

Biotech Daily

Wednesday November 30, 2022

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: MESOBLAST UP 12%; PATRYS DOWN 7%
- * MATER, UQ: 'CBD NO VALUE FOR PALLIATIVE CARE'
- * CRESO, ROOTS DIRECTOR JAMES ELLINGFORD BAILED ON 6 CHARGES
- * TGA APPROVES TOUCH COVID-19-INFLUENZA-A-B RAPID ANTIGEN TEST
- * EMVISION STARTS BRAIN SCANNER TRIAL
- * LITTLE GREEN PHASE III CBD SLEEP, STRESS TRIAL APPROVED
- * BTC 84% REMUNERATION REPORT 1st STRIKE
- * PARADIGM AGM 42% DEFEAT PLACEMENT FACILITY, VIRTUAL MEETINGS
- * MEDADVISOR AGM 40% DEFEAT PLACEMENT FACILITY
- * INCANNEX AGM 18% OPPOSE CHAIR TROY VALENTINE ELECTION
- * STARPHARMA AGM 83% BLOCK BOARD-OPPOSED JOHN WISE
- * MAYNE AGM 16% OPPOSE REMUNERATION REPORT
- * VECTUS LOSES DIRECTOR PETER BUSH
- * MERCHANT TAKES 14.2% OF INOVIQ
- * MERCHANT TAKES 10.8% OF HEXIMA

MARKET REPORT

The Australian stock market was up 0.43 percent on Wednesday November 30, 2022, with the ASX200 up 30.9 points to 7,284.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 17 fell, four traded unchanged and one was untraded.

Mesoblast was the best, up 11.5 cents or 11.6 percent to \$1.105, with 4.75 million shares traded. Clinuvel climbed 7.7 percent; Actinogen, Next Science and Polynovo rose more than four percent; Imugene improved 2.8 percent; Alcidion, Cochlear, Cyclopharm, Cynata, Immutep, Impedimed, Telix and Volpara were up more than one percent; with Genetic Signatures, Paradigm, Pro Medicus and Proteomics up by less than one percent.

This week's 40 percent best, Patrys, led the falls, down 0.2 cents or 7.1 percent to 2.6 cents, with 10.1 million shares traded. Compumedics, Dimerix and Universal Biosensors lost more than six percent; Antisense, Avita, Kazia and Pharmaxis fell more than four percent; Prescient was down 3.3 percent; Nanosonics, Neuren, Orthocell and Starpharma shed two percent or more; Amplia, Opthea and Resonance were down more than one percent; with CSL, Medical Developments and Resmed down by less than one percent.

MATER RESEARCH, UNIVERSITY OF QUEENSLAND

Mater Research and the University of Queensland say a 144-patient, phase IIb, randomized, controlled study shows no benefit for low dose cannabidiol for cancer pain. In a media release, Mater said patients were dosed with 100mg/mL cannabidiol (CBD) oil 100mg/mL given at 0.5mL once daily, or up-to 2.0mL three times a day (6.0mL a day), or a matched placebo, for 28 days, in combination with standard palliative care.

The research institute said that patients were assessed using the Edmonton Symptom Assessment Scale (ESAS) to "determine whether cannabidiol oil can improve symptom distress" including pain, depression, anxiety and quality of life, in patients with advanced cancer receiving palliative care.

The Mater said that the study, titled 'Phase IIb Randomized, Placebo-Controlled, Dose-Escalating, Double-Blind Study of Cannabidiol Oil for the Relief of Symptoms in Advanced Cancer', was published in the Journal of Clinical Oncology, with the abstract available at: https://ascopubs.org/doi/abs/10.1200/JCO.22.01632.

The research institute said the study was led by Mater director of palliative and supportive care Prof Janet Hardy.

The abstract said that the change in ESAS total symptom distress scores from baseline at day 14 was -6.2 for placebo and -3.0 for CBD with "no significant difference between arms (p = 0.24)" and that there was "no detected difference in proportion of responders" with 37 of 63 placebo patients and 26 of CBD patients (p = 0.13) reporting responses.

"The trial revealed CBD was no better than placebo in reducing symptom burden in patients with cancer receiving standard palliative care," Prof Hardy said.

"The trial found there was no detectable effect of CBD on change in physical or emotional functioning, overall quality of life, fatigue, nausea and vomiting, pain, dyspnoea or appetite loss," Prof Hardy said.

"There was no demonstration of an improvement in symptom control from CBD oil in patients with advanced cancer over that obtained from palliative care alone," Prof Hardy said.

"It demonstrated that CBD did not value add to palliative care," Prof Hardy said.

"Despite very limited evidence of benefit and no clear guidance around which cannabinoid or combination to use for which indication and at what dose, the use of cannabis for therapeutic benefit has risen exponentially over the past few years with strong public belief in its benefit," Prof Hardy said.

"Despite the lack of evidence of benefit, more than one third (36%) of participants in the first study elected to purchase a medicinal cannabis product after the trial, despite being unaware if they were taking the CBD or placebo," Prof Hardy said.

"Many participants reported a non-specific improvement in overall well-being, which has led us to consider some form of "happiness" scale in future studies."

The media release said that this was the first of three trials conducted by Mater and the University of Queensland, with the second looking at the impact of delta-9-tetrahydrocannabinol (THC) the "potentially intoxicating, psychoactive component of medicinal cannabis".

The Mater said that THC would be used in combination with CBD on palliative care patients with advanced cancer.

"The next stage of the trial should determine whether THC, despite having psychoactive effects, is of greater benefit for patients in palliative care," Prof Hardy said.

"We are aiming to have the findings of our second trial ready to publish in mid-2023," Prof Hardy said.

CRESO PHARMA, ROOTS SUSTAINABLE AGRICULTURAL TECHNOLOGIES

Creso executive director and Roots director James Anthony Ellingford, 57, has been bailed on six charges including contravention of a domestic violence order and stalking. An officer of the Southport Magistrates Court, on Queensland's Gold Coast, told Biotech Daily that Mr Ellingford appeared before Magistrate Janice Crawford on Friday November 25, 2022 charged with: two counts of contravention of a domestic violence order; one count of unlawful stalking; and three counts of "improper use of emergency call services, vexatious".

Queensland Police Prosecutions told Biotech Daily that Mr Ellingford was granted bail and would reappear at the Southport Magistrates Court on February 3, 2023.

Last year, following an Australian Securities and Investments Commission (ASIC) raid on the offices of Everblu Capital, Everblu chair Adam Blumenthal stood aside as the chair of Creso and Roots with Mr Ellingford appointed Creso interim chair (BD: Nov 17, 25, 2021). Two weeks ago, Creso director and Roots managing-director Boaz Wachtel replaced Mr Ellingford as Creso's chair (BD: Nov 17, 2022).

In 2020, Mr Ellingford was appointed as a director of Esense-Lab, which delisted in 2021 (BD: Jan 19, 2020; Aug 9, 10, 2021).

Creso was up 0.1 cents or 5.6 percent to 1.9 cents with 29.7 million shares traded. Roots was unchanged at 0.2 cents with 5.2 million shares traded.

TOUCH BIOTECHNOLOGY PTY LTD

Touch says the Australian Therapeutic Goods Administration has approved its 'Combo' severe acute respiratory syndrome coronavirus-2-influenza A-and-B rapid antigen test. The Sydney-based Touch said it was a manufacturer and developer of "advanced antimicrobial protection solutions and rapid in-vitro antigen tests".

The company said its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and influenza A and influenza B 'Antigen Combo Test Kit' was "one of the first Therapeutic Goods Administration approved multi-virus rapid antigen tests in the Australia Market, with approval obtained in September 2022".

Touch said its rapid antigen test had "more than 98 percent" sensitivity, and allowed for people to "test for all three [diseases] at the same time with a very high level of accuracy". Touch is a private company.

EMVISION MEDICAL DEVICES

Emvision says it has begun enrolment and scanning in its portable brain scanner trial at Sydney's Liverpool Hospital.

In October, Emvision said it had trial approval at Sydney's Liverpool Hospital, the Royal Melbourne Hospital and Brisbane's Princess Alexandra Hospital (BD: Oct 4, 2022). At that time, the company said the protocol was to be announced, but the first two stages would enrol at least 180 participants, including acute stroke and stroke mimic patients, with endpoints of verification, safety and data to "enhance artificial intelligence algorithms". Today, Emvision chief executive officer Dr Ron Weinberger said "the training process was smooth and easy across individuals from a range of clinical fields of expertise".

"Training was completed in less than a day and the team is excited to undertake the clinical trial," Dr Weinberger said.

"Usability is at the heart of our device and this was evident in the training," Dr Weinberger said.

Emvision was up 12 cents or six percent to \$2.13.

LITTLE GREEN PHARMA

Little Green says it has ethics approval for a phase III efficacy and safety trial of its 50 marijuana-derived cannabidiol CBD 50 for stress reduction and sleep quality.

Little Green did not state the number of patients in the placebo-controlled, pharmaco-kinetic 'Sleepwell' study.

The company said that the trial would support the registration of its 'Classic CBD 50' cannabis oil, (50mg cannabidiol and less than 1.5mg of tetrahydrocannabinol (THC)), with the Australian Therapeutic Goods Administration as a schedule 3, over-the-counter treatment for stress reduction and improved quality of sleep.

Little Green managing-director Fleta Solomon said the ethics approval was "a significant milestone for Australian patients".

Little Green was up 0.5 cents or 2.9 percent to 18 cents.

BTC HEALTH

BTC says its annual general meeting voted a remuneration report first strike with 95,056,370 votes (83.66%) in opposition and 18,568,138 votes (16.34%) in favor. BTC said all other resolutions passed easily.

According to its annual report, BTC had 281,846,354 shares, meaning the votes against the remuneration report was 33.7 percent of the company, sufficient to requisition extraordinary general meetings.

BTC was untraded at 3.8 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says up to 41.7 percent of its annual general meeting opposed special resolutions for a 10 percent placement facility and to amend its constitution.

Yesterday, Paradigm said it had withdrawn a resolution to approve the employee share plan and three resolutions to issue shares to directors (BD: Nov 29, 2022).

Today, the company said the two special resolutions, requiring 75 percent of the vote to pass, were defeated, with the 10 percent placement facility facing 41,729,671 votes (41.69%) against and 58,357,196 votes (58.31%) in favor, while the resolution to amend the constitution to allow for fully virtual meetings had 38.46 percent opposition.

Paradigm said the remuneration report faced 19.83 percent opposition meeting, the reelection of chair Paul Rennie had 15.93 percent against and all other resolutions passed. According to its most recent filing, Paradigm had 279,978,948 shares on issue, meaning that the votes against the placement facility amounted to 14.9 percent of the company, sufficient to requisition extraordinary meetings.

Paradigm was up one cent or 0.7 percent to \$1.41.

MEDADVISOR

Medadvisor says its annual general meeting defeated the 10 percent placement facility with 142,717,783 votes (39.98%) against and 214,229,302 votes (60.02%) in favor. Medadvisor said that the special resolution to approve the placement facility required 75 percent of the vote to pass, with all other resolutions passed easily.

According to its most recent filing, Medadvisor had 543,848,417 shares on issue, meaning that the votes against the placement facility amounted to 26.2 percent of the company, sufficient to requisition extraordinary meetings.

Medadvisor was up two cents or 10 percent to 22 cents.

INCANNEX HEALTHCARE

Incannex says the re-election of chair Troy Valentine as a director faced 116,047,774 votes (18.04%) in opposition and 527,198,716 votes (81.96%) in favor.

Incannex said the resolution to allow fully virtual meetings was opposed by 14.55 percent, the election of Dr George Anastassov was opposed by 10.39 percent and the remuneration report faced 7.68 percent dissent, with other resolutions passed more easily. According to its most recent filing, Incannex had 1,523,595,722 shares on issue, meaning the votes against Mr Valentine amount to 7.6 percent of the company, sufficient to requisition extraordinary votes.

Incannex fell half a cent or 2.1 percent to 23 cents with 2.3 million shares traded.

STARPHARMA HOLDINGS

Starpharma says its annual general meeting voted 82.56 percent opposition to the election of the "non-board endorsed candidate" John Wise as a director.

Starpharma said Mr Wise had 44,077,907 votes (17.44%) in favor but was defeated by 208,656,909 votes (82.56%) in opposition.

The company said that all other resolutions passed, with the issue of performance rights to Dr Jacinth Fairley opposed by 28,292,460 votes (11.68%), with 213,890,979 votes (88.32%) in favor, while the remuneration report had 10.27 percent dissent.

According to its most recent filing, Starpharma had 408,852,447 shares on issue, meaning the votes in favor of the election of Mr Wise amounted to 10.8 percent of the company, sufficient to requisition extraordinary meetings.

Starpharma fell one cent or two percent to 50 cents.

MAYNE PHARMA GROUP

Mayne says its remuneration report was opposed by 134,686,178 votes (16.22%) and supported by 695,528,032 votes (83.78%) in favor.

The company said the election of directors Ann Custin, Dr Kathryn MacFarlane, David Petrie and Prof Bruce Robinson faced between 9.50 to 12.03 percent dissent, while all other resolutions passed more easily.

The 20-to-one consolidation passed with 99.22 percent support.

According to its most recent filing, Mayne had a total of 1,739,815,508 shares on issue, meaning the votes against the remuneration report amounted to 7.7 percent of the company, sufficient to requisition extraordinary votes.

Mayne fell 4.5 cents or 16.4 percent to 23 cents with 75.5 million shares traded.

VECTUS BIOSYSTEMS

In an Appendix 3Z final director's interest notice, Vectus non-executive director Peter Bush says he resigned on November 23, the day of the annual general meeting. In its annual general meeting results announcement, Vectus said it had withdrawn the resolution to re-elect Mr Bush as a director.

Last week, the company said that Mr Bush "decided before the AGM that he would not stand for re-election as a director at this AGM and, accordingly, this resolution was withdrawn".

Vectus said Mr Bush had been a director since July 9, 2015 and thanked him for his service to the company.

Vectus was untraded at \$1.05.

INOVIQ

Merchant Funds Management Pty Ltd says it has increased its holding in Inoviq from 11,610,762 shares (12.63%) to 13,082,057 shares (14.22%).

The Perth-based Merchant said that between September 2, 2021 and November 30, 2022 it bought and sold shares "on market" with the single largest value purchase 625,000 shares for \$664,686 or \$1.06 a share on December 16, 2021 and the largest number of shares bought 918,350 for \$523,261 or 57.0 cents a share in May 2022. Inovig was up two cents or 3.5 percent to 59 cents.

HEXIMA

Merchant Funds Management Pty Ltd says it has increased its holdings in Hexima from 16,314,000 shares (9.77%) to 18,000,000 shares (10.78%).

The Perth-based Merchant said that it bought 1,686,000 shares between November 18 to 30, 2022 for \$28,029 or an average of 1.7 cents a share. Hexima was unchanged at 1.8 cents.