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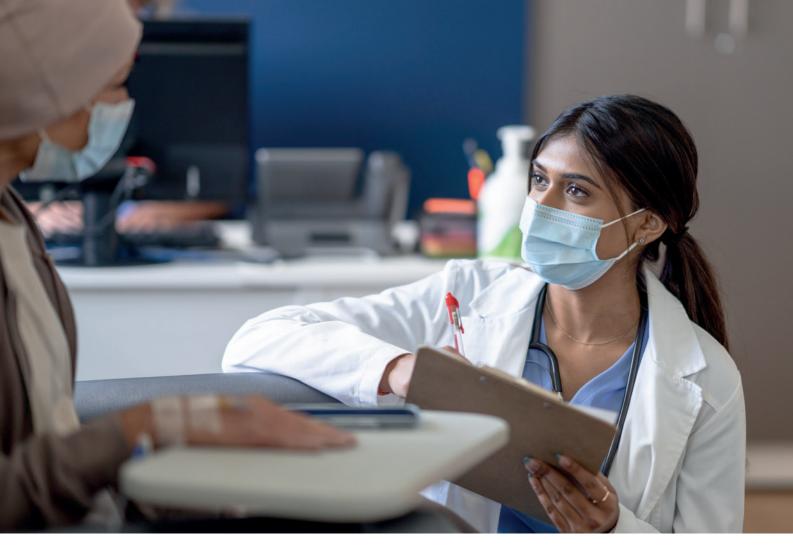
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#### 360biolabs®

**Spectral Flow Cytometry in Clinical Trials: How advancements in instrumentation can improve the characterisation of cell populations** 

Flow cytometry is a powerful technique in clinical trials for cell identification and characterisation. With advancements in instrumentation, spectral flow cytometry has resulted in a significant increase in the complexity and dimensionality of analysis that may be undertaken. Spectral flow cytometry is an especially powerful technique for immune monitoring and biomarker discovery in studies with limited starting material.

Flow cytometry is a versatile and powerful technology, which has become a critical tool in drug discovery and clinical research. Its ability to measure multiple parameters simultaneously, at a single-cell level, makes it a unique technique for assessing pharmacodynamic and pharmaco-kinetic (PK) responses. The advancements of spectral flow cytometry and the recent growth of commercial systems, allows for an even greater breadth and richness of information to be provided from a single sample. 360biolabs is excited to announce that we are adding to our expansive flow cytometry capabilities to include this cutting-edge technology. At 360biolabs, we have implemented the Cytek® Aurora 5-laser system and can offer our clients even greater levels of multiplexing, allowing for streamlined sample preparation and analysis, as well as providing better quality, higher resolution data from the same sample types. Spectral flow cytometry can significantly expand the capability of clinical sample analysis by substantially increasing the amount of measurable parameters that can be evaluated simultaneously.

#### Advantages of spectral flow cytometry

Conventional and spectral flow cytometry have similar fundamental functionality, as both measure the level of fluorescence of a pre-labelled molecule of interest. However, there are significant differences in the level of information they can produce.

FEATURES	CONVENTIONAL	SPECTRAL	ADVANTAGE
What is measured?	The near emission maxima for each fluorophore	Spectral fluorophore analysis monitoring small segments across the full light spectrum (~350-900nm)	Fluorophores with similar emission peaks but unique spectral characteristics
# of detectors for each fluorophore	One	Multiple	Increased number of fluorophores
Spectral resolution	Limited by the discrete number of detectors, and channels can suffer from spectral overlap that requires compensation	Provides a full spectrum per event and allows for mathematical deconvolution, eliminating the need for compensation	More precise identification of the spectral signatures of each fluorochrome, making it easier to resolve overlap between adjacent fluorescence signals
Data complexity	Data is usually represented in 2D plots or histograms showing individual fluorescence channels	Data is represented as multi-dimensional datasets with spectral profiles for each event	More complex visualization of cell populations

#### Table 1: Differneces between spectral flow and conventional flow cytometry and its advantage

#### Applications of spectral flow

With greater panel flexibility, reduced reliance on manual compensation and its ability to remove or utilise autofluorescence, spectral flow cytometry enables a more comprehensive analysis of cell populations in clinical samples. In clinical applications, where sample size can be limited, spectral flow cytometry can enhance resolution and increase sensitivity, enabling greater detection of rare cell populations or rare events. Spectral flow cytometry has a unique ability to identify autofluorescence and can be extremely useful in highly diverse autofluorescent samples, such as studies that utilise whole blood.

#### Examples of applications where spectral flow cytometry can excel:

- **Receptor occupancy assays:** precise quantification of binding and receptor occupancy is crucial. Spectral flow cytometry can measure multiple receptor states and interactions simultaneously without spectral overlap, improving the accuracy of measurements.
- Increased sensitivity to detect rare populations: spectral flow cytometry's ability to capture a wide range of fluorescence across many channels allows for the detection of low-abundance biomarkers, which is especially useful in solid tumors and minimal residual disease.
- Immunophenotyping for vaccine studies: high multiplexing capability and improved resolution for spectral flow allows for precise identification of different immune cell populations, including rare cell types, memory cells, and activation state.



#### Conclusion

As a world-leading authority in the field of flow cytometry, large and small molecule PK, immunogenicity, biomarkers, cell-based assays and virology, 360biolabs understands the nuances of bioanalysis. Our immunology experts offer comprehensive bioanalytical support for complex biologics, extensive immune monitoring capabilities and the flexibility to develop assays for new technologies, which may include delivering assays measuring specific or customised panels via spectral flow cytometry. Our experts understand the need for the implementation of best practices to combat the complexities of both sample preparation and the fluorophore selection for your spectral flow cytometry requirements.

#### **Global Harmonisation**

The addition of spectral flow cytometry to 360biolabs expansion flow cytometry suite, will give our clients access to this powerful and cutting-edge technology for clinical trial sample analysis. The expansion of the Cytek Aurora spectral flow cytometry system throughout the BioAgilytix global footprint (USA and Europe) ensures that our clients can conduct their early phase clinical study in Australia and transfer assays between our sites with the same high-quality systems and instrumentation, as they progress their programs from Phase 1 to Phases 2-4.

Ready to take your clinical research to the next level? Learn how flow cytometry can provide deeper insights and accelerate your discoveries. Contact our team today



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## CEO MESSAGE

#### BY REBEKAH CASSIDY, CEO, AUSBIOTECH

### I am delighted to welcome you to this edition of *Australasian Biotechnology*.

**2025 HAS STARTED** strong, and as I approach my first full year as CEO, I continue to be inspired by the ingenuity and ambition that drives Australia's life sciences sector. With a dedicated team and a clear strategic vision, AusBiotech is committed to advocating for and elevating our industry, and fostering a thriving ecosystem for Australia's life sciences.

Our sector is maturing, and we have every reason to be proud. The data tells a powerful story.

Today, more than 2905 life sciences organisations operate in Australia – nearly double the 2017 figures. Of these, 1592 are biotechnology and medical technology companies, including 691 in pharmaceuticals and biotech, and 901 in medtech. The sector now supports nearly 350,000 highly skilled jobs – approximately 1.7 per cent of the Australian workforce.

These numbers demonstrate our industry's critical role in contributing to the Australian economy, boosting productivity, and advancing health outcomes for Australians and patients worldwide.

Australia's life sciences sector attracts global investment and recognition. Our members operate competitively in global markets, including Europe, the Asia Pacific, and the Americas. Last year's AusBiotech 2024 conference clearly signalled this growing international interest. We hosted hundreds of delegates from more than 22 countries – our largest ever international delegation.

A thriving life sciences sector requires united, collaborative efforts to attract investment, shape policy and drive Australia's global leadership in life sciences innovation. As our sector grows and matures, a strong, collective voice is more crucial than ever.

#### Unifying the sector's voice

One of our key priorities has been strengthening the sector's voice. In an increasingly complex global landscape, we must continue to attract investment and be a sophisticated partner to government, advocating for policies that support industry growth.

We have taken major steps in this direction, including signing memorandums of understanding with Life Sciences Queensland, BioMelbourne Network, BioNSW and Life Sciences Western Australia. In November last year, we co-hosted the inaugural National Biotech and



Rebekah Cassidy

Medtech Development and Commercialisation Summit with MTPConnect, bringing together more than 100 industry stakeholders to shape a cohesive growth strategy for the sector.

The summit provided a key platform to tackle industry challenges, and explore strategies to accelerate the development and commercialisation of Australia's health and medical innovations. It also laid the foundation for the 2025–2026 AusBiotech and MTPConnect Pre-Budget Submission, strengthening a unified industry voice in government advocacy.

#### A shared responsibility for a thriving future

As we move through 2025, AusBiotech remains steadfast in our commitment to bipartisan advocacy. Our key advocacy asks include:

- developing Australia's first whole-of-government National Life Sciences Strategy to set clear policy priorities, and eliminate gaps and overlaps
- establishing an Australian Life Sciences Council a partnership between industry and government – to drive this strategy, address sector challenges and ensure value for investment
- investing in data collection to drive innovation, and improve policy and decision-making
- recognising life sciences as a priority under the government's industry policy frameworks.

Progress happens when industry and government work together. Through 2025, we intend to supercharge our advocacy efforts to drive meaningful change, prosecute our asks, and ensure that members' voices guide us every step of the way.

#### Engaging with impact

In early 2025, we hosted an industry roundtable with Rosemary Huxtable AO PSM, who is leading the development of the Australian Government's National Health and Medical Research Strategy. The discussion highlighted the need for bold action to optimise health and medical research investments, and strengthen commercialisation pathways to keep more Australian innovations onshore for longer. We will continue to advocate for a whole-of-government approach as part of our engagement in the strategy's development.

Further strengthening our commitment to member engagement and advocacy, we launched the Engage for Impact initiative, a member-only event series designed to deepen understanding of Australia's political landscape. The first in-person and webinar sessions featured the Hon Milton Dick MP, Speaker of the House of Representatives, who shared insights on engaging with policymakers to drive impactful industry change.

#### Nearly a decade of championing women in life sciences

This year, we hosted our first-ever Women in Life Sciences Leadership Summit, bringing together an extraordinary group of women shaping the future of health, medical science, pharmaceuticals, biotechnology and medical technology. Designed to empower more women to advance into senior roles, the summit focused on leadership pathways, fresh and diverse perspectives, hands-on skills development, and career guidance.

Following the summit, AusBiotech and Medicines Australia proudly hosted the ninth annual Women in Life Sciences (WILS) Luncheon, bringing together more than 600 industry leaders to mark International Women's Day 2025. This event is a platform for recognising women's contributions, highlighting their impact on life sciences, and addressing the barriers hindering career progression – particularly into senior leadership roles.

For nearly a decade, the WILS Luncheon has been the cornerstone event championing gender equity in the life sciences sector. This year's luncheon, themed around International Women's Day 2025's call to 'Accelerate Action', not only celebrated women's achievements, but also fostered meaningful discussions on how to drive systemic change.

#### Industry Growth Program

As an Industry Partner Organisation (IPO) under the Australian Government's Industry Growth Program (IGP), AusBiotech officially launched its IGP Program in March at the Translational Research Institute. This initiative aims to support Australian startups and small to medium-sized enterprises (SMEs) in commercialising their innovations.

As an IPO, AusBiotech delivers commercialisation advisory services for 26 IGP participants, leveraging its extensive industry expertise and networks to support biotech and medtech SMEs. To support IGP participants, AusBiotech has a network of expert mentors providing tailored commercialisation guidance through a structured mentoring program.

With nearly 80 per cent of Australia's life sciences companies classified as SMEs, programs like the IGP are crucial in fostering research translation, investment readiness and global connections. AusBiotech will make a real impact on commercial outcomes with its program for these SMEs, and we are excited to have hit the ground running with an industry-leading program.

#### Important AusBiotech updates

None of this work is possible without a strong team. At AusBiotech, our expert team is dedicated to ensuring our members' voices are at the heart of everything we do.

We welcome Dr Robyn Lindner as our new Director of State and Committee Engagement, a role designed to amplify member voices through our committees. Previously General Manager for New South Wales, Dr Lindner has driven engagement, partnerships, and advocacy, and will now integrate member insights into AusBiotech's strategic priorities in her expanded role. With extensive experience in research, biotechnology, and public health, she is well-positioned to strengthen our committees and enhance industry advocacy.

We also welcome Stephen Richardson as Senior Policy and External Affairs Manager, supporting AusBiotech's Director of Government and Policy, Karyn McIntosh.

#### Looking ahead: Australia's Biggest Week in Biotech

As we progress through 2025, AusBiotech is preparing for Australia's Biggest Week in Biotech – a series of flagship events designed to connect industry leaders, investors and government stakeholders. These events serve as vital platforms to advance the translation, development and commercialisation of Australia's life sciences innovations.

# AUSBIOTECH BOARD

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**Dr Marthe D'Ombrain** Head of Global Research Innovation, CSL Limited

**Dr Dean Moss** Chief Executive Officer, UniQuest Pty Ltd

**Dr Megan Baldwin** Chief Innovation Officer, Opthea Ltd

**Dr Liz Dallimore** Chief Executive Officer and Managing Director, Argenica Therapeutics Limited

**Professor John Skerritt** Enterprise Professor in Health Research Impact, The University of Melbourne

**Rebekah Cassidy** Chief Executive Officer, AusBiotech

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# AUSTRALIA'S BIGGEST WEEK IN BIOTECH

Last year, Australia's Biggest Week in Biotech shattered records, with a dynamic line-up of events from 31 October to 1 November 2024. Ausbiotech's two flagship events spotlighted the nation's remarkable biotechnology industry, driving fresh insights, sparking game-changing conversations and connecting industry leaders with investors to fuel the next wave of life sciences innovation.

**FROM THOUGHT-PROVOKING KEYNOTES** to deep-dive discussions, local and international experts discussed the industry's biggest challenges and opportunities. The event was proudly supported by host state partner, the Victorian Government, which supported AusBiotech in amplifying Australia's position as a global leader in health innovation.

#### AusBiotech 2024

BIGGEST WEEK IN BIOTECH

The Australian biotechnology sector convened in record numbers at the annual AusBiotech conference, held in

Melbourne. Recognised as one of the Asia-Pacific region's most significant life sciences gatherings, the four-day conference welcomed an unprecedented 1600 attendees, including more than 200 international delegates, with major delegations from South Korea and Taiwan.

The Hon Mark Butler MP, Federal Minister for Health and Aged Care, addressed last year's conference, reinforcing the current government's commitment to fostering innovation and strengthening commercialisation pathways for Australian medical advancements.

Minister Butler underscored the necessity of a comprehensive pipeline approach – from discovery and startup phases to clinical trials, manufacturing, export, access and reimbursement – highlighting the critical role of government–industry collaboration in realising the sector's full potential.

### HEALTH SECURITY SYSTEMS AUSTRALIA A Division of DMTC LIMITED



SUPPORTING RESEARCH / UPLIFTING INDUSTRY / ALIGNING PRIORITIES

Health Security Systems Australia (HSSA) leads and manages collaborative projects to develop innovations for the protection of civilian and military personnel against Chemical, Biological and Radiological (CBR) threats, emerging infectious diseases and pandemics.

As a division of DMTC Limited, HSSA's work is underpinned by DMTC's credibility in the defence and national security sectors; internationally accredited systems for quality and program management; and flexible collaboration, engagement and contracting mechanisms.

HSSA's success is driven by its ongoing collaboration and partnership with industry organisations, research institutions, and government partners.

#### HSSA AT A GLANCE

- Project Management (ISO9001)
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- Niche Ecosystem Expertise & Networks (both domestic and international)
- Multi-year Strategic Investment
- Facilitate TRL Progression
- Student and Early Career Researcher Support
- SME Enhancement





▲ Professor Bernd Rehm and his team at Griffith University's Centre for Cell Factories and Biopolymers are pivotal contributors to a national collaboration, led by HSSA, aimed at advancing novel vaccine platform technology.

#### LEVERAGING CONNECTION

HSSA conducts policy reviews, asset assessment, risk identification and health and economic modelling activities — providing decision-makers with direct advice and delivery support relevant to health security and resilience. HSSA draws on, and benefits from, a broad and deep network of national and international sector experts, and leverages an established process able to be tailored to provide quality advice to a broad range of stakeholders.

#### EMBRACING INNOVATION

HSSA has a strong interest in uplifting the capabilities, capacity and resilience of Australian small and medium-sized enterprises (SMEs) across biotechnology and medical technology industries, to bolster national health security. Leveraging DMTC's broader effort to improve defence sector supply chains, HSSA partners have benefited from joining an enduring and growing Community of Practice — a network of companies that share learnings and a common desire to realise the benefits of Industry 4.0, digitisation and enhanced cyber security for their business.

#### **HEALTH SECURITY SYSTEMS AUSTRALIA**

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#### Continued from page 8

The program featured more than 260 speakers across 60 sessions designed to facilitate knowledge exchange, foster collaboration and advance industry-wide objectives. Notable speakers included:

- Dr Daniel Timms, a US-based Australian innovator whose company, BiVACOR, achieved a landmark milestone with the first human implant of a fully artificial heart
- Dr Intan Oldakowska, Co-founder and CEO of Earflo, who presented a pioneering approach to chronic ear infections
- Michael Lopez-Algeria, Chief Astronaut at Axiom Space, who provided insights into medical experiments conducted aboard the International Space Station
- Michael Hund, Global Chief Executive Officer of EB Research Partnership, who explored how innovative business models accelerate progress in rare disease research.

This year's program also featured a one-day AgriBiotech & BioSecurity Summit, hosted in partnership with CSIRO, and the Cell & Gene Summit, hosted in partnership with Australia's Cell & Gene Catalyst, a joint venture between AusBiotech and Medicines Australia.

As AusBiotech celebrates more than 38 years of leadership in the sector, this year's record-breaking attendance highlights the industry's vibrancy, and underscores its pivotal role as Australia's national peak body for biotechnology and medtech innovation.

#### **AusBiotech's Depaz Oration**

AusBiotech was honoured to announce the establishment of the Depaz Oration, an annual keynote to be introduced at the AusBiotech 2024 Conference in memory of the late Dr Iris Depaz.

Known for her infectious enthusiasm, warmth, and compassion, Dr Depaz was a source of joy and inspiration to all who knew her. She embodied the true essence of leadership, deeply caring for her colleagues while tirelessly advocating for the advancement of the entire biotechnology sector.

Dr Depaz's leadership was pivotal in establishing Sanofi's Translational Science Hub – a \$280-million collaboration with the Queensland Government, The University of Queensland and Griffith University. As the hub's Managing Director, one of her primary goals was strengthening Australia's biomedical ecosystem.

The Depaz Oration will celebrate her enduring legacy and vision for a thriving biotechnology industry.



#### Early-Stage Innovation Forum

The Early-Stage Innovation Forum (ESIF) showcases some of Australia's most promising emerging life sciences technologies. It offers presenters a valuable opportunity to gain early, real-world feedback from a panel of industry experts and investors. This forum is crucial in shaping the commercialisation journey of early-stage projects and innovations.

At AusBiotech 2024, the forum featured rapid-fire pitch presentations, where industry leaders provided constructive insights to help advance these technologies towards market success. The event welcomed 15 pitches from research institutes, universities, hospitals, and pre-Series A companies, focusing on human therapeutics and enabling technologies.

Congratulations to our ESIF winners: Dr David Bibby from Monash University, and Dr James Tran from the Florey Institute of Neuroscience and Mental Health. Dr Bibby and Dr Tran presented novel screening, optimisation, and development of next-generation medicines for the treatment of key mental health disorders, and a novel platform to deliver next-generation genetic medicines to the central nervous system.

#### AusBioInvest 2024

Australia's premier life sciences investment event, AusBioInvest 2024, took place in Melbourne in October last year, and featured industry-leading international speakers, keynote addresses from global investment leaders, and pitch presentations from top biotechnology companies.



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#### Continued from page 10

This year, AusBiotech's one-day AusBioInvest event is welcoming more than 260 delegates from Australia's thriving life sciences companies, and Australian and global investors – including venture capital firms, private equity firms, and individuals – as well as research analysts, brokers, industry executives, and major global stakeholders.

AusBioInvest is just one way that AusBiotech continues to ensure its investment programs meet the evolving needs of members at all stages of capital raising, with a laser focus on creating meaningful connections.

The program offers insights and opportunities, beginning with an opening keynote by Dr Eric Shiozaki, Partner at DCVC Bio, exploring the transformative role of artificial intelligence and technology in biotech, and sharing valuable perspectives on what drives success from an investor's viewpoint.

The event also features thought-provoking panels.

Sarah Meibusch, Partner at OneVentures, will unpack investment trends and diverse funding options – public, private, debt and equity.

Rhenu Bhuller, AusBiotech's Global Investment Lead, will join experts Matt McNamara of Horizon 3 Healthcare, and Bianca Ogden of Platinum Asset Management, to discuss how investors and founders can effectively collaborate to drive biotech innovation.

The presentations at AusBioInvest, featuring 26 innovative private and listed Australian biotech companies, represent a significant opportunity for investors and potential partners to connect directly with companies seeking funding and collaborative development.

Presenting companies include: Amplia Therapeutics Limited (ASX: ATX), Arovella Therapeutics (ASX: ALA), Atticus Medical, BiomeBank, Blinklab Limited (ASX: BB1), Cambium Bio Limited (ASX: CMB), Carina Biotech Limited, Chimeric Therapeutics (ASX: CHM), EBR Systems (ASX: EBR), Evithé Biotechnology, FivepHusion, Immuron Limited (ASX: IMC), Imugene (ASX: IMU), Invion Limited (ASX: IVX), Neurizon Therapeutics (ASX: NUZ), Neurotologix, Novapep, Nyrada (ASX: NYR), Esfam Biotech, Polyactiva Pty Ltd, Servatus, Syntara (ASX: SNT), and Vaxxas.



#### SPONSORED CONTENT

# JAG PROCESS SOLUTIONS EXPANDS ITS OFFERING PORTFOLIO

### JAG Process Solutions' 10th anniversary in Australia marks a new chapter of growth for the company.

JAG PROCESS SOLUTIONS is building on its strengths in process engineering and process automation to help more pharmaceutical companies benefit from the latest advances in robotics, digitalisation, and lab automation.

JAG Process Solutions is the Australian subsidiary of JAG Jakob AG, a leading Swiss provider of process plants, automation and robotics.

JAG is best known in Australia for its state-of-the-art automation solutions that have helped CSL Behring manufacture some of the world's most complex biomedical products at its Broadmeadows facility in Melbourne's north.

JAG Jakob AG has a longstanding relationship with CSL in Switzerland, and opened its Australian office in 2015 to support CSL manufacturing here.

Managing Director Thomas Aeby says JAG Process Solutions offers the 'best of both worlds' for Australian pharmaceutical companies. 'We combine the resources of a global leader in



bioengineering with a strong, autonomous Australian operation that builds and implements solutions locally,' he says.

Aeby says JAG expanded into lab automation and robotics last year in response to client demand. 'Pharma companies told us they wanted a one-stop solution to design and automate their processes, including powder handling, integrating their MES software with other systems, and automating lab operations.'

JAG is uniquely positioned in Australia to provide this service, says Aeby. 'Having a large team of process engineers, software engineers, and validation and qualification engineers in this market means JAG can develop fully integrated, innovative turnkey operations for pharmaceutical companies.'

Aeby is relocating later this year from Australia to focus on JAG's global operations. His successor, Marcin Chomkowicz, will lead an in-demand business that aims to expand its presence in Australian lab automation.

Chomkowicz, an automation software engineer, was the first employee at JAG Process Solutions in 2015. He has watched the team grow from two to more than 30 during that period – and greatly expand its local capabilities.

'The quality and expertise of JAG's local engineering team is an asset for our clients,' says Chomkowicz. 'We have a vastly experienced team that has worked on dozens of complex bioengineering projects in Australia. We are harnessing those skills to create new value for clients through digitalisation, such as paper-on-glass solutions.'

Chomkowicz says the response to JAG's expanded service offering has so far exceeded expectation. 'We are receiving more inquiries from Australian pharmaceutical companies about our lab automation services. They can see the benefits that automation offers in terms of quality control, traceability, compliance and manufacturing efficiency. They also see opportunities to better integrate their systems, streamline data management and digitise their operations.'

Chomkowicz is proud of JAG's work in Australia and is excited about its future. 'We continue to recruit more engineers and expand our Australian capabilities for current and future clients. Local pharmaceutical companies have much to gain from implementing the latest technologies and working with providers, such as JAG, that offer world-class bioengineering solutions.' @

To learn more about JAG Process Solutions, visit www.jag-ps.com.au/en-au/.



# INNOVATING BEYOND BORDERS

### Australian medtech is shaping the future of respiratory care in the United States.

**ADHERIUM LIMITED'S (ASX: ADR)** ambition to proactively manage respiratory health conditions with its novel medication adherence technology – the Hailie<sup>®</sup> Smartinhaler<sup>®</sup> – has required the gift of patience, but its time is now.

#### The evolution of the Hailie Smartinhaler

Adherium's journey began in 2001, focusing on a critical healthcare challenge: helping people with respiratory conditions like asthma and chronic obstructive pulmonary disease (COPD) better manage their condition through improved medication adherence.

The company's flagship platform, the Hailie Smartinhaler technology, emerged from a simple yet powerful insight – that adherence to medication plays a pivotal role in reducing hospitalisations for individuals with asthma or COPD, and digital technology could transform how this is managed. Put simply, by ensuring consistent use of prescribed treatments, patients can better manage their symptoms, prevent severe exacerbations, and maintain improved disease control. This not only enhances their quality of life, but also reduces the strain on healthcare systems by lowering hospital admissions and potentially delaying the need for costly biologic medications. In 2015, Adherium was listed on the Australian Securities Exchange, and has since expanded its global reach and impact through strategic partnerships with major hospital systems, medical groups, and insurers in the United States. The company's vision is to be the leading digital solution for managing respiratory diseases, integrating devices and data to optimise outcomes for patients, healthcare professionals, and payers.

Adherium Interim CEO and Non-executive Director Jeremy Curnock Cook explains the foundational problem that drives the company's mission.

'What does the patient do when they're not standing in front of the doctor and they're not being instructed on how best to use their puffer, and when to use it? What the patient does is randomly take their drugs and lose the whole sense of pattern that needs to be established in treating any chronic disease, of which asthma is a great example.'

This understanding of real-world patient behaviour outside clinical settings pushed the company to advance its product into a sophisticated ecosystem of sensors, data analytics and patient engagement tools.

Today, the Hailie platform integrates bluetooth-enabled sensors with inhalers to monitor medication usage in real time,

providing actionable insights to patients, healthcare providers and researchers. The success of this technology has attracted notable expert investors, including pharmaceutical company AstraZeneca, specialist healthcare investor Bioscience Managers, and strategic investor Trudell Medical – a global leader in aerosol drug delivery and lung health devices.

#### The value of time

What sets Adherium apart is its deliberate approach to development. While many startups rush to market, Adherium recognised that creating a transformative healthcare solution required time, refinement and validation.

'The good luck in all of this was that we actually were forced to take our time in developing the product, in close and purposeful consultation with patients, clinicians and deeply experienced technology experts, too,' Curnock Cook says.

This development timeline allowed Adherium to refine its technology through multiple iterations, each addressing specific limitations identified through real-world testing and clinical feedback.

The company's sensors evolved from a simple device for medication reminders into a sophisticated platform technology capable of measuring not just whether medication was taken, but how effectively it was administered. The latest generation of Hailie devices can detect if patients are using their inhalers correctly, providing guidance on proper technique and even tracking lung function changes over time.

'Today's asthmatic can be monitored on a regular basis by sensors that are actually taking a measurement of the patient on a twice-daily basis, or every time they use their inhaler,' says Curnock Cook. 'In that context, we've also built in the support needed to ensure the patient is actually using the device properly.'

This focused investment of time has also allowed the company to assemble compelling clinical evidence – a cornerstone of Adherium's development strategy. With technology referenced in more than 100 peer-reviewed publications, clinical studies have consistently demonstrated improvements in patient outcomes. Data from a University of Sheffield study demonstrated a 144 per cent increase in medication adherence among the Hailie Smartinhaler™ group compared to the control group, along with a 37 per cent reduction in the number of oral steroid courses required over a 12-month period. Further research presented at the European Respiratory Congress validated these findings, showing that the Hailie Smartinhaler platform increased adherence to preventative medication by 180 per cent and reduced the use of reliever medication by 45 per cent.

The global impact is undeniable: Adherium's technology has been used in over 30 countries and more than 65 projects, including clinical studies and device validation. The company also has newly signed contracts with leading US healthcare organisations servicing more than one million respiratory patients.

#### Market alignment

A key strength for the Adherium team has been its ability to recognise and capitalise on shifting market dynamics. The company's steady development has positioned it to take advantage of transformative changes in healthcare delivery, particularly in the United States.

The introduction of reimbursement codes for remote patient monitoring in the United States has created a financial framework that supports the adoption of technologies like the Hailie platform.

'There are now fees paid to the operators to cover the introduction of the clinician to the patient, the introduction of the clinician to the device itself, and the introduction of the clinician to the billing systems that are available to make sure that reimbursement does actually take place,' Curnock Cook explained.

'We were lucky enough three years ago to find the United States Government introducing the concept of reimbursement for certain aspects of bringing the asthma sufferer in contact with the



The Hailie Smartinhaler digital platform

device, the drug and the clinician. There is now a reimbursement code that actually does cover the payment to the doctor for looking at data that the patients themselves generate.'

#### Innovating beyond the device

Adherium recognised that technology adoption also requires supporting infrastructure, bridging the gap between innovation and implementation.

'The big step forward that we've made over the past 18 months is to recognise that the onboarding procedure – getting the patient and doctor together with the device – is an important function of supporting patient outcomes.'

This insight has led to the development of specialised onboarding teams around Adherium's distribution structures and channel partners in the United States. This approach recognises that healthcare solutions must address the full ecosystem of care delivery. The Hailie platform facilitates information flow to healthcare systems, clinicians, pharmaceutical companies, governments, and insurers, connecting all participants in the patient's healthcare journey to ensure optimal patient outcomes.

#### A future made in Australia?

Despite our world-class healthcare system, one in nine Australians still struggles with asthma – and for those in high-risk groups, managing the condition remains a daily battle. The problem isn't just patient behaviour and adherence; it's also the fragmentation of care itself and our strained resources, where asthma management slips through the healthcare cracks. This leads to patients presenting at emergency departments, being hospitalised and facing progression of the disease.

The key to improving asthma control for millions of Australians is improved connectivity and proactive care.

Technology-based devices and platforms such as Adherium's have proven to be effective; however, despite their benefits, this (and other digital health technology innovations) remain unreimbursed in Australia, creating a barrier to access for those who could benefit from them the most. By reimbursing, we could ensure that all Australians, regardless of their financial situation, have access to the best possible care – all while supporting Australian-made technology at home.



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# REVOLUTIONISING DRUG DISCOVERY: THE IMPACT OF ARTIFICIAL INTELLIGENCE

As we've all seen, artificial intelligence has exploded in popularity, dominating headlines with accessible models transforming nearly every industry. Biotech is no exception and drug discovery, in particular, is undergoing significant improvements set to change the field as we know it today.

**ARTIFICIAL INTELLIGENCE'S (AI'S)** impact spans the entire drug discovery spectrum – from initial target identification through to clinical patient selection – promising to enhance efficiencies and reduce both time and costs associated with bringing new therapies to market.

#### **Target identification**

Arguably, the most difficult part of drug discovery is novel target identification. It's why we often see companies pursuing drugs towards the same targets. For instance, there are currently four approved CAR-T's targeting CD-19 (Yescarta, Kymriah, Tecartus and Breyanzi), and an additional 10 under clinical development. A well-validated, clinically proven target significantly de-risks the drug development pathway, while the discovery of novel targets, although important, has traditionally been a slow and laborious process, often reliant on serendipity and human expertise.

Over the past 20 years, advancements in computers, robotics, sensors, and other technologies have led us to an era of high throughput screens and immense data accumulation. AI excels at analysing vast amounts of information, and is well positioned to take advantage of these high-quality multi-omics datasets to analyse biological and genetic interactions at an unprecedented scale previously unattainable by traditional methods. Used properly, these platforms can uncover patterns and connections that otherwise might take decades for human researchers to identify, if at all.

However, as the saying goes, you reap what you sow. The key driver to a successful AI drug discovery platform lies in the quality of the datasets used; the more comprehensive and accurate the data, the more reliable the targets AI identifies. This includes an often misunderstood, but critical piece of any dataset: the metadata. Metadata is 'the data about the data', and for biological samples, this may include information about the patient, their diagnosis, and their previous medications. This data is often not curated, and becomes burdensome to translate into a digital format that AI could ingest, making it a differentiation factor and competitive advantage for those who thought about their data collection up-front.

To create better data utilisation and outputs, there will also need to be improved data collection and organisation methods; however, as this becomes more common practice and put in place more universally, it will significantly improve the speed and accuracy of data analysis and, hopefully, target identification.

#### Drug design and synthesis

Once targets are identified, the next challenge is the design of drug candidates. AI is proving invaluable here, too, particularly in the realms of RNA, protein and small molecule drug discovery. AI algorithms can predict how different chemical structures will interact with the target, allowing for the rapid synthesis and testing of novel drug compounds.

For instance, in small molecule drug discovery, AI models can quickly generate and screen millions of potential compounds by predicting their pharmacokinetic properties and potential toxicity. This rapid screening reduces the need for physical testing in the early stages, and helps to focus resources on the most promising candidates.

#### The key driver to a successful AI drug discovery platform lies in the quality of the datasets used; the more comprehensive and accurate the data, the more reliable the targets AI identifies

Moreover, Al-driven design tools are beginning to incorporate real-time feedback, continually refining drug designs based on the latest data. This relies on biological assays, which are inherently slower than the Al analysis, making it a critical piece of any Al drug discovery platform. The time it takes to start your Al analysis, determine the drug candidates of interest, synthesise those candidates, and run them through a predetermined set of assays before starting all over again is called 'cycle time'. The goal is to reduce the cycle time from the months or even years typically needed for traditional methods down to a matter of weeks. These time savings compound dramatically, improving lead optimisation and, overall, significantly reducing costs.

#### **Enhancing preclinical testing**

Preclinical testing traditionally relies on significant in-vitro and in-vivo experiments to predict how a drug will behave in humans; however, these methods often fail to accurately mimic human responses, leading to high attrition rates in later stages of drug development. Al is poised to transform this phase by leveraging big data to enhance the predictive accuracy of preclinical models.

Through the integration of diverse data types – including historical trial data, real-world patient data, and even simulated models – AI can provide a more nuanced prediction of a drug's effectiveness and safety. These advanced predictive models can drastically reduce the number of potential failures encountered during clinical trials, as only the most promising drug candidates are advanced. Finally, the reduced number of preclinical experiments needed, especially expensive in-vivo studies, should lead to further savings in both time and cost.

#### Initiating and running clinical trials

One of the most critical stages in drug discovery is the clinical trial phase, where trial initiation and patient selection play a pivotal role in determining the success of a trial.

#### ... Al can help in monitoring trial progress and outcomes in real time, allowing for faster adjustments and decision-making in adaptive trials ...

For anyone who has had the pleasure of organising and submitting an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration, it is likely abundantly clear how AI may improve the process. Every preclinical assay, every validation study, every change in manufacturing, and the complete history of clinical use needs to be summarised in a submission. Luckly, this is the type of work that large language models (LLMs) are experts at. It seems inevitable that LLMs will become the workhorse as a first pass at writing INDs, as well as other regulatory submissions. Al also has the potential to significantly improve the process of patient selection by identifying subsets of patients that are most likely to benefit from a specific treatment. This targeted approach not only increases the efficacy of clinical trials, but it also enhances patient safety by minimising exposure to less-effective treatments. Furthermore, Al can help in monitoring trial progress and outcomes in real time, allowing for faster adjustments and decision-making in adaptive trials, which are continuing to increase in popularity, as a way to further improve efficiency.

#### Conclusion

The integration of AI across all stages of drug discovery is not just a theoretical improvement, but also a practical innovation already underway. By increasing the speed and accuracy of each phase – from target identification through to clinical trials – AI is poised to significantly lower the overall cost and time it takes to bring new treatments to market. As technology advances and more data becomes available, the role of AI in drug discovery will only grow, promising a new era of faster, more effective therapeutic innovations. (9)





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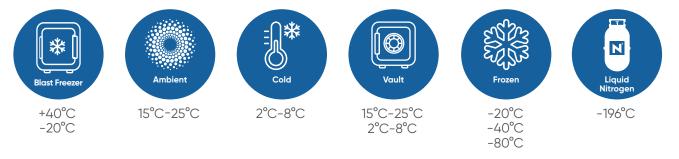
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# ONSHORING INNOVATION: STERILITY RAPID MICROBIOLOGY METHODOLOGY

BY RILEY FITZPATRICK AND KIRSTY BATES, SENIOR MICROBIOLOGISTS, CBE PURE SOLUTIONS

SCANRD

The introduction of bioMérieux's SCANRDI® rapid sterility test in Australia by CBE Pure Solutions marks a significant advancement in the Australian pharmaceutical and biotechnology sectors, offering a swift and reliable method for detecting microbial contaminants. This technology addresses the critical need for rapid sterility testing, ensuring patient safety and enhancing operational efficiency within the industry.

**COMPENDIAL STERILITY TESTING** has traditionally been performed, according to the European Pharmacopeia (Ph. Eur) chapter 2.6.1 and United States Pharmacopeia (USP) chapter 71, which requires a 14-day incubation period in growth media to allow any contaminants to grow, during and after the test samples are inspected visually. The compendial sterility test is a presence-absence test in which the turbidity of the culture media is indicative of microbial growth and verified by visual inspection. The culture media used in sterility testing are fluid thioglycolate medium (FTM) and soybean-casein digest medium (SCDM). FTM is used to detect aerobic and anaerobic microorganisms, and SCDM is used to detect aerobic bacteria and fungi. These long incubation periods result in subsequent delays to process understanding and product release, particularly for time-sensitive products like advanced therapy medicinal products, or short shelf-life products.

Sterility Rapid Microbiology Methodology (SRMM), established by CBE Pure Solutions (CBEPS), utilising bioMérieux's world-leading technology SCANRDI® platform<sup>1</sup> has revolutionised rapid microbial detection by delivering actionable sterility results in four hours. Its unique technology combines universal cell labelling with solid-phase cytometry, enabling the detection of bacteria, yeasts and moulds, both in vegetative and sporulated forms. This rapid detection capability allows manufacturers to make faster decisions regarding production processes, thereby minimising downtime and reducing the risk of distributing contaminated products.

SRMM using the SCANRDI Instrument System has four basic operational steps:

- 1. product filtration
- 2. labelling of microorganisms
- 3. laser scanning
- 4. verification of events detected.

Liquid samples are taken and aseptically filtered through a specialised 0.4  $\mu m$  pore track-etched membrane. Microbes retained on the membrane filter are then directly labelled in situ

with fluorescent viability markers, which enters the microorganism through the cell membrane. Living cells cleave the non-fluorescent viability substrate by an enzymatic reaction, releasing fluorescent particles (free fluorochrome) within the cell.

The prepared membrane is transferred to the SCANRDI, where laser excitation of fluorescent dye occurs (solid-phase laser cytometry). The entire surface of the membrane is laser-scanned, and the accompanying software analyses the resulting data. The SCANRDI system's laser-scanning capabilities ensure that any cell fluorescence



Riley Fitzpatrick



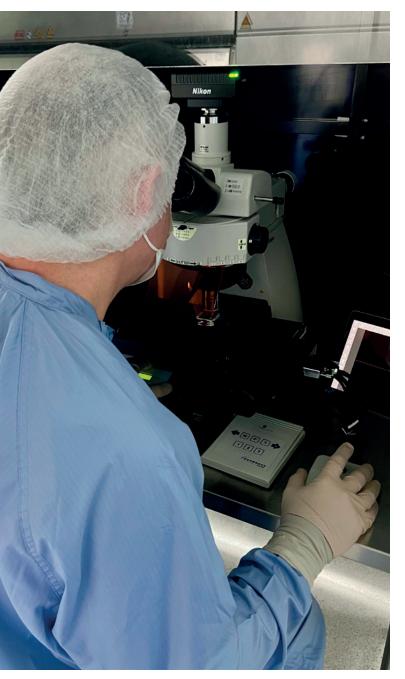
Kirsty Bates

on the membrane will be detected by the system's multiple detection channels. Non-living cells are not metabolically active and are not labelled.

To ensure reliable results, the system incorporates advanced proprietary discrimination parameters, which allows the system to differentiate between labelled microorganisms and background 'noise' (electronic, optical and auto-fluorescence from particles). The data is represented as an event map, which displays the location of each detected event. These stained microbes are then detected by an image analyser, and their presence is confirmed microscopically by a trained microbiologist. The whole process is completed within hours.

Regulatory acceptance of rapid microbiological methods (RMMs) like SCANRDI is supported by major regulatory bodies, including the U.S. Food and Drug Administration (FDA), European Medicines Agency, and the Australian Therapeutic Goods Administration (TGA). These agencies acknowledge that validated RMMs can be equivalent or superior to traditional methods, especially for products with short shelf lives where timely results are crucial. Implementing SRMM aligns with regulatory expectations and demonstrates a commitment to adopting innovative technologies that enhance product safety and quality.

The TGA utilises relevant sections in the Ph. Eur and British Pharmacopoeia in that these compendium also allow for the validation of alternate methods. They also rely on the validation guidance from USP Chapter 1223, Ph. Eur Chapter 5.1.6, PDA Technical Report #33, and ISO 17025 (validation of non-standard methods). Performance Qualification (PQ) of RMM for the Australian pharmaceutical landscape requires meticulous planning to ensure compliance with regulatory standards. CBEPS has performed extensive Design Qualification, Instrument Qualification and Operational Qualification, which also includes demonstrating equivalence or superiority to compendial sterility testing.<sup>2</sup> For qualitative SRMM testing, qualification addressed specificity, sensitivity, ruggedness, robustness and equivalence. For quantitative testing, accuracy, precision, ruggedness, robustness, equivalence, sensitivity, linearity and specificity were demonstrated.



CBEPS has developed a PQ package that will support clients on their product-specific needs to deliver a simplified validation process to provide a comprehensive data package, including all the necessary FDA Current Good Manufacturing Practice testing protocols.

Advantages associated with the adoption of CBEPS SRMM to Australian pharmaceutical and biotechnology manufacturers include:

- 1. Accelerated product release: Rapid detection of microbial contaminants enables quicker product release, which is particularly beneficial for products with a limited shelf life or those requiring immediate availability.
- 2. Enhanced process control: The ability to obtain early notification of positive results allows for real-time monitoring of manufacturing processes, facilitating prompt root cause investigations and corrective actions when necessary, and reducing the risk of large-scale contamination and preventing long shutdown of filling lines.
- 3. **Operational efficiency:** By reducing the time required for sterility testing, SRMM helps streamline production schedules, optimise inventory management and improve overall supply chain efficiency.
- 4. **Regulatory compliance:** Utilising a qualified and validated rapid sterility test method aligns with international regulatory guidelines, supporting compliance and potentially expediting approvals for new products.
- 5. **Automated results:** SRMM using the SCANRDI Instrument System provides automated readouts, reduced subjectivity and reduced human errors.

CBEPS's establishment and deployment of bioMérieux's SCANRDI rapid sterility test in Australia represents a pivotal advancement in microbial detection technology. By offering expedited and reliable sterility testing (within one to two days), SRMM addresses critical challenges faced by the pharmaceutical and biotechnology sectors, including the need for faster product release and enhanced process control. While implementation requires careful consideration of qualification, training and integration aspects, the potential benefits in terms of operational efficiency and regulatory compliance are substantial. As the industry continues to evolve, embracing innovative technologies like SRMM will be essential to meet the growing demands for safe and effective pharmaceutical and biotech products.

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# R E S O L I A N <



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## ACCELERATING BIOTECH FUNDING

#### BY ANDREW STEWART, CEO; CHARLIE VEENEKLAAS, BUSINESS ANALYST; AND TOM BALDRY, CREDIT ANALYST, ENDPOINTS CAPITAL

## The impact of Research and Development Tax Incentive finance on cost of capital and shareholder value is an important consideration.

**AUSTRALIA HAS A** world-class life sciences ecosystem of researchers, scientists and service providers delivering cutting-edge innovation. Despite its strong research and development (R&D) capabilities and best-in-class clinical practices, life sciences companies have faced significant funding challenges in recent years.

For early-stage and clinical research companies, equity can be expensive and extremely dilutive. These funding challenges ultimately affect enterprise value and long-term sustainability for many companies. This article has stemmed from the many hundreds of conversations we've had with business leaders, founders and investors in biotechs, medtechs and other life sciences companies about these challenges.

R&D finance has been shown to reduce equity dilution by more than 30 per cent through the clinical development life cycle, preserving more value for shareholders and founders. For institutional investors, it improves return on equity and enhances the overall attractiveness of this asset class. This article explores key financial concepts and valuation methods in the life sciences context. It demonstrates how R&D finance strengthens a company's financial position, enhances investment appeal and supports sustainable growth.

#### The Australian R&D Tax Incentive scheme

Most life sciences companies depend heavily on the Australian Government's R&D Tax Incentive scheme, which provides cash refunds of up to 43.5 per cent on eligible R&D expenditures. While these incentives are invaluable, companies often have long delays in receiving the rebate after they incur these costs – sometimes it is up to 18 months. R&D finance bridges this gap, enabling firms to unlock funds in advance, mitigating cash flow constraints and reducing reliance on dilutive equity rounds. So, how much of your R&D refund could you access today? Before you answer that, let us ask you this question ...

#### Is your R&D tax asset on your company's balance sheet?

Many companies are not acutely aware of the R&D tax asset that is accruing monthly on their company's balance sheet. For eligible R&D companies, as these R&D costs are incurred, the R&D tax asset is actually increasing every month! The universal law of accounting is that assets equal liabilities plus equity. Put a different way, assets are funded by debt and equity. Expanded again, assets are a combination of fixed assets (land, buildings and intellectual property) and working capital (cash, receivables and inventory).

In summary, a company's balance sheet is: fixed assets plus working capital funded by equity and debt. Congratulations, by reading this far you are now certified to practice as an accountant (almost).

### Understanding the cost of capital and its impact on biotech valuation

All investments should yield a return relative to the risk an investor is taking (compare government bonds and the roulette wheel in the casino). The pricing of this risk-adjusted return on each investment is calculated by understanding its cost of doing so. This cost of capital is the return a company must achieve to justify the investment. It consists of two primary components:

- Cost of equity: This concept has been the cornerstone of investing for more than 60 years, with the Capital Asset Pricing Model (CAPM) developed by Nobel Prize–winning economist William Sharpe in 1964. This 'cost' or 'target return' for an investment is calculated using the cost of debt, plus a risk factor relative to the market of all investments (beta) and a market risk premium. The return expected by shareholders for biotechs is typically a lot higher than for other asset classes (Biopharma Vantage, 2023).
- 2. **Cost of debt:** This is the effective interest rate on borrowed funds, which is lower than equity, plus it is tax deductible (CFI, 2024).

These two inputs yield a company's Weighted Average Cost of Capital (WACC), which reflects a company's overall financing cost. A lower WACC improves company valuations when utilising a discounted cash flow model as future cash flows are discounted at a lower rate, increasing their present value (Frank & Shen, 2016). Additionally, a lower WACC allows biotech firms to allocate more resources to R&D, rather than diverting funds to expensive capital costs.

#### Why equity costs more for biotechs

Biotechs face a higher cost of equity compared to other asset classes due to several factors, including:

- **Prolonged development timelines:** Many firms invest in R&D for years before generating revenue (Rottgen, 2018).
- Inherent risk: Success depends on clinical trial outcomes, regulatory approvals, and market adoption (McIntosh et al., 2022).

- Market volatility: The biotech sector is highly sensitive to industry trends and trial results (Haak et al., 2024).
- Equity dilution: Raising capital through share issuance reduces ownership stakes and affects long-term shareholder value (Fernando, 2024).

Given these challenges, biotech firms must optimise their capital structure to minimise financing costs and reduce dilution to enhance valuation. High equity costs often push companies towards issuing more shares, resulting in dilution that erodes long-term shareholder value. In contrast, R&D finance provides a non-dilutive and significantly cheaper cost of capital funds.

#### R&D financing: a cost-effective solution

Endpoints Capital specialises in R&D finance for biotechs, providing clients with a structured alternative to conventional equity funding. This financing model offers several advantages:

- 1. **Non-dilutive capital:** Unlike equity financing, R&D loans provide funding without diluting ownership of shareholders.
- 2. Lower cost of capital: Loans secured against government-backed R&D tax refunds reduce lender risk, leading to more competitive interest rates (Biotechgate, 2023).
- 3. **Improved cash flow management:** Companies can access funds up to 18 months earlier, sustaining operations without financial disruption (White Ark, 2022).
- 4. Lower WACC: By securing lower-cost financing, firms reduce their WACC, leading to improved valuation metrics (J Mauboussin, 2023).

In addition, R&D finance provides flexibility in financial planning. Unlike traditional bank loans, which impose rigid repayment schedules and stringent covenants, this form of financing improves and accelerates a company's cash inflows. This allows biotech firms to allocate capital efficiently to research, trial costs and regulatory approvals without immediate financial strain.

For companies pursuing partnerships, investment, or acquisitions, a healthier financial profile, reinforced by R&D financing, strengthens their balance sheet cash position, which strengthens their negotiating position. Investors favour firms with a lower WACC and a well-structured balance sheet, which signals sound financial sustainability and stewardship.

R&D finance is a transformative funding solution for biotech firms, offering an alternative to traditional financing methods, such as dilutionary equity rounds. By leveraging the government-backed

R&D rebates, R&D finance enables biotechs to secure necessary funding while avoiding dilution, ensuring ongoing innovation and therapeutic breakthroughs without disruptive funding gaps.

### Please visit www.endpointscapital.com.au to download the full white paper.

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# FROM PERTH TO THE WORLD STAGE: ORTHOCELL'S BLUEPRINT FOR GLOBAL IMPACT



30 Australasian BioTechnology

As Orthocell approaches U.S. Food and Drug Administration clearance for its innovative Remplir™ nerve repair technology, the Perth-based regenerative medicine company demonstrates how Australian biotechnology can successfully bridge the gap from local research to global impact.

WITH A DELIBERATE strategy built on domestic manufacturing excellence, clinical collaboration, and patient-centred innovation, Orthocell has created a blueprint for bringing life-changing medical technologies from Australian laboratories to patients worldwide – all while keeping its production firmly rooted on home soil.

#### Manufacturing as a strategic advantage

In an environment where offshore manufacturing has become the norm, Orthocell stands as a testament to the enduring value of domestic manufacturing capability. Under the leadership of Chief Executive Officer and Managing Director Paul Anderson, the company has purposefully maintained its research, development and manufacturing capabilities within Australia. This strategic commitment to local production forms the cornerstone of Orthocell's competitive edge, enabling the company to protect its intellectual assets, control quality standards, and nurture homegrown scientific talent in ways that offshore manufacturing simply cannot match.

'We've fiercely defended our ability to manufacture in this country,' explains Anderson. 'Right from intellectual property development, we've got over 80 patents delivered internationally from five different families, which underpins our ability and autonomy to maintain our own manufacturing capability.'

Orthocell's commitment to local manufacturing has yielded multiple strategic advantages. It has helped to maintain control over margins, as well as ensuring that production knowledge is retained internally.

'Intellectual property will only go so far in defence of your products,' Anderson says. 'It's the internal knowledge that complements intellectual property, and gives you great power and surety that others in this market can't take what you have.'

As a sovereign manufacturer with full control, Orthocell has created an integrated ecosystem that ensures strict standards across all areas of product development, from quality control through to regulatory affairs, and sales and marketing.

Critically, Anderson believes that manufacturing sovereignty has allowed Orthocell to cultivate local talent, providing opportunities for young Australian scientists and other innovation specialists to grow their careers on Australian shores. 'We've been able to develop local talent, and educate young, enthusiastic scientists and others to undertake career-defining activities and roles within our company. We have numerous examples of young scientists coming to us, working in production; and then moving from production into either quality control or quality assurance; and some even progressing into regulatory affairs and maintaining important roles within the company.'

#### Prioritising key opinion leader engagement

Orthocell's approach to clinical collaboration, particularly with key opinion leaders (KOLs), represents another pillar of its success strategy. The company recognised early that successful commercialisation depends on surgeon adoption, making KOL engagement fundamental to product development and market access.

'In our line of business, ultimately, surgeons hold your destiny in their hands,' Anderson continues. 'I've seen many other companies go down a long pathway of development with a lack of KOL engagement and, too often, you see them get to a point where they're putting these products into the hands of surgeons, and the surgeon says, "Gee, I wish you had turned left four years ago instead of turning right."

## Orthocell's methodical path to US market entry offers valuable lessons for Australian biotechs with global ambitions

Orthocell's systematic approach to KOL engagement spans the entire product development life cycle.

'It's incredibly important, strategically, that you engage with the very best surgeons that there are on offer in this country and internationally, to externally validate your own thoughts,' Anderson explains. 'Internal validation is great, and we all look introspectively, but sometimes you can't see through their highly trained expert eyes or understand what they need at their fingertips.'

This multi-layered engagement strategy serves several critical functions: validating the technology, securing surgeon buy-in, and developing clinical champions who can educate other practitioners. This approach has been especially valuable in Orthocell's strategy to enter the US market – the world's largest healthcare market.

#### Staged global market entry

Orthocell's methodical path to US market entry offers valuable lessons for Australian biotechs with global ambitions. Rather than immediately rushing towards the largest market, Anderson says the company strategically focused on establishing domestic success first. 'We decided to get our products registered and reimbursed in Australia first – to launch in our own jurisdiction first. That's enabled us to learn about our scientific narrative, to learn what resonates with clinicians in this country, and to understand the similarities, and the synergies that exist between surgeons in Australia and in the United States.'

#### As Orthocell approaches FDA clearance for Remplir in 2025, it stands as an exemplar of Australia's capacity to develop and commercialise sophisticated medical technologies that address critical healthcare needs globally

This deliberate approach has allowed Orthocell to refine its messaging and clinical presentation before tackling the complexities of the US healthcare system. Simultaneously, the company has built relationships with US-based KOLs, establishing foundational collaborations through pre-clinical research.

'By the time you get your clearance in the U.S. Food and Drug Administration (FDA), you need to have established your KOL network. You need to understand which of those KOLs are the teachers and the drivers and the influencers, and you need to understand which centres of excellence have resonance with the rest of the country and, indeed, globally too,' Anderson says.

Orthocell has further strengthened these international connections by including US surgeons in Australian training programs, creating valuable cross-pollination between Australian and US KOLs.

'It's that matrix, which is not simple. It's complex in its design, but enables you to effectively deploy your products in the market and to have control over the surgeon training, and delineation of the technologies that provide you with the best chance to be successful in those markets.'

#### **Patient-centred innovation**

Ultimately, and most importantly, behind Orthocell's commercial success lies the profound impact its technologies have on patients. The company's nerve repair product, Remplir™, has demonstrated remarkable clinical outcomes, enabling patients with paralysed limbs to regain function.

Anderson recounts one particularly moving case: a patient with tetraplegia who initially couldn't wheel himself into the surgeon's rooms who was, after treatment with Orthocell's Remplir<sup>™</sup> technology, able to drive his own car 18 months later. 'He spoke about being able to use his mobile phone again. He spoke about being able to toilet himself again. He spoke about being able to hug his children again.'

This transformative impact on patients' quality of life represents the ultimate validation of Orthocell's approach to innovation and commercial development.

As Orthocell approaches FDA clearance for Remplir in 2025, it stands as an exemplar of Australia's capacity to develop and commercialise sophisticated medical technologies that address critical healthcare needs globally.

With manufacturing anchored in Western Australia and driven by a culture of clinical excellence and KOL collaboration, Orthocell's journey presents a compelling blueprint for Australian medical innovations striving to reach global scale.

'We distribute to major jurisdictions globally, including the United States, Europe, Singapore, Canada, and soon Brazil, Thailand and other jurisdictions. In anyone's language, this is an extremely successful story that has seen Orthocell develop and translate world-leading techniques, technologies, and treatments into effective clinical products that are now earning export dollars, and providing us with the ability to expand the local innovation ecosystem in this country.'

#### Orthocell's blueprint for success

Orthocell's journey from Perth startup to globally successful company offers a unique blueprint for the Australian biotechnology ecosystem:

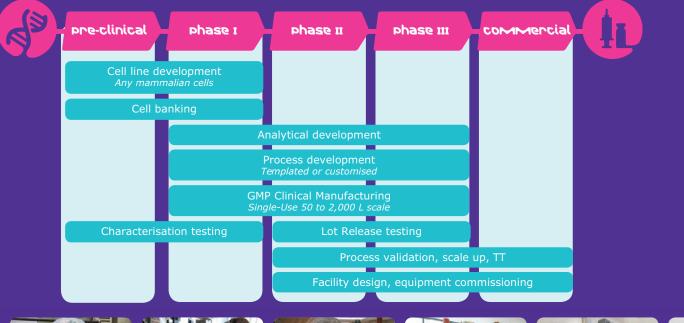
- Manufacturing sovereignty: Maintaining local manufacturing capabilities provides strategic advantages, including margin control, knowledge retention and a strong position against competitors.
- Strategic KOL engagement: Systematic engagement with clinical opinion leaders throughout product development ensures market-ready innovations and accelerates clinical adoption.
- Staged market entry: Establishing domestic success before pursuing international markets allows for refinement of clinical narratives and commercial strategies.
- Patient-centred innovation: Focusing on meaningful clinical outcomes that transform patients' lives provides both purpose and commercial differentiation.

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# ACCELERATING CINICAL TRIALS FOR AUSTRALIAN BIOTECHS

#### BY DR KHALID ABUBAKER AND DR ARDIAN LATIFI

Strategies for success and enhanced investment attractiveness.



**CLINICAL TRIALS ARE** essential but expensive.<sup>1,2</sup> Accelerating them without sacrificing quality is crucial for biotech companies to reach milestones, attract investment and deliver treatments faster. Speed reduces costs, shortens time to market and increases revenue potential, which are all investor priorities. Delays negatively impact valuation and future funding, potentially jeopardising future viability.

## Challenges and opportunities: an Australian investment perspective

Australia presents a unique biotech landscape. Geographic isolation is mitigated by digital technologies and decentralised trial models.<sup>3</sup> Access to capital remains a challenge, addressed by the strategies outlined herein. The increasing complexity of trials (e.g., more complex and higher number of procedures<sup>4</sup>) raises costs, but innovative designs offer mitigation.<sup>5</sup>

The Therapeutic Goods Administration's Clinical Trial Notification scheme in Australia provides a streamlined pathway that can potentially accelerate trial initiation compared to standard U.S. Food and Drug Administration and European Medicines Agency processes. While initiation within three months is achievable, timelines may vary.<sup>6</sup> World-class research infrastructure (including CSIRO and the Walter and Eliza Hall Institute of Medical Research, among others) and Australia's high-ranking in multi-regional clinical trials boost investor confidence.<sup>7</sup>

### Government support: de-risking biotech investment

The Australian Government actively supports clinical trials, reducing political and regulatory risk for investors. Here are some government initiatives and their benefits:

Initiative	Description	Investor perspective
National One Stop Shop: a national cross-government platform for health-related human research. <sup>8</sup>	This harmonises regulations and streamlines processes.	It reduces administrative burdens and costs, enhancing Australia's attractiveness for investment.
Clinical Trials Activity Initiative (Medical Research Future Fund). <sup>9</sup>	This includes \$750 million (2024–2034) to support clinical trial activities, particularly for trials in rare diseases, rare cancers, and unmet needs.	It de-risks investments in crucial therapeutic areas.
Research and Development Tax Incentive. <sup>10</sup>	This is a percentage tax offset for eligible research and development (R&D).	It significantly reduces trial costs, making Australia highly cost-competitive for R&D investment.
National Critical Research Infrastructure initiative <sup>11</sup>	This initiative will provide \$600 million over 10 years from 2024–25 for research infrastructure that will be used to conduct world-class health and medical research.	It positions Australia at the forefront of mRNA therapeutics, creating significant investment opportunities.

Table 1. Summary of key initiatives

# Achieving accelerated, capital-efficient trials

The following strategies enable accelerated trials that are capital-efficient:

- Innovative trial designs: These designs reduce patient numbers and trial duration, saving costs and generating data faster.
  - > Adaptive trials: These allow pre-planned modifications based on interim data (such as sample size adjustments and early stopping).<sup>12</sup>



Dr Khalid Abubaker



- > Umbrella studies: Umbrella studies evaluate multiple therapies for a single disease with different subtypes (as a hypothetical example, melanoma with different mutations).<sup>13,14</sup>
- Basket trials: These trials evaluate a single therapy across different diseases that share a common biomarker (an immunotherapy across various solid tumours, as a hypothetical example).<sup>13,14</sup>
- Master protocols: Such protocols encompass umbrella and basket trials, maximising efficiency. These provide multiple 'shots on goal'.<sup>15</sup>
- Decentralised cinical trials: These trials use technology (wearable sensors or telemedicine<sup>16</sup>) to conduct trials remotely, reducing site visits and expanding patient access, which is crucial in Australia.<sup>17</sup> This minimises delays and costs.
- Patient-centric protocols: Simplifying protocols improves recruitment and retention, accelerating completion and lowering costs.<sup>18</sup>
- Leveraging technology: Artificial intelligence–powered patient recruitment and EHRs streamline operations, reduce manual data entry, and improve data quality, leading to faster analysis and reduced costs. Data security is paramount.<sup>19</sup>
- **Strategic partnerships:** Collaborations with CROs (full-service or niche) and academic institutions provide expertise and resources, de-risking development.<sup>20,21</sup>

### Maximising capital efficiency

For limited-funding biotechs, the following strategies can maximise capital efficiency:

- Prioritise early-phase trials: Well-designed Phase I/IIa trials • generate data to attract Series A funding with lower initial outlay.
- Leverage government grants and incentives: • Non-dilutive funding extends the runway and maximises equity investment.22
- Collaborate with academic institutions: Access • infrastructure and expertise at reduced cost.23
- Explore alternative funding: Crowdfunding (e.g., • Venture Crowd<sup>24</sup>), venture philanthropy (e.g., Philanthropy Australia<sup>25</sup>) and angel investors diversify funding sources.<sup>26</sup>

Adapt to smaller trials: The median sample size has declined • from 1999 to 2020,<sup>27</sup> reducing costs.

### **Optimising CRO partnerships: mitigating investment risks**

While large CROs offer comprehensive services, the following challenges exist:28

- Lack of personalised attention: This can lead to delays and increased costs, impacting investor timelines.<sup>29</sup>
- High costs: High costs result in strained budgets, reducing ٠ runway and potentially delaying milestones. Costs can be significantly higher.<sup>30</sup>
- Communication barriers: Inefficient communication • slows progress, increasing costs and potentially affecting valuation.

Adaptive design type	Description	Potential benefits	Potential limitations	Investor-relevant points
Sample size re-estimation	The sample size is recalculated during the trial based on interim data, often using pre-specified rules based on observed variability or treatment effect. This can be blinded (without unblinding treatment assignments) or unblinded.	This can increase the probability of detecting a true treatment effect if the initial sample size was underestimated. It can also prevent unnecessarily large trials if the effect is larger than expected.	This may require more complex statistical analysis. There is risk of operational bias if unblinded. It also may extend trial duration if sample size is increased.	This allows for more efficient use of capital by adjusting trial size based on emerging data.
Early stopping for efficacy/futility	The trial can be stopped early if interim data show overwhelming evidence of either efficacy (benefit) or futility (lack of benefit). Pre-specified stopping boundaries are defined.	This saves time and resources by avoiding unnecessary continuation of a trial that is clearly positive or negative. There is an ethical benefit of exposing fewer patients to ineffective or overly effective treatments.	There is a risk of stopping too early based on chance findings (Type I or Type II error). Careful planning and strict adherence to pre-specified rules is required.	This reduces risk by allowing for early termination if the therapy is clearly ineffective or exceptionally effective.
Treatment arm dropping/selection	One or more treatment arms can be dropped during the trial if interim data show they are inferior to other arms.	This offers more efficient use of resources by focusing on the most promising treatments.	This requires careful planning to avoid bias, and may lead to loss of information about dropped arms.	This increases the likelihood of identifying the best treatment option, improving the chances of a successful outcome.
Adaptive randomisation	The randomisation ratio (the proportion of patients assigned to each treatment arm) is adjusted during the trial based on accumulating data, often favouring arms that are performing better.	More patients are assigned to the more promising treatment (s). This can improve the efficiency of comparing multiple treatments.	It can mean more complex statistical analysis, and require careful planning to avoid bias. It may be less acceptable to some regulatory agencies in certain situations.	This Improves the chances of identifying a winning treatment arm and potentially benefits more patients within the trial.
Population enrichment	The eligibility criteria for the trial can be modified during the trial to focus on a subpopulation that appears to be responding better to the treatment.	This can increase the probability of detecting a treatment effect if the effect is only present in a specific subpopulation.	It may limit the generalisability of the findings, and requires careful planning to avoid bias.	This allows for focusing resources on the patient population most likely to benefit, increasing the chance of a positive outcome.
Dose-finding/selection	Multiple doses of a drug are tested, and the trial can adaptively select the optimal dose(s) for further evaluation based on interim data on efficacy and safety.	This is more efficient than traditional dose-finding designs. It can identify the optimal dose faster.	This requires careful planning and sophisticated statistical methods. It may be more complex to implement.	This improves the chances of identifying the optimal dose, maximising efficacy and minimising toxicity.

Table 2. Summary of adaptive trial designs

- Industry shift: A survey by McKinsey & Company shows a move towards more personalised CRO services for biotechs.<sup>28,31</sup>
- Impacts of COVID-19: The pandemic impacts highlight a lasting increase in decentralised trials.<sup>32</sup>

**Overcoming CRO challenges: risk mitigation strategies** To overcome these challenges, biotechs can consider the following:

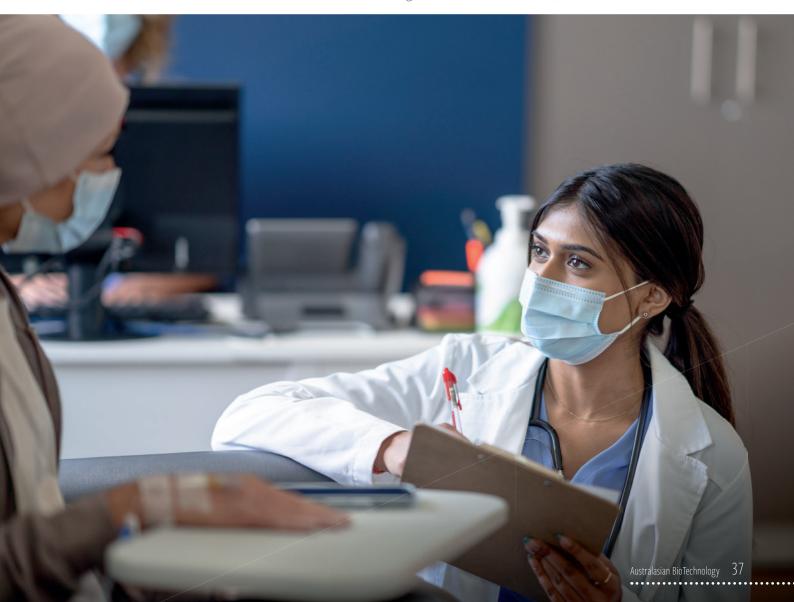
- Choose the right CRO: Selecting a CRO that aligns with the company's specific needs and budget, such as a smaller, specialised CRO, can lead to greater cost efficiency and a more personalised approach, maximising the value of the CRO partnership. Emphasise due diligence and getting proposals from several CROs.
- Establish clear communication channels: Open and consistent communication with the CRO is essential for

ensuring that the trial stays on track and within budget, minimising potential delays and cost overruns. Using project management software and designated points of contact can help.

• Negotiate flexible contracts: Negotiating contracts that include alternative payment models (e.g., milestone-based payments or risk-sharing agreements) and performance-based incentives (e.g., enrolment targets and data quality) can align the CRO's interests with those of the biotech and its investors, ensuring that the trial is conducted efficiently and cost effectively.<sup>33</sup>

## Synthesis and future directions: a call to action for investors and the Australian biotech sector

Future research should focus on optimising clinical trial designs, developing more efficient regulatory pathways, and fostering collaboration between biotechs, CROs, and academic institutions (e.g., through industry–academia partnerships or government-funded consortia).<sup>34</sup>



Key recommendations are as follows:

- For biotechs: Prioritise capital efficiency, embrace innovative trial designs and build strong relationships with the right partners.
- For investors: Look for Australian biotech companies with clear clinical development plans, a strong understanding of the regulatory landscape, a commitment to capital efficiency, and a plan for maximising the value of Australian Government incentives.
- For government: Continue to foster a supportive ecosystem through incentives.

### Investor call to action

Australian biotechs that embrace these strategies are well-positioned to attract investment, accelerate their clinical development programs and deliver significant returns. Investors should look for Australian biotech companies that demonstrate a commitment to innovative trial designs, capital efficiency, strong CRO partnerships and rigorous ethical standards.

Key questions for investors to ask include:

- What is the company's clinical trial strategy, and how does it maximise efficiency and minimise costs?
- How are they leveraging technology to improve trial efficiency and data quality?
- What is their plan for managing CRO relationships to ensure cost-effectiveness and timely execution?
- What is their approach to patient recruitment and retention, and how does it address potential challenges?
- How are they maximising the value of Australian Government incentives and non-dilutive funding opportunities?

By working together, stakeholders can create a more efficient and effective clinical trial environment in Australia, driving innovation and delivering life-saving therapies to patients faster, while generating strong returns for investors. @

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# AUSTRALIA'S CLINICAL TRIALS LANDSCAPE: KEY INSIGHTS FROM BELLBERRY'S LATEST DATA

BY DR LISA ECKSTEIN AND LEANNE WEEKES, BELLBERRY LIMITED





### **BELLBERRY HAS ACCESS** to

unique data on clinical trial trends in Australia through its role in providing ethical and scientific oversight for more than 40 per cent of Clinical Trial Notification (CTN) trials in Australia. Remarkably, in a given year, around half of the drugs approved by the U.S. Food and Drug Administration are seen by the Bellberry Human Research Ethics Committee.

Each year, Bellberry interrogates its review data to provide insights to the Australian clinical research sector on emerging trends. This data is presented in full in its annual Clinical Trials Activity Report (CTAR). As the



Dr Lisa Eckstein



majority of our review activity is conducted at private sites, the data cannot claim to be representative of the entire Australian clinical trials landscape; however, Bellberry's data provides a meaningful snapshot of key trends, particularly in early-phase, industry-sponsored trials conducted at private sites. These insights also align with broader datasets such as the Australian and New Zealand Clinical Trial Registry (ANZCTR) and ClinicalTrials.gov, providing an important perspective in sector trends.

### International investment and economic impact

One of the most striking findings from CTAR data is the sustained strength of international investment in clinical trials conducted in Australia. Approximately two-thirds of the trials Bellberry reviewed were the result of inward investment from international sponsors, with the United States accounting for nearly half. Other significant sponsor companies' countries were China, Switzerland, the United Kingdom, France, Germany, Sweden, and South Korea – all of which have featured prominently in previous CTAR analyses.

This international investment plays a vital role in supporting Australia's clinical research sector and broader economy. MTPConnect has estimated that in 2022, clinical trials contributed about \$1.6 billion to the Australian economy.<sup>1</sup>

The continued attractiveness of Australia for clinical trials is driven by factors such as efficient regulatory pathways under the CTN scheme, high-quality clinical trial data and world-class research infrastructure. Additional advantages include the Research and Development Tax Incentive, strong early phase expertise, globally recognised ethics and regulatory processes, and access to diverse patient populations. All of these work synergistically to enhance Australia's global competitiveness.

### Australia's strength in early-phase trials

Australia remains a preferred destination for early-phase trials – particularly first-in-human studies. Data from Bellberry's CTAR shows continued year-on-year growth in these early-phase studies. This aligns with broader trends in the sector, with data from the ANZCTR showing a tripling in the number of early-phase studies conducted in Australia between 2006 and 2020. (Latest update of the clinical trials landscape in Australia (2006–2020).)

International sponsors continue to show strong interest in Australia's early-phase research capabilities, with overseas sponsors investing in two-thirds of early-phase Australian clinical trials reviewed by Bellberry. The top countries are the United States, China, South Korea and the United Kingdom.

Again, this is in line with other available data, including a review of ClinicalTrials.gov for Phase I oncology trials being conducted in Australia between 2012 and 2022.<sup>2</sup>

The review reported that North America was the most common country of origin for Phase I oncology sponsors each year, with the exception of 2022. Between 2012 and 2022, there also was a substantial increase in Phase I oncology sponsorship from Asian countries, increasing from six per cent in 2012 to 39 per cent in 2022.<sup>3</sup>

### Therapeutic area trends

Cancer remains the therapeutic area with the most substantial proportion of Bellberry-reviewed trials overall, followed by neurology, infectious disease, dermatology and haematology. This is an area that diverges to some extent from slightly older published data on clinical trials. For instance, a review of ANZCTR-listed trials conducted in Australia reported the most common conditions under study between 2016 and 2020 were cancer, followed by mental health, neurological disorders, public health, and cardiovascular disease.<sup>4</sup> These shifts reflect how clinical trial trends are continuously shaped by scientific innovation and strategic research directions, both in Australia and globally.

### Looking ahead

Early analysis of Bellberry's 2024 CTAR data provides indications of key trends likely to shape the clinical trials environment. Continued international investment is expected to drive growth, especially in early-phase research. Oncology will remain a dominant area of focus, but interest in neurology and rare diseases could reshape the distribution of trials in coming years. Furthermore, geopolitical, regulatory, and policy developments – particularly in the United States, but also globally and in Australia – may influence the trial landscape, impacting where sponsors choose to conduct trials, as well as trial design.

These insights provided by Bellberry's CTAR reinforce Australia's standing as a global leader in early-phase research. By leveraging its strengths in world-beating startup times, scientific excellence and regulatory efficiency, Australia is well placed to maintain its leadership in the years ahead.

### Upcoming release of the 2024 CTAR

Bellberry's 2024 CTAR will be released on World Clinical Trials Day, 20 May 2025, providing further insights into emerging trends and the future of clinical research in Australia. @

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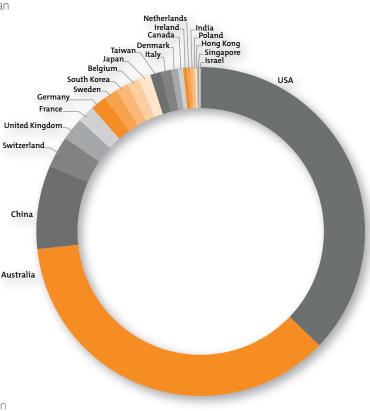


Figure 1. International investment in Bellberry trials, 2023

### SPONSORED CONTENT

# AUSTRALIAN INNOVATION AND ENTERPRISE

**BELLBERRY WAS FOUNDED** to solve a problem. Now, the company is recognised as a vital part of Australia's health infrastructure, providing scientific and ethical review for more than 40 per cent of Clinical Trials Notification (CTN) clinical trials.

Last year, Bellberry's innovation and achievements were recognised when it won the national Telstra Best of Business Award for Championing Health.

Bellberry is also the largest provider of Human Research Ethics Committee (HREC) services in Australia, recognised internationally for the quality, timeliness and robustness of its reviews of lifesaving vaccines, drugs, medical devices and diagnostics. But how did the institutionally independent, homegrown, not-for-profit company start?

In 2004, the buyers of a hospital in Adelaide axed the hospital's HREC with a stroke of a pen because they saw it as an insurance risk. Valuable research was being undertaken at the time, and the question was posed, 'Can we set up a HREC without a hospital?' It hadn't been done before. The answer? 'Yes'.

With Bellberry's creation, there were two objectives: to protect the welfare of human research participants, and to improve the quality, efficiency and effectiveness of medical research. Everything the company does is still centred on these objectives.

Bellberry started as a disrupter and a paradigm breaker. The company examined every step of the process of running HRECs,

employing a culture of curiosity and continuous improvement. Highly trained staff assist with the administration of the committees, so the expert reviewers can do what they love, which is having a front row seat to leading health innovations from across the globe.

Bellberry's quality assurance team proactively visits and monitors sites to ensure compliance with approved submissions. The aim for submissions is a turnaround time of 20 days from lodgement to a HREC decision, providing access to some of the fastest regulated clinical trial startup times in the world.

Bellberry is the only Australian organisation to gain the 'gold seal' accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

The business model means that there's an extraordinary alchemy to Bellberry. The core business is running HRECs and generating revenue. The surplus funds are reinvested into the Australian medical research sector to continue protecting the welfare of participants and improving the quality of research. To date, \$12 million has been invested, including initiatives like the Bellberry-Viertel Fellowship.

Many of the staff are hugely motivated by the company being a not-for-profit, and by knowing that by working at Bellberry, they are making a difference every single day. Bellberry has optimised the scientific and ethics review process focusing on its people, processes and systems, showing true Australian innovation and enterprise.



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# MEDI-SOLFEN® A TRANSFORMATIVE SOLUTION FOR WOUND CARE AND PAIN MITIGATION

**MEDI-SOLFEN PTY LTD EMERGES** as a research-driven enterprise poised to revolutionise wound care and pain management. With a clear vision of alleviating pain, promoting healing and minimising suffering associated with wounds in humans, Medi-Solfen<sup>®</sup> is set to redefine industry standards.

### Addressing a significant unmet need

Medi-Solfen addresses a significant unmet need for improved solutions in treating chronic and acute wound pain. The global wound care market is experiencing significant growth. It is currently valued at A\$32.3 billion and is expected to reach an estimated value of \$46.3 billion by 2030, growing at a compound annual growth rate of 4.12 per cent. Factors such as political unrest, social upheaval, environmental challenges and the prevalence of chronic diseases amplify the need for effective multi-modal wound care solutions. Medi-Solfen aims to improve the standard of care, potentially reducing the financial and personal costs associated with wound management.

### Proven

Medi-Solfen derived from the successful veterinary treatment Tri-Solfen® and uses the same Solfen-Tech® platform and active ingredients, which have been proven safe and effective in treating more than 200 million animals since 2006, and are also well established in the human medicine field. This established track record significantly reduces commercialisation risks for Medi-Solfen. The product's intellectual property is exclusively licensed from Medical Ethics Group, and protected by more than 40 patents in major markets until 2042. The use of globally established active ingredients, and replication of Tri-Solfen's formulation and manufacturing processes, streamlines the regulatory approval process for Medi-Solfen.

### Unique and effective solution

Medi-Solfen is a unique, topically applied combination agent offering anaesthetic, haemostatic and antiseptic properties. Key benefits include rapid pain relief (anaesthetising the wound from 30 seconds), bleeding control to initiate healing, and a reduced risk of contamination and infection via a locally applied antiseptic barrier. Notably, its unique formulation contains adrenaline/epinephrine with a 36-month shelf life at 25 degrees Celsius, achieved through the Solfen-Tech platform, enabling the stable combination of multiple actives in a viscous matrix for easy spray topical application.

### Clinical progress and promising potential

Clinical progress is underway, with Phase I trials for lacerations commencing in Kyiv, Ukraine, in January 2025, and Phase II trials for leg ulcers planned for the third quarter of 2026. Medi-Solfen has the potential to revolutionise the management of open wounds in humans, mirroring Tri-Solfen's impact in the veterinary field.

The U.S. Department of Defense has expressed interest in Medi-Solfen for frontline pain management, highlighting its priority for military personnel. As noted, 'The potential for this technology to have a positive, beneficial impact on military medicine for both military and civilian injuries is tremendous.' This interest underscores the product's significant commercial opportunity.

### Future leader in wound care

With its patented technology, patient-centric focus, accelerated development and unique formulation, Medi-Solfen is positioned to become a leader in wound care and pain mitigation. To accelerate Medi-Solfen's commercialisation, the company will launch a pre-IPO investor round in April 2025, followed by an IPO in 2026. Distribution agreements, like the Dechra PLC arrangement for veterinary licences, are planned for negotiation in 2026/2027.



# Revolutionary wound care solution

# Medi-Solfen targets \$46.7 billion market by 2030

- Proven platform
- Patented technology
- Phase I trials underway

For further information contact Chantalle Elliott email: celliott@medisolfen.com www.medisolfen.com Medi-Solfen's product platform has use cases across multiple clear and distinct markets, including:

### **Emergency Wound Care**

- Lacerations
- Military Use
- Natural Disasters

### **Chronic Wound Management**

- Debridement
- At home Community Care

### **Minor Surgical Procedures**

- Intra operative
- Post operative
- Burn Care
- Palliative Care
- **Over the Counter First Aid**



# SUSTAINABILITY IN PHARMACEUTICAL COLD CHAIN LOGISTICS

BY NICOLE ROY, BUSINESS DEVELOPMENT MANAGER AUSTRALIA & NEW ZEALAND, EMBALL'ISO



### In 2025, the pharmaceutical industry faces an urgent challenge: to maintain efficient cold chain logistics while reducing environmental impact.

**AS GLOBAL SUSTAINABILITY** goals and regulatory pressures increase, companies are re-evaluating their packaging strategies to align with eco-friendly practices. One company at the forefront of this

transition is EMBALL'ISO, which provides lightweight, reusable isothermal packaging solutions that significantly cut carbon emissions and waste.

### The importance of sustainable cold chain logistics

Cold chain logistics plays a vital role in ensuring the safe and effective delivery of temperature-sensitive pharmaceuticals;

however, traditional packaging solutions often contribute to high carbon dioxide emissions, excess waste, and significant costs. The industry is shifting towards sustainable alternatives, with reusable packaging emerging as essential to balance operational efficiency and environmental responsibility.

EMBALL'ISO has pioneered innovative isothermal packaging solutions that offer a significant reduction in carbon dioxide emissions of up to 75 per cent compared to conventional single-use containers. One of the company's stand-out innovations is the development of flat-packed Pallet Shippers, which not only decrease emissions, but also lower transportation and storage costs. These solutions align with global sustainability initiatives and help pharmaceutical companies meet their carbon footprint reduction targets.

EMBALL'ISO was approached to provide a solution for transporting US pallets by air to more than 10 different countries across two continents. The client sought a single, easy-to-use solution capable of transporting four pallets on a PMC without temperature excursions. Given the large volume of shipments, managing costs, including acquisition, transportation, storage, assembly, and end-of-life logistics, was critical. Initially, environmental considerations were not a priority; however, once the client realised the significant CO<sub>2</sub> and cost savings achieved through EMBALL'ISO's Reuse & Reverse Logistics model, sustainability became a key focus.

EMBALL'ISO delivered Pallet Shippers flat-packed to optimise transportation and storage costs. The Pallet Shippers were designed for quick and easy assembly, making them user-friendly and efficient.

### Case study: a global air transport solution

According to Florence Lehec, Head of Marketing and Sustainability at EMBALL'ISO, the Pallet Shipper is 70 per cent lighter than comparable active solutions, leading to significantly reduced carbon dioxide emissions during airfreight, the most impactful phase.

'The solutions are always validated by our teams who prepare shipments daily,' says Lehec. 'We are looking for solutions that are easy to use and lightweight to reduce risks for our employees.'

Upon reaching the destination, the Pallet Shippers are flat-packed again. The client then notifies EMBALL'ISO to arrange for the collection of packaging that was previously discarded under the former supplier's model. These Pallet Shippers are collected, refurbished at the nearest EMBALL'ISO service centre, and returned via sea freight to the client's departure sites, or reused within the same country. Over a three-year period (2022–2024), 24,000 Pallet Shippers were recovered, preventing 2500 tons of waste – the equivalent of about 600 20-foot containers. Each reuse allows the client to save 93 per cent of carbon dioxide emissions.

### The rise of reuse and reverse logistics models

Sustainability in cold chain logistics extends beyond packaging design to include circular economy principles. Reuse and reverse logistics models facilitate packaging recovery, cleaning, and refurbishment for repeated use, significantly reducing waste. Implementing such a system requires proper training for teams receiving the products to ensure correct disassembly and storage. Once established, the process is simple and more cost-effective than managing waste. The collection rate exceeds 90 per cent, demonstrating the efficiency of this model.

### Artificial intelligence and eco design driving innovation

Technology and sustainability go hand in hand in modern logistics. Artificial intelligence (AI) is now a critical tool in optimising pharmaceutical transportation. AI systems analyse routes, weather conditions, and temperature variations to recommend the most suitable packaging, minimising risks, costs, and environmental impact. In parallel, eco-design principles guide the development of new packaging solutions. Materials are carefully selected to be lighter and more durable, and compliant with strict environmental standards, ensuring that sustainability does not compromise product integrity.

## Regulatory and industry trends supporting sustainable practices

Governments and regulatory bodies worldwide are encouraging sustainability initiatives in the pharmaceutical sector. Policies such as extended producer responsibility and carbon taxation push companies to adopt greener logistics models.

Pharmaceutical firms that proactively implement sustainable solutions are not only meeting compliance requirements, but are also gaining a competitive edge by enhancing their corporate social responsibility profiles.

### The future of sustainable cold chain logistics

EMBALL'ISO is leading the way, proving that sustainability and efficiency can coexist. Through lightweight packaging, Al-driven optimisations, and eco-design innovations, the pharmaceutical industry can reduce its environmental footprint while maintaining high standards in product safety and delivery. The path forward involves continuous investment in sustainable solutions, industry-wide collaboration and adherence to evolving regulatory frameworks. By embracing these changes, pharmaceutical companies can contribute to a greener future while ensuring the integrity of their vital medical shipments. Reinforcing its commitment to sustainability, EMBALL'ISO has recently obtained the Ecovadis Committed assessment, further validating its dedication to environmental responsibility and ethical business practices.

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SUSTAINABILITY IN MEDTECH

Fontainea picrosperma fruit, found in the Queensland ecosystem, is the source of tigilanol tiglate

# UNLOCKING THE POWER OF NATURE FOR DRUG DEVELOPMENT

CONTENT PROVIDED BY QBIOTICS GROUP

AUSTRALIAN CLINICAL-STAGE LIFE sciences company QBiotics Group Limited (QBiotics) is currently celebrating its 25th year of operation. With a vision of becoming a global leader in biodiscovery by unlocking the potential of novel small cell signalling molecules from nature, QBiotics is striving to redefine health care by safely and effectively treating complex medical conditions for patients with unmet needs. QBiotics is currently focusing on treatments for cancer and wound healing, with two assets in human clinical development, and a registered oncology pharmaceutical for dogs.

Doctors Gordon and Reddell explored the diversity of nature, and how plants interact with their environment. Their pioneering research strove to understand whether these natural interactions and pathways could be adapted to create innovative medicines for human use

Co-founded in 2000 by former CSIRO scientists microbiologist Dr Victoria Gordon and forest ecologist Dr Paul Reddell, QBiotics originated from a modest basement home laboratory in Yungaburra, Queensland.

Doctors Gordon and Reddell explored the diversity of nature, and how plants interact with their environment. Their pioneering research strove to understand whether these natural



interactions and pathways could be adapted to create innovative medicines for human use. They created a unique discovery platform for small molecules with specific biological activity, which they trademarked EcoLogic™.

Queensland's natural environment provides a rich and abundant source of biologically active small molecules. EcoLogic enables QBiotics to generate search strategies for specific types of bioactivity (e.g., anticancer, anti-inflammatory or antibiotics), informed by observations of plant–animal interactions in



megadiverse environments, to discover novel, small molecules with potential as pharmaceuticals.

According to Non-executive Director, former CEO and Managing Director Dr Gordon, the natural environment is a rich source of novel, highly biologically active small molecules.

'Discovering more effective treatment options with less severe and fewer side-effects for human health has always been our motivation at QBiotics,' says Dr Gordon. 'By researching the way plants defend themselves in their environment, we've been able to identify molecules with specific disease-targeting abilities. Plants have developed these extraordinary, elegant systems in order to protect themselves. This is mostly through chemical defence, but these pathways can be researched and used to solve medical problems.

'In addition to our unique discovery platform EcoLogic, another one of QBiotics's distinguishing factors is our ability to use extensive, real-word data from our animal programs to



inform and minimise the potential risks in future human disease management,' Dr Gordon says.

'We are currently focusing on a broad range of solid tumours and chronic wounds, both representing areas of significant unmet need in the patient population.<sup>1,2,3</sup> We have also started expanding into additional, early programs in antibiotics and anti-inflammatories,' says Dr Gordon.

### Approved and marketed for the treatment of mast cell tumours in dogs in Australia, the United States, Europe and the United Kingdom, tigilanol tiglate is undergoing human Phase II clinical trials in head and neck cancer, and soft tissue sarcoma

Part of the overall drug discovery and development approach taken by QBiotics is phenotypic screening, which offers the advantage of identifying potential drug candidates based on their effects on disease-related biological processes, rather than relying solely on predefined molecular targets, thus allowing for the discovery of novel mechanisms and unexpected therapeutic pathways.<sup>4,5</sup> In addition to phenotypic screening, QBiotics uses data from treatment of real-world veterinary diseases to contribute to the QBiotics drug development process. These robust disease models inform human clinical development and thus reduce the risk of the initial move into humans.<sup>5</sup>

QBiotics' lead anticancer small molecule, tigilanol tiglate, was discovered through the EcoLogic platform. Originating from the Queensland native tree *Fontaine picrosperma* (blushwood), tigilanol tiglate demonstrated tumour-killing properties at an early stage in deveopment.<sup>6</sup> Approved and marketed for the treatment of mast cell tumours in dogs in Australia, the United States, Europe and the United Kingdom,<sup>78</sup> tigilanol tiglate is undergoing human Phase II clinical trials in head and neck cancer, and soft tissue sarcoma.<sup>3,9,10</sup>

Tigilanol tiglate is an intratumoural treatment, injected directly into the tumour, and has a unique mode of action. The drug rapidly destroys the tumour through multifactorial effects, including: (i) disruption of tumour vasculature (including via activation of Protein Kinase  $\beta$ I and  $\beta$ II), resulting in hypoxia and capillary damage; (ii) induction of pyroptosis (via ER stress) in tumour and tumour stroma, leading to immunogenic cell



death; the release of DAMPs; antigen uptake and specific T cell responses; and (iii) promotion of immune cell recruitment into tumour through PKC-induced inflammatory response and cytokine release. Tigilanol tiglate also stimulates wound re-epithelialisation and wound closure of the site post tumour destruction through the promotion of expression of pro-wound resolution genes and proteins in immune cells, fibroblasts, and keratinocytes.<sup>5,9,10</sup>

Tigilanol tiglate has been awarded orphan drug designation by the U.S. Food and Drug Administration for the treatment of soft tissue sarcomas.<sup>11</sup>

QBiotics is exploring additional small molecules derived from the *Fontainea picrosperma* seed for their medicinal properties. The semi-synthetic small molecule EBC-1013 is being investigated for the treatment of acute and chronic wounds and burns. A clinical Phase I safety trial for EBC-1013 in patients with venous leg ulcers is also currently underway.<sup>12</sup> QBiotics has further programs in antibiotics and anti-inflammatories.

To commemorate QBiotics' success to date, and 25 years of operation, the life-sciences company recently sponsored the Unseen Worlds exhibition at the World Science Festival, Brisbane, which took place from 21–30 March 2025. Science enthusiasts of all ages viewed images and microscopic slides of the QBiotics EcoLogic approach to discovery of new medicines from nature.

Reflecting on 25 years of QBiotics, Dr Gordon says she is honoured to have collaborated with extraordinary people during her tenure and is proud of the company's achievements to date.

'QBiotics is no ordinary company. Over the past 25 years, we have learnt much, refined our approach, and created a unique path to drug discovery and development that is truly transformative.

'We are developing potentially life-changing drugs, and we are excited about the future of the company,' says Dr Gordon.

'Collaboration plays a crucial role in drug development. Over the past 25 years, we have built lasting partnerships, collaborating with a range of world-class institutes, universities, hospitals, and companies within Australia, and globally in the United Kingdom, Europe and the United States.

'At QBiotics, we're building a company for the future. Our discovery platform EcoLogic is an extraordinary source of innovation – but we can't do everything ourselves,'



Dr Gordon says. 'We see QBiotics as the centre hub of a group of collaborative partners, all working together to provide better treatment options for those living with complex medical conditions.'

QBiotics Group CEO Stephen Doyle says it's only the beginning for the Australian biotechnology company.

It's been a successful 25 years. During this period, we have connected scientific discovery, development and commercialisation, leveraging the power of nature to identify small molecules with the greatest potential for pharmaceutical development.

'Our EcoLogic platform holds the power for future drug discoveries to ultimately improve lives for those in need,' says Doyle. (9)

To learn more about QBiotics and its oncology, wound healing, anti-inflammatory and antibiotics programs, visit qbiotics.com. Watch Dr Victoria Gordon reflecting on QBiotics's 25 years of operation here: vimeo.com/1065696513/b2782541b1?share=copy.

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Cicada Innovations Clarity Pharmaceuticals Clever Culture Systems Ltd CMAX Clinical Research Pty Ltd Cochlear Limited Collaborative Drug Discovery, Inc Commissioning Agents International (Australia) Pty Ltd Cook Medical Crux Biolabs Cryosite Ltd CSIRO CSL Limited Cyban Pty Ltd Cynata Therapeutics Ltd Cytiva Datapharm Australia Pty Ltd Davies Collison Cave De Motu Cordis Pty Ltd Deloitte Touche Tohmatsu Department of Jobs, Skills, Industry and Regions (VIC) Department of Jobs, Tourism, Science and Innovation (WA) Department of State Development (SA) Diagnostic Technology Pty Ltd Dimerix Limited DMTCLtd Doherty Clinical Trials Ltd Douglas Pharmaceuticals Ltd E&P Financial Group EMBALL'ISO ENA Respiratory Encap Solutions Pty Ltd Endpoints Capital Enimera RegsPlus Pty Ltd Eurofins | ams Evaluate Eversana Evithe Biotechnology Exigence EZZ Life Sciences Holdings Limited Facet Life Sciences, Inc Facio BioTherapies Pty Ltd FB Rice Fenix Innovation Group Pty Ltd Field Orthopaedics Pty Ltd FivepHusion Formrite Group Pty Ltd

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Radium Capital Recce Pharmaceuticals Ltd Research Australia Limited Research, Innovation & Commercialisation (RIC), The University of Melbourne Resolian Bioanalytics Resolutum Global Pty Ltd Resonance Health Pty Ltd Respiri Limited **Respirion Pharmaceuticals** RheumaGen Australia Pty Ltd Roche Australia RSM Australia Pty Ltd Sanofi ANZ Sartorius Australia Pty Ltd Scientia Clinical Research Ltd Sementis Limited Servatus Ltd Smartways Logistics for Lifescience Snoretox Ltd Sonic Clinical Trials Pty Ltd Southern Clinical Development Consulting Southern RNA PTY LTD Southern Star Research Pty Ltd SpeeDx Pty Ltd Spruson & Ferguson St Vincent's Hospital Melbourne Starpharma Holdings Limited Svneos Health SYNERGIE Global Syngene International Ltd Svntara Takeda Pharmaceuticals Australia Pty Ltd Technovalia Pty Ltd TekCyte Pty Ltd Telix Pharmaceuticals Pty Ltd Tenmile Ventures TEVA Australia The Florey Institute of Neuroscience and Mental Health The Kids Research Institute Australia

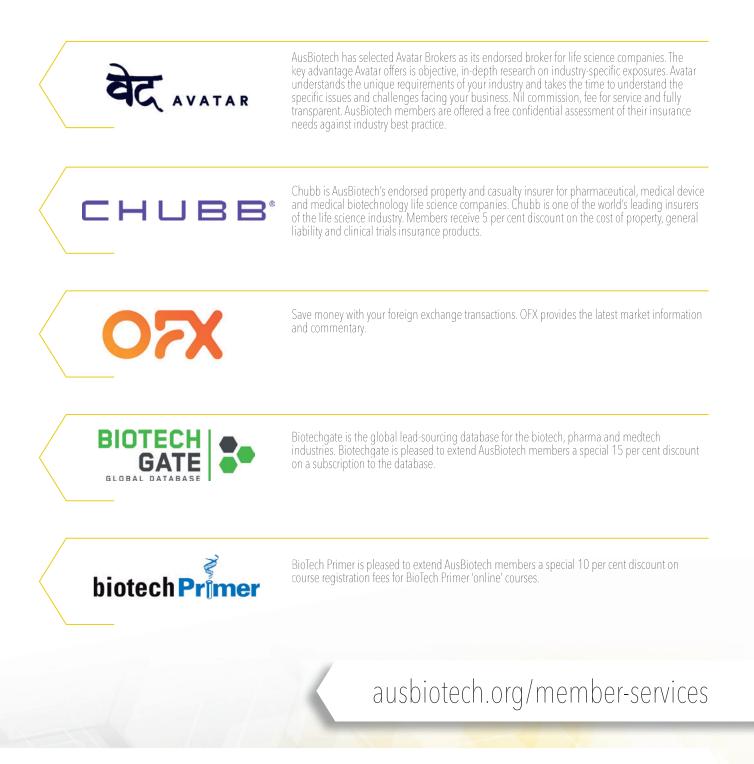
The University of Newcastle, Knowledge Exchange and Enterprise (KEE) The University of Queensland, Biotechnology Program The University of Sydney Therapeutic Goods Administration Therapeutic Innovation Australia Thermo Fisher Scientific Translational Research Institute Australia TruScreen Pty Ltd UniQuest Pty Ltd Universal Biosensors Pty Ltd University of South Australia -Enterprise Partnership Unit University of Technology Sydney, Faculty of Science University of Wollongong - Faculty of Science, Medicine and Health UNSW Industry & Innovation UNSW RNA Institute UNSW School of Biotechnology and **Biomolecular Sciences** Vaxxas Pty Ltd Venture Valuation Vertex Pharmaceuticals (Australia) Pty Ltd Vetter Pharma International GmbH Vial Health Technology, Inc. Viatris Viedoc Technologies AB Viral Vector Manufacturing Facility Pty Ltd Vitura Health Limited Wallonia.be - Export & Investment (Belgium) Walter & Eliza Hall Institute of Medical Research (WEHI) Wellumio West Pharmaceutical Services Australia Pty Ltd Wrays

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# Business Solutions Program

**Aus**Biotech



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# NEW AUSBIOTECH MEMBERS

### ADHERIUM



Adherium is a provider of integrated digital health solutions and a worldwide leader in connected respiratory medical devices, with more than 180,000 devices sold globally. Adherium's Hailie® platform solution provides clinicians, healthcare providers, and patients the ability to remotely monitor medication usage parameters and adherence, supporting reimbursement for qualifying patient management. The Hailie solution includes a suite of integration tools to enable the capture and sharing of health data via mobile and desktop apps, software development kit, and application programming interface integration tools, and Adherium's own broad range of sensors connected to respiratory medications. Adherium's Hailie solution is designed to provide visibility to healthcare providers of medication use history to better understand patterns in patient respiratory disease.

### CAD-IT AUSTRALIA



CAD-IT Australia is a leading expert in providing tailored digital solutions to the Australian life sciences sector. Its mission is to revolutionise life sciences by utilising knowledge of medtech and pharmaceutical industries to support digitisation and streamlining of product development. CAD-IT Australia partners with world leaders in product management to provide customised digital solutions, catered to any stage of development or manufacturing. Working with CAD-IT Australia will ensure efficient and compliant product development – from ideation to realisation.

Phone: 0459 797 391 | Email: sales@caditaus.com.au

### CENTRE FOR BIOPHARMACEUTICAL EXCELLENCE



The Centre for Biopharmaceutical Excellence (CBE) comprises a group of highly experienced professionals who provide consulting services and training to the life sciences industry, specialising in biopharmaceutical products. The team offers broad, deep and diverse experience in the key areas of quality, engineering, manufacturing operations, commercialisation, and research and development. CBE offers a range of value-add consulting services and training solutions to assist customers across Australia and the Asia-Pacific region. CBE's mission is to ensure customers are successful, efficient and compliant, and that they manufacture safe and effective products. **Email: enquiries@cbe-ap.com.au | Web: www.cbe-ap.com.au | Training: uplift@learnworlds.com** 

### EZZ LIFE SCIENCE HOLDINGS



EZZ Life Science is an Australian health supplement and skincare company focused on developing and marketing innovative products that enhance health and wellbeing. With a product portfolio tailored to address key areas such as genetic longevity, gut health and immune function, EZZ is committed to delivering scientifically backed solutions. The company's growth strategy targets local and international markets, leveraging research and consumer trends to create high-demand, premium offerings.

Email: info@ezzlife.com.au | Web: www.ezzlife.com.au



GENSCRIPT BIOTECH

Founded in 2002 in New Jersey, United States, GenScript Biotech Corporation accelerates innovation in health care and consumer goods by providing researchers and companies with the building blocks needed to develop groundbreaking treatments and products. Guided by its mission to make people and nature healthier through biotechnology, and its role as a trusted global leader, GenScript has a team of more than 5000 employees and has served more than 200,000 customers across 100 countries.

Email: support.ap@genscript.com | Web: www.genscript.com/establishment-announcement-au.html

### IMEC



imec is a world-leading research and innovation centre in nanoelectronics and digital technologies. As a pioneer in deep technology, imec brings the power of chip technology to the world of health care. Together with its partners in life sciences, medtech, pharma, biotech and more, imec develops next-generation technologies requiring extremely high sensitivity (down to the level of single-molecule interaction to analyse DNA and gene expression), single-cell manipulation, massive parallelisation, miniaturisation, low power, and so much more. imec offers extensive chip processing facilities; state-of-the-art bio-lab infrastructure for surface and bioassay characterisation; biosensor set-ups; DNA research; and world-renowned expertise in chip technology, micro-electromechanical systems, bioelectronics, sensors, photonics, imagers, microfluidics, biosciences, and high-performance computing. Jeremy Yang PhD, Strategic Partnerships Manager, Health, GCSO region

Phone: +86 21 5017 2918 | Email: jeremy.yang@imec-int.com I Web: www.imec-int.com

#### JAG PROCESS SOLUTIONS



As a turnkey engineering solutions provider, JAG Process Solutions (JAG PS) is dedicated to enhancing the life sciences development and manufacturing industry. It specialises in process engineering, process automation, lab automation, manufacturing digitalisation and robotics solutions. With extensive experience supporting pharmaceutical manufacturers, the JAG PS team offers a comprehensive package that includes engineering, procurement, project management, commissioning and qualification services for your upcoming project needs. JAG PS is your partner for all process technology and robotics needs.

Ayman Elmallah, Business Development Manager

Phone: 04725 184 799 | Email: a.elmallah@jag-ps.com.au | Web: www.jag-ps.com.au



PULSE ECONOMICS

Pulse Economics is a leading consultancy specialising in Health Technology Assessment for pharmaceuticals, medical devices and diagnostic tools. The company offers comprehensive services, including research and development planning; market access and reimbursement strategies; commercialisation and growth planning; health economic and financial modelling; and statistical analysis. Pulse Economics guides clients through the complexities of the healthcare market, ensuring optimal product positioning and patient access. It is committed to delivering tailored, evidence-based solutions that maximise the value of healthcare innovations.

Oona Reardon, CEO

Phone: 02 8985 7308 | Email: contact@pulse-economics.com.au | Web: www.pulse-economics.com.au

### PURECDM



PureCDM specialises in optimising clinical trial operations through customised, data-driven strategies. Specialising in flexible, cost-effective solutions, PureCDM moves beyond the one-stop shop model, leveraging expert data managers and fit-for-purpose technology. Its approach streamlines database builds, reduces risks and ensures data integrity with risk-based strategies. Designed for biotech and medtech startups, PureCDM solutions provides a hassle-free alternative to full-service CROs, ensuring efficient, real-time access to high-quality clinical data, with a strong focus on compliance and security.

Helen Poliviou, Founder/Managing Director Email: helen@purecdm.com.au | Web: www.purecdm.com.au

### SERVATUS LTD



Servantus is a global leading therapeutics company with first-in-class clinical results for the safe and effective treatment of rheumatoid arthritis using live biotherapeutics. Servatus has built an efficient, integrated drug development pipeline founded upon a pragmatic, results-driven approach to research and development. This approach has enabled Servatus to successfully complete a Phase IIa trial in RA, as well as IBS-C (Phase I) and insomnia (Phase IIa). Efficacy results, in combination with an excellent safety profile, position Servatus to become one of the first companies to realise the enormous potential of microbial biotherapeutics. **Mark Williams, CEO** 

Email: mark.williams.com.au | Web: servatus.com.au



#### SOUTHERN CLINICAL DEVELOPMENT CONSULTING

Southern Clinical Development Consulting (Southern CDC) is a service provider that aims to advance drug development and improve patient outcomes through accelerated clinical trials bespoke solutions. Southern CDC rapidly engages and aligns with sponsor expectations, leveraging cutting-edge services. With a focus on scientific discoveries, it supports clients throughout the clinical development life cycle. The company's diverse clientele includes pharmaceutical companies, biotech firms, academic institutions and investigators, all united in expediting life-changing treatments where every day counts.

#### THE UNIVERSITY OF SYDNEY



The University of Sydney is a premier partner for biotech innovation, offering cutting-edge research, state-of-the-art facilities and a collaborative ecosystem. As one of the world's leading comprehensive research and teaching universities, the university tackles problems from all angles, combining expertise from multiple disciplines. Commercial development and industry partnerships offer novel technologies, research expertise and professional services. With the Sydney Biomedical Accelerator set to open in 2028, The University of Sydney is changing the landscape of health care and translational research. **Email: engage.team@sydney.edu.au** 

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# INDEX

### BY DAVID NAYAGAM AND THOMAS WEGNER, HEALTHCARE RESEARCH, E&P

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ASX	lssuer Name	Principal Activity	Market Cap	Last Price	Year High	Year Low	EPS (cents)	PER	Net asset value per share	DIV (cents)
1AD	Adalta Limited	AdAlta Limited is an Australia-based clinical-stage biotechnology company. The company uses its i-body platform to discover and develop protein therapeutics addressing drug targets that are challenging for other technologies.	4.5	0.007	0.041	0.016	-0.85	-0.82		
1AI	Algorae Pharmaceuticals Limited	Algorae Pharmaceuticals Limited is an Australia-based artificial intelligence (AI) enabled drug discovery and development company. The company is actively engaged in expanding its therapeutic pipeline using a proprietary AI drug discovery and development platform, known as Algorae Operating System (AlgoraeOS).	8.4	0.005	0.013	0.005	-0.08	-6.25		
4DX	4Dmedical Limited	4DMedical Limited is an Australia-based medical technology company. Through its flagship patented XV Technology, the company enables physicians to understand regional airflow in the lungs, and identify respiratory deficiencies earlier and with greater sensitivity as they breathe.	112.6	0.25	0.715	0.245	-11.44	-2.19		
ACR	Acrux Limited	Acrux Limited is an Australia-based specialty pharmaceutical company. The company is engaged in developing and commercialising a pipeline of topically applied pharmaceutical products.	9	0.022	0.088	0.022	-2.02	-1.09		6
ACW	Actinogen Medical Limited	Actinogen Medical Limited is an Australia-based biotechnology company. The company is engaged in the development of a therapy for neurological and neuropsychiatric diseases associated with dysregulated brain cortisol.	104.8	0.033	0.099	0.019726	-0.32	-10.31		
ADO	Anteotech Limited	AnteoTech Limited is an Australia-based company engaged in providing solutions for the clean energy and life sciences markets using applied materials technology. The principal activities of the company consist of development and commercialisation of nanotechnologies with surface management applications.	32.5	0.012	0.0366929	0.01	-0.38	-3.16		
ADR	Adherium Limited	Adherium Limited is a digital health company. The company provides integrated digital health solutions and connected respiratory medical devices.	6.8	0.009	0.0887685	0.009	-2.16	-0.42		
AFP	AFT Pharmaceuticals Limited	AFT Pharmaceuticals Limited is a New Zealand–based multinational pharmaceutical company. The company develops, markets, and distributes a portfolio of pharmaceutical products across a range of therapeutic categories, which are distributed across three pharmaceutical distribution channels: over the counter, prescription and hospital.	251.6	2.3	3.16	2.15	10.24	22.46		1
AGH	Althea Group Holdings Limited	Althea Group Holdings Limited is engaged in the manufacturing, sales and distribution of cannabis-based medicines and recreational cannabis products. The company operates through two business units: Althea and Peak Processing Solutions.	11.5	0.022	0.054	0.017	-4.13	-0.53		
AGN	Argenica Therapeutics Limited	Argenica Therapeutics Limited is an Australia-based biotechnology company, developing novel therapeutics to reduce brain tissue death after stroke and other types of brain injury and neurodegenerative diseases to improve patient outcomes. The company's lead neuroprotective peptide candidate, ARG-007, has been demonstrated to improve outcomes in preclinical stroke models, traumatic brain injury and hypoxic ischemic encephalopathy.	96.1	0.75	0.985	0.535	-4.82	-15.56		
АНХ	Apiam Animal Health Limited	Apiam Animal Health Limited is an Australia-based rural and regional veterinary group providing services to the companion animal and livestock industries, which includes dairy, beef, pig, sheep, and poultry. Its segments include dairy and mixed, feedlot and pigs.	70.8	0.385	0.56	0.325	0.08	481.25		1
ALA	Arovella Therapeutics Limited	Arovella Therapeutics Limited is a biotechnology company. The company is focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours.	81.9	0.077	0.21	0.071	-0.63	-12.22		

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ASX	Issuer Name	Principal Activity	Market Cap	Last Price	Year High	Year Low	EPS (cents)	PER	Net asset value per share	DIV (cents)
ALC	Alcidion Group Limited	Alcidion Group Limited is a health care technology company. The company's principal activities include the development and licensing of its own health care software products (Miya Precision and its associated modules, including Miya Observations, Flow, Task Management and PAS); the reselling of selected health care software products from its strategic partners; and the delivery of product implementation, product support and maintenance, systems integration, and data analysis services to health care customers in Australia, New Zealand, and the United Kingdom.	99.4	0.074	0.115	0.044	-0.37	-20		
ANN	Ansell Limited	Ansell Limited is an Australia-based company offering safety solutions. The company is an integrated manufacturer of personal protection equipment for health care and industrial workplaces.	4410.5	30.22	37.85	23.87	127.81	23.64	13.2	34.9
ANO	Advance ZincTek Limited	Advance ZincTek Limited is an Australia-based company, which manufactures aluminum oxide powder (Alusion), zinc oxide dispersions and zinc oxide powder (ZinClear) for the personal care sector.	47.5	0.76	0.82	0.72	-0.96	-79.17		6
ARX	Aroa Biosurgery Limited	Aroa Biosurgery Limited is a soft-tissue regeneration company. It develops, manufactures, sells, distributes medical and surgical products to improve healing in complex wounds and soft tissue reconstruction.	143.1	0.415	0.87	0.44	-2.01	-20.65		
AT1	Atomo Diagnostics Limited	Atomo Diagnostics Limited is an Australia-based medical device company. The company supplies integrated rapid diagnostic test devices to the global diagnostic market.	10.2	0.016	0.044	0.016	-1.01	-1.58		
ATH	Alterity Therapeutics Limited	Alterity Therapeutics Limited is an Australia-based clinical-stage biotechnology company. The company is focused on developing disease modifying treatments for neurodegenerative diseases.	53.3	0.008	0.008	0.002	-0.4	-2		
ATX	Amplia Therapeutics Limited	Amplia Therapeutics Limited is an Australia-based clinical-stage, drug development company. The company is focused on developing proprietary, orally available, small molecule focal adhesion kinase inhibitors as candidate drugs for the treatment of cancer and various fibrotic diseases.	23.3	0.06	0.176418	0.0539055	-2.85	-2.11		
AUA	Audeara Limited	Audeara Limited is a global hearing health company. The company specialises in listening solutions for people with hearing challenges.	5.6	0.031	0.0575	0.025	-1.46	-2.12		
AVE	Avecho Biotechnology Limited	Avecho Biotechnology Limited is an Australia-based biopharmaceutical company. The company develops and commercialises human and animal health products using its drug delivery system called Tocopheryl Phosphate Mixture.	15.8	0.005	0.009	0.001	-0.1	-5		
AVH	AVITA Medical Incorporated	AVITA Medical Incorporated is a commercial-stage regenerative medicine company.	327.2	2.39	5.62	2.34	-384.43	-0.62		
AVR	Anteris Technologies Global Corporation	Anteris Technologies Global Corporation is a structural heart company, which is engaged in providing cardiac care by science-driven and measurable advancements to restore heart valve patients to healthy function.	192	5.6	13.36	5.38	-605.91	-0.92		
AXE	Archer Materials Limited	Archer Materials Limited is a technology company, which operates within the semiconductor industry. It is engaged in developing advanced semiconductor devices, including chips relevant to quantum computing and medical diagnostics.	66.3	0.26	0.585	0.175	-2.51	-10.36		
AYA	Artrya Limited	Artrya Limited is a medical technology company focused on commercialising its artificial intelligence (AI) platform. The principal activities of the company are the development of medical technology using AI to identify patients at risk of coronary artery disease.	67.3	0.68	1.04	0.2	-18.17	-3.74		
BDX	BCAL Diagnostics Limited	BCAL Diagnostics Limited is an Australia-based screening and diagnostic company focused on early diagnosis of breast cancer. The company's core activity is the development of a novel blood screening test to improve the early diagnosis and monitoring of breast cancer, which is available to all women.	35.5	0.097	0.185	0.085	-2.65	-3.66		
BGT	Bio-Gene Technology Limited	Bio-Gene Technology Limited is an Australia-based agriculture technology development company enabling the next generation of novel insecticides derived from nature to achieve high impact globally. Its technology is based on compounds with a novel mode of action proven to overcome insecticide resistance with minimal impact on human health and the environment.	7.2	0.036	0.075	0.028	-1.19	-3.03		
BIO	Biome Australia Limited	Biome Australia Limited is an Australia-based microbiome health company. The company develops, licenses, commercialises and markets evidence-based live biotherapeutics (probiotics) and complementary medicines.	106.4	0.485	0.87	0.25	0.15	323.33		
BIT	Biotron Limited	Biotron Limited is an Australia-based biotechnology company. The company is primarily engaged in the funding and management of intermediate and applied biotechnology research and development projects.	6.3	0.0035	0.12	0.016	-0.15	-2.33		
BOT	Botanix Pharmaceuticals Limited	Botanix Pharmaceuticals Limited is an Australia-based dermatology company. The company is engaged in the development and commercialisation of treatments for common skin diseases and infections.	733.1	0.4	0.535	0.205	-2.24	-17.86		
BP8	BPH Global Limited	BPH Global Limited is a plant-focused biotechnology company. The company is focused on producing foods, health and cosmetic products, which deliver traditional Chinese medicine–based health outcomes.	2.4	0.004	0.01	0.002	0.27	1.48		
BXN	Bioxyne Limited	Bioxyne Limited is an Australia-based international consumer health and pharmaceutical company. The company is focused on health and wellness products, psychotropic and investigational medicines.	56.3	0.026	0.053	0.004	0.12	21.67		

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CAN	Cann Group Limited	Cann Group Limited is an Australia-based company that is focused on developing, producing and supplying innovative cannabis medicines.	15.1	0.027	0.1277235	0.023	-10.76	-0.25		
CBL	Control Bionics Limited	Control Bionics Limited is a medical device company assisting patients whose ability to communicate verbally or via text and social media is compromised by illnesses, such as motor neuron disease and amyotrophic lateral sclerosis. The company's products include Control Bionics Trilogy Systems, NeuroStrip, NeuroNode, Cosmos Connect and accessories.	15.6	0.053	0.105	0.034	-3.04	-1.74		
CDX	CardieX Limited	CardieX Limited is an Australia-based digital health technology company. The Company develops and markets noninvasive patient monitoring technologies for assessing cardiovascular health.	27.2	0.067	0.175	0.045	-6.76	-0.99		
CGS	CogState Limited	Cogstate Limited is a neuroscience technology company optimising brain health assessments to advance the development of new medicines and to enable earlier clinical insights in health care. Its principal activities are the creation, validation, and commercialisation of digital brain health assessments; and design and provision of quality assurance services in clinical trials, focused on the administration, scoring, and recording of conventional brain health assessments.	239	1.39	1.44	0.795	6.74	20.62		
СНМ	Chimeric Therapeutics Limited	Chimeric Therapeutics Limited is an Australia-based clinical-stage cell therapy company. The company is focused on the discovery, development, and commercialisation of cell therapies for patients with cancer.	9.1	0.004	0.043	0.006	-2.52	-0.16		
CLV	Clover Corporation Limited	Clover Corporation Limited is focused on technology, new product development and commercialisation. The principal activities of the company are the refining and sale of natural oils, the production of encapsulated powders, and the research and product development of functional food and infant nutrition ingredients.	86.8	0.52	0.595	0.3375	2.71	19.19		0.8
СМВ	Cambium Bio Limited	Cambium Bio Limited, formerly Regeneus Limited, is an Australia-based clinical- stage regenerative medicine company focusing on the development of biologics for ophthalmology and tissue repair applications.	5.1	0.28	1.6	0.3	-28.08	-1		
СМР	Compumedics Limited	Compumedics Limited is a medical device company, which is involved in the development, manufacture, and commercialisation of diagnostics technology for sleep, brain, and ultrasonic blood flow monitoring applications. Its geographic segments include the Americas, Australia and the Asia Pacific, and Europe and the Middle East.	59.6	0.31	0.365	0.22	-1.7	-18.24		
сон	Cochlear Limited	Cochlear Limited provides implantable hearing solutions, and a range of implants and sound processor upgrades. Its segments include cochlear implants, services and acoustics.	17068.6	261	350.31	255.69	565.88	46.12	28.1	215
CSL	CSL Limited	CSL Limited is an Australia-based biotechnology company. The company's areas of focus include rare and serious diseases, influenza vaccines, and iron deficiency and nephrology.	122650.9	253.3	313.55	265.14	917.29	27.61	40.1	207.1
CSX	Cleanspace Holdings Limited	CleanSpace Holdings Limited is an Australia-based designer and manufacturer of respiratory protection equipment for industrial and health care solutions. The company's product offerings include CleanSpace HALO, CleanSpace WORK, CleanSpace CST PRO, CleanSpace CST ULTRA, and CleanSpace EX.	34	0.435	0.635	0.22	-1.91	-22.77		
CT1	Constellation Technologies Limited	Constellation Technologies Limited is an Australia-based Internet of things (IoT) and digital solutions company. The company is focused on offering solutions to market, which leverage cloud, IoT, edge-computing sensors, big data, analytics, machine learning, artificial intelligence and other advanced technologies.	2.9	0.002	0.003	0.001	0.01	20		
CTE	Cryosite Limited	Cryosite Limited is engaged in providing outsourced clinical trials depot services. The company manages the entire clinical trial supply chain from importation, receipt, specialised ambient, cold, frozen, and liquid nitrogen storage for temperature-sensitive products, distribution and reverse logistics management.	39	0.8	1.25	0.64	3.76	21.28		2
CU6	Clarity Pharmaceuticals Limited	Clarity Pharmaceuticals Limited is an Australia-based clinical-stage radiopharmaceutical company. The company is focused on developing theranostic (therapy and imaging) products, based on its platform SAR Technology.	539.9	1.68	8.975	1.68	-16.3	-10.31		
CUV	Clinuvel Pharmaceuticals Limited	Clinuvel Pharmaceuticals Limited is an Australia-based global specialty pharmaceutical company. The company is focused on developing and commercialising treatments for patients with genetic, metabolic, systemic, and life-threatening, acute disorders, as well as health care solutions for specialised populations.	527.6	10.54	17.71	11.85	77.5	13.6		5
CYC	Cyclopharm Limited	Cyclopharm Limited is an Australia-based radiopharmaceutical company. The company's principal activity is engaged in the manufacture and sale of medical equipment and radiopharmaceuticals, including associated research and development and distribution of third-party products to the diagnostic imaging sector.	131.1	1.18	2.5	1.1	-12.83	-9.2		0.5
СҮР	Cynata Therapeutics Limited	Cynata Therapeutics Limited is an Australia-based clinical-stage stem cell and regenerative medicine company. The company is focused on the development of therapies based on Cymerus, which is a therapeutic stem cell platform technology.	37.3	0.165	0.345	0.11	-4.87	-3.39		
DVL	dorsaVi Limited	dorsaVi Limited is an Australia-based company focused on developing motion analysis device technologies for use in clinical applications, elite sports, and occupational health and safety. Its segments include clinical and workplace.	5.1	0.007	0.021	0.006	-0.2	-3.5		

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ASX	lssuer Name	Principal Activity	Market Cap	Last Price	Year High	Year Low	EPS (cents)	PER	Net asset value per share	DIV (cents)
DXB	Dimerix Limited	Dimerix Limited is an Australia-based clinical-stage biopharmaceutical company. The company is focused on developing lives of patients with inflammatory diseases, including both kidney and respiratory diseases.	234.9	0.42	0.665	0.16	-4.45	-9.44		
EBO	EBOS Group Limited	EBOS Group Limited is a marketer, wholesaler and distributor of health care, medical and pharmaceutical products. The company is a marketer and distributor of animal care brands.	7051	35.69	38.09	28.75	127.2	28.06		45.9
EBR	EBR Systems Incorporated	EBR Systems Incorporated is engaged in the treatment of patients suffering from cardiac rhythm diseases by providing physiological stimulation through endocardial pacing.	559.3	1.5	2.08	0.82	-20.91	-7.17		
ECS	ECS Botanics Holdings Limited	ECS Botanics Holdings Limited is an Australia-based medicinal cannabis cultivator and manufacturer located in north-west Victoria. The company utilises progressive and cultivation methodologies to produce medicine in a sustainable way, adopting regenerative and organic horticultural practices and renewable energy sources.	16.2	0.0125	0.023	0.012	-0.09	-13.89		
EMD	Emyria Limited	Emyria Limited is an Australia-based early-stage drug development company. The company is focused on delivering and developing treatments for mental health and select neurological conditions, guided by real-world data collected with patients across its wholly owned clinical service subsidiaries.	13.3	0.027	0.067	0.024	-0.18	-15		
EMV	EMvision Medical Devices Limited	EMVision Medical Devices Limited is an Australian medical device company. The company is focused on the development and commercialisation of neurodiagnostic technology for stroke diagnosis and monitoring, as well as other medical imaging needs.	160.8	1.88	2.54	1.705	-7.43	-25.3		
EOF	Ecofibre Limited	Ecofibre Limited is an advanced manufacturing and technology business focused on sustainable polymers and natural materials, natural health care, and hemp seed genetics. It also owns interest in a life sciences business that is developing treatments for malignant and non-malignant gynecological diseases.	6.4	0.017	0.087	0.017	-2.86	-0.59		
EYE	Nova Eye Medical Limited	Nova Eye Medical Limited is an Australia-based medical technology company that develops, manufactures, and sells a portfolio of proprietary ophthalmic treatment technologies and devices. The company operates through three segments, including AlphaRET and Glaucoma surgical devices.	27.3	0.096	0.3	0.092	-3.71	-2.59		13.5
FGH	Foresta Group Holdings Limited	Foresta Group Holdings Limited is an Australia-based company engaged in manufacturing of natural and renewable pine chemicals and biomass pellets. The company has developed a proprietary process to naturally extract pine chemicals by employing the tree's own solvent chemicals to extract rosin and terpenes.	23.9	0.009	0.015	0.003	-0.46	-1.96		
FPH	Fisher & Paykel Healthcare Corporation Limited	Fisher & Paykel Healthcare Corporation Limited designs, manufactures, and markets products and systems for use in acute and chronic respiratory care, surgery, and the treatment of obstructive sleep apnoea. The company provides medical device products and systems for use in both hospital and home care settings.	18772.8	31.38	35.76	22.94	27.79	112.92	3	16.8
FRE	Firebrick Pharma Limited	Firebrick Pharma Limited is an Australia-based pharmaceutical company. The principal activity for the company is the clinical development and partnering of Nasodine, a broad-spectrum antimicrobial spray for the treatment of the common cold.	19.5	0.087	0.11	0.045	-0.87	-10		
GLH	Global Health Limited	Global Health Limited is an Australia-based provider of digital health solutions to the Australian health care industry. The company helps streamline the delivery of health care services and provide health outcomes across various health sectors, including acute and community settings.	6.7	0.115	0.16	0.09	-1.49	-7.72		1
GSS	Genetic Signatures Limited	Genetic Signatures Limited is an Australia-based specialist molecular diagnostics (MDx) company. The company's principal activities include research and commercialisation of identifying individual genetic signatures to identify diseases and the sale of associated products into the diagnostic and research marketplaces.	112.4	0.495	0.85	0.475	-10.4	-4.76		
нст	Holista CollTech Limited	Holista CollTech Limited is a research-driven biotech company. The company is focused on researching, developing, manufacturing and marketing health- style products.	9.1	0.032	0.035	0.004	-0.03	-106.67		
HIQ	HitiQ Limited	HITIQ Limited is an evidenced-based brain care solution company deploying technologies. It operates in the health care equipment sector, providing and further developing a transformative, end-to-end concussion management technology platform.	11	0.03	0.05	0.012	-1.1	-2.73		
HMD	Hera Med Limited	Hera Med Limited is an Israel-based company that develops pregnancy monitoring solutions for home and professional use. It offers hardware solutions supported by software applications.	14	0.016	0.031	0.013	-1.03	-1.55		
HYD	Hydrix Limited	Hydrix Limited is an Australia-based specialist product designing, engineering and medical device distribution company. The company is engaged in the development of comprehensive products.	4.9	0.018	0.032	0.01	-2.5	-0.72		
IBX	Imagion Biosystems Limited	Imagion Biosystems Limited is a medical imaging company engaged in developing medical imaging technologies for various cancer types. The company uses bio-safe magnetic nanoparticles to detect cancer and other diseases.	2.8	0.014	0.097	0.014	-4.6	-0.3		
IDT	IDT Australia Limited	IDT Australia Limited is a pharmaceutical manufacturing company. The company is engaged in the supply of products and provision of research and development and other technical services within the pharmaceutical and allied industries.	39.5	0.092	0.145	0.074998	-1.19	-7.73		

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IIQ	INOVIQ Limited	INOVIQ Limited is an Australia-based biotechnology company developing diagnostics and therapeutics for cancer. The company's commercialised products include EXO-NET exosome isolation technology for biomarker discovery and diagnostics development, and the hTERT test as an adjunct test for bladder cancer.	46.3	0.415	0.8	0.345	-6.99	-5.94		
ILA	Island Pharmaceuticals Limited	Island Pharmaceuticals Limited is an Australia-based drug repurposing company. The company is focused on areas of unmet need for antiviral therapeutics to address infectious diseases.	35.7	0.17	0.28	0.05	-2.82	-6.03		
IMC	Immuron Limited	Immuron Limited is an Australia-based biopharmaceutical company focused on developing and commercialising orally delivered targeted polyclonal antibodies for the treatment of infectious diseases. It operates through two segments: research and development, and hyperimmune products.	14.7	0.063	0.17	0.065	-3.22	-1.96		
IMM	Immutep Limited	Immutep Limited is an Australia-based clinical-stage biotechnology company. The company is focused on developing Lymphocyte Activation Gene (LAG)-3 immunotherapies for cancer and autoimmune diseases.	371.2	0.255	0.480538	0.23	-3.31	-7.7	0.1	
IMU	Imugene Limited	Imugene Limited is a clinical-stage immune-oncology company. It is engaged in developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours.	194.1	0.026	0.13	0.035	-1.76	-1.48		
IPD	ImpediMed Limited	ImpediMed Limited is an Australia-based medical technology company. The company uses bioimpedance spectroscopy technology to generate data to maximise patient health.	80	0.0395	0.105	0.039	-1.05	-3.76		
IRX	Inhalerx Limited	InhaleRx Limited is an Australia-based health care company. The company is focused on developing medicinal drug-device products to address unmet medical needs in the pain management and mental health sectors.	5.3	0.025	0.05	0.02	-0.6	-4.17		
IVX	Invion Limited	Invion Limited is an Australia-based life science company. The company is engaged in the research and development of Photosoft technology for the treatment of a range of cancers, atherosclerosis and infectious diseases.	8.1	0.105	0.6	0.1	-10.66	-0.98		
IXC	Invex Therapeutics Limited	Invex Therapeutics Limited is an Australia-based biopharmaceutical company. The company is focused on focused on the repurposing of an already approved drug, Exenatide, for efficacious treatment of neurological conditions derived from or involving raised intracranial pressure, including traumatic brain injury, stroke and hydrocephalus.	5.1	0.068	0.09	0.059	0.16	42.5		
LDX	Lumos Diagnostics Holdings Limited	Lumos Diagnostics Holdings Limited is an Australia-based company that specialises in point-of-care (POC) diagnostic test technology to help health care professionals diagnose and manage medical conditions. The company offers customised assay development and manufacturing services for POC tests and digital reader platforms.	17.2	0.023	0.0647427	0.02	-1.43	-1.61		
LGP	Little Green Pharma Limited	Little Green Pharma Limited is a global, vertically integrated and geographically diverse medicinal cannabis business with operations from cultivation and production, through to manufacturing and distribution.	36.4	0.12	0.165	0.076	-3.14	-3.82		
M7T	Mach7 Technologies Limited	Mach7 Technologies Limited is an Australia-based medical imaging systems provider. The principal activity of the company is the development and commercialisation of medical imaging and data management software solutions for global health care enterprises.	77.2	0.32	0.745	0.305	-2.2	-14.55		
MAP	Microba Life Sciences Limited	Microba Life Sciences Limited is an Australia-based precision microbiome company. The company is engaged in the discovery and development of therapeutics for major chronic diseases and delivering gut microbiome testing services globally to researchers, clinicians, and consumers.	80.6	0.18	0.325	0.145	-3.05	-5.9		
MEM	Memphasys Limited	Memphasys Limited is an Australia-based reproductive biotechnology company. The company is engaged in developing medical devices, diagnostics, and media with application to assisted reproductive technology in humans and animals.	14.2	0.008	0.012	0.004	-0.14	-5.71		
MSB	Mesoblast Limited	Mesoblast Limited is an Australia-based company, which is engaged in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. It has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates.	2242.5	1.765	2.025	0.255	-14.62	-12.07		
MVF	Monash IVF Group Limited	Monash IVF Group Limited is an Australia-based company, which is primarily involved in assisted reproductive services. The company is also a provider of specialist women's imaging services.	411.1	1.055	1.53	1.04	-0.6	-175.83		2.6
MVP	Medical Developments International Limited	Medical Developments International Limited is an Australia-based company that delivers emergency medical solutions dedicated to improving patient outcomes in both domestic and international markets. The company operates in two segments: pain management and respiratory.	58.6	0.52	0.94	0.3652875	-34.54	-1.51		2
MX1	Micro-X Limited	Micro-X Limited is an Australia-based company engaged in developing and commercialising a range of products for global health and security markets, based on cold cathode, carbon nanotube emitter technology.	37.9	0.057	0.128791	0.049535	-1.86	-3.06		
MYX	Mayne Pharma Group Limited	Mayne Pharma Group Limited is an Australia-based specialty pharmaceutical company focused on commercialising novel pharmaceuticals. The company also provides contract development and manufacturing services to clients worldwide.	585.8	7.21	7.46	3.74	-155.64	-4.63		
NAN	Nanosonics Limited	Nanosonics Limited is an Australia-based infection prevention company. The company's principal activities include the manufacturing and distribution of the trophon ultrasound probe disinfector and its associated consumables and accessories.	1408.7	4.64	5.18	2.62	5.47	84.83		

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NC6	Nanollose Limited	Nanollose Limited is an Australia-based biomaterials company. The company is engaged in commercialising scalable technology to create fibres, fabrics, and other novel materials with minimal environmental impact.	9.5	0.041	0.032	0.016	-0.82	-5		
NEU	Neuren Pharmaceuticals Limited	Neuren Pharmaceuticals Limited is an Australia-based biopharmaceutical company developing therapies for neurodevelopmental disorders. The company is developing new drug therapies to treat multiple serious neurological disorders that emerge in early childhood and have no or limited approved treatment options.	1242.8	9.86	24	9.78	111.17	8.87		
NGS	Nutritional Growth Solutions Limited	Nutritional Growth Solutions Limited is an Israel-based company. The main acitivity of the company is developing of evidence-based, clinically tested nutritional solutions for children.	4.3	0.032	0.08	0.02	-0.06	-53.33		
NOU	Noumi Limited	Noumi Limited is an Australian fast-moving consumer goods company. The company produces dairy and plant-based beverages, nutritional products and ingredients that are used in the health and fitness industries.	40.2	0.145	0.31	0.105	-55.12	-0.26		3.3
NOX	Noxopharm Limited	Noxopharm Limited is a biotech company. It is engaged in discovering and developing novel treatments for cancer and inflammation, including a pioneering technology to enhance messenger ribonucleic acid (mRNA) vaccines.	20.5	0.07	0.15	0.051	-0.79	-8.86		
NSB	NeuroScientific Biopharmaceuticals Limited	NeuroScientific Biopharmaceuticals Limited is an Australia-based company that is engaged in developing peptide-based pharmaceutical drugs that target a number of neurodegenerative conditions with high unmet medical demand.	5.2	0.036	0.078	0.033	0.82	4.39		
NTI	Neurotech International Limited	Neurotech International Limited is an Australia-based clinical-stage biopharmaceutical development company. The company is focused predominately on pediatric neurological disorders with a broad-spectrum oral cannabinoid drug therapy called NTI164.	31.5	0.03	0.12	0.028	-1.21	-2.48		
NUF	Nufarm Limited	Nufarm Limited is an Australia-based crop protection and seed technology company. The company is engaged in developing and manufacturing crop protection solutions and Beyond Yield seed technologies.	1455.3	3.8	5.445	3.47	-1.47	-258.5		4
NXS	Next Science Limited	Next Science Limited is an Australia-based medical technology company. The company's primary focus is on the development and commercialisation of its proprietary XBIO technology to reduce the impact of biofilm-based infections on human health.	29.2	0.1	0.5	0.081	-5.84	-1.71		
NYR	Nyrada Incorporated	Nyrada Incorporated is a biotechnology company focused on the discovery and development of small-molecule therapies, specifically targeting Transient Receptor Potential Canonical ion channels.	19.7	0.0935	0.155	0.032	-2.23	-4.19		
occ	Orthocell Ltd	Orthocell Limited is an Australia-based regenerative medicine company. The company is focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries.	340	1.405	1.27	0.35	-1.6	-87.81		
OIL	Optiscan Imaging Limited	Optiscan Imaging Limited is an Australia-based company, which is engaged in the development, manufacturing and commercialisation of confocal endomicroscopic imaging technologies for medical, translational and preclinical applications. The company's technology enables real-time, non-destructive, three-dimensional, in-vivo imaging at the single-cell level.	108.6	0.13	0.26	0.08	-0.59	-22.03		
ONE	Oneview Healthcare PLC	Oneview Healthcare PLC is a health care technology company. The company provides digital tools for patients, families, and caregivers.	186.7	0.245	0.425	0.24	-2.65	-9.25		
OPL	Opyl Limited	Opyl Limited is an Australia-based artificial intelligence company. The company leverages data and technology to transform the landscape of clinical trials and medical research.	6	0.031	0.033	0.014	-1.16	-2.67		
OPT	Opthea Limited	Opthea Limited is an Australia-based clinical-stage biopharmaceutical company. The company is engaged in developing novel therapies to address the unmet need in the treatment of prevalent and progressive retinal diseases, including wet age-related macular degeneration and diabetic macular edema.	738.8	0.6	0.955	0.335	-45.77	-1.31		
OSL	Oncosil Medical Limited	OncoSil Medical Limited is an Australia-based medical device company focused on localised treatments for patients with unresectable locally advanced pancreatic cancer. The company is focused on the development and commercialisation of its lead product candidate, the OncoSil localised radiation therapy for the treatment of pancreatic and distal cholangiocarcinoma.	18.4	0.004	0.015	0.004	-0.43	-0.93		
PAB	Patrys Limited	Patrys Limited is focused on the development of its deoxymab platform of cell-penetrating antibodies as therapies for a range of different cancers. The company's deoxymab platform is based on the deoxymab 3E10 antibody that is identified as an autoantibody in a mouse model of the human disease systemic lupus erythematosus.	4.1	0.002	0.01	0.003	-0.15	-1.33		
PAR	Paradigm Biopharmaceuticals Limited	Paradigm Biopharmaceuticals Limited is a late-stage drug development company. The company is engaged in discovering, developing, and delivering pharmaceutical therapies.	116.8	0.3	0.61	0.165	-5.34	-5.62		
PCK	PainChek Limited	PainChek Limited is an Australia-based company, which develops pain assessment technologies. The company's principal activities are development and commercialisation of mobile medical device applications that provide pain assessment for individuals that are unable to communicate with their carers.	60.8	0.033	0.043186	0.024	-0.53	-6.23		
PEB	Pacific Edge Limited	Pacific Edge Limited is a global cancer diagnostics company. The company is engaged in the development and commercialisation of bladder cancer diagnostic and prognostic tests for patients presenting with hematuria or surveillance of recurrent disease.	102.3	0.125	0.18	0.07	-3.19	-3.92		

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PER	Percheron Therapeutics Limited	Percheron Therapeutics Limited, formerly Antisense Therapeutics Limited, is a biotechnology company. The company is engaged in developing and commercialising antisense pharmaceuticals for large unmet markets in rare diseases.	12	0.011	0.14	0.005	-1.61	-0.68		
PGC	Paragon Care Limited	Paragon Care Limited is an Australia-based company, which is engaged in the health care sector. The company is a provider of medical equipment, devices, pharmaceuticals, and consumables to the health care markets in Australia, New Zealand and Asia.	662.1	0.4	0.59	0.31	1.25	32		0.6
PIQ	Proteomics International Laboratories Limited	Proteomics International Laboratories Limited is an Australia-based medical technology company. The company is engaged in predictive diagnostics and bioanalytical services.	55	0.42	1.295	0.42	-5.51	-7.62		
PME	Pro Medicus Limited	Pro Medicus Limited is an Australia-based health care informatics company. The company provides a full range of medical imaging software and services to hospitals, imaging centres and health care groups in Australia, North America and Europe.	19824.4	189.77	298.98	98.81	94.12	201.63	1.8	25
PNV	Polynovo Limited	PolyNovo Limited is an Australia-based medical device company, which is focused on advanced wound care that designs, develops and manufactures dermal regeneration solutions using its patented NovoSorb biodegradable polymer technology. Its solutions include NovoSorb Biodegradable Temporizing Matrix and NovoSorb MTX.	725.4	1.05	2.78	1.05	0.85	123.53		
PTX	Prescient Therapeutics Limited	Prescient Therapeutics Limited is an Australia-based clinical-stage oncology company. The company is developing personalised medicine approaches to cancer, including targeted and cellular therapies.	34.6	0.043	0.068	0.037	-0.87	-4.94		
PYC	PYC Therapeutics Limited	PYC Therapeutics Limited is an Australia-based clinical-stage biotechnology company creating a new generation of ribonucleic acid (RNA) therapies to change the lives of patients with genetic diseases. The company utilises its proprietary drug delivery platform to enhance the potency of precision medicines within the rapidly growing and commercially proven RNA therapeutic class.	600.5	1.09	2.1	0.721386	-11.08	-9.84		
RAC	Race Oncology Limited	Race Oncology Limited is an Australia-based clinical-stage biopharmaceutical company. The company is focused on improving the lives of cancer patients around the world by developing a novel approach to both treating the cancer and protecting the heart.	198	1.14	2.09	0.64	-4.65	-24.52		
RAD	Radiopharm Theranostics Limited	Radiopharm Theranostics Limited is an Australia-based clinical-stage radiotherapeutics company developing a platform of radiopharmaceutical products for diagnostic and therapeutic applications in areas of high unmet medical need.	53.7	0.023	0.1	0.023	-6.22	-0.37		
RCE	Recce Pharmaceuticals Limited	Recce Pharmaceuticals Limited is an Australia-based company engaged in the development and commercialisation of a new class of synthetic anti-infectives designed to address the urgent global health problems of antibiotic-resistant superbugs and emerging viral pathogens.	82.3	0.355	0.695	0.31	-9.19	-3.86		
RGT	Argent Biopharma Limited	Argent BioPharma Limited, formerly MGC Pharmaceuticals Limited, is an Australia-based drug discovery company. The company is focused on developing and supplying accessible and ethically produced plant-derived medicines, combining in-house research with technologies.	11.9	0.2	0.57	0.12	-40.72	-0.49		
RHT	Resonance Health Limited	Resonance Health Limited is an Australia-based health care technology and services company engaged in the development and commercialisation of software-as-medical-device technologies and services for the quantitative analysis of radiological images in a regulated and quality-controlled environment.	17	0.037	0.088	0.036	-0.07	-52.86		
RHY	Rhythm Biosciences Limited	Rhythm Biosciences Limited is an Australia-based medical diagnostics company. The company is engaged in delivering simple, affordable blood tests for accurate and early detection of cancers.	22.7	0.08	0.14	0.042	-0.92	-8.7		
RMD	Resmed Incorporated	The company, through its subsidiaries, is in the development, manufacturing, distribution and marketing of medical devices and cloud-based software applications that diagnose, treat and manage respiratory disorders, including sleep disordered breathing.	49880.4	33.86	40.75	27.05	781.21	4.33	33.1	5.8
RSH	Respiri Limited	Respiri Limited is an Australia-based e-health software-as-a-service company that supports respiratory health management and remote patient monitoring. It is engaged in research, development and commercialisation of medical devices, and the development of mobile health applications.	53.6	0.034	0.1	0.021	-0.68	-5		
SDI	SDI Limited	SDI Limited is an Australia-based dental technology company that is involved in the research and development, manufacturing, and marketing of specialist dental materials. The principal activities of the company include manufacture and distribution of dental restorative materials, tooth whitening systems, other dental materials, and product research and development.	99.8	0.84	1.25	0.7425	8.88	9.46		1.5
SDV	SciDev Limited	SciDev Limited is an Australia-based environmental solutions company that is focused on water-intensive industries. The company's primary business segment is the treatment of industrial waste.	81.7	0.43	0.66	0.22	1.08	39.81		
SHG	Singular Health Group Limited	Singular Health Group Limited is an Australia-based medical technology company. The company is focused on helping practitioners and patients via personalised surgical planning solutions that drive health outcomes.	59.8	0.225	0.3	0.074	-3.55	-6.34		
SHL	Sonic Healthcare Limited	Sonic Healthcare Limited is an Australia-based health care provider. The company is engaged in laboratory medicine/pathology, radiology, and primary care medical services, across operations in Australia, Europe, and North America.	12778.7	26.6	29.35	23.58	113.9	23.35	16.8	44

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SNT	Syntara Limited	Syntara Limited is an Australia-based clinical-stage drug development company. The company is targeting extracellular matrix dysfunction with its amine oxidase chemistry and other technologies to develop novel medicines for blood cancers and conditions linked to inflammation and fibrosis.	91	0.056	0.095	0.014	-0.93	-6.02		
SOM	Somnomed Limited	SomnoMed Limited is an Australia-based company engaged in producing and selling devices for the oral treatment of sleep-related disorders. It provides treatment solutions for sleep-related breathing disorders, including obstructive sleep apnoea, snoring, and bruxism.	114.5	0.53	0.695	0.19	-3.4	-15.59		
SPL	Starpharma Holdings Limited	Starpharma Holdings Limited is an Australia-based biotechnology company. The principal activities of the company consist of research, development and commercialisation of dendrimer products for pharmaceutical and health care applications.	39.7	0.095	0.15	0.086	-3.05	-3.11		
TD1	Tali Digital Limited	Tali Digital Limited is a digital health company. The company is focused on delivering diagnostic and therapeutic solutions to enhance attention and overall cognitive function.	3.3	0.001	0.002	0.001	-0.01	-10		
TLX	Telix Pharmaceuticals Limited	Telix Pharmaceuticals Limited is an Australia-based biopharmaceutical company focused on the development and commercialisation of therapeutic and diagnostic radiopharmaceuticals and associated medical devices. It develops a portfolio of clinical- and commercial-stage products that addresses significant unmet medical needs in oncology and rare diseases.	7984.1	23.63	25.8	9.13	14.46	163.42	1.7	
TRI	TrivarX Limited	TrivarX Limited, formerly Medibio Limited, is an Australia-based mental health technology company engaged in the use of objective measures to aid in the early detection and screening of mental health conditions. Through the company's corporate health product, it offers mental wellbeing solutions for businesses and is also developing products to serve the health care provider market.	6.8	0.012	0.045	0.011	-0.04	-30		
TRJ	Trajan Group Holdings Limited	Trajan Group Holdings Limited is an Australia-based global developer and manufacturer of analytical and life sciences products and devices. The company's products and solutions are used in the analysis of biological, food, and environmental samples.	118.1	0.775	1.31	0.675	-18.67	-4.15		
TRP	Tissue Repair Limited	Tissue Repair Limited is an Australia-based Phase 3 advanced biotechnology company developing second generation wound healing agents.	14.8	0.245	0.5	0.185	-7.04	-3.48		
TRU	Truscreen Group Limited	Truscreen Group Limited is a New Zealand-based medical device company. The company is engaged in the development of an artificial intelligence-enabled device that can detect precancerous and cancerous cervical changes in real-time via optical and electrical measurements of cervical tissue.	16	0.026	0.033	0.013	-0.35	-7.43		
UBI	Universal Biosensors Incorporated	Universal Biosensors Incorporated is a biosensor company.	19.4	0.065	0.205	0.065	-5.27	-1.23		
UCM	Uscom Limited	Uscom Limited is a medical technology company. It specialises in the development and marketing of non-invasive cardiovascular and pulmonary medical devices.	6.8	0.027	0.045	0.011	-1.4	-1.93		
VBS	Vectus Biosystems Limited	Vectus Biosystems Limited is an Australia-based drug discovery and development company. The company focuses on medical research and development.	4	0.076	0.32	0.076	-3.85	-1.97		
VIT	Vitura Health Limited	Vitura Health Limited is engaged in a diversified digital health business. The company, through its subsidiaries, operates businesses, including Burleigh Heads Cannabis, Canview, Doctors on Demand, Cortexa, CDA Clinics, and Cannadoc.	45	0.068	0.19	0.0665	0.33	20.61		1
VLS	Vita Life Sciences Limited	Vita Life Sciences Limited (Vita Life) is a pharmaceutical and health care company. The company is involved in formulating, packaging, sales and distributing vitamins and supplements.	102.6	1.85	2.46	1.62	15.97	11.58		6.5
WNX	Wellnex Life Limited	Wellnex Life Limited is an Australia-based company, which is engaged in the consumer health care business. The company is developing, licensing, and marketing registered products and brands to customers in the health care market segment.	23.5	0.35	1.45008	0.32	-18.14	-1.93		
WOA	Wide Open Agriculture Limited	Wide Open Agriculture Limited is an Australia-based ingredient company focusing on the next generation of plant protein ingredients for food and drink manufacturers globally. The principal activities of the company include the sale of regenerative food and beverage products, and the commercialisation of lupin protein isolate.	10.1	0.019	0.125	0.004	-5	-0.38		
XRF	XRF Scientific Limited	XRF Scientific Limited is an Australia-based company, which manufactures and sells chemicals, equipment and accessories to production mines, construction material companies and commercial analytical laboratories, in Australia and overseas. These finished goods are primarily used in the preparation of samples for analysis.	234.7	1.67	2.17	1.17	6.7	24.93		3.9
ZLD	Zelira Therapeutics Limited	Zelira Therapeutics Limited is an Australia-based biopharmaceutical company. The company is engaged in the research, development and commercialisation of clinically validated cannabinoid-based medicines.	5.7	0.48	1.09	0.28	-41.68	-1.15		
ANR	Anatara Lifesciences Limited	Anatara Lifesciences Limited is an Australia-based life sciences company. The company is engaged in developing evidence-based solutions for gastrointestinal diseases in humans and animals.	1.7	0.008	0.073	0.021	-1.02	-0.78		

Data current at 7 April 2025. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Evans and Partners Pty Ltd and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.

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# This quarter's top ASX healthcare sector performers

ASX Code	Company Name	<b>Closing Price</b>	Quarter Return %	ASX Code	Company Name	Closing
WOA.AX	Wide Open Agriculture Limited	\$0.02	171.4%	OCC	Orthocell Limited	\$1.41
NC6.AX	Nanollose Limited	\$0.04	110.9%	НСТ	Holista CollTech Limited	\$0.03
HCT.AX	Holista CollTech Limited	\$0.03	77.8%	BXN	Bioxyne Limited	\$0.03
AVE.AX	Avecho Biotechnology Limited	\$0.01	66.7%	SNT	Syntara Limited	\$0.06
HYD.AX	Hydrix Limited	\$0.02	63.6%	ILA	Island Pharmaceuticals Limited	\$0.17
OPL.AX	Opyl Limited	\$0.03	63.2%	MSB	Mesoblast Limited	\$1.77
NAN.AX	Nanosonics Limited	\$4.64	55.7%	CT1	Constellation Technologies Limited	\$0.00
MYX.AX	Mayne Pharma Group Limited	\$7.21	55.4%	SHG	Singular Health Group Limited	\$0.23
FRE.AX	Firebrick Pharma Limited	\$0.09	40.3%	TLX	Telix Pharmaceuticals Limited	\$23.63
BP8.AX	BPH Global Limited	\$0.00	33.3%	SDV	SciDev Limited	\$0.43
TRU.AX	Truscreen Group Limited	\$0.03	30.0%	PME	Pro Medicus Limited	\$189.77
CGS.AX	CogState Limited	\$1.39	26.9%	AYA	Artrya Limited	\$0.68
CLV.AX	Clover Corporation Limited	\$0.52	25.3%	SOM	Somnomed Limited	\$0.53
ALC.AX	Alcidion Group Limited	\$0.07	23.3%	NC6	Nanollose Limited	\$0.04
MVP.AX	Medical Developments International Limited	\$0.52	22.4%	NAN	Nanosonics Limited	\$4.64
ACW.AX	Actinogen Medical Limited	\$0.03	22.2%	BOT	Botanix Pharmaceuticals Limited	\$0.40
PER.AX	Percheron Therapeutics Limited	\$0.01	22.2%	EBR	EBR Systems Incorporated	\$1.50
PCK.AX	PainChek Limited	\$0.03	22.2%	ALC	Alcidion Group Limited	\$0.07
AGN.AX	Argenica Therapeutics Limited	\$0.75	20.0%	PEB	Pacific Edge Limited	\$0.13
RGT.AX	Argent Biopharma Limited	\$0.20	17.6%	ATH	Alterity Therapeutics Limited	\$0.01
DXB.AX	Dimerix Limited	\$0.42	16.7%	FRE	Firebrick Pharma Limited	\$0.09
CMP.AX	Compumedics Limited	\$0.31	14.8%	DXB	Dimerix Limited	\$0.42
SOM.AX	Somnomed Limited	\$0.53	10.4%	XRF	XRF Scientific Limited	\$1.67
EBR.AX	EBR Systems Incorporated	\$1.50	9.9%	OIL	Optiscan Imaging Limited	\$0.13
AYA.AX	Artrya Limited	\$0.68	9.7%	BIO	Biome Australia Limited	\$0.49
NSB.AX	NeuroScientific Biopharmaceuticals Limited	\$0.04	9.1%	CSX	Cleanspace Holdings Limited	\$0.44
EBO.AX	EBOS Group Limited	\$35.69	7.4%	FPH	Fisher & Paykel Healthcare Corporation Limited	\$31.38
NUF.AX	Nufarm Limited	\$3.80	5.0%	CBL	Control Bionics Limited	\$0.05
BXN.AX	Bioxyne Limited	\$0.03	4.0%	ANN	Ansell Limited	\$30.22
NYR.AX	Nyrada Incorporated	\$0.09	0.5%	AVE	Avecho Biotechnology Limited	\$0.01

This year's top ASX healthcare

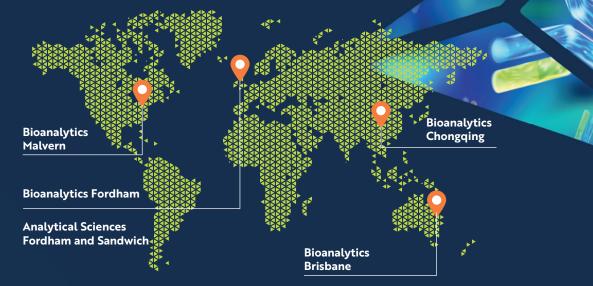
238.6% 220.0% 188.9% 180.0% 169.8% 104.0% 100.0% 95.7% 89.6% 87.0% 81.2% 78.9% 77.9% 75.7% 73.8% 70.2% 64.3% 60.9% 60.3% 60.0% 55.4% 52.7% 44.1% 41.3% 36.6% 35.9% 34.3% 32.5% 29.1% 25.0%

sector performers

Data current at 7 April 2025. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Evans and Partners Proprietary Limited and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.

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