



Biotech Daily

Thursday October 6, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH UP: POLYNOVO UP 23%; ONCOSIL DOWN 9%**
- * **POLYNOVO: 'RECORD \$12.5m 1st QUARTER NOVOSORB SALES'**
- * **KAZIA: 2 AUSTRALIAN SITES JOIN PAXALISIB, ONC201 GLIOMA TRIAL**
- * **CLARITY IMAGES 1st CU-64 SAR-BOMBESIN PATIENT**
- * **ACTINOGEN REQUESTS 'ALZHEIMER'S TRIAL RESULTS' TRADING HALT**
- * **CRESO RECRUITS PHASE II PSILOCYBIN PTSD TRIAL**
- * **REGAL TAKES 19.6% OF OPTHEA**
- * **AUSTRALIAN ETHICAL INCREASES, DILUTED TO 4.98% IN IMMUTEP**
- * **KEFFORD INCREASES, DILUTED TO 5.7% IN VECTUS**
- * **MICHAEL LIEW BELOW 5% OF OSTEOPORE**
- * **IRENE CHEN TAKES 8.6% OF OSTEOPORE**
- * **DR BEATA EDLING REPLACES TRUSCREEN CEO JULIET HULL**
- * **ATSE APPOINTS DR KATHERINE WOODTHORPE 'PRESIDENT'**
- * **MARK EDWARDS TO REPLACE INOVIQ CFO, CO SEC TONY DI PIETRO**
- * **AUDEARA LOSES CFO, CO SEC MALCOM THOMPSON**
- * **HYDRIX SENDS PETER LEWIS TO BOSTON TO INCREASE US SALES**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Thursday October 6, with the ASX200 up 1.8 points to 6,817.5 points. Twenty-one Biotech Daily Top 40 stocks were up, eight fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Polynovo was the best, up 34 cents or 23.2 percent to \$1.805, with 6.1 million shares traded. Paradigm climbed 19.5 percent; Starpharma was up 10.6 percent; Dimerix rose 7.1 percent; Cynata climbed 6.15 percent; Amplia, Neuren, Patrys, Prescient and Volpara were up five percent or more; Immutep improved four percent; both Alcidion and Universal Biosensors were up 3.85 percent; Pharmaxis rose 2.5 percent; Atomo, Mesoblast, Nanosonics and Next Science were up more than one percent; with Clinuvel and Telix up by less than one percent.

Oncosil led the falls, down 0.4 cents or 8.7 percent to 4.2 cents, with 235,754 shares traded. Micro-X lost 6.45 percent; Emvision fell 4.1 percent; Avita, Genetic Signatures and Opthea shed more than two percent; Impedimed was down 1.5 percent; with Cochlear, CSL, Pro Medicus and Resmed down by less than one percent.

POLYNOVO

Polynovo says it has “record” Novosorb BTM sales of \$12.5 million for the three months to September 30, 2022, up 73.3 percent from the prior corresponding period.

The company said it had a “record” \$5.4 million in Novosorb biodegradable temporizing matrix (BTM) in September, its first month of more than \$5 million sales.

Polynovo chief executive officer Swami Raote said the financial results were “a vindication of surgeon recognition of consistent outcomes, better patient experience along with hospital systems acknowledgement of lower complexity and cost ... [of] Novosorb BTM”.

“I am pleased with how our teams are now beginning to translate our burn heritage and supremacy into trauma and other acute surgical soft tissue reconstruction opportunities,” Mr Raote said.

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KAZIA THERAPEUTICS

Kazia says it has opened two Australian sites in the 216-patient phase II trial of paxalisib and ONC201 for diffuse intrinsic pontine glioma and other gliomas.

Kazia said that the trial was sponsored by the Pacific Pediatric Neuro-Oncology Consortium and was “the first time that paxalisib has been the subject of a clinical trial in Australia”.

The company said that diffuse gliomas comprised about 15 percent of brain tumors in children and life expectancy from diagnosis was about nine to 11 months, with no US Food and Drug Administration-approved drug treatments.

Kazia said the PNOC022 study combined paxalisib with the Durham, North Carolina-based Chimerix Inc’s ONC201.

According to www.clinicaltrials.gov, the trial also incorporated radiation therapy, was sponsored by the University of California San Francisco, and expected to be completed by July 2027.

The website said the primary outcome was progression-free survival at six months with a secondary outcome of overall survival at seven months.

In June, the company said that two patients who received the combination under compassionate access showed “dramatic reductions in tumor volume and complete resolution of disease symptoms, extending overall survival” (BD: Jun 14, 2022).

Today, Kazia said recruitment had been “robust since it opened in November 2021” starting at the University of California, San Francisco and currently active at nine sites in the US and two in Australia, with activation in other countries under discussion.

Kazia chief executive officer Dr James Garner said that brain cancer was “the leading cause of childhood cancer death and [diffuse midline gliomas] represent one of the most challenging types of tumor”.

“The pre-clinical data supporting the combination of paxalisib and ONC201 is substantial and persuasive,” Dr Garner said.

Kazia said the study had cohorts of patients with newly diagnosed disease, patients who had initial radiotherapy and patients who with disease progression after treatment, with all receiving a combination of ONC201 with paxalisib, with initial data expected in 2023.

The company said the GBM Agile pivotal study of paxalisib in glioblastoma was ongoing, with final data expected in 2023 and “depending on the results ... Kazia may use such data to support a new drug application to the FDA”.

In August, Kazia said the first stage of the paxalisib arm in the GBM Agile study did not meet the criteria for continuing in its “primary path-to-market” (BD: Aug 1, 2022).

Kazia was unchanged at 19 cents.

CLARITY PHARMACEUTICALS

Clarity says it has imaged its first of 50 patients in its phase II, US, 64-copper sarcophagine (Sar)-bombesin for prostate cancer imaging trial.

In June, Clarity said the US Food and Drug Administration had approved the 'Sabre' 50-patient single-arm, open-label, 64-SAR-bombesin positron emission tomography (PET) imaging trial investigational new drug application (BD: Jun 6, 2022).

Last month, the company said the trial's primary objective was "to investigate safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer" (BD: Sep 5, 2022).

Clarity fell one cent or 1.6 percent to 61.5 cents.

ACTINOGEN MEDICAL

Actinogen has requested a trading halt "pending an announcement of the results of the phase II biomarker study in people with mild Alzheimer's disease".

Trading will resume on October 10, 2022 or on an earlier announcement.

Actinogen last traded at 9.6 cents.

CRESO PHARMA

Creso says its Canadian subsidiary Halucenex Life Sciences has recruited the 20 patients for its phase II trial of psilocybin for post-traumatic stress disorder.

Previously, Creso said Health Canada approved the trial for treatment-resistant post-traumatic stress disorder (PTSD) including cohorts using selective serotonin reuptake inhibitors (SSRIs or anti-depressants) (BD: Jul 18, Sep 14, 2022).

Today, the company said the phase II, single-arm, open-label trial would "determine the feasibility of future trials of psilocybin in this indication" and would include military veterans, police, firefighters, emergency medical responders, psychologists, security officers and solicitors, with each participant exhibiting symptoms associated with PTSD as well as other mental illnesses including anxiety, suicidal thoughts, attention deficit hyperactivity disorder, obsessive compulsive disorder, depression and anger.

Creso said that Halucenex would use its formulated synthetic psilocybin aqueous solution Lucenex, in 10mg and 25mg formats, and that it expected the trial to be completed by December 14, 2022.

Halucenex chief executive officer Bill Fleming said his company had "been receiving a steady stream of inquiries since news of the trial was announced and we are very pleased to have completed the patient recruitment process in such an efficient manner".

"Halucenex will now begin preparing its relevant treatment facilities for first dosages, which will be administered within the next two weeks," Mr Fleming said.

Creso was unchanged at 3.2 cents with 1.1 million shares traded.

OPTHEA

Regal Funds Management Pty says it has increased its holding in Opthea from the equivalent of 72,389,923 shares (17.88%) to 91,100,873 shares (19.60%).

The Sydney-based Regal said that it bought and sold shares between September 1 and October 3, 2022, with the single largest purchase of 17,428,267 shares for \$20,042,507 or \$1.15 a share.

Opthea fell three cents or 2.7 percent to \$1.065.

IMMUTEP

Australian Ethical says it has increased and been diluted in Immutep from 43,323,364 shares (5.00%) to 43,459,437 shares (4.98%).

Australian Ethical said that on September 29, it bought 136,073 shares at 25.2 cents a share and on October 3, 2022 was diluted by the conversion of 6,702,207 rights.

Immutep was up one cent or four percent to 26 cents with 3.6 million shares traded.

VECTUS BIOSYSTEMS

Kefford Holdings Pty Ltd says it has increased and been diluted in Vectus from 2,549,321 shares (7.28%) to 2,688,321 shares (5.69%).

The Brisbane-based Kefford said that it bought, sold and transferred shares between July 1 and August 9, 2022, with the most recent purchase 60,000 shares for \$55,500 or 92.5 cents a share.

Kefford did not disclose how it was diluted.

Yesterday, the Sydney-based Regal Funds said that it converted 4,114,714 convertible notes (BD: Oct 5, 2022).

Vectus was untraded at 70 cents.

OSTEOPORE

Michael Marcus Liew says he has ceased his substantial holding in Osteopore, selling 2,053,000 shares for \$413,405 or an average of 20.1 cents a share.

In August, the Singapore-based Mr Liew said he held 7,581,191 shares or 6.46 percent and Biotech Daily calculates he holds 5,528,191 shares (4.7%) (BD: Aug 25, 2022).

Today, Mr Liew said that on September 13, he sold 33,000 shares for \$9,405 or 28.5 cents a share and October 3, 2022 he sold 2,020,000 shares in an "off-market sale" for \$404,000 or 20 cents a share.

Osteopore was up half a cent or 2.2 percent to 23.5 cents.

OSTEOPORE

The Kuala Lumpur, Malaysia-based Irene Ng Ai Chen says she has increased her holding in Osteopore from 8,082,625 shares (6.89%) to 10,102,625 shares (8.61%).

Ms Chen said that on October 3, 2022 she bought 2,020,000 shares in an "off-market purchase" for \$404,000 or 20 cents a share (see above).

TRUSCREEN GROUP

Truscreen says it has appointed its head of medical affairs and market access lead Dr Beata Edling as chief executive officer, replacing director Juliet Hull.

Truscreen said Dr Edling joined the company in October 2020 and previously worked for Sanofi-Aventis, Shire, Eli Lilly and Amgen, and was a Noxopharm director.

The company said Dr Edling held a Doctor of Medicine from the Medical University, Gdansk, Poland, a Master of Business Administration from Sydney's Australian Graduate School of Management and a Doctor of Philosophy from the University of New South Wales in Sydney.

Truscreen thanked non-executive director Juliet Hull for her work as interim chief executive officer for the past 20 months.

Truscreen was up 0.6 cents or 14.6 percent to 4.7 cents.

[ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING](#)

The Academy of Technological Sciences and Engineering says it has appointed Dr Katherine Woodthorpe as its tenth president, effectively the chair of its board.

The Academy described itself as Australia's "premier organization for engineers, technologists and applied scientists".

ATSE said that Dr Woodthorpe was the first woman to lead the Academy in its 47-year history and takes up her tenure on January 1 2023.

The Academy said that Dr Woodthorpe had been a company director for more than over 20 years including as chair of Natural Hazards Research Australia, the Antarctic Science Foundation and the Hearing Cooperative Research Centre, the Olivia Newton-John Cancer Research Institute, Bioplatforms Australia, the Australian Renewable Energy Agency, Vast Solar, Sirtex and Anteotech.

In 2015, Sirtex said it had appointed Dr Woodthorpe as a director and she was the then Australian Venture Capital Association chief executive officer (BD: Sep 22, 2015).

ATSE said the Dr Woodthorpe previously chaired the National Climate Science Advisory Committee and currently chaired the Federal Government's 'Vision 2040' committee reviewing the strategy for investment in medical research for the next two decades.

The Academy said that Dr Woodthorpe held a Bachelor of Science from the University of Manchester, a Doctor of Philosophy from the University of Leicester and an Honorary Doctorate from the University of Technology Sydney.

[INOVIQ](#)

Inoviq says Mark Edwards will replace chief financial officer and company secretary Tony Di Pietro, effective from November 2, 2022.

Inoviq said Mr Di Pietro had been with the company for eight years and would continue until November 11, 2022.

The company said Mr Edwards most recently was Medical Developments chief financial officer and company secretary and previously worked for Cogstate and Ernst & Young.

According to his LinkedIn page, Mr Edwards held a Bachelor of Accounting from Melbourne's Monash University.

Inoviq was up four cents or 7.5 percent to 57.5 cents.

[AUDEARA](#)

Audeara says Malcom Thompson has resigned as chief financial officer and company secretary "due to personal circumstances" effective from October 7, 2022.

Audeara managing-director Dr James Fielding said "on behalf of the board and team at Audeara we thank Malcolm for his work over the past six months, and particularly his efforts recently throughout the unexpected loss of a close family member".

"We have appreciated his professionalism and dedication at this challenging time and we wish Malcolm and his family the very best," Dr Fielding said

Audeara said that Stephen Buckley had been appointed company secretary on September 21, 2022 and that staff in the financial services team would share the work previously undertaken by Mr Thompson.

Audeara was untraded at 8.8 cents.

HYDRIX

Hydrix says head of business development Peter Lewis will relocate to Boston and be replaced in Australia by business development executive Peter Riddell.

Hydrix said that Hydrix Services was its wholly-owned US subsidiary and that Mr Lewis would focus on “growing the Hydrix Services business unit” in the US.

The company said Mr Lewis had more than 30 years of experience and previously worked for the Australian Trade Commission in San Francisco as senior trade commissioner and consul general, and was formerly the Hydrix chief executive officer.

Hydrix said that Mr Riddell worked for the Invetech Group for more than 20 years in various roles.

Hydrix was up 0.1 cents or 1.7 percent to 6.1 cents.