



Biotech Daily

Wednesday November 22, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: 4D MEDICAL UP 21%; NEXT SCIENCE DOWN 13%**
- * **RACE IN-THE-MONEY BONUS, PIGGYBACK OPTIONS FOR \$37m**
- * **ALTERITY 'COMMITMENTS' FOR \$4.8m PLACEMENT; UP-TO \$2m SPP**
- * **VICTORIA \$45k PREMIER'S AWARDS OPEN**
- * **4D MEDICAL SIGNS XV LVAS DETROIT, MEMPHIS RADIOLOGY DEALS**
- * **PROTEOMICS US CMS \$596 PROMARKERD REIMBURSEMENT**
- * **MESOBLAST: BMT CTN 'TO DEVELOP' REMESTEMCEL GVHD TRIAL**
- * **EPSILON DETAILS FINANCES TO ASX QUERY**
- * **IMMUTEP: INSIGHT-003 TRIAL EXPANDS TO 4 GERMAN SITES**
- * **CONTROL BIONICS RECEIVES \$481k FEDERAL R&D TAX INCENTIVE**
- * **INVEX WINS EU PRESENDIN PATENT**
- * **MEMPHASYS 35.5% REMUNERATION REPORT 1st STRIKE**
- * **CURVEBEAM 18% OPPOSE DIRECTOR RIGHTS, OPTIONS**
- * **REALTEK TAKES 19.7% OF NUHEARA**
- * **RACE: DR DANIEL TILLET CEO ON \$237.5k PA IN CASH, OPTIONS**
- * **NUHEARA LOSES CO-FOUNDER, DIRECTOR DAVID CANNINGTON**
- * **ARGENICA APPOINTS CELINA CHEW BUSINESS DEVELOPMENT HEAD**
- * **EPSILON 'TERMINATES CEO PETER GIANNOPOULOS'**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Wednesday November 22, 2023, with the ASX200 down 4.8 points to 7,073.4 points. Seven of the Biotech Daily Top 40 stocks were up, 22 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

4D Medical was the best, up 14 cents or 20.9 percent to 81 cents, with 5.4 million shares traded. Universal Biosensors climbed 8.6 percent; Amplia was up 6.7 percent; Proteomics improved 4.4 percent; Starpharma was up 3.7 percent; CSL rose one percent; with Cochlear, Medical Developments, Resmed and Volpara up by less than one percent.

Next Science led the falls, down four cents or 13.1 percent to 26.5 cents, with 263,572 shares traded. Imugene lost 11.6 percent; Avita fell 10.3 percent; Actinogen and Alcidion were down eight percent or more; Polynovo shed 7.6 percent; Genetic Signatures was down 6.25 percent; Antisense, Orthocell and Prescient fell more than four percent; Impedimed, Micro-X and Pharmaxis lost more than three percent; Compumedics, Mesoblast and Telix shed more than two percent; Clinuvel and Immunep were down more than one percent; with Emvision, Nanosonics, Neuren and Pro Medicus down by less than one percent.

RACE ONCOLOGY

Race says it hopes to raise up to \$36.7 million through the issue of one-for-20 'in-the-money' bonus options with three 'piggyback' options for every bonus option exercised. Race said the bonus options would be exercisable at 75 cents each by June 4, 2024 and the 'piggy back' options would be exercisable at \$1.25 each by May 29, 2026.

The company said the record date for the bonus options would be November 30, with an issue date of December 4, 2023 and the closing date for the piggyback options would be June 4, 2024.

Race said it would raise up to \$6,115,079 if all the bonus options were exercised and a further \$30,575,396 if all the piggyback options were exercised.

The company said the option offer would "reward shareholders for continuing to support the company", provide a potential source of additional capital and raise funds incrementally to support planned activities.

Race fell 4.5 cents or 4.7 percent to 91 cents with 1.1 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has 'binding commitments' for a \$4.8 million placement and hopes to raise up-to \$2.0 million in a share purchase plan, at 0.35 cents a share.

Alterity said that for every share bought, investors would receive one short-dated option, exercisable at 0.7 cents by August 31, 2024; and one long-dated option, exercisable at 1.0 cents by August 31, 2026, for every three shares.

The company said \$1.3 million of the placement would be issued about November 29, 2023, with the remaining \$3.5 million and options subject to shareholder approval, and the placement included about \$100,000 in subscriptions from its directors and associates.

Alterity said the share purchase plan had a record date of November 21, and was expected to close on January 31, 2024.

The company said the funds would be used for its phase II trials of ATH434-201 and ATH434-202 for multiple system atrophy, a potential phase III trial in neurodegenerative diseases, including Parkinson's disease as well as general working capital.

Alterity said MST Financial Services Pty Ltd managed the placement.

Alterity fell 0.3 cents or 42.9 percent to 0.4 cents with 55.5 million shares traded.

VICTORIA GOVERNMENT

Victoria says that submissions for the 2024 Premier's Awards for Health and Medical Research have opened, with a total of \$45,000 in prize money available.

The State Government said the recipient of the Premier's Excellence Award would win \$20,000, with the winners of the basic science researcher, clinical researcher, Aboriginal researcher, health services researcher and public health researcher receiving \$5,000, each.

A media release from the Minister for Medical Research Ben Carroll said the awards were established in 1995 in partnership with the Australian Society for Medical Research and highlighted Victorians undertaking medical research in the state.

"Victoria's medical researchers are trailblazers in developing cutting-edge treatments and cures – changing and saving lives in Victoria and globally," Mr Carroll said.

"We have no shortage of talent and it's wonderful we can celebrate and acknowledge the important work of our medical researchers," Mr Carroll said.

The media release said applications and further information were available at:

<https://www.health.vic.gov.au/about/premiers-awards-for-health-and-medical-research>.

4D MEDICAL

4D Medical says two US-based radiology practices, Precision IR and Memphis Vascular Center, will use its XV Lvas scans under software-as-a-service deals.

Last week, 4D Medical said the US Centres for Medicare and Medicaid Services (CMS) would reimburse \$US299 (\$A456) for its XV lung ventilation analysis software (Lvas) scans for lung disease, effective from January 1, 2024 (BD: Nov 13, 2023).

Today, the company said the Detroit, Michigan-based Precision IR and the Memphis, Tennessee-based Memphis Vascular Center would use its XV Lvas imaging system at their outpatient facilities, from January 1, 2024.

4D Medical did not state the commercial terms, but said the agreements showed “a successful and scalable pathway to additional revenue”.

4D Medical managing-director Prof Andreas Fouras said that “not all patients needing scans want to visit a hospital environment for a lung assessment, and we are pleased to grow these options in the US, in parallel with expanding our traditional hospital providers”. “That we are signing on partners before January 1, when CMS payment becomes available, and within just a few days of the announcement by CMS, highlights the game-changing nature of access to reimbursement,” Prof Fouras said.

“I have never been more excited by the size and scope of our near-term commercial opportunities, and I look forward to sharing this progress over coming weeks and months,” Prof Fouras said.

4D Medical was up 14 cents or 20.9 percent to 81 cents with 5.4 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the US Centres for Medicare and Medicaid Services (CMS) will reimburse Promarked for \$US390.75 (\$A595.92), effective from January 1, 2024.

In September, Proteomics said its Promarkerd diabetic kidney disease test would be reimbursed in the US at \$US391 per test and be distributed by the Austin, Texas-based Sonic Healthcare (BD: Sep 29, 2023).

Today, Proteomics chief executive officer Dr Richard Lipscombe said that “as we prepare for the US launch of Promarkerd, the CMS price is an essential component of the roll-out strategy, both because of the number of people it covers, and because many private payers follow CMS pricing”.

Proteomics was up four cents or 4.4 percent to 95 cents.

MESOBLAST

Mesoblast says the Blood and Marrow Transplant Clinical Trials Network will “develop a pivotal trial” of remestemcel L for graft-versus-host-disease (GvHD).

Last week, Mesoblast said that it expected to contract the Blood and Marrow Transplant Clinical Trials Network (BMTCTN) for its US phase III trial of remestemcel L for GvHD (BD: Nov 15, 2023).

Today, Mesoblast said the US Food and Drug Administration’s September 2023 draft guidance to industry for GvHD stated “that a marketing application might be supported by positive results from a single-arm trial in a population with refractory [acute] GvHD where there are no available therapies”.

The company said the trial would be “developed and executed” by BMTCTN in patients 12-years-of-age and older who resisted treatment with both corticosteroids and a “second-line agent like ruxolitinib”, but did not state the expected number of patients.

Mesoblast fell one cent or 2.5 percent to 39.5 cents with 8.9 million shares traded.

EPSILON HEALTHCARE

Epsilon has told the ASX that a \$388,000 discrepancy between its quarterly reports and its half year report was due to the difference between gross and net payments.

In a five-page query, the ASX noted multiple financial statements, an auditor's report and loan announcements and then asked 16 questions, including multi-part questions.

The ASX query and response was posted to the ASX today with the statement from the ASX: "In light of information in the notice of extraordinary general meeting published on the ASX Market Announcements Platform on November 21, 2023, [the] ASX is seeking additional information and clarifications from the entity".

Yesterday, founder and deputy chair Alan Beasley Epsilon requisitioned an extraordinary general meeting to replace director Stuart Cameron and chair Xiao (Josh) Cui, citing "the governance of the board" (BD: Nov 21, 2023).

According to Commsec, Mr Bealey, Mr Cui and Mr Cameron are the company's directors. The ASX began with the \$388,000 discrepancy as well as asking the company to confirm that it did not incur any cash outflow for research and development, advertising and marketing, leased assets or admin and corporate costs in the financial quarters ending March 31, June 30 and September 30, 2023.

The ASX questioned Epsilon's loans and their repayment and asked why they were not disclosed in the Appendix 4Cs and to the ASX and asked whether the board of directors authorized the Appendix 4Cs for the three months ending December 31, 2022, March 31, June 30 and September 30, 2023.

The ASX asked whether Epsilon would be able to "fund near term anticipated activities from operating cash flows" and whether it was "a going concern".

In a six-page response signed by Mr Cui, Epsilon said it used "a full absorption basis for allocating costs in costing generally and within Appendix 4C" and said that because research and development involved testing and analysis of products "whether these costs constitute research and development arises only after analysis and confirmation by Rimon Advisory Services Pty Ltd" when it filed its annual income tax return.

The company said that advertising and marketing, leased assets, administration and corporate costs were included in product manufacturing and operating costs and not shown separately.

Epsilon said that "all directors" authorized or consented to the Appendix 4Cs for December 31, 2022, March 31 and June 30, 2023 and for the September 30, 2023 quarter "the majority of directors approved Appendix 4C" (sic).

Epsilon said "the directors believe that Epsilon will be able to fund its anticipated activities from operating cash".

The company said it had been "restructuring its operations to reduce costs and improve efficiencies ... [and] progressing in the introduction of new products or/and services, this will see an increase in revenue and available cash".

"However, the company notes that some of the changes can take longer than expected due to internal and external factors resulting in a longer-than-expected period of implementation," Epsilon told the ASX.

The company said it did "not plan to raise further cash to fund its operation via the issue of securities ... [and] the directors of the company consider Epsilon to be a going concern".

Epsilon said it paid its Mitchell Assets Management loan with a secured loan from Oracles Holdings Pty Ltd of \$2,850,000 and had a further credit facility of \$950,000.

The company told the ASX that the Oracle loan had an interest rate of 15 percent a year and a default rate of 24 percent a year, maturing on November 19, 2023, it would be able to repay the Oracle loan and Oracle extended the first payment to December 1, 2023.

Epsilon was up 0.7 cents or 35 percent to 2.7 cents.

IMMUTEP

Immutep says its Insight-003 phase I trial has expanded to four sites in Germany, including the Bochum University Clinic and the Cologne-Merheim hospital.

Earlier this year, Immutep said it had enrolled all 20 patients in its trial of eftilagimod alpha, or efti and formerly IMP321, with standard-of-care anti-programmed cell death protein-1 (anti-PD-1) therapy and chemotherapy using carboplatin and/or pemetrexed for non-small cell lung cancer (BD: Feb 6, 2023).

In May, the company said the investigator-led trial at the Frankfurt Institute of Clinical Cancer Research showed the triple combination of efti with anti-PD-1 and chemotherapy to be well tolerated and showing “promising initial signals of efficacy” (BD: May 24, 2023). Immutep fell half a cent or 1.7 percent to 28.5 cents.

CONTROL BIONICS

Control Bionics says it has received \$480,501 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Control Bionics said the rebate related to expenditure for the year to June 30, 2023.

Control Bionics fell 0.1 cents or 2.4 percent to four cents.

INVEX THERAPEUTICS

Invex says the European Patent Office has granted it a patent for Presendin to treat neurological conditions caused by raised intracranial pressure, including hydrocephalus. Invex said the patent, titled ‘Elevated intracranial pressure treatment’, would protect the company’s intellectual property “until at least August 2035”.

The company said that Presendin was sustained release exenatide and the patent provided additional claims for the use of exenatide and other Glucagon-like peptide-1 (GLP-1) receptor agonists in reducing elevated intracranial pressure associated with the treatment of hydrocephalus, normal pressure hydrocephalus or meningitis.

Invex fell half a cent or 2.1 percent to 23 cents.

MEMPHASYS

Memphasys says that 35.5 percent of its annual general meeting voted a remuneration report first strike, with 43.1 percent opposing the company’s option incentive plan.

Memphasys said that 4,003,235 votes (35.51%) opposed the remuneration report, with 7,270,177 votes (64.49%) in support.

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 if passed the directors must stand for re-election within 90 days.

The company said that the option incentive plan was opposed by 5,038,750 votes (43.08%), with 6,658,096 votes (56.92%) in favor.

Memphasys said and the 10 percent placement capacity and the election of director Andrew Goodall were passed more than 98.93 percent of the vote.

According to its most recent notice, the company had 959,520,382 shares on issue, meaning that the 5,038,750 votes against the option incentive plan amounted to 0.5 percent of the company, not sufficient to requisition extraordinary general meetings.

Memphasys was unchanged at 1.1 cents.

CURVEBEAM AI

Curvebeam says its annual general meeting carried all resolutions, but with 17.8 percent opposition to the issue of share rights and zero-exercise price options (Zepos) to directors. Last month, Curvebeam said investors would vote to issue 109,375 Zepos each to Hashan De Silva and Kate Robb and 72,917 rights to chair Rob Lilley (BD: Oct 20, 2023). Today, the company said Mr Lilley's rights, Ms Robb's and Mr De Silva's Zepos were opposed by up to 18,355,164 votes (17.79%), with 84,804,158 votes (82.21%) in favor. Curvebeam said the election of Mr Lilley, Mr De Silva, Ms Robb and Arun Singh, and share rights in lieu of fees to Mr Singh passed with more than 96.3 percent. According to its most recent filing, Curvebeam had 320,138,492 shares on issue, meaning the votes against the rights and options amounted to 5.7 percent of the company, sufficient to requisition extraordinary general meetings. Curvebeam fell 2.5 cents or 6.9 percent to 33.5 cents.

NUHEARA

Realtek Semiconductor Corporation says it has increased its shareholding in Nuheara from 25,998,211 shares (15.16%) to 45,396,172 shares (19.77%). The Taiwan-based Realtek said it bought 19,397,961 shares through interest conversion shares, a placement and an entitlement offer between July 6 and November 13, 2023, at prices ranging from 13.0 cents to 14.5 cents a share. In June, Nuheara said it had raised \$4.4 million in a placement at 14.5 cents a share, supported by Realtek Semiconductor Corp, Farjoy and Salter Brothers (BD: Jun 6, 2023). Last month, the company said it raised \$2.5 million of a hoped-for \$10 million in an institutional rights offer at 13 cents a share (BD: Oct 12, 2023). Nuheara was unchanged at 12.5 cents.

RACE ONCOLOGY

Race says it has appointed former executive director Dr Daniel Tillett as its chief executive officer, starting on \$237,500 a year in cash and options. Dr Tillett said he requested that 50 percent of the salary be paid in cash and the balance in options exercisable at \$4.25 each "above the all-time high share price". Race said it would issue performance-based bonuses up to 40 percent of salary, pending hurdles, and "executive options" valued at \$712,500, being 150 percent of his base salary, vesting over three years and exercisable at a 48 percent premium to the 20-day volume-weighted average price within five years. In 2019, Race said it raised \$1.45 million at 6.6 cents a share, in a placement led by Dr Tillett who then held 8,758,421 shares (8.96%) and was later appointed as a director and chief scientific officer (BD: Aug 20, Sep 17, Oct 1, 2019). Last year, Damian Clarke Bruce was appointed managing-director and chief executive officer on \$475,000 a year, resigning in August (BD Dec 14, 2022; Aug 22, 2023.) In March, the company said Dr Tillett resigned to be replaced as chief scientific officer by Prof Tim Hammond from June 2023 (BD: Mar 24, 2023). In August, Race said director Dr Peter Smith has been appointed an executive director, on \$190,000 a year, replacing Mr Clarke-Bruce and director Dr John Cullity would retire, with Dr Tillett appointed a consultant on its bisantrene technology (BD: Aug 22, 2023). Today, Race said Dr Peter Smith would continue as an executive director. The company said that Dr Tillett was the founder and chief executive officer of Nucleics and a senior lecturer at Melbourne's La Trobe University.

[NUHEARA](#)

Nuheara says co-founder and non-executive director David Cannington has retired from the board, effective from November 21, 2023.

Nuheara chair Cheryl Edwardes said Mr Cannington retired from his executive duties in March 2022.

“We extend our deepest thanks for his valuable contribution, hard work and strong commitment to Nuheara,” Ms Edwardes said.

“We wish Mr Cannington all the best in his retirement,” Ms Edwardes said.

[ARGENICA THERAPEUTICS](#)

Argenica says it has appointed Celina Chew as its head of business development in a part-time role, effective from December 1, 2023.

Argenica said Ms Chew was previously an executive with Bayer, including as head of the greater China area from 2014 to 2019.

The company said Ms Chew would “assist on all business development activities, including partnering and merger and acquisition activities”.

According to her LinkedIn profile, Ms Chew held a Bachelor of Laws from the University of Western Australia and a Master of Laws from the University of Hong Kong.

Argenica was up four cents or 9.5 percent to 46 cents.

[EPSILON HEALTHCARE](#)

Epsilon says it “terminates Mr Peter Giannopoulos as the role of the Chief Executive Officer ... effective immediately at 3:35pm November 21, 2023”.

Yesterday, Epsilon founder and deputy chair Alan Beasley requisitioned an extraordinary general meeting to replace director Stuart Cameron and chair Xiao (Josh) Cui, citing “the governance of the board” (BD: Nov 21, 2023).

According to Commsec, Mr Bealey, Mr Cui and Mr Cameron are the company’s three directors.

Today, in an announcement “approved for release by the majority of the board of directors”, Epsilon said that “Mr Giannopoulos did not complete his probationary period”. “This decision aligns with the terms and conditions outlined in the employment contract, specifically regarding the clause ‘probation’,” the company said.

Epsilon said that general-manager Daniel Sanghera had been appointed interim chief executive officer.