



Biotech Daily

Monday May 29, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: MEDICAL DEVELOPMENTS UP 9%; EMVISION DOWN 9%**
- * **4D 'OVERSUBSCRIBED' PLAN RAISES \$25m; TOTAL \$45m**
- * **BLUECHIIP SHARE PLAN RAISES \$727.5k; TOTAL \$2.9m**
- * **MEDIBIO PLAN RAISES \$264k OF HOPED FOR \$1.5m; TOTAL \$1.5m**
- * **EMVISION STARTS STAGE 2 OF PORTABLE BRAIN SCANNER TRIAL**
- * **TISSUE REPAIR: 'FDA OKAYS TR-987 PHASE III LEG ULCER PROGRAM'**
- * **RADIOPHARM TO FILE FDA RAD101 PHASE IIB/III BRAIN IMAGING IND**
- * **AMPLIA 'AMP945 BOOSTS FOLFIRINOX FOR PANCREATIC CANCER, IN MICE'**
- * **MICRO-X FIELD-TESTS ARGUS IED X-RAY CAMERA**
- * **IMMUTEP APPOINTS CHARLES RIVER FOR IMP761 TOXICOLOGY STUDY**
- * **AUSTCO TO PAY \$3.85m FOR NURSE CALL RESELLER TEKNOCORP**
- * **RECCE TRAINS NURSES TO INCREASE R327 TRIAL POPULATION**
- * **USPTO ALLOWS AVECHO TPM PATENT**
- * **ZELIRA REQUESTS 'TRIAL RESULTS' TRADING HALT**
- * **ANTERIS WITHDRAWS PLACEMENT, 1.5m OPTIONS RESOLUTIONS**
- * **ORTHOCELL APPOINTS JOHN VAN DER WIELEN CHAIR**

MARKET REPORT

The Australian stock market was up 0.87 percent on Monday May 29, 2023, with the ASX200 up 62.6 points to 7,217.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and one was untraded.

Medical Developments was the best, up 6.5 cents or 9.1 percent to 78 cents, with 163,215 shares traded. Amplia improved 7.1 percent; Antisense and Nova Eye climbed more than six percent; Atomo, Micro-X and Pharmaxis were up more than three percent; Avita and Kazia rose more than two percent; CSL was up 1.3 percent; with Clinuvel, Cochlear, Paradigm, Pro Medicus and Proteomics up by less than one percent.

Emvision led the falls, down 14.5 cents or 9.4 percent to \$1.40, with 42,370 shares traded. Patrys lost 8.3 percent; Impedimed and Telix were down more than six percent; both Compumedics and Universal Biosensors were down 5.88 percent; Next Science fell 4.9 percent; Cynata, Immunetep and Polynovo were down more than three percent; Genetic Signatures, Opthea, Orthocell and Resonance shed more than two percent; Nanosonics, Neuren and Prescient were down one percent or more; with Mesoblast and Resmed down by less than one percent.

4D MEDICAL

4D Medical says its oversubscribed share plan at 89 cents a share has raised \$25 million - \$10 million more than planned – taking the total raised to \$45 million.

Earlier this month, 4D said it had completed a \$20 million placement at 91 cents a share, with an up-to \$15 million share purchase plan to follow (BD: May 8, 2023).

Today, the company said the share plan was at 89 cents a share, being the lower of 91 cents and the price calculated as a 2.5 percent discount to the volume weighted average price of shares in the five days to the closing date.

4D Medical said the share purchase plan brought the total raised under the placement to \$45 million before costs, with the funds to be used to accelerate the commercialization of its respiratory imaging software and strengthen its balance sheet.

The company said Bell Potter Securities Ltd was sole lead manager and bookrunner for the placement and share purchase plan.

4D Medical chief executive officer Andreas Fouras the company was “delighted with the very strong demand received for the share purchase plan”.

“Funds raised from the share purchase plan will help further accelerate our commercialization efforts, capitalizing on our recent momentum,” Dr Fouras said.

Dr Fouras said the momentum included the first commercial scan and authority to operate at the Harry S Truman Hospital, a US Department of Defense commercial pilot program win and the launch of the CT:VQ computed tomography ventilation-perfusion product at the American Thoracic Society meeting where the company won “best in show”.

4D Medical fell one cent or 1.2 percent to 84 cents.

BLUECHIIP

Bluechiip says its share purchase plan at 2.5 cents a share has raised \$727,500 above a hoped for \$300,000, taking the total raised with a placement to \$2,927,500.

Earlier this month, Bluechiip said it had raised \$2.2 million in a placement at 2.5 cents a share and hoped to raise \$300,000 through a share plan (BD: May 5, 2023).

Today, the company said the share plan showed “strong interest from Bluechiip’s existing shareholders”.

Bluechiip managing-director Andrew McLellan said the company was “pleased to have received significant interest and support from our shareholders”.

“The proceeds from the [plan] together with the recently completed placement further strengthens our balance sheet, providing additional capacity to continue production scaling and sales expansion, especially in the North American market and ongoing working capital,” Mr McLellan said.

Bluechiip was up 0.1 cents cent or 3.45 percent to three cents.

MEDIBIO

Medibio says its share plan at 0.15 cents a share has raised \$246,000 of a hoped for \$1,500,000, leaving a shortfall of \$1,254,000 shortfall.

In February, Medibio said it had commitments for a \$1,245,000 placement and hoped to raise \$1.5 million in a share plan underwritten by chair David Trimboli and director Chris Ntoumenopoulos to \$350,000 (BD: Feb 15, 2023).

Today, the company said on May 23, 2023

Medibio said the shortfall would be placed at the discretion of the directors in consultation with CPS Capital Group Pty Ltd.

Medibio was unchanged at 0.1 cents.

EMVISION MEDICAL DEVICES

Emvision says it has begun its up-to 150-patient, stage two, multi-site trial of its portable brain scanner for stroke and stroke mimic patients at emergency departments.

In February, Emvision said it had scanned all 30 participants in its stage one, healthy volunteer trial of its brain scanner at Sydney's Liverpool hospital (BD: Feb 1, 2023).

Today, the company the trial would take place at the Liverpool Hospital, the Royal Melbourne Hospital and Brisbane's Princess Alexandra Hospital, all of which had a stroke patient population and research team to support faster enrolment.

Emvision said it expected to have all three sites activated by the end of July, enrolment completed within six months and regulatory submissions and approvals in 2025.

Emvision chief executive officer Dr Ron Weinberger said the technical and usability information from stage one of the trial had refined the device for stage two and although modifications were "not major, they will result in significant improvements in performance". "We have now achieved the critical and noteworthy phase of acquiring data from suspected stroke patients in the acute setting," Dr Weinberger said.

Emvision fell 14.5 cents or 9.4 percent to \$1.40.

TISSUE REPAIR

Tissue Repair says it has US Food and Drug Administration approval to progress its 600-patient, phase III program of TR-987 for chronic venous leg ulcers.

Tissue Repair said that it would submit its phase III protocol for final review by the FDA and clearance for patient enrolment, which it expected to begin by the end of 2023.

The company said the phase III program would be conducted as two trials of 300 patients each in Australia and the US.

Tissue Repair said that the primary endpoint would be the "incidence of complete closure over a 16-week treatment period" with secondary endpoints including reduced ulcer size and amelioration of pain.

Tissue Repair co-founder Tony Charara said that entering phase III was "a big milestone" and that the company had a "genuine shot at delivering the first drug to be approved for treatment of chronic venous leg ulcers in almost two decades".

Tissue Repair was up 2.5 cents or 10 percent to 27.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it will file an investigational new drug application for a phase IIb/III trial of F18-pivalate, or RAD101, for imaging brain metastasis by October 2023.

Radiopharm said that it had "positive guidance" from the FDA and hoped to have the first patient dosed by the end of the year.

Radiopharm chief executive officer Riccardo Canevari said pivalate was "a new class of targeted radio-pharmaceuticals, with RAD101 data demonstrating very positive performance in brain metastasis".

"We are engaging with the FDA to expedite clinical development of RAD 101, considering the high unmet medical need in around 300,000 patients that are diagnosed with brain [metastasis] in the US every year," Mr Canevari said.

"Being so close to late-stage development is highly exciting for us and for the medical community," Mr Canevari said.

Radiopharm was up two cents or 15.4 percent to 15 cents with one million shares traded.

AMPLIA THERAPEUTICS

Amplia says AMP945 with Folfirinox (5-fluorouracil, leucovorin, irinotecan and oxaliplatin) shows improved overall survival compared to Folfirinox alone, in mice.

Amplia said the study showed “a statistically significant increase in survival” of up-to 35 percent in mice treated with AMP945 before a 12-day cycle of Folfirinox compared to Folfirinox alone.

The company said Folfirinox was a combination chemotherapy widely used for pancreatic cancer with a median overall survival of 11.1 months.

Amplia said that Folfirinox was reserved for younger, fitter patients in Australia and a standard-of-care therapy in other countries including the US, UK, Canada and France.

Amplia chief executive officer Dr Chris Burns said the results “indicate the potential of AMP945 in pancreatic cancer treatment when used in combination with standard-of-care therapies”.

The company said that previously AMP945 combined with gemcitabine and nab-paclitaxel had “shown promising activity in models of pancreatic cancer with the two most common first-line chemotherapy regimens”.

Amplia said the Gavan Institute of Medical Research study would be presented at the American Society of Clinical Oncology meeting in Chicago, June 2 to 6, 2023, and was available at <https://meetings.asco.org/abstracts-presentations/225112>.

Amplia was up 0.6 cents or 7.1 percent to 9.1 cents.

MICRO-X

Micro-X says it has completed the first field testing of its Argus improvised explosive device (IED) x-ray camera.

Micro-X said that the device was tested over several days in Adelaide and was able to transmit high-definition images to an operator more than 1,500 meters from the target.

The company said it tested the Argus x-ray camera on common scenarios experienced by military and law enforcement bomb technicians including high-definition images of an IED training aid through a car door and a shallow-buried anti-personnel mine, providing “the potential to support military missions such as large area clearance and buried threat detection”.

Micro-X is developing its portable x-ray technology for a range of human health as well as security applications.

Micro-X was up 0.3 cents or 3.45 percent to nine cents.

IMMUTEP

Immutep says it has appointed Charles River Laboratories for its pre-clinical toxicology study of its LAG-3 antagonist antibody IMP761 for autoimmune diseases.

Immutep said that the Wilmington, Massachusetts-based Charles River Laboratories would evaluate the safety and toxicity of IMP761.

Immutep chief scientific officer Prof Frédéric Triebel said that with its “ability to enhance the signaling of the LAG-3 inhibitory receptor and down-regulate auto-reactive memory T-Cells at the centre of many autoimmune diseases, we believe IMP761 has the potential to change how immune disorders are treated”.

Immutep fell one cent or 3.2 percent to 30.5 cents with 2.6 million shares traded.

AUSTCO HEALTHCARE

Austco says it expects to buy Melbourne security and healthcare provider Teknocorp for \$1,900,000 upfront in cash, \$700,000 in shares and a \$1,250,000 earn-out.

Austco said Teknocorp was a certified Austco Nurse Call reseller and the acquisition would allow it to build its direct sales capability, accelerate growth and enhance its range of products.

The company said the earnout was 3.5 times Teknocorp's annualized earnings before interest, taxation, depreciation and amortization (Ebitda) for the period from completion to December 31, 2024, estimated to be about \$1,250,000.

Austco said it planned to integrate Teknocorp's business which included more than 300 customers into its existing operations and retain key personnel.

The company said it expected the agreement to immediately increase earnings per share, provide significant revenue synergies, including the ability to cross-sell products and services and streamline operations

Austco was unchanged at 13.5 cents.

RECCE PHARMACEUTICALS

Recce says it has trained out-patient nurses from New South Wales healthcare provider Ascott Sales to broaden its diabetic foot infection trial patient population.

Last year, Recce said it had approval for an up-to 32-patient, phase I/II trial of R327 spray-on antibiotic for mild skin and soft tissue diabetic foot infections (BD: Dec 9, 2022).

Today, the company said accredited nurses would "provide and replicate the high level of care patients would receive if attending on-site clinical trial visits, increasing the profitability of protocol adherence and dosing completion".

Recce said that Ascott's nurses were currently supporting 29 active clinical trials in Australia and New Zealand.

Recce was up 1.5 cents or 2.7 percent to 57.5 cents.

AVECHO BIOTECHNOLOGY

Avecho says the US Patent and Trademarks Office has allowed a patent relating to the manufacturing process for its tocopheryl phosphate mixture (TPM).

Avecho said the patent titled 'Process' protected its TPM vitamin E-derived human and animal drug delivery system for increased solubility and oral, dermal and transdermal absorption until December 2037.

The company said TPM was already patent protected in India, Japan, Mexico, Russia and Singapore, with further patents for TPM in combination with cannabinoids under review in other territories.

Avecho chief executive officer Dr Paul Gavin said the extended patent protection was "timely given the new products under development combining TPM formulations with cannabinoids".

Avecho was up 0.1 cents or 20 percent to 0.6 cents with 3.1 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has requested a trading halt "pending an announcement in relation to top line results of its ... multi-arm, head-to-head study of its diabetic nerve pain drug".

Trading will resume May 31, 2023, or on an earlier announcement in relation to the trial.

Zelira last traded at 94 cents.

ANTERIS TECHNOLOGIES

Anteris says it has withdrawn annual general meeting resolutions to issue 1,455,000 options to directors, as well as the 10 percent placement facility.

Earlier this month, Anteris said its annual general meeting would vote to approve the 10 percent placement facility and issue 1,000,000 options to chief executive officer Wayne Paterson, 225,000 options to chair John Seaberg, 115,000 options to director and company secretary Stephen Denaro and 115,000 options to director Wenyi Gu, exercisable at \$21.19 each within five years (BD: May 1, 2023).

Today, the company said the resolution to grant the director options was withdrawn “in light of the share price increase since when the 20-day [volume weighted average price] was calculated”.

Anteris said “the proxy support received thus far is supportive for these resolutions”.

The company said that the 10 percent placement resolution was withdrawn as its market capitalization exceeded \$300 million and it was illegible under ASX Listing Rule 7.1A.

The company said that all other resolutions passed easily, with opposition ranging from 0.77 percent to 7.62 percent of votes at the meeting.

Anteris was up 18 cents or 0.8 percent to \$23.85.

ORTHOCELL

Orthocell says it has appointed John Van Der Wielen as a director and chair, replacing Dr Stewart Washer who continues as an executive director, effective from June 1, 2023.

Orthocell said Mr Van Der Wielen had more than 35 years of experience, most recently as HBF Health Ltd managing-director.

The company said that previously Mr Van Der Wielen was the chief executive officer of Friends Life UK, Clerical Medical, Halifax Life & Heidelberger Leben and Lloyds Banking Group/HBOS Plc.

Orthocell said that Mr Van Der Wielen was previously a director of Kyckr, Partners Life, Friends Provident International and Lombard International Assurance, and chair of Crown Perth.

The company said Mr Van Der Wielen held a Master of Business Administration from the University of Western Australia.

Orthocell said that as well as his director’s fees, Mr Van Der Wielen would be issued 4,000,000 options, exercisable at 40 cents each within five years, and subject to shareholder approval would place 250,000 shares to Mr Van Der Wielen at 36.5 cents a share.

Orthocell fell one cent or 2.7 percent to 35.5 cents.