

Biotech Daily

Wednesday May 31, 2023

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: COMPUMEDICS UP 10%; NEXT SCIENCE DOWN 11%
- * IMMUTEP PLACEMENT, RIGHTS TO RAISE \$80m
- * NEWCASTLE UNI GLIOMA WORK BACKS ONC201, KAZIA'S PAXALISIB
- * AROA REVENUE UP 60% TO \$63.3m; LOSS DOWN 95% TO \$396k
- * ANTERIS DURAVR 'EXCEPTIONAL HAEMODYNAMIC FUNCTION'
- * NEUROTECH NTI164 MARIJUANA COMPASSIONATE USE FOR AUTISM
- * ZELIRA CLAIMS MARIJUANA ZLT-L-007 SUCCESS FOR NERVE PAIN
- * FIREBRICK RECRUITS 82% OF PHASE III NASODINE TRIAL
- * HERAMED AGM 21.5% OPPOSE DIRECTOR DORON BIRGER
- * DVT: IQ DEED PROPONENTS FINAL EXTENSION
- * ARGENICA REQUESTS 'CAPITAL RAISING' TRADING HALT
- * VELOCIMETRY, ANDREAS, HELEN FOURAS DILUTED TO 19% OF 4D
- * AUSTRALIAN SUPER TAKES 6.55% OF TRAJAN
- * VIBURNUM TAKES 6.2% OF MAYNE PHARMA
- * PLATINUM TAKES 18.7% IN ADALTA
- * MEURS DILUTED TO 14.6% OF ADALTA
- * SCOTT KIRKLAND TO REPLACE EMVISION M-D DR RON WEINBERGER
- * QBIOTICS LOSES NEVILLE MITCHELL; DR STEVEN OGBOURNE OFF-BOARD

MARKET REPORT

The Australian stock market fell 1.64 percent on Wednesday May 31, 2023, with the ASX200 down 118.0 points to 7,091.3 points. Nine of the Biotech Daily Top 40 stocks were up, 17 fell, 12 traded unchanged and two were untraded. All three Big Caps fell.

Compumedics was the best, up 1.5 cents or 9.7 percent to 17 cents, with 360 shares traded. Imugene and Micro-X improved more than four percent; Telix climbed 3.4 percent; Dimerix rose 2.9 percent; Neuren was up one percent; with Avita, Clinuvel and Volpara up by less than one percent.

Next Science led the falls, down six cents or 10.6 percent to 50.5 cents, with 170,043 shares traded. Antisense and Cynata lost more than six percent; Alcidion, Cyclopharm and Opthea fell more than four percent; Polynovo and Starpharma were down more than three percent; Genetic Signatures, Mesoblast and Resmed shed more than two percent; Emvision, Nanosonics, Nova Eye, Orthocell, Paradigm, Pharmaxis, and Pro Medicus were down one percent or more; with CSL and Cochlear down by less than one percent.

IMMUTEP

Immutep says it will raise \$80 million in a fully underwritten \$50 million placement and pro rata, non-renounceable \$30 million one-for 7.6 rights offer at 26 cents a share. Immutep said the rights offer had a \$15 million institutional and \$15 million retail offer, with the 26 cents price a 13.3 percent discount to the last closing price on May 30, 2023. The company said the funds would be used for its trials for non-small cell lung cancer and head and neck small cell carcinoma, and a potential IMP761 trial for autoimmune disease. Immutep said the institutional placement and rights offer would open on May 31 with results on June 2, while the retail offer had a record date of June 2, would open on June 6 and close on June 23, 2023.

Immutep said it had appointed Bell Potter Securities Ltd, Jefferies Australia Pty Ltd and Wilsons Corporate Finance Ltd as joint lead managers and underwriters to the offer. Separately, Immutep requested a trading halt for the placement and institutional rights offer "to take place in an orderly fashion" with trading to resume on June 2, 2023. Immutep last traded at 30 cents.

UNIVERSITY OF NEWCASTLE (NEW SOUTH WALES), KAZIA THERAPEUTICS

The University of Newcastle says the in-vitro research and two case studies support the use of its ONC201 with Kazia's paxalisib for paediatric diffuse midline gliomas. The University of Newcastle said the drug combination "could improve the life expectancy of children with brain cancer, dramatically extending their average survival".

The University said diffuse midline gliomas, including diffuse intrinsic pontine gliomas were the most lethal of childhood cancers, with palliative radiotherapy the only established treatment, with families advised their child was expected to survive nine to 11 months. The University said the research article, titled 'ONC201 in combination with paxalisib for the treatment of H3K27-altered diffuse midline glioma' was published in the journal Cancer Research with an abstract and the full article available at: bit.ly/3ouBEE4.

The research article cites in-vitro investigations of the combination in cell lines as well as two case studies from a current 101-patient trial of the combination.

The article said that a six-year-old girl had "tumor regression ... after 20 weeks on the drug combination" with the patient continuing on the combination at 22 months; while a 16-year-old female had tumor regression following radio-therapy while receiving the combination, with tumor regressing observed at 20 weeks on the combination therapy.

"[The] patient continued to receive ONC201 and paxalisib for the next three months and then contracted pneumonia and passed away 24 months from diagnosis," the article said. The University of Newcastle said that oral ONC201 was currently being investigated in 12 clinical trials, across many cancer types, with one titled 'Combination Therapy for Diffuse Midline Glioma' led by the University's Prof Matt Dun and his team.

"ONC201 appears to improve some patient outcomes, extending median survival to 20, from 11 months," Prof Dun said.

"As more data becomes available, we'll know the extent of benefit," Prof Dun said. Prof Dun said the trial was being conducted in the US, New Zealand, The Netherlands, Switzerland and Israel and was open to patients at all disease stages, irrespective of past treatments and was adaptive, with new drugs or approaches to be evaluated as additional arms of the trial as supporting data becomes available.

Prof Dun said specialist techniques had shown how two emerging therapies exerted their anti-cancer effect, particularly, the mechanisms controlling whether a patient responded, and the benefits of using them in combination.

Kazia was unchanged at 17.5 cents.

AROA BIOSURGERY

Aroa says revenue for the year to March 31, 2023 was up 59.7 percent to \$NZ63,360,000 (\$A58,640,000), with net loss after tax down 95.4 percent to \$NZ396,000 (\$A366,000). Aroa said revenue came primarily from increased sales of its sheep-stomach-derived Myriad for soft tissue repair and its Ovitex 'bio-scaffold' products for hernia repair, with Endoform sales increasingly "modestly as expected".

The company said loss was down due to the company's improved operating performance as it increased its working capital position resulting from year-on-year sales, but that it had continued to make large investments in its Enivo platform.

The company said its diluted loss per share fell 95.1 percent from 2.45 NZ cents in the year to March 31, 2022 to 0.12 NZ cents in the year to March 31, 2023.

Aroa said that its diluted loss per share fell 95.1 percent to 0.12 NZ cents.

The company said that net tangible assets per security was the same as the prior corresponding period at 23 NZ cents.

Aroa said it had cash and cash equivalents of \$NZ9,540,000 at March 31, 2023 compared to \$NZ6,165,000 at March 31, 2022.

Aroa fell 7.5 cents or 7.4 percent to 93.5 cents with 1.5 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says its Duravr trans-catheter heart valve showed "exceptional haemodynamic outcomes" in a seven patient third cohort of its first-inhuman study of the device. Last year, Anteris said eight patients in the second cohort of its 10-patient first-inhuman study conducted at Georgia's Tbilisi Heart and Vascular Clinic showed "clinically significant improvements" after 30 days (BD: Jul 11, 2022).

Earlier this year, Anteris said its treated cow tissue Duravr trans-catheter heart valve trial met all performance endpoints with "remarkable haemodynamic function ... [at] 12 months" (BD: Jan 22, 2023).

Today, the company said trans-oesophageal echocardiogram images taken 48 hours post-procedure in third cohort patients showed an average effective orifice area increase from 0.76 square centimetres to 2.11 sqcm with mean pressure gradients decreasing by 84 percent.

Anteris chief executive officer Wayne Paterson said 21 patients had been treated "all of whom have had outstanding results".

"This recent cohort of patients further validates the exceptional clinical characteristics of Duravr [trans-catheter heart valve] and the performance of our novel first-in-class biomimetic design," Mr Paterson said.

Anteris was up 19 cents or 0.8 percent to \$23.80.

NEUROTECH INTERNATIONAL

Neurotech says it has ethics committee approval for 11 patients in its trial of NTI164 marijuana for autism spectrum disorder to continue treatment under compassionate use. Neurotech said the extension under the special access scheme category B allowed patients to continue taking NTI164 beyond the 18-month trial period from July, and it would continue to collect periodic safety information from the compassionate use patients. Neurotech executive director Dr Thomas Duthy said all 11 patients had "requested to continue treatment with NTI164 for the foreseeable future, given the significant improvements seen in their clinical symptoms and excellent safety profile". Neurotech fell 0.3 cents or 6.7 percent to 4.2 cents.

ZELIRA THERAPEUTICS

Zelira says a 60-patient trial shows that its marijuana-based oral ZLT-L-007, formerly ZLD007, outperformed pregabalin (Lyrica) for diabatic nerve pain.

Last year, Zelira said it had completed enrolment of the three-arm trial evaluating the safety, tolerability and efficacy of ZLD007 for diabetic nerve pain against a then unnamed existing drug (BD: Nov 21, 2022).

Today, Zelira said that the use of ZLT-L-007 had achieved "a significant reduction in [the numerical rating scale] pain scores, indicating a decrease in symptom severity" but did not disclose a probability value.

The company said that the trial met its primary endpoints and ZLT-L-007 "was found to be safe and well-tolerated ... with no serious adverse events".

Zelira said a range of secondary endpoints were also met.

The company said that the trial compared 22 patients in the 300mg pregabalin alone arm, 18 patients in the ZLT-L-007 alone arm and 20 patients taking the combination of pregabalin with ZLT-L-007, with the 74.5mg marijuana product given twice daily and if

there was no response after two weeks up to three times daily.

Zelira said at the 30-day follow up pregabalin and ZLT-L-007 both showed a median 33.33 percent decrease in pain scores, while the combination showed a 20 percent decrease. The company said at 60 days, pregabalin alone had a median 20.00 percent reduction.

ZLT-L-007 alone had a 71.43 percent decrease and the combination had a 50.00 percent decrease.

Zelira said that at 90 days, pregabalin alone had a median 36.00 percent reduction, ZLT-L-007 alone had a 78.57 percent decrease, while the combination had a 72.50 percent decrease.

Zelira managing-director Dr Oludare Odumosu said the company was "thrilled with the results from our ... trial in the US".

"The findings underscore the exceptional efficacy of our treatments in managing pain, with ZLT-L-007 demonstrating the most substantial reduction in pain severity, particularly at the 60-day and 90-day follow-up periods," Dr Odumosu said.

"We are particularly proud that this unique, multi-arm comparative study yielded positive results for our primary endpoint of safety in addition to several secondary endpoints," Dr Odumosu said.

"These results align perfectly with our strategy of generating scientifically rigorous and clinically validated data for our patent-protected proprietary cannabinoid-based drugs," Dr Odumosu said. "The trial results further affirm the safe and effective use of Zelira's innovative and patent-protected technology, Zyraydi, which was utilized to create the free-flowing powder formulation used for ZLT-L-007."

"The Zyraydi technology enabled us to deliver ZLT-L-007 in an easy to swallow, relatively small pharmaceutical grade size 2 capsule," Dr Odumosu said.

Zelira climbed \$2.11 or 224.5 percent to \$3.05 with 1.2 million shares traded.

FIREBRICK PHARMA

Firebrick says it has recruited 160 patients, or 82 percent, of the 196 patients for its phase III study of Nasodine nasal spray treatment for the common cold.

Firebrick said it hoped to recruit 196 patients with early-stage colds confirmed by polymerase chain reaction (PCR) tests to have viral infections, not including Covid-19. The company said the results would be used for international regulatory filings for Nasodine, including a European approval submission.

Firebrick fell half a cent or 2.9 percent to 17 cents.

<u>HERAMED</u>

Heramed says all four resolutions at its annual general meeting were passed, but with dissent of 21.5 percent to the election of Doron Birger as a director.

Heramed said 11,935,086 votes (21.51%) opposed the election of Mr Birger, with 43,544,376 votes (78.49%) in favor.

The company said the adoption of a remuneration report, the election of Emily Slade as director and the approval of its 10 percent placement capacity were passed, with 6.50 percent, 4.03 percent and 3.69 percent dissent, respectively.

According to its most recent filing, Heramed had 242,657,048 shares on offer, meaning the 11,935,086 votes against the appointment of Mr Birger amounted to 4.918 percent of the company, not sufficient to requisition extraordinary general meetings.

Heramed was up 0.2 cents or 2.6 percent to eight cents.

IQ GROUP (IN ADMINISTRATION)

IQ Group administrators, Sydney's DVT (de Vries Tayeh) says that deed of company arrangement has been granted a final extension.

Last year, IQ3 said it had entered voluntary administration, with the Sydney's DVT Group "to maximise the outcome for all stakeholders" (BD: Mar 11, 2022).

Today, the DVT Group said that proponents of the deeds of company arrangement for the IQ Group of companies, IQ Group Global Ltd, IQX Limited, IQ3Corp Ltd and Life Science Biosensor Diagnostics Pty Ltd had requested a series of extensions due to delays in raising sufficient funds to pay the contribution sums under each of the deeds.

DVT said it would "grant a final extension to the deed proponents to complete their due diligence and raise sufficient funds for the purpose of providing the contribution sums to June 30, 2023.

"The deed administrators will not provide any further extensions beyond June 30, 2023," DVT said.

"In the event that by 30 June 2023, the Deed Proponents have not completed their due diligence and raised sufficient funds for the Contribution Sums, the Deed Administrators will convene a Concurrent Meeting of Creditors to be held in July 2023, to seek instructions from the creditors on the future of the Companies.

ARGENICA THERAPEUTICS

Argenica says it has requested a trading halt "pending an announcement by the company regarding a capital raising".

Trading will resume June 2, 2023, or on an earlier announcement. Argenica last traded at 42.5 cents.

4D MEDICAL

Velocimetry Consulting, Prof Andreas and Helen Fouras say their 66,350,161 shareholding in 4D Medical has been diluted from 20.92 percent to 19.22 percent. In three notices, Velocimetry Consulting, Prof and Ms Fouras said they had been diluted in the "oversubscribed" share purchase plan which raised \$25 million (BD: May 29, 2023). 4D Medical fell 8.5 cents or 9.9 percent to 77 cents with 1.8 million shares traded.

TRAJAN GROUP HOLDINGS

Australian Super Pty Ltd says it has increased its substantial shareholding in Trajan from 7,259,742 shares (5.39%) to 9,958,728 shares (6.55%).

The Melbourne-based Australian Super said that between November 18, 2022 and May 24, 2023 it bought shares at prices ranging from \$1.52 to \$1.92 and that on June 23, 2022 it had acquired 1,750,000 shares in an off-market transfer.

Trajan fell three cents or 2.1 percent to \$1.42.

MAYNE PHARMA GROUP

Viburnum Funds Pty Ltd says it has increased its substantial shareholding in Mayne Pharma from 4,362,521 shares (5.13%) to 5,236,799 shares (6.16%). The Perth, Western-Australia based Viburnum said that between May 23 and 30, 2023 it bought 874,278 shares for \$3,114,504, or \$3.56 a share.

Mayne fell 10 cents or 2.7 percent to \$3.56 with 2.9 million shares traded.

ADALTA

Platinum Asset Management Ltd says it has increased its substantial shareholding in Adalta from 49,048,028 shares (16.51%) to 68,667,239 shares (18.73%). The Sydney-based Platinum said that on May 29, 2023 it bought 19,619,211 shares for

\$490,480, or 2.5 cents a share. Last week, Adalta said its rights offer at 2.5 cents a share raised \$1,282,591, with

commitments for \$1,871,167 meeting the \$3,153,760 target (BD: May 25, 2023). Adalta fell 0.1 cents or 4.2 percent to 2.3 cents.

ADALTA

Melbourne's Meurs Group says its substantial shareholding of 53,594,168 Adalta shares has been diluted from 17.06 percent to 14.62 percent.

EMVISION MEDICAL DEVICES

Emvision says it has appointed Scott Kirkland as chief executive officer and managing director after co-founder Dr Ron Weinberger retires, effective from July 1, 2023. Emvision said Dr Weinberger had been its managing-director and chief executive officer for more than five years and would continue as a non-executive director and consultant to management until July, 2024 to support clinical product development, commercial partnering and regulatory approvals.

The company said Mr Kirkland co-founded Emvision with Dr Weinberger in 2017 and had previously been head of client sales at Quantcast.

Emvision said it had appointed its head of new product development Forough Khandan as chief technology officer.

"Dr Weinberger has been a trusted advisor, friend and mentor and I'm grateful to be able to continue to access his insights and strategic advice," Mr Kirkland said.

Emvision fell 2.5 cents or 1.8 percent to \$1.38.

QBIOTICS GROUP

Qbiotics says director Neville Mitchell has resigned today and Dr Steven Ogbourne will continue as an executive but not seek re-election as a director at the annual general meeting.

Qbiotics said that Mr Mitchell had been "a valuable contributor during his six years as a board member" and for most of his tenure was chair of the audit and risk management committee.

The company said that chief translational research officer Dr Steven Ogbourne had served two terms as a director and would continue as an executive. Qbiotics is a public unlisted company.