

# **Biotech** Daily

## Tuesday November 21, 2023

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: PRESCIENT UP 18%; AVITA DOWN 9%
- \* VOLPARA RECORD H1 REVENUE UP 17.5% TO \$18m; LOSS DOWN 17% TO \$4m
- \* PRO MEDICUS DR SAM HUPERT, ANTHONY HALL SELL 2m SHARES
- \* AVITA 3.85% REVENUE GUIDANCE WARNING
- \* PHARMAUST OPTION OFFER TO RAISE UP-TO \$396k
- \* NOMINATIONS OPEN FOR \$750k PM SCIENCE PRIZES
- \* FEDERAL \$5m FOR MONASH CAR-T-CELL PROSTATE CANCER THERAPY
- \* MTP CONNECT RECOMMENDATIONS FOR ANTI-MICROBIAL RESISTANCE
- \* EPSILON'S ALAN BEASLEY REQUISITIONS CHAIR, DIRECTOR REMOVAL EGM
- \* CANN \$15m OBSIDIAN NOTE FACILITY; DRAWS DOWN \$2m
- \* BTC AUSTRALIAN APPROVAL FOR RHYTHMIC INFUSION PUMP
- \* ADALTA INTERIM PHASE I AD214 EXTENSION 'SAFE WELL-TOLERATED'
- \* ANTERIS 'OUTSTANDING' 30-DAY DURAVR RESULTS
- \* ADHERIUM ENROLS 1st SENTA HAILIE PATIENTS
- \* INVION GMP INV043 FOR PHASE I TRIAL
- \* PAINCHEK: EU 'ACCEPTS' PAIN ASSESSMENT PATENT
- \* TRAJAN, METABOLON: NEOTERYX MITRA FOR METABOLOMIC RESEARCH
- \* HERAMED, TELSTRA HEALTH PARTNER FOR FOETAL HEART MONITOR
- \* ALCIDION AGM 43% DEFEAT 10% PLACEMENT CAPACITY
- \* IMMURON AGM 26% BLOCK PLACEMENT CAPACITY; 22% OPPOSE REM REPORT
- \* RADIOPHARM RECEIVES \$4.9m FEDERAL R&D TAX INCENTIVE
- \* VIKING TAKES 12.3% OF LBT; B MORAN 5.6%; HETTICH DILUTED BELOW 5%
- \* GREG HUTCHINSON REPLACES EMYRIA CHAIR DR STEWART WASHER

#### MARKET REPORT

The Australian stock market was up 0.28 percent on Tuesday November 21, 2023, with the ASX200 up 19.8 points to 7,078.2 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and five were untraded.

Prescient was the best, up 1.1 cents or 18.0 percent to 7.2 cents, with 1.65 million shares traded.

Nova Eye and Patrys climbed 12 percent or more; Mesoblast was up 11 percent; Imugene improved 6.7 percent; Dimerix, Genetic Signatures and Proteomics were up more than three percent; Neuren, Opthea, Polynovo, Telix and Volpara rose more than two percent; Clinuvel, Pro Medicus and Resmed were up more than one percent; with Emvision up by 0.9 percent.

Avita led the falls, down 36 cents or 9.4 percent to \$3.48, with 599,382 shares traded.

4D Medical and Universal Biosensors lost more than five percent; Atomo fell 4.35 percent; Starpharma was down 3.6 percent; Alcidion, Nanosonics and Paradigm shed more than two percent; Antisense and Immutep were down more than one percent; with Cochlear and CSL down by less than one percent.

#### VOLPARA HEALTH TECHNOLOGIES

Volpara says revenue for the six months to September 30, 2023 was up 17.5 percent to \$NZ19,837,000 (\$A18,264,000), with net loss after tax down 16.6 percent to \$NZ4,408,000 (\$A4,058,000).

Volpara said record revenue came from recurring subscriptions for its breast cancer detection mammography software and related services, which were up 19 percent on the prior corresponding period to \$NZ19.3 million.

The company said that software-as-a-service was up 28 percent to \$NZ15,303,000, with software maintenance down four percent \$NZ3,212,000, capital sales down 22 percent and lung contracts down 18 percent to \$NZ512,000.

Volpara said its diluted loss per share was even at 2.0 NZ cents and that it had cash and cash equivalents of \$NZ9,525,000 at September 30, 2023 compared to \$NZ9,711,000 at September 30, 2022.

Volpara was up 1.5 cents or 2.1 percent to 71.5 cents.

#### PRO MEDICUS

Pro Medicus says co-founders chief executive officer Dr Sam Hubert and executive director Anthony Hall have sold 1,000,000 company shares each.

In directors' interest notices Dr Hupert and Mr Hall said that on November 21, 2023 they each sold 1,000,000 shares for \$88.02 a share.

Pro Medicus said that Dr Hupert retained 25,137,660 shares or 24.07 percent of the company and Mr Hall retained 25,179,000 shares or 24.11 percent of the company. Pro Medicus was up \$1.05 or 1.2 percent to \$89.07 with 189,741 shares traded.

## **AVITA MEDICAL**

Avita says it has reduced 2023 revenue guidance from \$US51-53 million (\$A78-81 million) to \$US49.5-50.5 million (\$75.4-77 million).

Avita said that the lower and upper bounds of the revised guidance reflected "growth rates of approximately 45 percent and 48 percent, respectively, over the same period in 2022". The company said the change was "a result of slower-than-anticipated progression through the customer's value analysis committee (VAC) processes, driven by the expanded label applications of its newest indication, full-thickness skin defects". Avita chief executive officer Jim Corbett said the expanded label for full-thickness skin defects "opens up an abundance of exciting applications".

"With a wider range of potential uses, more clinicians within the hospital are engaged in the VAC process, leading to longer hospital approval timelines," Mr Corbett said. "Although the VAC processes are taking longer than anticipated, we expect that once completed, the process will yield positive approvals and an expanded market opportunity,"

Mr Corbett said. "The broader clinical involvement validates the substantial market opportunity this expanded label represents, which is greater than 10 times the size of the burn market."

In August, Avita gave revenue guidance for the three months to September 30, 2023 as \$US13 million to \$US14 million with a gross profit margin of 83 percent to 85 percent (BD: Aug 11, 2023).

Earlier this month, the company reported \$US13.5 million in revenue for the three months to September 30, 2023 with a gross profit margin of 84.5 percent (BD: Nov 9, 2023). Avita fell 36 cents or 9.4 percent to \$3.48 with 599,382 shares traded.

#### <u>PHARMAUST</u>

Pharmaust says it hopes to raise up-to \$396,125 in options to eligible lapsed option holders at an issue price of 0.5 cents each and exercisable at 15 cents each.

Pharmaust said the offer had a record date, the date which the lapsed options expired, of October 31, would open on November 24 and close December 8, 2023.

The company said the issued options would expire on April 30, 2026, and that it would use the funds for additional working capital and to meet offer expenses.

Pharmaust said Blue Ocean Equities Pty Ltd was lead manager to the raise.

Pharmaust was up 0.1 cents or 1.2 percent to 8.4 cents.

#### FEDERAL GOVERNMENT

The Federal Government says nominations for the seven Prime Minister's prizes for science, worth a total of \$750,000, have opened.

A media release from the Minister for Industry and Science Ed Husic said the prizes recognized "significant advancement of knowledge" in a range of science fields, as well as the role of teachers in inspiring the next generation of scientists.

The Federal Government said the seven awarded categories included the Prime Ministers prize for science, the prize for innovation, the Frank Fenner prize for life scientist of the year, the Malcolm McIntosh prize for physical scientist of the year, a prize for new innovators and prizes for excellence in science teaching in primary schools and secondary schools.

The media release said nominations, made by peers and colleagues, were open until February 8, 2024.

For more information, go to: https://industry.gov.au/PMPrizes.

## FEDERAL GOVERNMENT

The Federal Government says it has granted Monash University's Prof Gail Risbridger \$5 million to develop chimeric antigen receptor-T-cell therapy for prostate cancer.

A media release from the Minister for Health and Aged Care Mark Butler said chimeric antigen receptor (CAR) T-cell therapy took immune cells from a patient's body and programmed them to identify and attack cancer cells, and had successfully treated some blood cancers at advanced stages when other treatments failed.

The media release said the therapy had yet to be effective in treating solid cancers like prostate cancer, which was the most commonly diagnosed cancer in Australia.

The Government said Prof Risbridger would use "integrated" methods of generating CAR-T-cells, with models to test them and imaging tools to help bring the therapy to the clinic. The media release said Prof Risbridger's grant was one of 10 sharing a \$50 million pool from the National Health and Medical Research Council's Synergy Grant.

Mr Butler said CAR-T-cell therapy "promises to turn medicine on its head, by unlocking the ability of a patient's own immune system to find and destroy cancer and other disease". "This is world leading health research and the Albanese Government is proud to fund this

important work," Mr Butler said.

National Health and Medical Research Council chief executive officer Prof Steve Wesselingh said "the Synergy Grant scheme supports high-performing research teams to tackle complex research questions and improve human health".

"These grants offer opportunities to foster collaboration between diverse researchers to ensure a range of skills and perspectives are brought together to solve a problem," Prof Wesselingh said.

## MTP CONNECT

MTP Connect says it has nine recommendations to protect Australia against antibioticresistant bacteria, in response to an Australian Parliament report.

MTP Connect said the recommendations included trialing subscriptions for two novel antimicrobials; strengthening and introducing data exclusivity options for anti-microbials; increasing the amount of research; establishing and funding an anti-microbial therapy accelerator; promoting further research and development; making regulatory approval easier; developing fit-for-purpose "health technology assessments" for easier approval; demarcating the field as Australia's eleventh national health priority area; and encouraging more point-of-care testing for anti-microbial infections.

The company said its report was developed by specialist health advisory firm Evohealth. MTP Connect chief executive officer Stuart Dignam said the recommendations provided "a way forward to begin taking immediate action to tackle this urgent threat to our health system".

"We are running out of effective antibiotics and fast approaching a post-antibiotic era where minor infections, currently easily treated with common antibiotics, may become deadly," Mr Dignam said.

"The costs of [research and development] are too high, and the commercial returns are currently too low to justify investment in infectious disease medicine, particularly compared to other therapeutic areas," Mr Dignam said.

"We need to act now to change how we fund and pay for novel antibiotics and other antimicrobial medicines," Mr Dignam said.

MTP Connect said the report, titled 'Fighting superbugs: Ensuring Australia is ready to combat the rise of drug resistant infections', was available at: <u>https://bit.ly/3uvAKJO</u>.

## EPSILON HEALTHCARE

Epsilon deputy chair Alan Beasley has requisitioned an extraordinary general meeting to replace director Stuart Cameron and Xiao (Josh) Cui.

Epsilon said investors would vote to replace Mr Cameron and Mr Cui with chief executive officer Peter Giannopoulos and former directors, Lou Cattelan and Gary Radcliff. In the notice of meeting, Mr Beasley said he had "grown increasingly concerned about the governance of the board" and recommended shareholders vote in favor of the resolutions. Mr Beasley said that he wrote to Mr Cui seeking his resignation, with his letter to Mr Cui and Mr Cui's response available at: www.investorvote.com.au/EPN2023egm.

"Mr Cui's response has not satisfied my concerns," Mr Beasley wrote. "Given he has not resigned, I consider I have no choice but to take this serious step of convening an extraordinary general meeting to propose resolutions to re-comprise the board." The meeting will be held at Baker McKenzie Level 46, Tower One, 100 Barangaroo Avenue, Barangaroo, Sydney on December 22, 2023 at 9am (AEDT). Epsilon fell 0.1 cents or 4.8 percent to two cents.

### CANN GROUP

Cann Group says it has an up-to \$15 million convertible note facility with New York's Obsidian Global GP LLC, and has drawn down an initial \$2 million.

Cann Group said the facility had a maximum \$3 million at a time draw-down and would expire in 18 months.

The company said the funds raised would be used to help reach an annual production of 12.5-tonne of marijuana crop, forecast to be delivered by June 30, 2026.

Cann Group said the notes had a face value of \$US1.15 (\$A1.75) each, converting at the lesser of 80 percent of the lowest volume weighted average price 10 days to the date of notice and a 75 percent premium to the 5-day volume-weighted average price.

Cann Group said subject to shareholder approval it would issue Obsidian options worth 33 percent of the total face value of the first draw-down divided by the 5-day volume weighted average price to the first purchase, with the options exercisable at 200 percent of 5-day volume weighted average price.

The company said Everblu was lead manager for the raising and would receive a six percent fee and, pending shareholder approval, options valued on the same terms as the options to Obsidian.

Cann Group was unchanged at 11 cents with 1.5 million shares traded.

## BTC HEALTH

BTC says it has approval from the Australian Therapeutic Goods Administration to market its Rhythmic Evolution electronic infusion pump for hospital and homecare.

BTC said Rhythmic was an electronic, ambulatory infusion pump with administration sets and related accessories for use in hospital and homecare.

The company said Rhythmic pump could be used in post-operative pain management, obstetrics, antibiotic therapy, oncology and immunoglobulin infusions.

BTC chair Dr Richard Treagus said "the new Rhythmic infusion pumps form a key part of our strategy to replace the Ambit product range during 2024".

"It is a modern, no compromise electronic pump, which covers a wide range of therapy areas, and we look forward to making it immediately available to all hospitals and clinical staff," Dr Treagus said.

BTC was up 0.6 cents or 10.3 percent to 6.4 cents.

## <u>ADALTA</u>

Adalta says interim results from its phase I extension study of AD-214 for idiopathic pulmonary fibrosis shows a dose of 10mg/kg is safe and well-tolerated.

Last month, Adalta said that its eight-participant phase I extension study of AD-214 showed that three 10mg/kg doses had a similar "favorable tolerability profile" as lower doses (BD: Oct 23, 2023).

Today, the company said the results showed the frequency of mild infusion-related reactions appeared to be lower at 10mg/kg doses than that observed at 5mg/kg doses in the original phase I study.

Adalta said the bioavailability of AD-214 and the blocking of its target receptor, CXCR4 was in line with prior single dose studies, consistent across all three doses and, most significantly, in line with the predictions of previously announced dose simulation models. The company said the immune response to AD-214 was lower at the time the interim results were collected than what it had observed in prior multi-dose studies.

Adalta said participants would receive a fourth and final dose 12 weeks after their third dose, with the aim of confirming that there was no immune response that might affect efficacy and safety, and that full results were due by April, 2024.

Adalta said the results reinforced the drug's safety profile and the potential efficacy of the 10mg/kg dose, de-risking its planned phase II study and increasing partnering discussions.

Adalta managing-director Dr Tim Oldham said the results were "very much in-line with our expectations".

Adalta was up 0.1 cents or 5.3 percent to two cents.

## ANTERIS TECHNOLOGIES

Anteris says "outstanding" data from 12 of 15 patients in its Duravr transcatheter heart valve trial show "no significant change" in valve efficacy at 30-days after implant. Last month, Anteris said it had "unprecedented positive hemodynamic results" from its US early feasibility study of its Duravr heart valve, including a mean effective orifice area at discharge of 2.36cm<sup>2</sup> and a mean pressure gradient of 7.88mm/Hg (BD: Oct 26, 2023). Today, the company said 30-day hemodynamic results showed patients had a mean effective orifice area of 2.13cm<sup>2</sup> and a mean pressure gradient of 7.9mm/Hg. Anteris said in addition to the efficacy results, the trial showed "excellent safety data, with no incidence of stroke, myocardial infarction, life-threatening bleeds, or all-cause mortality".

Anteris was up 40 cents or two percent to \$20.20.

## **ADHERIUM**

Adherium says the first patients have been enrolled for remote patient monitoring with its Hailie asthma adherence software, as part of its partnership with Senta.

In September, Adherium said the Atlanta, Georgia-based Southern Ear, Nose, Throat and Allergy (Senta) would use its Hailie asthma adherence software (BD: Sep 18, 2023).

Today, the company said enrolment would expand to more patients and providers next year within Senta's 48 locations in six states.

Adherium said it would be paid for sensor sales and received monthly, per patient fees for generating and transmitting respiratory data.

Adherium fell 0.05 cents or 14.3 percent to 0.3 cents with 4.2 million shares traded.

## **INVION**

Invion says manufacture of photo-activated INV043 treatment for cancers is a "major milestone towards clinical trials".

Invion said that IDT Australia had manufactured INV043 to good manufacturing practice (GMP) standards, to produce high-containment and high potency active pharmaceutical ingredients which was a "significant step towards commencing clinical trials".

Invion chief executive officer Thian Chew said "this is an important achievement because it puts Invion ahead of the curve on the drug manufacturing front".

"We are not only well placed for our upcoming phase I clinical trials but for subsequent clinical trials as well," Mr Chew said. "As a next generation photo-dynamic therapy,

INV043 has the potential to provide new therapeutic options for multiple cancers without significant off-target issues."

Invion was up 0.1 cents or 16.7 percent to 0.7 cents with 9.7 million shares traded.

### PAINCHEK

Painchek says the European Patent Office has accepted a patent for its pain assessment and monitoring technology.

Painchek said the patent, titled 'A Pain Assessment Method and System' would protect its intellectual property until 2035.

The company said the patent gave it exclusive rights to the commercialization of its technology in the 39 member states of the European Patent Organization.

Painchek chief executive officer Philip Daffas said "this acceptance letter is the precursor to a fully granted patent, securing our intellectual property in the significantly large European markets which is key to our global strategy, including the UK".

Painchek fell 0.3 cents or 6.4 percent to 4.4 cents with 1.2 million shares traded.

## TRAJAN SCIENTIFIC AND MEDICAL, METABOLON INC

Trajan says the Raleigh, North Carolina-based Metabolon will use its Neoteryx Mitra biological sample collection devices in metabolomic research.

In an email not published to the ASX, Trajan said research was frequently constrained by the inability to secure stable biological samples and its Mitra devices used a volumetric absorptive micro-sampling method that was "minimally invasive and user friendly". Metabolon chief scientific officer Dr Rangaprasad Sarangarajan said the collaboration "democratizes the ability to collect sufficient, stable blood samples for metabolomic analysis".

Trajan fell 1.5 cents or 1.2 percent to \$1.23.

#### <u>HERAMED</u>

Heramed says it has joined Telstra Health's smart marketplace to educate and market its Heracare remote foetal heart monitor to general practitioners in Australia.

Heramed said it would integrate Heracare into Telstra Health's Medicaldirector Clinical which serviced the general practitioner customer base through Telstra Health software. The company said Medicaldirector was a practice management software designed to enable "safe and more efficient provision of care" for healthcare professionals. Heramed said that integration was underway, with education and marketing strategies to

be developed, and the product expected to be launched with Telstra Health by April 2024. Heramed was up 0.1 cents or 2.2 percent to 4.7 cents.

## **ALCIDION GROUP**

Alcidion says its annual general meeting defeated the special resolution to approve the 10 percent placement capacity, with 209,501,724 votes (42.53%) in opposition.

Special resolutions require a 75 percent majority to pass.

The company said the remuneration report was opposed by 13.90 percent of the vote with 7.75 percent dissent against the re-election of chair Rebecca Wilson as a director.

According to its most recent notice, Alcidion had 1,337,433,279 shares on issue, meaning the votes against the placement capacity amounted to 15.7 percent of the company, sufficient to requisition extraordinary general meetings.

Alcidion fell 0.2 cents or 2.8 percent to 6.9 cents with 8.25 million shares traded.

#### **IMMURON**

Immuron says its annual general meeting narrowly voted down the 10 percent placement capacity special resolution and 21.51 percent opposed the remuneration report. Immuron said the increased placement capacity was opposed by 11,479,555 votes (26.32%), with 32,137,321 votes (73.68%) in favor.

Special resolutions require a 75 percent majority to pass.

The company said the remuneration report faced 21.51 percent opposition, the issue of options to chair Paul Brennan had 18.02 percent dissent, with all other resolution passed by more than 85 percent of the vote.

According to its most recent notice, Immuron had 227,798,346 shares on issue, meaning that the votes against the placement capacity amounted to 5.04 percent of the company, sufficient to requisition extraordinary general meetings.

Immuron was unchanged at eight cents.

## RADIOPHARM THERANOSTICS

Radiopharm says it has received \$4,851,839 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

Radiopharm said the rebate related to expenditure for the year to June 30, 2023. Radiopharm fell 0.1 cents or 1.3 percent to 7.4 cents.

#### LBT INNOVATIONS

Brisbane's Viking BCM Pty Ltd says it has increased its substantial shareholding in LBT from 115,576,792 shares (10.78%) to 141,776,792 shares (12.27%). Yesterday, Viking said it became substantial with 115,576,792 shares (BD: Nov 20, 2023). Today, Viking said it bought 26,200,000 shares in a placement at 0.5 cents a share. Last month, LBT said it hoped to raise \$4.5 million in a four-for-one rights offer at 0.5 cents a share, with Candour Advisory Pty Ltd the underwriter (BD: Oct 13, 2023). LBT was untraded at half a cent.

#### LBT INNOVATIONS

Sydney's B Moran Pty Ltd says it has become a substantial shareholder in LBT with 60,499,336 shares, or 5.64 percent.

B Moran director Brendan Moran said that with Morcap Pty Ltd he bought 49,433,400 shares on November 15, 2023 for \$247,167, or 0.5 cents a share (see above).

#### LBT INNOVATIONS

Hettich GmbH says its 30,660,377 shares in LBT have been diluted below five percent. The Tuttlingen, Germany-based Hettich Holding said on November 15, 2023 its holding was diluted due to the issue of shares by the company (see above).

In 2021, LBT said it would pay Hettich GmbH \$1 million in cash and \$3 million through the issue of 30.66 million shares for its 50 percent of Clever Culture systems, taking full ownership of the joint venture (BD: Jan 16, 2022).

According to its most recent filing, LBT had 1,155,900,323 shares on issue. Biotech Daily calculates Hettich retains about 2.7 percent of the company.

#### **EMYRIA**

Emyria says Greg Hutchinson will replace chair Dr Stewart Washer, on \$80,000 a year as well as 500,000 sign-on incentive shares and 2,500,000 performance rights.

Emyria said Dr Washer would be "stepping down to an unpaid advisory role where he will continue to provide strategic support".

The company said Mr Hutchinson was previously Sonic Healthplus chief executive officer, the founder of 5D Clinics and a chain of private physiotherapy clinics, and had been a director of Tennis Australia since 2015.

Emyria said Mr Hutchinson's performance rights were subject to shareholder approval and would vest in a 500,000 tranche, and two 1,000,000 tranches, vesting at a 10-day volume-weighted average price of 15 cents, 25 cents and 40 cents, respectively.

Emyria managing director Dr Michael Winlo said Dr Washer had "been instrumental in our journey so far, laying the foundations of a company committed to personalized therapy and data acquisition to guide the development of innovative treatments to address unmet clinical needs".

Emyria was up 0.2 cents or 2.8 percent to 7.4 cents.