airxpanders, Antisense, Compumedics, Mesoblast and Universal Biosensors rose more than two percent; with Clinuvel, Cynata and Dimerix up more than one percent.

Osprey led the falls, down 1.5 cents or 13.0 percent to 10 cents with 449,055 shares traded. Prescient lost seven percent; Oncosil was down 5.7 percent; Optiscan and Uscom fell four percent or more; Impedimed and Kazia were down more than three percent; Prana, Pro Medicus and Telix shed more than two percent; Cochlear, CSL, Genetic Signatures, Pharmaxis and Volpara were down one percent or more; with Neuren, Opthea, Resmed and Starpharma down by less than one percent.

<u>ARAVAX</u>

Melbourne's Aravax says its 48-patient, phase I dose-escalation PVX108 trial shows "a highly favourable safety profile, even in patients with severe peanut allergies". The presentation, titled 'Safety and tolerability of a novel peptide-based immunotherapy for peanut allergy' presented on February 25, 2019 at the San Francisco-based 2019 American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Meeting. Aravax said PVX108 targeted peanut-specific T cells "believed to be the underlying cause of the disease".

The company said the study had two parts, first with a randomized single, ascending dosing stage of 0.05 nanomol to 150 nanomol on eight cohorts of six participants. Aravax said the second stage was on 18 randomized participants who received six injections of 150 nanomol over 16 weeks.

The company said there was no serious adverse reactions, adverse events were graded mild or moderate and deemed not of clinical concern, and there was no relationship between dose or frequency and the severity of adverse events.

Aravax chief executive officer Pascal Hickey said, "peanut allergy is the most common cause of food allergy-related deaths in children, and there is an urgent need for safe, effective and convenient therapies that address the underlying cause of this potentially fatal disease".

Mr Hickey said the results demonstrated "a positive safety profile, so now we are working with the clinical community to design a phase II study of PVX108, which will be conducted in Australia and the United States".

Aravax is a private company.

IMUGENE

Imugene says a phase I safety, dosing and immunogenicity data for its B-cell vaccines shows an anti-tumor response and may "avoid therapeutic resistance".

The article, titled 'Phase I immunotherapy trial with two chimeric HER-2 B-cell peptide vaccines emulsified in montanide ISA 720VG and nor-MDP adjuvant in advanced solid tumors' was published in Clinical Cancer Research.

Last year, Imugene said it had acquired a suite of B-cell vaccines for cancer from the Mayo Clinic and Ohio State University (BD: Jun 7, 2018).

Today, Imugene said the vaccines Herceptin and Perjeta were approved for clinical use, but patients often developed a resistance to the therapies.

Ohio State University Prof Pravin Kaumaya said "we have advanced a new paradigm in immunotherapy that focuses on humoral responses based on conformational B-cell epitope vaccines".

"The study vaccine is safe, exhibits anti-tumor activity and shows preliminary indications that peptide vaccination may avoid therapeutic resistance and offers a promising alternative to monoclonal antibody therapies," Prof Kaumaya said.

Imugene was unchanged at 1.6 cents with 25.0 million shares traded.

OPTISCAN IMAGING

Optiscan says its confocal microscope for early detection, screening and intraoperative margin is being used at the New York-based Memorial Sloan Kettering Cancer Center. Optiscan said the technology scanned for oral, oesophageal and cervical dysplasias and carcinoma in early stage cancer.

Optiscan fell 0.3 cents or 4.9 percent to 5.8 cents.

OPTISCAN IMAGING

Optiscan says it will work New Jersey's Summit Biomedical Imaging to commercialize its Viewnvivo confocal endomicroscope and SBI's PARPi-FL imaging agent. Optiscan said it would use PARPi-FL in its cancer tumor margin assessment trial.

ELIXINOL GLOBAL

Elixinol says revenue for its first half year was \$37,131,000, with a net loss after tax of \$860,000.

Elixinol said it first listed on the ASX in December 2018, to develop hemp supplements and skin care, food and medical cannabis products (BD: Jan 21, 2018).

The company said revenue for its first half was driven by hemp seed and other food additive sales, as well as its emerging medical marijuana business, Nunyara Pharma. The company said net tangible assets per share was up 157 percent to 46.15 cents, diluted loss per share was down 98.8 percent to 0.76 cents and it had cash and cash equivalents of \$42,922,000 at December 31, 2018 compared to \$18,834,000 at December 31, 2017.

Elixinol was up 22 cents or 6.6 percent to \$3.55 with 298,364 shares traded.

PROBIOTEC

Probiotec says revenue for the six months to December 31, 2018 was up 34.8 percent to \$37,042,052 with net profit after tax up 257.5 percent to \$1,146,762.

Probiotec said it would pay a fully-franked dividend of 1.0 cent a share for holders at the record date of March 3 on March 19, 2019.

Probiotec said revenue came from its contract drug manufacturing services and product development.

The company said net tangible assets per share was up 33.1 percent to 58.3 cents, diluted earnings per share was up 1001.7 percent to 19.5 cents at December 31, 2018, and it had cash and cash equivalents of \$19,807,297 at December 31, 2018 compared to \$943,609 at December 31, 2017.

Probiotec fell 1.5 cents or one percent to \$1.50.

BENITEC BIOPHARMA

Benitec says revenue for the six months to December 31, 2018 was up 3392.1 percent to \$14,667,000, turning a previous loss into a net profit after tax of \$9,065,000.

Benitec said revenue largely was a result of its partnership with the London and Bermuda based Axovant Sciences to develop its DNA-directed RNA interference (ddRNAi) platform and included an upfront licence payment of \$13.568 million and a reimbursement of labor cost of \$804,000 (BD: Jul 9, 2018).

The company said net tangible assets per share was up 39.7 percent to 10.9 cents, it turned a diluted loss per share of 2.8 cents into an earnings per share of 3.5 cents at December 31, 2018, and had cash and cash equivalents of \$23,186,000 at December 31, 2018 compared to \$10,271,000 at December 31, 2017.

Benitec was up one cent or 8.3 percent to 13 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the six months to December 31, 2018 was up 27 percent to \$8,981,388 with net profit after tax up 188.8 percent to \$4,075,519.

Clinuvel said revenue came from sales of its Scenesse treatment for erythropoietic protoporphyria (EPP).

The company said net tangible assets per share was up 57.9 percent to 90 cents, diluted earnings per share was up 192.9 percent to 8.2 cents at December 31, 2018, and it had cash and cash equivalents of \$42,826,297 at December 31, 2018 compared to \$27,938,889 at December 31, 2017.

Clinuvel was up 40 cents or 1.65 percent to \$24.68 with 173,419 shares traded.

OSPREY MEDICAL

Osprey says revenue for the year to December 31, 2018 was up 54.2 percent to \$US2,514,117 (\$A3,512,749) with net loss after tax up 22.2 percent to \$US17,521,967 (\$A24,481,867.50).

Osprey said revenue for the year was the result of sales of its cardiac contrast reducing Dyevert system.

The company said net tangible assets per share was down 36.8 percent to 12 US cents, diluted loss per share was constant at 10 US cents, and it had cash and cash equivalents of \$US25,251,790 at December 31, 2018 compared to \$32,134,848 at December 31, 2017.

Osprey fell 1.5 cents or 13.0 percent to 10 cents.

LBT INNOVATIONS

LBT says revenue for the six months to December 31, 2018 was down 48.7 percent to \$1,780,000 with net loss after tax up 58.9 percent to \$1,672,000.

LBT said revenue comprised of interest, sales revenue, consulting income and a reimbursement for expenses from joint venture company, Clever Culture Systems AG. The company said net tangible assets per share fell 11 percent to 6.81 cents, diluted loss per share was up 12.2 percent to 0.83 cents at December 31, 2018, and it had cash and cash equivalents of \$5,710,000 at December 31, 2018 compared to \$4,233,000 at December 31, 2017.

LBT was unchanged at 7.4 cents.

BOTANIX PHARMACEUTICALS

Botanix says that an independent analysis shows its Permetrex BTX1503 for acne delivers up to five times the amount of cannabidiol compared to othercreams or gels. Botanix said that the comparative analysis by Tioga Research demonstrated that, relative to the closest comparator cannabidiol (CBD) topical product, BTX1503 delivered more than five times as much CBD to the epidermis and more than three times as much CBD to the dermis, and significantly more than other CBD topical creams and gels. The company said that BTX1503 delivered more CBD in each dose used by patients in

clinical studies, than in the entire package of each of the comparator products. Botanix executive director Matt Callahan said the company was "extremely pleased with the results of this comparable analysis, as delivering pharmaceuticals deep into the skin to treat disease remains a significant challenge in dermatology and medicine". Botanix fell one cent or 8.7 percent to 10.5 cents.

MGC PHARMACEUTICALS

MGC says the University of Ljubjana has verification and validation of the company's tetrahydrocannabidiol (THC) and cannabidiol (CBD) genetic strains".

MGC said the Slovenia-based University of Ljubjana Biotechnical Faculty and Pharma Lab reported that strain MXC-10 had 35 percent THC.

Earlier this month, MGC said it produced 700kg of biomass and 30 percent more flowers than the previous year and developed a new proprietary genetic strain MXC-10, which contained more than 35 percent THC (BD: Feb 1, 2019).

The company said its THC and CBD strains were now being registered with the European Union.

MGC fell 0.1 cents or 2.5 percent to 3.9 cents with 1.5 million shares traded.

CARDIEX

Cardiex says it has appointed Harry Kim to its advisory board, effective from March 1, 2019.

Cardiex said Mr Kim was the senior vice president and general manager at American Well, led the health and life sciences division at Hewlett Packard and was formerly the lead at the Samsung Electronics health business.

The company said Mr Kim would provide strategic advice and help develop its "global wearable, digital health, and telehealth partnerships".

Cardiex was unchanged at 6.1 cents with 4.5 million shares traded.