

Biotech Daily

Monday March 9, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH TUMBLE: ALTERITY UP 8%; USCOM DOWN 21%
- * MEDLAB: 'MARIJUANA NANABIS SAFE, EFFICACY FOR CANCER PAIN'
- * FDA GRANTS IMMUTEP IMP321 FOR BREAST CANCER IND
- * ANTEO, MERCK KGAA DEVELOP ANTOBIND EUROPIUM P-O-C TESTS
- * MGC DOSES 1st PATIENT IN COGNICANN MARIJUANA TRIAL
- * L1 CAPITAL TAKES 5.5% OF CRESO
- * NAOS TAKES 23% OF BTC
- * RESAPP REQUESTS 'REGULATORY UPDATE' TRADING HALT
- * NEUROSCIENTIFIC REQUESTS 'PIG GLAUCOMA STUDY' TRADING HALT
- * TELIX APPOINTS PROF FREDERIK GIESEL ADVISOR
- * MEDIBIO APPOINTS KELLY TRUPOVIC, DR STEPHEN ADDIS

MARKET REPORT

The Australian stock market fell 7.3 percent on Monday March 9, 2020, with the ASX200 down 455.6 points to 5,760.6 points, its steepest dive since the 2008 Global Financial Crisis and lowest point since April 2018.

Just one of the Biotech Daily Top 40 stocks was up, 37 fell and two traded unchanged. All three Big Caps fell. Alterity (Prana) was the only company to improve, on no news, up 0.1 cents or 7.7 percent to 1.4 cents with 651,431 shares traded.

Uscom led the falls, down 7.5 cents or 21.1 percent to 28 cents, with 4.2 million shares traded. Oncosil lost 20 percent; Proteomics and Universal Biosensors fell more than 17 percent; Medical Developments was down 16.25 percent; Impedimed and Paradigm fell 15 percent or more; Neuren, Next Science and Polynovo shed 14 percent or more; Volpara was down 13.5 percent; Mesoblast, Orthocell and Prescient were down more than 12 percent; Clinuvel and Opthea lost 11 percent or more; Amplia, Cynata and Telix were down 10 percent or more; Genetic Signatures and Kazia shed more than nine percent; Avita, Imugene, LBT, Nanosonics and Pharmaxis were down eight percent or more; Antisense was down 7.55 percent; Compumedics, Dimerix and Resmed were down more than six percent; CSL, Ellex, Patrys, Pro Medicus and Starpharma fell five percent or more; Cochlear lost 3.7 percent; Actinogen and Immutep shed more than two percent; with Cyclopharm down one percent.

MEDLAB CLINICAL

Medlab says its 30-patient, phase IIa trial of Nanabis for cancer pain was safe, tolerable and showed efficacy, but the company did not provide statistical data.

Medlab said the trial of the marijuana-derived Nanabis was conducted at Sydney's Royal North Shore Hospital with Prof Stephen Clarke as principal investigator.

The company said that Nanabis was a standardized equal parts blend of marijuanaderived cannabidiol (CBD) and tetrahydrocannabinol (THC) in the company's Nanocelle oro-buccal spray, or in the mouth and cheek, delivery platform.

The company said the total cohort had "meaningful pain reduction", with a specific patient subset of breast or prostate cancer patients with bone metastasis having an average of 40 percent improvement in pain scores from baseline, but did not provide statistical analysis or a probability (p-value) for the claimed efficacy.

Medlab said that patients with breast or prostate cancers with bone metastasis showed significantly less morphine milliequivalent of dispensed opioid analgesics prescribed than the remaining cohort, with no change in the number of rescue medication doses.

The company said that Nanabis was "fast acting" reaching maximum concentration in serum at 54 minutes and dose tolerance was achieved at 60 percent of the maximum dose with predominantly mild or moderate expected adverse events.

Medlab said Nanabis showed improvements in quality of life measures, specifically in emotional functioning and insomnia.

The company said that the trial details were available at the Australian New Zealand Clinical Trial Registry at: https://bit.ly/3aAUuwz.

Medlab said the trial "delivered strong results allowing [it] to focus on phase III designs, specifically in the patient group with metastatic bone pain where breast or prostate are the primary cancers".

Medlab chief executive officer Dr Sean Hall said the company had "primary evidence that Nanabis is safe, tolerable and provided a significant benefit in managing pain associated with metastatic cancers".

"There were a number of notable secondary gains, one of the biggest worth mentioning was a drastic reduction of breakthrough medication used by those patients with breast or prostate cancers with bone [metastases]," Dr Hall said.

"We can confidently argue, Nanabis has a strong indication for use in pain management and is a compelling therapy for this patient group," Dr Hall said.

Medlab said that since the end of the trial, the majority of patients have elected and been approved to continue on Nanabis free of charge.

Medlab was up 1.5 cents or 6.7 percent to 24 cents.

IMMUTEP

Immutep says US Food and Drug Administration has approved an investigational new drug application for a 24-patient phase I trial of IMP321 for metastatic breast cancer. Immutep said the approval allowed it to begin the Aipac-002 trial of IMP321, or eftilagimod alpha, in combination with the chemotherapy drug paclitaxel, following "other preparatory steps and pending positive results from its larger Aipac phase IIb study, which are expected ... by the end of March 2020".

In 2018, the company said it had FDA investigational new drug approval for IMP321 for non-small cell lung carcinoma, or head and neck carcinoma, which allowed it to start its US Tacti-002 phase II combination study to evaluate the of IMP321 and anti-programmed death-1 (PD-1) therapy Keytruda, or pembrolizumab (BD: Jul 31, 2018).

Immutep fell one cent or 2.8 percent to 34.5 cents with 1.5 million shares traded.

ANTEOTECH (FORMERLY ANTEO DIAGNOSTICS)

Anteo says it has an agreement with the Darmstadt, Germany-based Merck KGaA to develop Anteobind activated europium particles for point-of-care diagnostic testing. Anteo said the co-developed products would use Merck's europium "to offer an advanced toolset for assay developers".

Europium-63 is described as the most reactive and softest lanthanide and a ductile rare earth metal.

Anteo said the combined products would "harness the fluorescent qualities of Europium and the conjugation improvement properties of Anteobind".

Anteo said the commercial contract was being finalized and would "mirror product development processes governed by the quality policies of both organizations.".

The company said it expected to launch the Anteobind activated europium particles by April 2021.

Anteo chief executive officer Derek Thompson said that "the opportunity to co-develop a product set leveraging Merck's vast customer base, business development capability and distribution network will enable Anteobind to be utilized across abroad and growing sector of the global lateral flow assay development market".

Anteotech was up 0.2 cents or 11.8 percent to 1.9 cents with 21.1 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has dosed the first of 50 patients in its phase II trial of marijuana-derived Cognicann for dementia and Alzheimer's disease.

MGC said the randomized, double blind, crossover, placebo-controlled trial at Perth's University of Notre Dame Australia would involve patients aged 65 and older to confirm the clinical efficacy of Cognicann and determine the therapeutic individual dose response. The company said that participants would be "involved for 18 weeks" but did not describe the dosing regimen.

MGC said it expected the results by October 2021.

The company said that Cognicann was "the only dementia targeting phytocannabinoid-derived product available for prescription in Australia, putting the company in a unique position to access a large patient population in Australia and key international markets via early access schemes".

MGC fell 0.1 cents or four percent to 2.4 cents with 7.7 million shares traded.

CRESO PHARMA

L1 Capital Global Opportunities Master Fund says it has become a substantial shareholder in Creso with 11,390,976 shares or 5.48 percent of the company. The Melbourne and Cayman Islands-based L1 Capital did not disclose the date(s) or price(s) paid for the shares.

Last month, Creso said it had a convertible note agreement with L1 Capital for up to \$17,482,500, including the ability to request an initial \$1,750,000 advance in two equal tranches in exchange for 9,000,000 collateral shares, a four percent fee of the advance, and a potential 11,000,000 additional collateral shares (BD: Feb 5, 2020). Creso fell 0.7 cents or 9.1 percent to seven cents with 2.1 million shares traded.

BTC HEALTH

The Sydney-based Naos Asset Management says it has increased its substantial shareholding in BTC from 53,035,248 shares (21.55%) to 55,775,214 shares (22.66%). Naos said that on March 5, 2020 it acquired 2,739,966 shares on-market, but did not disclose the price of the shares as required under the Corporations Act. BTC was untraded at 9.8 cents.

RESAPP HEALTH

Resapp has requested a trading halt "pending the release of an announcement regarding an update on the company's regulatory approval process".

Trading will resume on March 11, 2020 or on an earlier announcement.

Resapp last traded at 17 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific has requested a trading halt "pending release of the results of the company's pre-clinical pig study in glaucoma".

Trading will resume on March 11, 2020 or on an earlier announcement.

Neuroscientific last traded at 14 cents.

TELIX PHARMACEUTICALS

Telix says it has appointed Prof Frederik Giesel to its scientific advisory board. Telix said Prof Giesel would advise the company on its research and development and clinical activities relating to its prostate cancer, kidney cancer and glioblastoma programs. The company said Prof Giesel was vice chair of the department of nuclear medicine at Germany's University of Heidelberg and a leader in the field of cancer imaging and the use of positron emission tomography (PET) for the evaluation of prostate cancer. Telix chief executive officer Dr Chris Behrenbruch said Prof Giesel had been "at the vanguard of the development of cancer-specific PET tracers and has been instrumental in the clinical introduction of [prostate specific membrane antigen]-based imaging for men with prostate cancer".

Telix fell 14 cents or 10.85 percent to \$1.15 with 852,389 shares traded.

MEDIBIO

Medibio says it has appointed Kelly Trupovic as partnerships and marketing manager for the Asia-Pacific and Dr Stephen Addis as a consultant.

Medibio said Ms Trupovic had 15 years' experience as a risk consultant in finance and had previous works for Mercer Marsh.

The company said Dr Addis was a founding Medibio shareholder with more than 20 years' experience as a principal investigator and investigator in pharmaceutical trials, and was previously head of psychiatry at Perth's Fremantle Hospital.

Medibio was unchanged at 0.7 cents.