

Biotech Daily

Monday February 3, 2025

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: MEDICAL DEVEL UP 20%; MEDADVISOR DOWN 11%
- * JANUARY BDI-40 UP 11%, ASX200 UP 5%, BIG CAPS UP 3.5%
- * AUSHEALTH VENTURES: \$5m/YEAR FOR RESEARCH
- * MONASH SPINS-OUT PHRENIX FOR SCHIZOPHRENIA
- * PARADIGM \$112m LOYALTY, PIGGY-BACK OPTIONS OFFER
- * ALTERITY US ATM RAISES \$2.1m
- * DORSAVI \$77k US SENSOR ATHLETE INJURY PREVENTION STUDY
- * FISHER & PAYKEL EXPECTS US TARIFFS TO INCREASE COSTS
- * OPTISCAN STARTS ENDO-MICROSCOPE G-I PRE-CLINICAL STUDY
- * ORTHOCELL FILES CANADA REMPLIR APPLICATION
- * FLINDERS UNIVERSITY LAUNCHES PHAGE DEVELOPMENT TOOL
- * ISLAND LOSES DIRECTOR ALBERT HANSEN
- * GENETIC SIGNATURES APPOINTS MICHAEL SAPOUNTZIS CO-CO SEC

MARKET REPORT

The Australian stock market fell 1.79 percent on Monday February 3, 2025, with the ASX200 down 152.9 points to 8,379.4 points. Seven of the Biotech Daily Top 40 stocks were up, 30 fell, two traded unchanged and one was untraded. All four Big Caps fell.

Medical Developments was the best of the seven, up 13 cents or 19.55 percent to 79.5 cents with 1.8 million shares traded. Nova Eye was up 7.1 percent; Curvebeam climbed 4.55 percent; Universal Biosensors was up 3.45 percent; Imugene rose 2.8 percent; with Cyclopharm and EBR up by more than one percent.

Medadvisor led the falls, down two cents or 10.8 percent to 16.5 cents, with 2.4 million shares traded. Paradigm and Prescient lost more than nine percent; Atomo, Genetic Signatures, Immutep, Opthea, Polynovo, Proteomics and Syntara were down seven percent or more; Clarity and Orthocell shed six percent or more; Clinuvel and Neuren were down more than five percent; Alcidion and Starpharma fell more than four percent; Avita, Dimerix, Pro Medicus and Resmed were down three percent or more; 4D Medical, Amplia, Aroa, Cochlear, Emvision, Impedimed, SDI and Telix shed two percent or more; with Compumedics, CSL, Cynata, Mesoblast, Nanosonics and Resonance down by one percent or more.

BIOTECH DAILY TOP 40 INDEX (BDI-40)

January pushed the Biotech Daily Top 40 Index (BDI-40) further into record territory, up 11.2 percent in the month to \$25,841 million.

For the year to January 31, 2025, adjusting for the November Pro Medicus promotion to the Big Caps, the BDI-40 was up 70.1 percent to \$48,473 million. Without the adjustment, in raw data terms, the BDI-40 was up 0.1 percent compared to January 31, 2024.

That means, that despite removing Pro Medicus worth \$20,360 million at the time, the BDI-40 is still above where it was 12 months ago.

The benchmark ASX200 was up 4.6 percent in January and 11.1 percent for the year to January 31, 2025. The Nasdaq Biotechnology Index was up 5.1 percent for the month and 3.4 percent for the year.

The four Big Caps of Cochlear, CSL, Pro Medicus and Resmed (which are not included in the BDI-40) were up a collective 3.5 percent in January and 11.2 percent for the year to January 31, 2025. Resmed improved the most numerically, up \$5,012 million, but Cochlear was the percentage best, up \$1,905 million or 10.0 percent to \$20,872 million, followed by Pro Medicus up \$2,268 million or 8.7 percent to \$28,405 million, with CSL easing 0.1 percent to \$135,447 million.

The BDI-40 had many rises and small falls. Twenty-two companies were up, 16 by more than 10 percent, six by more than 20 percent; with 17 down, 10 by more than 10 percent.

Telix added the most to the total - \$1,405 million - but the percentage best was Medical Developments up \$29 million or 63.0 percent to \$75 million, followed by EBR (61.05%), Paradigm (56.2%), Cyclopharm (40.3%), Dimerix (32.1%), Opthea (28.5%), Nanosonics (18.3%), Telix (17.1%). Orthocell (16.0%), Neuren (15.6%), Alcidion (14.8%), 4D Medical (14.1%), Percheron (12.5%), Resonance (12.5%), Compumedics (12.2%), Prescient (10%) and Mesoblast up \$333 million or 9.4 percent.

Avita led the falls – on a January 8 revenue warning - down \$166 million or 29.6 percent to \$394 million, followed by Aroa (24.8%), Proteomics (20.0%), Medadvisor (17.7%), Curvebeam (17.3%), Universal Biosensors (16.1%), SDI (15.3%), Nova Eye (13.5%), Syntara (11.9%) and Clarity (10.2%).

The 11 companies in Cannabis Corner were up 5.0 percent to \$294 million, but down 23.6 percent for the year to January 31, 2025; with Bioxyne up 63.6 percent to \$90 million and Avecho up 25.0 percent to \$10 million; while six fell, led by Inhalerx down from \$7 million by \$3 million or 42.9 percent to \$4 million and three were unchanged.

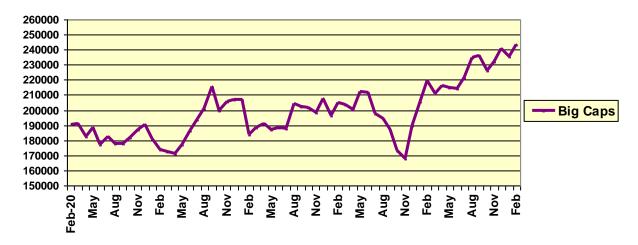
On the Nasdaq, Bionomics was unchanged at \$8 million, Kazia was up 16.7 percent to \$14 million, Eyepoint (Psivida) was up 2.3 percent to \$841 million, Incannex fell 21.7 percent to \$47 million and Protagonist slipped 2.4 percent to \$3,629 million.

Outside the BDI-40, Argenica, Arovella, Artrya, Austco, Botanix, Clever Culture, Control Bionics, Echo IQ, Imricor, Island, Microba, Optiscan, Race, Radiopharm, Respiri, Somnomed and Tryptamine, were all vying for promotion.

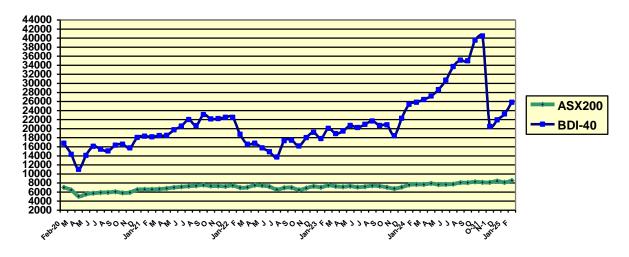




Big Caps \$m (COH, CSL, PME, RMD) Jan 31, 2020 – Jan 31, 2025 (PME from Oct 31, 2023)



BDI-40 (\$m) v S&P ASX 200 – Jan 31, 2020 – Jan 31, 2025 (Pre-Covid to date) (The large fall is the November removal of Pro Medicus to the Big Caps)



AUSHEALTH VENTURES (FORMERLY AUSHEALTH RESEARCH)

Aushealth Ventures says it will provide \$5 million a year in funding for its "accelerator hub" in Underdale, Adelaide to support medical technology research and.

According to its website, the company was a "provider of workplace health and safety services, products, training and education" including drug and alcohol testing, as well as health care services including hospital patient billing, revenue and debt services.

Aushealth said it was established in 1985 and "had contributed more than \$50 million to South Australian-led research in cell therapies, pain management, bowel and breast cancer, diabetes and new diagnostics".

The company said its accelerator had a 20-person team that would support medical technology and biotechnology companies to help them attract investors, and would be led by its chief operating officer Dr Justin Coombs.

Aushealth said its charity would contribute \$5 million to an annual research fund for the hub, with further investment from its in-house capital group, called the Wellspring Consortium, which was supported by government and private capital.

The company said the hub would provide intellectual property strategy, business development and commercialization, artificial intelligence products and marketing and communications.

Dr Coombs said Australia had "long been home to brilliant medical research, but as a nation, we've never been very good at profiting from those ideas".

"Instead of creating a home-grown cancer therapy or an Aussie Ozempic, our ideas too often go overseas, or they're simply left in a lab," Dr Coombs said.

"Aushealth Ventures is changing that by supporting research and helping interested parties translate their medical research 'from the bench to the bedside', in other words, Aushealth Ventures is a public unlisted company.

PHRENIX THERAPEUTICS, MONASH UNIVERSITY

Monash University says spin-out Phrenix has secured a "major funding boost from US and Australian venture capital firms" to develop its therapies for schizophrenia.

A University spokesperson told Biotech Daily the amount was "commercial in confidence". A media release from Melbourne's Monash University said Phrenix was founded in 2022 with the Florey Institute of Neuroscience and that its chief executive officer was Prof Chris Langmead and chief scientific officer was Dr Greg Stewart.

According to the company's website it was developing a pipeline of G protein-coupled receptor (GPCR)-targeted therapeutics for cognitive impairments associated with schizophrenia.

Monash University said the seed investment was provided by Curie Bio and Brandon Capital with funding from the Federal Medical Research Future Fund and Therapeutic Innovation Australia, as well as from the Monash Research Impact Fund and Monash Investment Holdings.

Prof Langmead said the research and early successes of Phrenix were "due to a meeting of minds and mission between the three co-founders, supported by Monash University and the Florey".

"This investment brings scale, acceleration, and deep expertise from our partners at Curie.Bio and Brandon Capital," Prof Langmead said. "It gives Phrenix the best possible chance to progress our programs into the clinic and make a real difference to the lives of individuals, families and communities," Prof Langmead said.

Phrenix is a private company.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it may raise up-to \$111.96 million through the issue of loyalty options and piggy-back options.

Paradigm said it would issue one loyalty option for every four shares held by investors on the record date of February 7, 2025, with the loyalty options exercisable at 65 cents each by February 11, 2026.

The company said it would issue an additional piggy-back option for every two loyalty options exercised by investors on, or before, the option expiry date, exercisable at \$1.00 each before February 11, 2028.

Paradigm said that the full exercise of the loyalty options could raise about \$63.28 million and it could raise about \$48.68 million if the total number of piggy-back options were issued and exercised.

The company said the funds raised would be used to funds its phase III clinical trials. Paradigm fell 5.5 cents or 9.4 percent to 53 cents with 4.4 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has raised \$2.13 million in the US through an at-the-market facility to fund the clinical and regulatory development of ATH434 for Parkinson's disease.

In 2023, Alterity said it filed a US Securities and Exchange Commission F-3 form, allowing it to offer up-to \$US50 million (\$A79.4 million) in American depositary shares (ADS) and warrants (BD: Oct 4, 2023).

At that time, the company said each ADS was equivalent to 600 ordinary Australian shares, and it might offer the shares "from time to time" in one or more series or issuances, with the shares listed on the Nasdag under the ticker code ATHE.

Alterity chair Geoffrey Kempler told Biotech Daily at that time that the facility replaced an expiring facility, which it had used "for many years and it provides us the opportunity to use the 'at-the-market' facility or to do a direct raising".

Today, Alterity said it had raised about \$2.13 million through the facility following positive topline results from its phase II trial of ATH434 for multiple system atrophy.

Last week, Alterity climbed 137.5 percent on its phase II trial of ATH434 showing a "statistically significant improvement" for multiple system atrophy (BD: Jan 30, 2025). Today, the company said it expected to receive about \$5.69 million in its research and development tax incentive by April 2025.

Alterity was up 0.2 cents or 16.7 percent to 1.4 cents with 205.7 million shares traded.

<u>DORSAVI</u>

Dorsavi says it will receive \$US46,750 (\$A76,750) to conduct a US study of its wearable sensors and artificial intelligence algorithms for athlete injury prevention.

Dorsavi said it had been selected by US foot and ankle surgeon Dr Chirag Patel to conduct the study during the first half of 2025 using its wearable sensors and artificial intelligence video tracking algorithm to "optimize the fusion algorithm for high speed, multi-directional sporting and clinical needs".

The company said Dr Patel was managing-director of New Horizons Foot and Ankle Associates, founding chief executive officer of Health Analysyst and resident injury expert at ESPN (Entertainment and Sports Programming Network).

Dorsavi said the study would use its technology to "identify the movement traits and patterns that may pre-dispose an athlete to a higher risk of injury".

Dorsavi was unchanged at 0.9 cents with 5.3 million shares traded.

FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says it expects its costs will "likely increase" due to the US 25 percent tariff imposed on Mexico, where it manufactures about 45 percent of its products. Fisher & Paykel said the US had announced a 25 percent tariff to products imported from Mexico and Canada and a 10 percent tariff on products imported from China, effective from February 4, 2025.

The company said for the six months to September 30, 2024, about 43 percent of revenue from sales of its devices and software for obstructive sleep apnoea were from the US and about 60 percent of US volumes were supplied from its factories in Mexico.

Fisher & Paykel said it did not currently expect the announced tariffs to have a material impact on its net profit after tax for the year to March 31, 2025.

The company said "the economic environment, global response to US tariffs and foreign currency movements may be fluid over this period" and that the tariffs may have added two-to-three years to it reaching its gross margin target of 65 percent.

Fisher & Paykel managing-director Lewis Gradon said that the company took "a long-term view and will be working with global suppliers and US customers to provide solutions to best mitigate the impact of the tariffs on all parties".

"Across the business we are continuing to make improvements that reduce costs or improve efficiencies," Mr Gradon said. "This proven combination is how we navigate all the various cost challenges that come our way over time."

Fisher & Paykel fell \$2.55 or 7.4 percent to \$31.80 with 1.6 million shares traded.

OPTISCAN IMAGING

Optiscan says it has begun pre-clinical studies of its second endo-microscope for imaging gastro-intestinal tracts with Germany's University Medical Center Mainz.

Optiscan said the study was collecting images with its second-generation endomicroscope to be used to assess the real-time imaging capability of its technology in diagnosing and treating gastro-intestinal diseases, including cancer, and progress planning for the upcoming clinical phase to follow over coming months.

The company said this staged approach to collecting pre-clinical and then clinical data with the prototype would assist its engineers in the development of a third-generation flexible endo-microscope, to be used in future clinical trials.

Optiscan said the study would allow it to collect imaging datasets of various disease processes to assist the development of an artificial intelligence program with partner Monash University and it was "working towards receiving ethical clearance for the clinical phase of its planned studies".

Optiscan managing-director Prof Camile Farah said the company was "thrilled to be undertaking this study with the prestigious University Medical Center of Mainz".

"It will be under the leadership of renowned world-leading gastro-enterologist Prof Ralph Kiesslich and represents a major step forward in helping to better understand and manage one of the world's biggest health issues," Prof Farah said.

"Our partnership with Prof Kiesslich and his team represents a pivotal step forward in extending the capabilities of Optiscan's real-time, high-resolution imaging technology, as the company plans to re-enter the [gastro-intestinal] endoscopy market with its own private label device," Prof Farah said. "Prof Kiesslich was instrumental in the design, deployment and clinical uptake of Optiscan's [generation one] flexible endo-microscope in partnership with Pentax in the early 2000s and will also play a key role in advancing Optiscan's [generation three] device over the coming year," Prof Farah said. Optiscan was up half a cent or 3.1 percent to 16.5 cents.

ORTHOCELL

Orthocell says it has applied for a medical device licence to market and sell its Remplir collagen wrap for peripheral nerve repair with Health Canada.

Last year, Orthocell said it had submitted a 510(k) application to the US Food and Drug Administration for Remplir for peripheral nerve repair (BD: Dec 19, 2024).

Today, the company said it expected Remplit to be approved in Canada by the end of 2025, with a further regulatory submissions planned including Thailand by April 2025, the UK and the European Union by October 2025 and Brazil by December 2025.

Orthocell said Health Canada was the regulatory authority responsible for regulating the importation, manufacture, export, and supply of medical devices.

The company said preparations for the US market launch were "well underway ahead of market clearance from the FDA".

Orthocell said it expected "market clearance for Remplir late March or early April 2025, with sales to commence shortly thereafter".

Orthocell fell 10 cents or 6.4 percent to \$1.47 with 1.6 million shares traded.

FLINDERS UNIVERSITY

Adelaide's Flinders University says it has launched its Sphae free online genomic platform for developing phage therapies for antibiotic resistant bacterial infections.

Flinders University said bacterio-phage viruses killed specific bacteria and could be a "fast and effective" treatment for antibiotic resistant 'superbugs'.

The University said the platform was developed by Flinders Accelerator for Microbiome Exploration in collaboration with "an international group of microbial experts" and could assess if a phage was "suitable for a targeted therapy in under 10 minutes".

Flinders University said Georgia and Poland had been using phages for infections for decades and that recent advancements had shown the effectiveness of phage therapy in countries such as the US, Australia, UK, and parts of Europe.

The University said an article, titled 'Sphae: An automated toolkit for predicting phage therapy candidates from sequencing data' was published in the journal Bioinformatics Advances, with the full article available at: <u>https://bit.ly/4aI7Y9T</u>.

Flinders Accelerator for Microbiome Exploration co-director Prof Robert Edwards said "Sphae not only aids in therapeutic research but also advances our broader understanding of microbial ecosystems and their impact on global health and climate".

"When conventional antibiotics are not effective anymore, personalized phage therapy could become a standard part of medical practice," Prof Edwards said.

ISLAND PHARMACEUTICALS

In an Appendix 3Z, Albert Hansen says he ceased to be a director of Island, effective on January 28, 2025.

Last week, Island said its extraordinary general meeting defeated the re-election of Mr Hansen as a director by 81.34 percent of the vote (BD: Jan 28, 2025). Island fell 2.5 cents or 15.15 percent to 14 cents.

GENETIC SIGNATURES

Genetic Signatures says it has appointed Michael Sapountzis as joint company secretary, along with chief financial officer Karl Pechmann, effective from today. Genetic Signatures fell 4.5 cents or 7.3 percent to 57.5 cents.

BIOTECH DAILY TOP 40 WITH MARKET CAPITALIZATION AT JAN 31, 2025

| Company \$Am | Jan 31, 2024 | Dec 31, 2024 | Jan 31, 2025 |
|----------------------|--------------|--------------|--------------|
| Cochlear | 19,942 | 18,967 | 20,872 |
| CSL | 145,749 | 136,343 | 135,447 |
| Pro Medicus | 10,608 | 26,137 | 28,405 |
| Resmed | 42,949 | 53,995 | 59,007 |
| BDI-20 | ,0 .0 | , | 00,001 |
| Avita | 642 | 560 | 394 |
| Clarity | 616 | 1,338 | 1,201 |
| Clinuvel | 787 | 604 | 611 |
| Compumedics | 67 | 49 | 55 |
| Cyclopharm | 165 | 176 | 247 |
| Cynata | 25 | 54 | 52 |
| Genetic Signatures | 90 | 143 | 141 |
| Immutep | 416 | 531 | 509 |
| Impedimed | 223 | 105 | 108 |
| Medical Developments | 75 | 46 | 75 |
| Mesoblast | 269 | 3,555 | 3,888 |
| Nanosonics | 902 | 914 | 1,081 |
| Neuren | 3,006 | 1,598 | 1,847 |
| Nova Eye | 51 | 37 | 32 |
| Opthea | 315 | 997 | 1,281 |
| Polynovo | 1,315 | 1,409 | 1,471 |
| SDI | 87 | 137 | 116 |
| Starpharma | 64 | 46 | 44 |
| Syntara | 16 | 126 | 111 |
| Telix | 3,726 | 8,238 | 9,643 |
| Second 20 | | | |
| 4D Medical | 229 | 198 | 226 |
| Actinogen | 67 | 78 | 85 |
| Alcidion | 77 | 81 | 93 |
| Amplia | 16 | 35 | 34 |
| Aroa | 199 | 266 | 200 |
| Atomo | 15 | 12 | 12 |
| Curvebeam | 75 | 52 | 43 |
| Dimerix | 91 | 190 | 251 |
| EBR Systems | 215 | 380 | 612 |
| Emvision | 148 | 162 | 159 |
| Imugene | 717 | 275 | 276 |
| Medadvisor | 154 | 124 | 102 |
| Micro-X | 62 | 49 | 46 |
| Orthocell | 76 | 325 | 377 |
| Paradigm | 110 | 146 | 228 |
| Percheron | 51 | 8 | 9 |
| Prescient | 48 | 40 | 44 |
| Proteomics | 130 | 105 | 84 |
| Resonance | 25 | 24 | 27 |
| Universal Biosensors | 39 | 31 | 26 |

* Biotech Daily editor, David Langsam, owns shares in 4D Medical, Acrux, Actinogen, Alcidion, Alterity, Amplia, BTC Health, Clarity, Cochlear, Control Bionics, Cynata, Nanosonics, Neuren, Patrys, Polynovo, Syntara and Telix as well as non-biotech stocks. Through Australian Ethical Superannuation he has an indirect interest in other companies: https://www.australianethical.com.au/personal/ethical-investing/companies-we-invest-in/. These holdings are liable to change.

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