



Biotech Daily

Wednesday March 18, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ONCOSIL UP 30%; IMPEDIMED DOWN 17%**
- * **TBG: CE MARK FOR COVID-19 TEST; 'SCHULTZ' TO ASX 1,054% QUERY**
- * **ONCOSIL: PANCREATIC CANCER DEVICE 'FDA BREAKTHROUGH STATUS'**
- * **RACE COMPLETES PHASE II BISANTRENE AML TRIAL RECRUITMENT**
- * **ANTISENSE TRIAL DATABASE LOCK, RESULTS IN APRIL**
- * **AZURE WINS ASX LISTING REMOVAL EXTENSION**
- * **NEUROSCIENTIFIC: EMTINB RE-MYELINATES MS, IN-VITRO**
- * **LUMYNA SUBSTANTIALS IN IDT, ONCOSIL**
- * **CRYOSITE DIRECTOR ANDREW KROGER TAKES 40%**
- * **PENDAL GROUP BELOW 5% IN ALTHEA**
- * **NEXT SCIENCE LAUNCHES ON-LINE ACNE CREAM**

MARKET REPORT

The Australian stock market fell 6.43 percent on Wednesday March 18, 2020, with the ASX200 down 340.2 points to 4,953.2 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell, 11 traded unchanged and one was untraded.

Oncosil was the best, up 2.8 cents or 30.4 percent to 12 cents, with 12.5 million shares traded. Actinogen climbed 12.5 percent; Resmed rose 7.7 percent; Orthocell was up 5.9 percent; LBT improved 4.55 percent; Universal Biosensors was up 3.3 percent; Cynata rose 2.3 percent; with Next Science and Polynovo up by less than one percent.

Impedimed led the falls, down 1.1 cents or 16.7 percent to 5.5 cents, with two million shares traded. Opthea lost 12.5 percent; Avita and Paradigm fell more than 11 percent; Compumedics and Nanosonics were down 10 percent or more; Clinuvel, CSL, Mesoblast and Neuren retreated eight percent or more; Alterity, Antisense and Uscom lost more than seven percent; Ellex and Kazia were down more than five percent; Immutep fell 4.8 percent; Medical Developments, Prescient and Telix were down more than three percent; Cochlear was down one percent; with Pro Medicus and Volpara down by less than one percent.

TBG DIAGNOSTICS

TBG says its 46.65 percent subsidiary TBG Biotechnology Xiamen Inc has Conformité Européenne (CE) mark approval for its Covid-19 nucleic acid diagnostics kit.

TBG said that CE mark certification “indicates that the Covid-19 nucleic acid diagnostics kit meets the essential health, safety and environmental protection requirements of the applicable European regulations to allow the sale of the kit throughout the European Economic Area”.

The company said that the RNA-based diagnostic kit used real time polymerase chain reaction (PCR) technology platform with three-color labeling to detect distinctive segments within RDRP, N and E genes of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2).

TBG said that the approval enabled the test to be sold as an in-vitro diagnostic for the diagnosis of SARS-CoV-2 (the virus) or Covid-19 (the illness) in all regions that accepts CE marking.

The company said that TBG Xiamen’s kit would be available for immediate validation and purchase.

Yesterday, TBG called a trading halt for the news, trading up 13 cents or 92.9 percent to 27 cents with 1.2 million shares traded, prior to the halt.

Today, TBG told the ASX it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price rose 1,053.8 percent from 2.6 cents to 30 cents “in the last few days” and noted a significant increase in the trading volume.

According to Commsec data, TBG last traded at 2.6 cents on February 26 with no trades until Monday March 16 when it opened at 10 cents and climbed to close at 14 cents, opening at 14.5 cents yesterday March 17 and closing at 27 cents.

Today, TBG remained in a trading halt at 27 cents.

ONCOSIL MEDICAL

Oncosil says the US Food and Drug Administration has granted breakthrough device status for its pancreatic cancer radiation device combined with systemic chemotherapy.

Oncosil said the designation would expedite development, assessment, review, and approval of the Oncosil phosphorus-32 radio-isotope device in the US.

The company said it would work with the FDA to ensure that the proposed premarket approval evidence development and clinical trial design captured clinically meaningful data collection.

Oncosil was up 2.8 cents or 30.4 percent to 12 cents with 12.5 million shares traded.

RACE ONCOLOGY

Race says its investigator-led, open-label phase II trial of Bisantrone for relapsed or refractory acute myeloid leukaemia has completed recruitment.

Race chief executive officer Peter Molloy told Biotech Daily that “the trial data was still in the hands of the investigators at Israel’s Sheba Medical Centre”.

The company said the trial was expected to recruit 12 adults over 12 months and to report complete responses and a range of secondary endpoints including leukaemia free survival and overall survival.

Race was up 2.5 cents or 9.4 percent to 29 cents.

ANTISENSE THERAPEUTICS

Antisense says the database for its phase II trial of ATL1102 for Duchenne muscular dystrophy has been locked for final analysis, with results expected in April.

In December, Antisense said its nine-patient, open label, six-month phase II dosing trial of ATL1102 for Duchenne muscular dystrophy, at Melbourne's Royal Children's Hospital, showed safety, tolerability and efficacy (BD: Dec 17, 2019).

Antisense fell 0.3 cents or 7.3 percent to 3.8 cents with 1.1 million shares traded.

AZURE HEALTH TECHNOLOGY

Azure says the ASX has granted it an extension to its listing removal date to April 9, 2020.

In February, Azure said it hoped to raise up to \$10 million for a backdoor listing of Invictus Biopharma and an extraordinary general meeting earlier this month passed all resolutions to acquire Invictus (BD: Feb 5, Mar 6, 2020).

Today, Azure said if it had not re-complied by April 9, 2020, it would be removed.

Azure was in a suspension.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its Emtinb increases the total number of oligodendrocyte precursor cells and oligodendrocytes, in-vitro showing potential for multiple sclerosis.

Neuroscientific said multiple sclerosis caused damage to the protective sheath or myelin that covered nerve fibres, disrupted communication with the brain, and Emtinb's effect on oligodendrocytes indicated a "very significant effect on re-myelination".

The company said the study, by the Marseille, France-based contract research organization Neuron Experts, showed that Emtinb increased the total number of cells by up to five times, the number of oligodendrocyte precursor cells by up to seven times and the number of mature oligodendrocytes by up to 10 times.

Neuroscientific was up two cents or 13.8 percent to 16.5 cents.

IDT AUSTRALIA, ONCOSIL MEDICAL

The London and Luxembourg Lumyna Investments says it holds 14,095,000 IDT shares (6.0%) and 46,358,040 Oncosil shares (7.35%).

In a series of late substantial shareholder notices, covering 55 pages, Lumyna said that on June 24, 2019 it became substantial in IDT with 12,220,000 shares or 5.2 percent of the company, on June 25 ceased its substantial holding, on June 28 returned to substantial with 12,220,000 shares (5.2%), on July 11, increased to 16,517,000 (7.0%), on August 26, reduced to 12,577,184 shares (5.3%), October 15 increased to 15,020,000 shares (6.3%), on November 13, increased to 18,020,000 (7.6%) and on November 18, 2019 reduced to 14,095,000 shares (6.0%).

The company said the holdings related to an arrangement with Merrill Lynch and a "reverse repurchase (repo) agreement".

Lumyna said it became substantial in Oncosil on November 13, 2019 with 35,459,584 shares (5.62%) and increased on January 24, 2020 to 46,359,040 shares (7.35%).

Most of the substantial shareholder notices were signed by Lumyna director Daryl Wright.

On his LinkedIn page, Mr Wright said he was an executive board member and head of product and investment management at Lumyna.

IDT was unchanged at 10 cents.

CRYOSITE

Cryosite director Andrew Kroger says he has increased his substantial shareholding in Cryosite from 18,193,450 shares (38.83%) to 18,765,166 shares (40.05%).

The London-based Mr Kroger said that on March 13, 2020 he acquired 571,716 shares for \$40,015.78 or an average of 6.95 cents a share.

Cryosite was untraded at 7.2 cents.

ALTHEA GROUP HOLDINGS

The Sydney-based Pental Group says it has ceased to be a substantial shareholder in Althea.

Last October, Pental said it had become a substantial shareholder with 12,000,000 shares or 5.14 percent of the company (BD: Oct 30, 2019).

Today, Pental said that on March 12, 2020 it sold 915,000 shares for \$183,000 or 20.0 cents a share.

Althea was up one cent or 5.4 percent to 19.5 cents with 1.0 million shares traded.

NEXT SCIENCE

Next Science says its acne cream is available through Sydney-based online skincare direct marketer, TBH Skincare in Australia, New Zealand, the UK and parts of Europe.

Next Science said its acne cream used its Xbio technology in a non-salicylic acid-based topical cream which was “non-toxic and gentle on the skin ... [and broke] down the protective biofilm layer to expose acne bacteria and reduce acne symptoms”.

The company said that “multi-site ongoing clinical testing ... [showed] superior results in the resolution of mild to moderate acne compared to leading competitive brands, including products containing benzoyl peroxide.

Next Science chief executive officer Judith Mitchell told Biotech Daily that the 50-patient trial data was confidential at this stage.

The company said that TBH Skincare had run its own trial of the acne cream with a sample group of 20 females.

Next Science was up one cent or 0.6 percent to \$1.60.