



Biotech Daily

Monday October 31, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ALCIDION UP 10.5%; KAZIA DOWN 10%**
- * **VICTORIA \$8.5m FOR 17 CANCER FELLOWSHIPS**
- * **CLINUVEL Q1 RECEIPTS UP 43% TO \$25.5m**
- * **ALCIDION: Q1 RECEIPTS UP 83% TO \$12m**
- * **ALTHEA Q1 RECEIPTS UP 82% TO \$8.1m, 'CAPITAL RAISE' HALT**
- * **CORRECTION: QBIOTICS GROUP**
- * **NUHEARA: FDA APPROVES HEWLETT-PACKARD HEARING PRO**
- * **BOTANIX RAISES \$5m, SHARE PLAN FOR \$3m MORE**
- * **EMYRIA RAISES \$3m**
- * **VOLPARA JOINS EPIC SOFTWARE PROGRAM**
- * **IMUGENE DOSES 1st INTRA-TUMORAL VAXINIA PATIENT**
- * **POLYNOVO AGM FACES 22% OPPOSITION**
- * **TOTAL BRAIN AGM APPROVES SONDERMIND SALE, REM REPORT 1st STRIKE**
- * **LIVING CELL SPILL: HAINSWORTH, DILKES IN; TUCH, WILLCOCKS, KELLY OUT**
- * **CRONOS DIRECTOR SPILL, NAME CHANGE TO 'VITURA' AGM**
- * **REGAL TAKES 5.6% OF PHARMAXIS**
- * **RADIOPHARM CHAIR PAUL HOPPER INCREASES, DILUTED TO 32%**
- * **EPSILON APPOINTS 9% HOLDER XIAO CUI DIRECTOR**
- * **ANTEO APPOINTS KATRINA BYRNE COO, DR CHARLIE HUANG CIO**

MARKET REPORT

The Australian stock market was up 1.15 percent on Monday October 31, 2022, with the ASX200 up 77.8 points to 6,863.5 points. Twenty-two of the Biotech Daily Top 40 were up, 11 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Alcidion was the best, up 1.5 cents or 11.5 percent to 14.5 cents, with seven million shares traded. Nanosonics, Paradigm and Universal Biosensors climbed more than seven percent; Imugene improved 6.1 percent; Nova Eye was up 5.9 percent; Clinuvel and Mesoblast climbed more than four percent; Avita, Immutep, Orthocell, Pro Medicus, Resonance and Starpharma were up more than three percent; Amplia, Compumedics, CSL, Impedimed, Polynovo and Proteomics rose more than two percent; Cochlear, Neuren, Pharmaxis and Telix were up more than one percent; with Resmed up 0.4 percent.

Kazia led the falls, down 1.5 cents or 10 percent to 13.5 cents, with 1.4 million shares traded. Antisense fell 4.8 percent; Atomo, Dimerix, Medical Developments and Micro-X lost more than three percent; Oncosil and Opthea shed more than two percent; Cynata and Genetic Signatures were down more than one percent; with Volpara down by 0.7 percent.

VICTORIA GOVERNMENT

The Victoria Government says it will provide \$8.5 million for 17 fellowships for cancer researchers through the Victorian Cancer Agency.

In a media release the Victoria Minister for Health Mary-Anne Thomas said fellowships would be awarded to nine early-career and eight mid-career cancer researchers to support its Victorian Cancer Plan 2020-2024, aiming to improve cancer survival rates and achieve equitable outcomes in Victoria.

The State Government said the Walter and Eliza Hall Institute's Prof Naiyang Fu, Peter MacCallum Cancer Centre's Dr Clare Slaney, Lung Foundation Australia's Dr Mara Zeissig, and Ovarian Cancer Australia's Dr Dale Garsed were awarded fellowships.

Ms Thomas said that cancer survival was "at an all-time high but too many people are still dying from the disease ... that's why we have an ambitious plan to save more lives and invest in more research to find a cure".

CLINUVEL PHARMACEUTICALS

Clinuvel says receipts from customers for the three months to September 30, 2022 were up 43.4 percent to \$25,512,000 compared to the prior corresponding period.

Clinuvel said it had "recorded its highest quarterly results from customer receipts since the commencement of commercial operations in Europe in June 2016 and United States in April 2020".

The company said the revenue was primarily from its Scenesse photosensitivity treatment for erythropoietic protoporphyria (EPP).

Clinuvel said it had cash and cash equivalents of \$137,648,000 at September 30, 2022 compared to \$93,383,000 at September 30, 2021.

Clinuvel was up 90 cents or 4.8 percent to \$19.56 with 88,894 shares traded.

ALCIDION GROUP

Alcidion says receipts from customers for the three months to September 30, 2022 were up 83.2 percent to \$12,006,000 compared to the previous year.

Alcidion said that total contracted revenue at September 30, 2022 was up 68.6 percent to \$29.0 million, primarily from the sales its hospital management and patient care software across the UK, New Zealand, and Australia.

The company said it had a cash burn rate of \$483,000, cash and cash equivalents of \$16,209,000 and 33 quarters of funding available at September 30, 2022.

Alcidion was up 1.5 cents or 11.5 percent to 14.5 cents with seven million shares traded.

ALTHEA GROUP

Althea says receipts from customers for the three months to September 30, 2022 were up 81.57 percent to \$8,120,000, and requested a 'capital raise trading' halt.

Althea said revenue came from sales and distribution of pharmaceutical and non-pharmaceutical marijuana-based products, including its new cannabidiol CBD25 soft gel capsules and tetrahydrocannabinol THC25 dried flower product.

The company said it had cash and cash equivalents of \$3,557,000 at September 30, 2022, with 1.3 quarters of funding available.

Trading will resume on November 2, 2022 or on an earlier announcement.

Althea last traded at 8.3 cents.

CORRECTION: QBIOTICS GROUP

Friday's edition incorrectly reported that Qbiotics tigilanol tiglate was also known as EBC-46 and EBC-1013.

EBC-46 is another name for tigilanol tiglate and is being trialled for tumors, but EBC-1013 is a semi-synthetic analogue of tigilanol tiglate being developed for wound healing.

The mistake was made by the Friday sub-editor who has been seconded to the Yungaburra Herald-Tribune for tropical rainforest accuracy training.

Qbiotics is a public unlisted company.

NUHEARA

Nuheara says it has US Food and Drug Administration 510(k) approval for its self-fitting, over-the-counter Hewlett-Packard Hearing Pro hearing aid.

In April, Nuheara said it had a licence to develop and manufacture its sound filtering and hearing products under the Hewlett Packard (HP) trademark (BD: Apr 26, 2022).

Today, the company said the regulatory category for over-the-counter (OTC) hearing aids in the US had been established on October 17, 2022, and it allowed for hearing aids to be sold in that category for "perceived mild to moderate hearing loss".

Nuheara said the Hewlett-Packard Hearing Pro combined "medical grade hearing aid technology... with highly desired features of wireless ear buds into a multifunctional device" sold both online in the US and in retail stores.

The company said the hearing aids recommended retail price was \$US699 (\$A1,089).

Nuheara managing-director Justin Miller said it was a significant day for his company, and "since establishing the business in 2015, we have been driven by our ambitious vision that our affordable and leading-edge hearing devices could help to solve the consumer imbalance of accessibility".

"How fitting for our efforts, that concurrent with receiving our 510(k) clearance from the US FDA, over the counter sales can also commence in the US ... even better that our first hearing aid product for this new market, the HP Hearing Pro, will now be released under one of the most recognized and trusted brands in the world," Mr Miller said.

"Not surprisingly, the response from retailers has been strong, and we are well-placed to deliver Nuheara's sophisticated hearing solutions to the growing OTC hearing aid market," Mr Miller said.

Nuheara was up four cents or 23.5 percent to 21 cents with 1.9 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has a commitment for a \$5 million placement at 6.3 cents a share to Antares Capital and will offer an up-to \$3 million, non-underwritten share plan.

Botanix said the placement and share plan prices were at the price of last close on October 26, 2022 with no discount and no options attached.

The company said the placement to Melbourne's Antares Capital would be in two tranches, with the second tranche subject to shareholder approval.

Botanix said that the share purchase plan had a record date of October 28, would open on November 9 and close on November 23, 2022.

Botanix said funds would be used to progress its dermatology assets, prepare for a US Food and Drug Administration approval of its sofipironium bromide for excessive sweating and for general working capital.

The company said Sydney's Jefferies Australia Pty Ltd was the placement lead manager.

Botanix was up 0.2 cents or 3.2 percent to 6.5 cents.

EMYRIA

Emyria says it has raised \$3 million in a placement at 18 cents a share, with one option for every two shares, exercisable at 35 cents each within three years.

Emyria said the raising was 'corner-stoned' for \$1 million from lead manager, Perth's Sixty Two Capital, \$500,000 from Tattarang and \$150,000 from directors, subject to approval.

The company said the offer price of 18 cents was a 14.3 percent discount to the closing price on October 26, 2022 and the funds would advance its phase III trials and commercialisation of EMD-RX5, support its phase I trial of EMD-RX7, develop pre-clinical screening programs for its drug discovery program, and for working capital.

Emyria was up half a cent or 2.4 percent to 21.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has an agreement with the Verona, Wisconsin-based Epic Systems to join its software application market program.

According to Wikipedia, Epic Systems was a private healthcare software company which had medical records of 78 percent of US patients and three percent of patients worldwide.

Volpara said the agreement provided it with access to "technologies, testing tools, and technical support to help enable its [applications] to interoperate effectively with Epic software and users' Epic workflows," but did not disclose the commercial terms.

The company said the agreement allowed it to integrate its products with Epic and provide information about its products directly to Epic customers.

Volpara fell half a cent or 0.7 percent to 67.5 cents.

IMUGENE

Imugene says it has dosed the first patient in the second cohort of intra-tumoral dosing in its phase I trial of CF33-hNIS, or Vaxinia, virotherapy in advanced solid tumors.

In May, Imugene said it had dosed the first of up-to 100 patients, in its phase I trial of intra-tumoral and intra-venous Vaxinia and pembrolizumab for metastatic or advanced solid tumors (BD: May 18, 2022).

Last month, the company said it dosed the first intra-venous patient (BD: Sep 21, 2022).

Today, the company said the trial had delivered a low dose to patients with metastatic or advanced solid tumors who have had at least two prior lines of standard of care treatment.

Imugene was up one cent or 6.1 percent to 17.5 cents with 29.4 million shares traded.

POLYNOVO (FORMERLY CALZADA, METABOLIC))

Polynovo says its annual general meeting voted more than 22.4 percent in opposition to issue 1,200,000 options to chief technical and scientific officer Dr David McQuillan.

Polynovo said the resolution to issue the options to former director Dr McQuillan was opposed by 60,779,947 votes (22.42%) with 210,292,051 votes (77.58%) in favor.

Last month, the company said Dr McQuillan was appointed a director of the then Calzada in 2012 and resigned on September 1, 2022 (BD: Sep 1, 2022).

The company said the re-election of directors David Williams and Leon Hoare faced about 10 percent opposition, with the remuneration report passed more easily.

According to its annual report, Polynovo had 661,688,044 shares on issue meaning that the opposition to Dr McQuillan's options amounted to 9.2 percent of the company, sufficient to requisition extraordinary general meetings.

Polynovo was up 4.5 cents or 2.3 percent to \$2.00 with 1.6 million shares traded.

TOTAL BRAIN

Total Brain says its annual general meeting approved its acquisition by Sondermind, and but voted 26.24 percent against the remuneration report, delivering a 'first strike'.

Total Brain said 61,401,853 votes (92.97%) supported the proposed acquisition by the Denver, Colorado-based Sondermind Health for \$US10 million (\$A14.4 million) with 4,643,647 votes (7.03%) opposed (BD: Sep 5, 2022).

In a separate announcement, the company said the transaction was expected to occur on November 1, 2022.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and at the later meeting, and if passed, the directors must stand for re-election at a subsequent meeting within 90 days.

Total Brain said the re-election of director Matthew Morgan was opposed by 5,482,826 votes (9.15%), with David Torrible re-elected as a director by a wider margin.

According to its most recent filing, Total Brain had 133,721,131 shares on issue, meaning the vote against the re-election of Mr Morgan amounted to 4.1 percent of the company, not sufficient to call extraordinary general meetings.

Total Brain was unchanged at 3.8 cents with 1.5 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says David Hainsworth and Mr Bradley Dilkes have replaced directors Prof Bernie Tuch, Robert Willcocks and Dr Andrew Kelly prior to the annual general meeting.

In September, Living Cell said it had received a section 249D board spill notice from shareholders controlling more than five percent of the company, calling for the removal of executive chair Prof Bernie Tuch and directors Robert Willcocks and Dr Andrew Kelly, to be replaced by David Hainsworth and Bradley Dilkes, directors of Melbourne's Alignment Capital (BD: Sep 14, 2022).

Today, the company said that Prof Tuch would continue as interim chief executive officer until the end of January 2023 and Prof Carolyn Sue would continue as a director.

Living Cell said that the three outgoing directors "decided to resign in advance of resolutions for their removal being put to the company's annual general meeting on November 10, 2022 when it appeared that such resolutions would pass".

"It was felt that doing so would enable the orderly and efficient transition to the new directorships," the company said.

In 2017, Living Cell fell as much as 88.8 percent to 2.3 cents on news there was no statistical significance for the efficacy of its NTCcell treatment for Parkinson's disease, although three of the four primary endpoints were met in its 18-patient, phase IIb trial, with no product or procedure adverse events and no evidence of xenogeneic infection in patients and their partners (BD: Nov 10, 2017).

In 2018, the company said that 12-month data showed a "statistically significant improvement" in patients who had 40 or 80 NTCcell capsules implanted to the putamen on both sides of the brain, but patients implanted with 120 NTCcell capsules did not appear to have a significant improvement change (BD: May 15, 2018).

In 2021, Living Cell said it raised \$361,264 of a hoped for \$4 million in a rights issue for a third trial of NTCcell for Parkinson's disease (BD: Mar 21, 2021).

Living Cell was unchanged at 1.3 cents.

CRONOS AUSTRALIA

Cronos says its annual general meeting will vote on the board-opposed resolutions to remove executive directors Rodney Cocks and Guy Headley.

Last month, Cronos said it had received a notice from Matua Hasyo Charlie Jansen calling for the removal of the two directors (BD: Sep 14, 2021; Sep 20, 2022).

Cronos said at that time that Dr Matua Jansen was a founder of Cannabis Doctors Australia, which it acquired in 2021, and a former doctor with the company.

Today, the company said shareholders would vote to remove chief executive officer Mr Cocks and chief commercial officer Mr Headley as directors, but that the resolutions were not endorsed by the board.

Cronos said the meeting proposed to change its name to Vitura Health, a special resolution requiring a 75 percent votes.

The company said that is approved the ASX code would change to VIT.

Cronos said shareholders would vote to re-elect directors Jenelle Lee Frewen and Dr Simone Louise Scovell and adopt the remuneration report.

The meeting will be held at Thomson Geer, Level 23, Rialto South Tower, 525 Collins Street, Melbourne, on November 29, 2022 at 10am (AEDT) and online at:

<https://meetnow.global/MMRTMGQ>.

Cronos was unchanged at 87 cents.

PHARMAXIS

Regal Funds Management Pty Ltd says it has become substantial in Pharmaxis with 35,516,473 shares or 5.62 percent.

The Sydney-based Regal said that on October 26, 2022 it bought 38,439,773 shares for \$2,306,386 or six cents a share.

The company did not explain the discrepancy between the number of shares bought and the number of shares held.

Pharmaxis was up 0.1 cents or 1.6 percent to 6.3 cents.

RADIOPHARM THERANOSTICS

Executive Chair Paul Hopper says he has increased and been diluted in Radiopharm from 90,000,000 shares (35.5%) to 94,221,428 shares (31.78%).

Mr Hopper said that between November 29, 2021 and April 14, 2022, he bought 650,000 shares for prices ranging from 22.5 to 47 cents, and that on October 26 he participated in an institutional offer, buying 3,571,428 shares for 14 cents each.

Earlier this month, Radiopharm said it raised about \$5.5 million in an institutional offer at 14 cents a share (BD: Oct 20, 2022).

Radiopharm was unchanged at 12 cents with 1.8 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has appointed Xiao Cui as a director, effective from October 28, 2022.

Epsilon said Mr Cui was the founder and chief executive officer of Watercrest Capital Pty Ltd and co-founded West Garden International Pty Ltd.

Last month, Watercrest Asset Management, director Stuart Cameron and Karantzias Superfund said they had become substantial in Epsilon with 26,639,516 shares or 8.98 percent (BD: Sep 29, 2022).

Epsilon was up 0.1 cents or 3.45 percent to three cents.

[ANTEOTECH](#)

Anteo says it has appointed Katrina Byrne as chief operating officer and 'transitioned' Dr Charlie Huang to chief innovation officer, effective from today.

Anteo said Ms Byrne joined the company in July 2022 as head of programs and had previously worked at Airbus Australia Pacific as program manager of commercial operations, at Boeing as operation manager and at Phantom Works.

The company said Ms Byrne held a Bachelor of Engineering from the University of Queensland in Brisbane and a Master of Business Administration from the Australian Graduate School of Management at the University of New South Wales in Sydney.

Anteo said Dr Huang joined the company in 2013 and was appointed head of diagnostics and life science in 2019, and previously worked for Panbio, Alere, Cellestis and Qiagen.

Anteo said Dr Huang held a Bachelor of Science and a Master of Engineering from the National Chung Hsing University in Taiwan and a Doctor of Philosophy from the University of Queensland.

Anteo was unchanged at 5.5 cents with 1.85 million shares traded.