



Biotech Daily

Monday May 6, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: ONCOSIL UP 16%; IMPEDIMED DOWN 21%**
- * **ALTERITY: 'PBT434 PASSES BLOOD-BRAIN-BARRIER, WELL-TOLERATED'**
- * **KAZIA '60mg GDC-0084 FOR GLIOBLASTOMA TOLERATED'**
- * **ELLEX LAUNCHES EYE PRIME DIAGNOSTIC**
- * **PHARMAUST MONEPANTEL DOG CANCER STUDY 'FLEXIBLE DOSING'**
- * **TBG COMPLETES ZHANGSHA ZHANGYE ACQUISITION**
- * **MGC APPOINTS GROW BIOTECH, IPS SPECIALS UK DISTRIBUTORS**
- * **W WHITNEY GEORGE, SPROTT TAKE 24% OF RHINOMED**
- * **ANTEO REQUESTS CAPITAL RAISING TRADING HALT**
- * **HAMISH GEORGE REPLACES DIMERIX CFO, CO SEC IAN HOBSON**
- * **POLYNOVO APPOINTS ASHOK SRINIVASAN COO**
- * **INVITROCUE APPOINTS DR WAHAB INSURANCE ADVISOR**
- * **ONEVENTURES APPOINTS JIM SCOPA, DR DAN BAKER**

MARKET REPORT

The Australian stock market fell 0.82 percent on Monday May 6, 2019, with the ASX200 down 52.1 points to 6,283.7 points. Nine of the Biotech Daily Top 40 stocks were up, 24 fell, four traded unchanged and three were untraded.

Oncosil was the best for the third trading day in a row on no news, recovering a further 1.2 cents or 16.2 percent to 8.6 cents, with 9.6 million shares traded. Avita and Proteomics climbed more than seven percent; Kazia was up 6.6 percent; Alterity rose five percent; Orthocell improved 4.55 percent; Universal Biosensors was up 2.3 percent; Compumedics was up 1.85 percent; with Clinuvel up 0.1 percent.

Impedimed, led the falls for the second trading day in a row, on clarification that its study published on Friday did not meet statistical significance, down 5.5 cents or 20.75 percent to 21 cents with 5.1 million shares traded. Osprey lost 11.5 percent; Antisense shed 7.8 percent; both Optiscan and Uscom eased 5.9 percent; Dimerix and Neuren fell more than four percent; Immutep and Medical Developments were down more than three percent; Nanosonics, Paradigm, Polynovo, Prescient and Telix shed more than two percent; Ellex, Genetic Signatures, LBT, Pro Medicus, Resmed and Volpara were down more than one percent; with CSL, Cyclopharm, Cynata, Mesoblast, Opthea and Starpharma down by less than one percent.

[ALTERITY THERAPEUTICS \(FORMERLY PRANA BIOTECHNOLOGY\)](#)

Alterity said its phase I trial of PBT434 shows that it passes through the blood-brain-barrier in clinically relevant at doses and is well-tolerated in healthy volunteers.

Alterity said that oral PBT434 was well-tolerated with adverse event rates comparable to placebo and dose dependent systemic exposure.

The company said that PBT434 crossed the blood-brain-barrier, confirming previous observations in animal studies and clinically-tested doses achieve concentrations in the brain that exceeded those associated with efficacy in animal models, with no serious adverse events reported and no subject discontinued due to adverse events.

Last year, Prana chief medical officer Dr David Stamler said the first part of the trial would be a single ascending dose study of up to 48 healthy volunteers, in cohorts of eight subjects per dose, investigating the drug's pharmacokinetics, safety and blood levels, as well as finding the maximum tolerated dose followed by a multiple ascending dose with daily dosing of three different levels of PBT434 for one week (BD: Jun 27, Jul 4, 2018).

Today the company said that PBT434 was "the first of a new generation of small molecules designed to inhibit the aggregation of alpha-synuclein" implicated in neurodegenerative diseases such as Parkinson's disease and atypical parkinsonism.

Alterity said the data, titled 'A First in Human Study of PBT434, a Novel Small Molecule Inhibitor of α Synuclein Aggregation' would be presented by Dr Stamler at the American Academy of Neurology meeting in Philadelphia from May 4 to 11, 2019.

The company said the study was expected to be completed in mid-2019, but it had been invited to present interim data from the four single and the three multiple dose cohorts.

Alterity said that a secondary goal was to evaluate pharmacokinetic measures that would allow it to understand how PBT434 was absorbed and metabolized by the body.

Alterity was up 0.2 cents or 5.0 percent to 4.2 cents.

[KAZIA THERAPEUTICS](#)

Kazia says an eight-patient, phase IIa, safety study of GDC-0084 for glioblastoma has established that a 60mg dose is tolerated.

Kazia said that when it licensed the drug from the San Francisco-based Genentech that 45mg was the maximum tolerated dose, but its study of newly-diagnosed patients showed 60mg was tolerated.

The company said the study would move into the dose-expansion cohort and an additional 20 patients would receive a 60mg dose.

Kazia said the second part of the study was designed to provide confirmatory efficacy signals and was expected to report initial data by the end 2019.

The company said dose-limiting toxicities in this study included mouth ulcers and elevated blood sugar levels, both of which were expected effects of the phosphoinositide 3-kinase (PI3K) inhibitor class of drugs.

Kazia chief executive officer Dr James Garner said the results were "an important milestone".

Dr Garner said that Genentech's study examined GDC-0084 in very advanced patients and reached a maximum tolerated dose of 45mg, which was expected to be within the therapeutic range, but Kazia focussed on newly-diagnosed patients, who were generally in better health.

"The fact that the drug appears better tolerated here than in the previous study validates our strategy for GDC-0084 and bodes well for the clinical efficacy of the drug," Dr Garner said.

Kazia was up three cents or 6.6 percent to 48.5 cents.

[ELLEX MEDICAL LASERS](#)

Ellex says it has launched its Eye Prime ultrasound diagnostic for eye pathology. Ellex said the US Food and Drug Administration cleared Eye Prime on April 12 and it was launched at the American Society of Cataract and Refractive Surgery meeting in San Diego, California, from May 3 to 7, 2019.

The company said the diagnostic had “a multifocal array of six focal points to provide ... [a] crisp focus to improve image definition and clarity”.

Ellex said the increased depth-of-field and dynamic imaging permitted “materially enhanced viewing of the fine and intricate structures inside the eye” which could not be seen with competitor products.

Ellex fell one cent or 1.7 percent to 58.5 cents.

[PHARMAUST](#)

Pharmaust says its phase I trial of monepantel and monepantel sulfone shows that healthy beagle dogs can be dosed with up to five tablets a day for nine days.

Pharmaust said it was preparing the trial design for its phase II program in dogs with cancer and the phase I trial tested safety and serum levels of monepantel and its major metabolite monepantel sulfone in the blood of healthy dogs.

The company said that both monepantel and monepantel sulfone provided anti-cancer activity and while one tablet a day at an undisclosed dose provided long-term blood levels exceeding its target, five tablets daily tripled the target levels.

Pharmaust said the results provided “flexibility in designing dosing schedules for therapeutic treatment of dogs with cancer”.

Pharmaust’s chief scientific officer Dr Richard Mollard said the results allowed the company to “assess several different clinical strategies to determine which best fits monepantel’s anti-cancer properties” including low-dose maintenance therapy to keep problematic cancers under control or short-term very high dose therapy aimed at eradicating other cancers.

Pharmaust was up 0.1 cents or three percent to 3.4 cents.

[TBG DIAGNOSTICS](#)

TBG says it has completed the acquisition of the Zhangsha Zhangye Medical Laboratory Corp through its TBG Biotechnology Xiamen subsidiary.

Last year, TBG said it would acquire Zhangye through TBG Xiamen, with Zhangye taking 42.1 percent of TBG Xiamen (BD: Dec 17, 2018).

Today, the company said it would hold 46.65 percent of TBG Xiamen, and TBG Xiamen would hold 100 percent of Zhangye.

TBG said the Zhangsha, Hunan Province-based Zhangye provided medical laboratory testing services to hospitals and the community.

TBG fell 0.2 cents or 4.9 percent to 3.9 cents.

[MGC \(MEDICAL GRADE CANNABIS\) PHARMA](#)

MGC says it has appointed Grow Biotech PLC and IPS Specials to distribute its medical marijuana in the United Kingdom for five years.

MGC said the London-based Grow Biotech and IPS would distribute their Cannepil for epilepsy and Cognicann for Alzheimer’s pending registration.

MGC was unchanged at five cents with 19.7 million shares traded.

[RHINOMED](#)

W Whitney George and Sprott Asset Management say they have increased their holding in Rhinomed from 32,528,955 shares (22.92%) to 33,951,741 (23.92%).

The Carlsbad, California-based Mr George said that between February 28 and May 3, 2019 he bought 1,422,786 shares for \$US188,520 (\$A270,243) or 19.0 cents a share. Rhinomed was up one cent or 4.4 percent to 23.5 cents.

[ANTEO DIAGNOSTICS](#)

Anteo has requested a trading halt pending an “announcement to the market in relation to the capital raising”.

Trading will resume on May 8, 2019 or on an earlier announcement.

Anteo was unchanged at 1.8 cents with 1.3 million shares traded.

[DIMERIX](#)

Dimerix says it has appointed Hamish George as chief financial officer and company secretary replacing Ian Hobson effective from today May 6, 2019.

Dimerix said Mr George had experience in financial advice and chief financial officer services, expertise in financial and management reporting, company secretarial, cash flow management, taxation including research and development tax incentives, company establishments, company valuations, budgeting and forecasting.

The company said Mr George was an executive of the Melbourne-based BTC Health subsidiary Bio101, a financial services firm.

Dimerix said Mr George held a Bachelor of Commerce from the University of Melbourne and a Master of Accounting from the Royal Melbourne Institute of Technology.

Dimerix fell 0.4 cents or 4.65 percent to 8.2 cents.

[POLYNOVO](#)

Polynovo says it has appointed Ashok Srinivasan as chief operating officer responsible for manufacturing, engineering, supply chain and facilities.

Polynovo said Mr Srinivasan had 25 years' experience and led a joint venture with the Warsaw, Indiana-based Biomet Inc in Jinhua, China and was responsible for starting a green-field plant manufacturing orthopaedic surgical instruments and implants for the US and Europe, and more recently Mr Srinivasan was the chief operating officer for Orange, California-based Meral and Global Health Industries.

Mr Srinivasan's LinkedIn profile said he held a Bachelor of Engineering from the Coimbatore, Tamil Nadu, India-based Coimbatore Institute of Technology and a Master of Engineering from the Cookeville-based Tennessee Technological University.

Polynovo fell 2.5 cents or 2.35 percent to \$1.04 with 2.65 million shares traded.

[INVITROCUE](#)

Invitrocue says it has appointed Dr Sharifuddin Abdul Wahab as insurance advisor for its oncology patient-derived organoid (Onco-PDO) service.

Invitrocue said Dr Wahab was a veterinarian and chairman of the Jakarta, Indonesia-based KSK insurance and was previously chief executive officer of the Hong Kong-based Schmidt Biomedtech Asia.

Invitrocue fell 0.2 cents or 2.9 percent to 6.8 cents.

ONEVENTURES

Oneventures says it has appointed Jim Scopa and Dr Dan Baker to its healthcare team to provide insight and access to their networks in the US healthcare system.

The Sydney-based Oneventures venture capital firm said that its \$170 million Healthcare Fund III was investing \$10 million to \$20 million in companies commercializing medical devices, drugs in clinical development or diagnostics and currently invested in five healthcare sector companies including Blade Therapeutics developing small molecule drugs for fibrosis and Bivacor for its total artificial heart to replacement a failing heart (BD: May 17, 2018).

The company said that Dr Baker was appointed as a venture partner in March 2019 and had 19 years of clinical and business development experience in drug development, product commercialization and research and growth strategy.

Oneventures said that most recently, Dr Baker was Janssen's head of immunology drug development.

The company said that Mr Scopa had been appointed as its director on the board of Blade Therapeutics and as a member of the Healthcare Fund III advisory and investment committees (BD: Aug 11, 2017).

Oneventures said that Mr Scopa was previously MPM Capital's managing-director and a member of its investment committee leading investments in biopharmaceuticals, medical devices and diagnostics.

The company said that Mr Scopa held a Doctor of Jurisprudence and a Master of Business Administration from Harvard University.