



Biotech Daily

Wednesday May 8, 2024

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: SYNTARA UP 12.5%; UNIVERSAL BIO DOWN 6%**
- * **BUDGET CUTS BREAKTHROUGH VICTORIA \$360m; OTHERS UNTOUCHED**
- * **BDI-40: VOLPARA GONE; IMPEDIMED UP; MEDADVISOR IN**
- * **HEADSAFE HOPES TO RAISE \$5m FOR NEUROCHEK CONCUSSION TEST**
- * **POLYNOVO RECORD \$10m MONTHLY REVENUE**
- * **UNIVERSAL BIOSENSORS RIGHTS RAISE \$10m; TOTAL \$12.5m**
- * **ISLAND USES \$962k OF US DEFENCE GRANT FOR PHASE II TRIAL**
- * **QUEENSLAND UNI \$15m RADIO-PHARMACEUTICAL HUB**
- * **ALTERITY PHASE II ATH434 MSA TRIAL PASSES 3rd SAFETY REVIEW**
- * **INVION, HANLIM INV043 BRAIN CANCER PROOF-OF-CONCEPT STUDY**
- * **TDM GROWTH TAKES 31% OF SOMNOMED**
- * **REGAL FUNDS REDUCES, DILUTED TO 9.3% OF ADHERIUM**
- * **REGAL FUNDS DILUTED BELOW 5% OF GENETIC SIGNATURES**
- * **BIO-MELBOURNE APPOINTS KAREN PARR CEO**

MARKET REPORT

The Australian stock market was up 0.14 percent on Wednesday May 8, 2024, with the ASX200 up 11.2 points to 7,804.5 points. Fifteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and two were untraded. All three Big Caps were up.

Syntara was the best, up 0.2 cents or 12.5 percent to 1.8 cents, with 3.7 million shares traded. Polynovo improved eight percent; Avita and Clarity climbed six percent or more; Curvebeam and Emvision were up more than five percent; Cyclopharm, Medadvisor and Starpharma were up more than four percent; Percheron was up 3.9 percent; Medical Developments, Pro Medicus and Telix rose more than two percent; Nanosonics was up one percent; with Clinuvel, Cochlear, CSL and Resmed up by less than one percent.

Universal Biosensors led the falls, down one cent or 6.25 percent to 15 cents, with 1.6 million shares traded. Immutep lost 5.15 percent; Prescient and Resonance fell more than four percent; Alcidion, Mesoblast and Opthea were down more than three percent; 4D Medical, Dimerix, Impedimed, Next Science and Paradigm shed two percent or more; Imugene, Nova Eye, Orthocell and Proteomics were down more than one percent; with Genetic Signatures and Neuren down by less than one percent.

VICTORIA BUDGET

The Victoria Budget delivered by Treasurer Tim Pallas yesterday appears to have had very little impact on biotechnology and medical research.

The Budget said the \$2 billion Breakthrough Victoria budget would be reduced by \$360 million over four years and the fund's "investment profile" extended from 10 to 15 years".

Mr Pallas said the State Government had "invested \$59 billion into our healthcare system, and the workers we need to run it, since taking office in 2014".

"From that base, this Budget now delivers the biggest investment in our healthcare system, ever ... including more than \$8.8 billion in operating funding for hospitals".

The Budget papers said that funding continued for small business, start-ups and the Biontech mRNA program, with the allocation for Industry, Small Business and Medical Research increasing 10.2 percent to \$476.0 million in 2024-'25, of which \$418.7 million was for Industry and Small Business and \$57.3 million for Medical research.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

With the departure of Volpara from the BDI-20, Impedimed has been promoted and Medadvisor included in the consequential vacancy in the Second 20.

Volpara Health Technologies was acquired by the Seoul, South Korea's Lunit Inc in a scheme of arrangement at \$1.15 a share, valuing the company at \$295.7 million, and is expected to be delisted on May 22 (BD: Dec 14, 2023; Apr 12, 2024).

While Impedimed's market capitalization has fallen over the past 12 months, Biotech Daily has confidence in the new management and expects progress in the coming months.

Other contenders for promotion included Alcidion, Curvebeam and Proteomics.

Medadvisor has made considerable strides over the past year and has been promoted into the Second 20 of the BDI-40, with Aroa, Immuron, Mach7, Microba, EBR Systems, Argenica, Botanix and Neurotech all strong competitors.

David Langsam
Editor

HEADSAFE MFG PTY LTD

The Sydney based Headsafe says it hopes to raise \$5 million for its Neurochek two-minute wearable concussion test.

Headsafe chief executive officer Dr Adrian Cohen told Biotech Daily that the company was founded in 2017 and the Neurochek system received US Food and Drug Administration clearance in December 2023, and the company hoped for Australian Therapeutic Goods Administration approval this year.

In a slide deck, Headsafe said there was a US traumatic brain injury "every 21 seconds ... [with] undiagnosed concussions risking long-term damage and high treatment costs".

The company said that current diagnostic methods were often subjective and lengthy.

Headsafe said that Neurochek's two-minute assessment was "rapid, objective, affordable, baseline-free [and] easy to use".

The company said it had conducted eight clinical trials in the US, Australia and New Zealand.

Headsafe said that Neurochek included visual stimulus and sensor electronics and analyzed more than 400,000 data points.

The company said that each headset cost \$4,500 with a fee of \$45 per test.

Dr Cohen said that the company's pre-capital raise valuation was \$35 million and interested investors should write to: investor@team.headsafe.com.

Headsafe is a private company.

POLYNOVO

Polynovo says revenue from sales of its Novosorb and other wound treatments for of April 2024 was up 68.6 percent to a record \$10.1 million compared to April 2023.

Polynovo said US sales for April were up 75.0 percent to \$6.9 million compared to the previous corresponding period, with non-US sales up 68.2 percent to \$2.4 million.

The company said the unaudited revenue for the month included payments received from the US Biomedical Advanced Research and Development Authority (BARDA), with commercial sales of accounting for \$9.2 million of the monthly total.

Polynovo chief executive officer Swami Raote said the company had treated more than 42,000 patients in 39 countries.

Polynovo was up 17 cents or eight percent to \$2.29 with 4.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has raised \$10 million at 15 cents per Chess depository interest (CDI) in its one-for-3.47 entitlement offer, taking the total raised to \$12.5 million.

Earlier this year, Universal Biosensors said it raised \$2.5 million in a placement at 15 cents and hoped to raise \$10 million in a rights offer (BD: Mar 1, Mar 22, Apr 11, 2024).

Today, the company said the entitlement offer raised \$7.7 million from existing shareholders, with Viburnum Funds underwriting the remaining \$2.3 million.

Universal Biosensors said an additional \$500,000 had been raised from the exercise of options by chief executive officer John Sharman and Viburnum Funds.

Mr Sharman said the proceeds would be used "to accelerate the US roll-out of Xprecia and to promote sales across the portfolio of products".

Universal Biosensors fell one cent or 6.25 percent to 15 cents, with 1.6 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has re-allocated \$US625,000 (\$A962,000) of its US Department of Defense grant to fund parts of its planned phase IIa trial of ISLA-101 in dengue fever.

Last year, Island said was awarded \$US1.3 million (\$A1.95 million) from the US Department of Defense's Congressionally Directed Medical Research Program for its phase IIa trial of ISLA-101 for dengue fever (BD: Jul 7, 2023).

Today, the company said the grant had been awarded to Syracuse, New York's State University of New York to conduct additional laboratory testing and data analysis for the phase II study.

Island said although the additional analysis and testing was "considered scientifically important information owned by Island, it is not essential at this point in time and these funds were not being prioritized to Island's direct clinical trial costs".

The company said the State University of New York had agreed the funds could be re-allocated to its clinical trial, which provided "a significant reduction to Island's overall costs for the ISLA-101 phase IIa trial".

Island said the phase IIa study was expected to begin by October 2024.

Island chief executive officer Dr David Foster said the company was "most appreciative of this meaningful source of new, non-dilutive funding.

"As cases of dengue fever continue to spike around the globe, finding both preventatives and treatments are paramount," Dr Foster said. "We are extremely hopeful about our potential to bring a new tool forward to combat the escalating dengue issue."

Island was up 0.3 cents or 5.4 percent to 5.9 cents with 1.4 million shares traded.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has opened a \$15 million research and manufacturing hub to develop targeted radio-pharmaceutical cancer treatments.

The University of Queensland said the hub, called the Australian Research Council hub for Advanced Manufacture of Targeted Radiopharmaceuticals, or AMTAR, would be a “one-stop-shop” that connected biotechnology firms with facilities for designing, testing and delivering cancer treatments.

The University said the hub would operate from the Australian Institute for Bioengineering and Nanotechnology at its St Lucia, Brisbane campus and was funded with a \$5 million Australian Research Council grant and more than \$10 million in industry funds.

The University of Queensland said that radio-pharmaceuticals were “an emerging group of drugs designed to spare the body from the harsh effects of cancer treatment” and the hub had begun manufacturing “a range of hyper accurate cancer drugs”.

The University said the hub working with the University of Sydney, Telix, Starpharma, Clarity, Advancell, Cyclowest and Glytherix.

The University of Queensland said other partners included the UK’s University of Nottingham, Japan’s University of Tokyo as well as Roane County, Tennessee’s Oak Ridge National Laboratory and New York’s Memorial Sloan-Kettering Cancer Centre. Australian Institute for Bioengineering and Nanotechnology director of research Prof Kris Thurecht said the medical technology was “still very much in development, but radio-pharmaceuticals already represent a multi-billion-dollar industry that will be integral to modern healthcare.”

“Through AMTAR we have an opportunity to position Australia as a global leader in this field,” Prof Thurecht said.

“Radio-pharmaceutical science has been around for decades, but it is only through recent advances in scientific infrastructure and instrumentation that we have been able to conceive and create commercially viable products,” Prof Thurecht said.

ARC acting chief executive officer Dr Richard Johnson said the AMTAR hub would “help unlock the power of radio-pharmaceuticals”.

Telix chief scientist Dr Michael Wheatcroft said it was “an exciting partnership ... [which would] accelerate the development and commercialization of novel radio-pharmaceuticals in Australia and the team of high quality industry, academic and research partners will enable the translational science required to bring these innovative new technologies to patients”.

ALTERITY THERAPEUTICS

Alterity says it has data monitoring committee approval to continue its 77-patient, double-blind, placebo-controlled phase II trial of ATH434 for multiple system atrophy (MSA).

In 2022, Alterity said it had dosed the first patients in its randomized, double-blind, placebo-controlled phase II trial; and last year, said it had enrolled all 77 patients in the trial (BD: Jul 6, 2022, Nov 8, 2023).

Today, Alterity said the committee reviewed unblinded clinical data and “expressed no concerns about safety and recommended that the study continue without modification”.

The company said it expected top-line data in January 2025, with the data from the phase II trial patients treated with ATH434 for 12 months to be used to design a phase III study.

Alterity managing-director Dr David Stamler said the recommendation was “important as ATH434 continues to demonstrate a favorable safety profile with long-term exposure” with the trial on-track to complete in November 2024 and report top-line data in January 2025.

Alterity was unchanged at 0.6 cents with two million shares traded.

INVION

Invion says it has a two-year partnership with Seoul, South Korea's Hanlim Pharma Co Ltd to conduct proof-of-concept, in-vivo studies of its Photosoft INV043 for brain cancer. Invion said Hanlim Pharma was "one of the largest pharmaceutical groups in South Korea with 2023 revenues of about \$US240 million (\$A365 million)".

The company said Hanlim Pharma entered into the partnership after assessing its data showing the effectiveness of INV043 against various cancer types using in-vitro and in-vivo models.

Invion said Hanlim would conduct the proof-of-concept studies at the Seoul St Mary's Hospital to show INV043's diagnostic potential and therapeutic efficacy for the brain cancer glioblastoma multiforme.

The company said it would supply the Photosoft compounds to be used in the study and retain all benefits and rights to the technology, including any intellectual property from the collaboration.

Invion said subject to the study outcome, it may negotiate a co-development agreement for INV043 with Hanlim Pharma.

Invion executive chair Thian Chew said the collaboration "could provide an alternative treatment for [glioblastoma multiforme] and possibly reduce some of the risks associated with current treatments".

"INV043 has proven itself to be very versatile in the variety of cancers we have treated in-vitro and in-vivo," Mr Chew said.

"Collaborations with leading companies, such as Hanlim, further demonstrates the potential of Photosoft," Mr Chew said.

Invion was unchanged at half a cent with 10.1 million shares traded.

SOMNOMED

TDM Growth Partners Pty Ltd says it has increased its substantial share-holding in Somnomed from 32,572,382 shares (30.00%) to 67,716,079 shares (31.33%).

The Sydney-based TDM Growth Partners said that on May 8, 2024 it bought 35,143,697 shares in a rights offer at 21 cents a share.

On Monday, Somnomed said it raised \$16.8 million at 21 cents share in its, fully-underwritten retail rights offer, taking the total to \$22.6 million (BD: May 6, 2024).

Somnomed was unchanged at 20 cents.

ADHERIUM

Regal Funds Management Pty Ltd says it has reduced its substantial shareholding in Adherium and been diluted to 36,243,028 post-consolidation shares (9.29%).

Last year, Adherium said investors approved a 15-to-one consolidation, with 333,439,981 post-consolidation shares on issue (BD: Dec 1, Dec 7, 2023).

Today, the Sydney-based Regal Funds said it previously held 545,518,201 pre-consolidation shares, or 10.91 percent, and on February 1 and April 15, 2024 it sold 124,853 shares for \$7,778, or 6.2 cents a share, and was diluted on May 3, 2024 due to the issue of 50,000,000 shares by the company.

Last month, Adherium said it had "commitments" to raise up-to \$1.57 million in a placement at 2.0 cents a share, followed by a \$6.8 million underwritten, one-for-one rights offer (BD: Apr 26, 2024).

Adherium was up 0.2 cents or 12.5 percent to 1.8 cents with 2.1 million shares traded.

GENETIC SIGNATURES

Regal Funds Management Pty Ltd says it has reduced its shareholding in Genetic Signatures and been diluted below the five percent substantial threshold.

The Sydney-based Regal Funds said that on April 30, 2024 it sold 800 shares for \$533, or 66.6 cents a share, and was diluted due to the exercise of 40,000 options on May 3, 2024. In March, Regal said it became substantial in Genetic Signatures with 9,325,195 shares, or 5.00 percent (BD: Mar 13, 2024).

According to its most recent filing, the company had 186,522,642 shares on issue, meaning that Regal's remaining 9,324,395 shares amounts to about 4.999 percent of the company.

Genetic Signatures fell half a cent or 0.7 percent to 71.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it has appointed Karen Parr as its chief executive officer, effective from June 3, 2024.

The Bio-Melbourne Network said Ms Parr was a director at Ausbiotech and had worked for the New Zealand Government and the UK Bioindustry organization as well as founding Australia's Cell and Gene Catalyst.

According to her LinkedIn profile, Ms Parr held a Bachelor of Arts from New Zealand's Victoria University of Wellington.

The Network said Ms Parr would "help steer our sector to create growth opportunities with the delivery of innovative science and technology, research and development and delivering commercial success".