

Australasian BioTechnology

The journal of
AusBiotech

Where life science leaders thrive



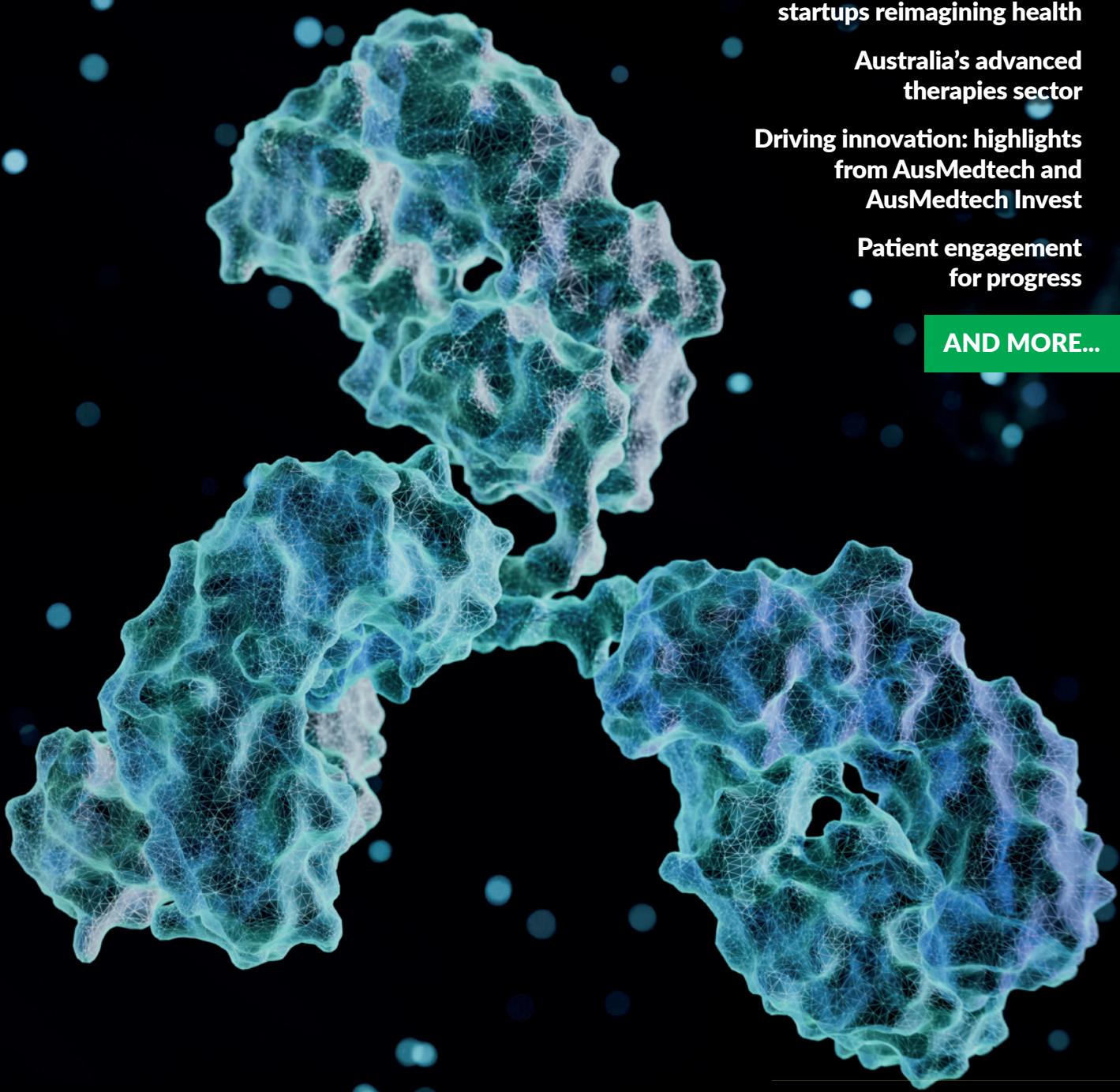
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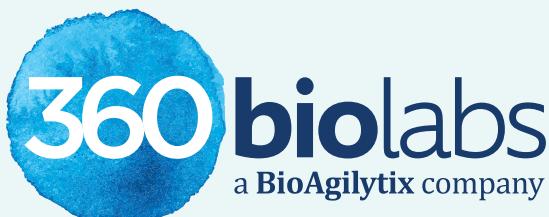
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ACCELERATING RESEARCH STARTUP AT ST VINCENT'S HOSPITAL MELBOURNE

St Vincent's Hospital Melbourne is a leader in research excellence, conducting trials from first-in-human to Phase IV, with expertise in biomedical engineering, drugs, devices, diagnostics and digital health interventions.

A KEY STRENGTH of St Vincent's Hospital Melbourne (SVHM) is the efficiency of its Human Research Ethics Committee (HREC), which is credentialled for National Mutual Acceptance (NMA). This is a national scheme that streamlines the review of multi-site clinical trials across most Australian states and territories. Under this model, a single HREC review can be accepted by multiple participating institutions, avoiding duplication and significantly reducing trial startup times.

With the SVHM HREC meeting every two weeks throughout the year, researchers benefit from faster ethical approvals compared with many other institutions.

Research Valet™, your lead site solution

To support all levels of clinical trials for staff and industry, SVHM offers the sector-leading Research Valet™ Service, providing fast, facilitated preparation of HREC submissions and ongoing liaison throughout the approvals process.

With a competitive timeline of under 30 days from initial meeting to final submission outcome (except for first-in-human and Phase I studies), and with more than 30 years of combined experience among senior team members, this service is unmatched. Studies do not need to include SVHM as a site to access Research Valet or the SVHM HREC.



By streamlining ethics submissions and reviews, Research Valet allows researchers to focus on study delivery rather than administrative hurdles. This innovative service positions SVHM as a lead site solution, providing staff and industry partners with a faster, smoother, and more reliable pathway to study commencement.

Priority Pre-Review Package for first-in-human trials

Recognising the particular needs of early-phase research, SVHM also offers the Priority Pre-Review Package. Designed specifically for first-in-human and Phase I studies, this bundled service provides expert guidance and a streamlined approach to support rapid clinical trial startup. Integrating scientific and ethical pre-review ensures that high-quality, early-phase research can progress quickly, safely, and efficiently.

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- participate in surveys, clinical trials and community events
- stay informed with webinars, articles and expert-led resources on the latest medical breakthroughs
- engage directly in live Q&A sessions and share your insights
- make an impact by helping improve healthcare outcomes for your family and community.

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- Broad expertise across clinical disciplines
 - Trusted by sponsors and researchers
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Priority Pre-Review Package

A streamlined service supporting FIH & Phase 1 trial start-up.

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CEO MESSAGE

BY REBEKAH CASSIDY, CHIEF EXECUTIVE OFFICER AND MANAGING DIRECTOR, AUSBIOTECH

Welcome to this edition of *Australasian Biotechnology*, AusBiotech's official journal.

SINCE OUR LAST edition, there has been a remarkable period of activity and transformation across both our sector and our organisation. As the peak body representing Australia's life sciences, AusBiotech is proud to play its role as a trusted advocate, super-connector and ecosystem enabler.

Our members are advancing breakthroughs that transform human health, and we are proud to elevate their voices, create connections, and share knowledge so that biotechnology can play an even greater role in the future health and wealth of our nation.

Advancing our policy agenda

The May re-election of the Albanese Government meant continuity of our advocacy work and renewed momentum to advance our life sciences policy agenda.

Throughout the year, AusBiotech has continued to deliver a clear and forward-looking policy agenda designed to unlock our sector's full potential. It reflects the growing maturity of the Australian ecosystem and is built to overcome the longstanding fragmentation of policy for our sector that currently sits across nine federal portfolios. Our agenda positions the life sciences sector as a driver of economic resilience, health security and improved health outcomes for all Australians.

As our global peer nations sharpen their strategies and invest heavily in national life sciences capabilities, AusBiotech has been steadfast in ensuring both the government and the opposition understand the critical timing and economic opportunity before Australia. We continue to call for:

- developing Australia's first whole-of-government National Life Sciences Strategy to set clear priorities, eliminate duplication and align Australia with other countries competing for global investment
- establishing a whole-of-government Life Sciences Council, in partnership with industry, to guide the strategy and ensure investment delivers health, security, and economic outcomes
- recognising life sciences under the Future Made in Australia Act to create focus and coordination across portfolios
- investing in data and evidence to strengthen innovation, anticipate global interdependencies, and drive better decision-making.



Rebekah Cassidy

On behalf of the sector, we have actively contributed to the government's Strategic Examination of Research and Development and the National Health and Medical Research reviews, leading member roundtables and preparing formal submissions. I was also pleased to recently join the Technical Advisory Group supporting the next phase of development for the National Health and Medical Research Strategy.

AusBiotech continues to work with members and a number of government departments on rapidly evolving global trade dynamics. Over recent months, we have kept members informed through regular updates, hosted member roundtables, and overseen a series of briefings with departmental leaders to ensure our industry's voice is heard.

Of course, with a membership as broad as AusBiotech's, we are also engaging with members on a number of sector-specific issues and opportunities at any given time. In recent months, our Government and Policy team has been focused on: a review, led by Professor John Skerritt AM and with input from the Therapeutic Goods Administration, into regulatory challenges faced by our medical technology members; challenges associated with the importation of biologics; the Research and Development Tax Incentive; major business settings; visa options; and much more. If you have a topic you would like to discuss with our policy team members, please reach out to them directly.

Strengthen global connections

The life sciences industry is inherently global, and Australia's success depends on strong ties with international networks and markets. Since our last edition, we have reinforced Australia's presence on the world stage through active participation in a number of international roundtables, partnerships and conventions.

Highlights include being a major supporter of team Australia at BIO International Convention 2025 and representing Australia on behalf of the International Council of Biotechnology Associations. AusBiotech represented national priorities at key roundtables spanning clinical trials, manufacturing capability and supply chain resilience. We also played a central role in bilateral and multilateral discussions, including in:

- the Asia Pacific: through engagement with the Japan Bioindustry Association, the Japanese Government, and Taiwan Bio Industry Organization — highlighting Australia's strengths in clinical trials, infectious diseases, radiopharmaceuticals, and regenerative medicine
- North America: through collaboration with peer associations in Canada and the United States focusing on workforce development and embedding the patient voice in product development

- the United Kingdom: through a high-level bilateral roundtable, jointly hosted by AusBiotech and the UK BioIndustry Association, focused on enhancing policy alignment and fostering deeper industry collaboration, particularly in relation to the Australia/UK BioBridge proposal.

Maximising the opportunities associated with so many key stakeholders in one place, we also joined Australian Trade and Investment Commission (Austrade); the Department of Industry, Science and Resources; Global Victoria; and Canadian officials for site visits to the facilities of our members Moderna and Sanofi — underscoring the ripple effects of global investment in Australia's ecosystem.

We continue to represent industry in discussions on a proposed BioBridge between Australia and the United Kingdom under our free trade agreement. This strategic initiative would connect the Australian and United Kingdom life sciences ecosystems to foster greater collaborative innovation, commercialisation, and trade growth.

Spotlight launched

In May, we launched Spotlight — a new video series celebrating Australia's life sciences success stories. Designed to amplify sector achievement, the series profiles companies from across the ecosystem and highlights homegrown capabilities. The debut episode featured Navbit, a Sydney-based medtech innovator addressing real-world challenges in orthopaedic surgery.

Episode two featured BiomeBank, an Adelaide-based biotech on a mission to restore gut microbial ecology, treating Australian patients with its world-first approval for microbial therapy to treat *Clostridioides difficile* infection.

Spotlight supports our mission to tell the story of the sector's remarkable capabilities to a broader audience.

AusMedtech and AusMedtech Invest 2025

Australia's premier medtech conference returned to Sydney in May, bringing together nearly 500 delegates from across Australia and more than 10 international markets. Across two days, AusMedtech 2025 delivered an industry-led program of keynotes, panels and showcases, reinforcing its place as the biggest week in medtech. Preceding the conference, AusMedtech Invest 2025 connected emerging companies with local and international investors through spotlight pitches and expert-led sessions on capital flows, markets, and innovation pathways.

Read more about AusMedtech 2025 and AusMedtech Invest 2025 on page 12.

Industry-leading programs

Industry Growth Program

As an Industry Partner Organisation under the federal government's Industry Growth Program, AusBiotech has been supporting innovative small and medium-sized enterprises (SMEs) to commercialise and grow. Since April, AusBiotech's Innovation Activation Program has been delivering targeted support to 37 biotech and medtech startups across capability development, international connections, and access to capital.

Participants have benefited from one-on-one industry mentoring, professional financial analysis, tailored workshops, global investment readiness activities and access to major AusBiotech events. The program is strengthening Australia's early-stage life sciences ecosystem, with a second national cohort commencing in November 2025.

TradeStart

In June, AusBiotech announced a new partnership with Austrade under the national TradeStart network — enhancing support for Australia's life sciences sector. The AusBiotech TradeStart Adviser will work with SMEs in biotech, medtech, and digital health to accelerate international growth, offering tailored export advisory services, guidance on regulations, market entry strategies, and commercialisation support.

This program reinforces AusBiotech's commitment to building Australian life sciences capability within a globally competitive life sciences ecosystem.

State Committees

Our State Committees are critical to AusBiotech, serving as a key mechanism for hearing from and engaging with the breadth and diversity of our membership nationwide. In July 2025, we announced expanded committees and new appointments across New South Wales, Victoria, Queensland, Western Australia and South Australia, welcoming new chairs and members.

Comprising leaders from industry, research, investment and services, they catalyse local insights, strengthen connections, and inform AusBiotech's national advocacy agenda.

Congratulations to all our new State Committee members, and in particular our State Committee Chairs:

- New South Wales Chair: Lis Boyce (Partner, Piper Alderman)
- Queensland Chair: Michael Junger (Director Industry and Government Relations, Vaxxas)
- South Australia Chair: Mathew Palmer (Chief Growth and Commercial Officer, Accelagen Pty Ltd)



IGP participant Dr Fang-Xu Jiang, Founder and Executive Director at Healthregen

- Victoria Chair: Helen Fisher (Non-Executive Director, Biotech Capital Impact Fund (BCIF))
- Western Australia Chair: Paul Anderson (CEO and Managing Director, Orthocell Ltd).

We look forward to tapping into our State Committees for their expertise as we continue to deliver for our sector.

Biggest week in biotech

Australia's biggest week in biotech (21–24 October 2025) is headlined by the annual AusBiotech 2025 International Conference, bringing together more than 250 leading local and international voices. Covering global trends, investment and partnership, advanced therapeutics, artificial intelligence deployment, sustainability, and more, the conference will explore the global shifts and emerging opportunities shaping Australia's biotech future, while diving into the sector's most important discussions.

As the flagship event of the week, the conference offers more opportunities than ever before to network, create new connections and forge partnerships. Kicking off the week, our premier investment conference, AusBiotech Invest 2025, connects innovative life sciences companies with crucial funding.

Looking ahead with confidence

As we look to the future, our vision remains bold and unwavering: for Australia to be recognised globally as a leader in developing and commercialising high-quality, innovative life sciences companies.

The challenges before us — from intensifying global competition to the urgency of turning research into real-world patient outcomes — are real. But the opportunities are just as great. With our clear strategy and the collective talent of our members, AusBiotech is leading the voice of our sector into its next phase of growth and impact.

On behalf of AusBiotech, I thank our members and partners for their support and shared commitment. Together, we will continue to build a thriving, globally connected Australian life sciences ecosystem. 

PARTNER WITH US

FOR YOUR NET ZERO 2050 GOALS

At Merck, sustainability is more than just a trendy word...it's a mindset. Our data-driven approach to sustainability combined with a broad portfolio of Greener Products & Solutions and a variety of innovative programs focused on environmental and social responsibility uniquely enables us to act as a sustainability multiplier for our customers. Learn more about how partnering with us and conducting a sustainability audit will benefit your efforts to Net Zero by 2050.

Relevant Certifications

All our facilities are certified under ISO 14001 for environmental management and ISO 50001 for energy management across 14 sites. We also adhere to ISO 9001, which includes GxP practices in the pharmaceutical industry. Merck undergoes regular audits for these certifications and can provide detailed reports to support our customers.

Greener Products and Solutions



3,879 Greener Alternative Products, including Greener Solvents and ZooMAb® animal component-free antibodies. Look out for our green icon!



We've partnered with Planet Protector Packaging in Australia to eliminate polystyrene! We have replaced over 3.6 tons of expanded polystyrene in cold-chain packaging materials each year by using Woolpack technology, made from 100% sheep waste wool from Australian and New Zealand farmers. All packaging components are either recyclable or home compostable, reducing environmental impact.



BIG SCIENCE smaller footprint

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Collaborations and Ratings



Our Sustainability Strategy is aligned with the United Nations Sustainable Development Goals. It is defined by 3 main goals and 7 focus areas in which we are pursuing numerous initiatives and projects. To learn more visit:

[SigmaAldrich.com/
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Rebekah Cassidy

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FOSTERING AUSTRALIAN BIOTECHNOLOGY: FROM LOCAL INNOVATION TO GLOBAL IMPACT

AUSTRALIA'S BIOTECHNOLOGY MARKET continues to expand, driven by growing demand for novel therapies and the increasing adoption of precision medicine. Beyond the advantage of choosing Australia as an ideal trial-initiating country, developing strategy that assures a successful drug development path, emphasising early integration of regulatory and market access strategies, must also be taken into consideration. This must be designed from the earliest stages of development and coordinated throughout the product life cycle to ensure timely patient access to new therapies, regulatory acceptance and commercial success in rapidly evolving global markets.

Early and integrated planning

Modern best practices strongly advocate for early integration of regulatory strategy (the road map for meeting global regulatory requirements) and market access strategy (ensuring product uptake via pricing, reimbursement and formulary listing). Early planning allows companies to design clinical development programs and data packages that simultaneously satisfy regulatory agency standards and payer evidence requirements, reducing delays and costly post-hoc data generation.

Adaptability and stakeholder engagement

Regulatory and market access strategies must remain adaptable to evolving science, shifting regulatory frameworks and changing market dynamics. Continuous cross-functional collaboration spanning clinical, regulatory, market access and commercial teams is essential for identifying risks, early adapting plans to new evidence or guidelines, and ensuring consistent messaging to regulatory bodies and payers.

Global harmonisation and local nuances

With increased global harmonisation efforts (e.g. ICH Guidelines), companies benefit from streamlined multi-region submissions; however, national differences in regulatory requirements and health technology assessments continue to pose hurdles, necessitating robust intelligence and the customisation of strategies for key markets.

Going global with a forward-thinking approach

The growing biotechnology innovation in Australia is accompanied by increasing

competition. To transfer early phase results to the global arena and maintain a competitive edge, biotechs need to think ahead to:

- generate globally acceptable data for inclusion in global development programs
- navigate regulatory processes and specialised programs
- accelerate time to market with prudent operational strategies
- submit robust evidence that demonstrates the value of an asset
- optimise commercial opportunities.

Formerly operating as Covance/Labcorp, Fortrea is one of the longest-serving international clinical research organisation (CRO) in Australia (since 1988). As a leading global CRO, Fortrea is well-positioned to provide local resources and parlay initial success in Australia into the next phases of clinical development and navigate a global market.

Its fully integrated consulting and clinical development teams provide strategic and outcome-focused support across all phases of drug development, from early-phase candidate selection, preclinical research and clinical development, through to full-scale commercialisation.

Learn more about how Fortrea can help Australian biotechs anticipate potential challenges, navigate complexity and evolve to meet global demands, bringing life-changing treatments to patients faster. 

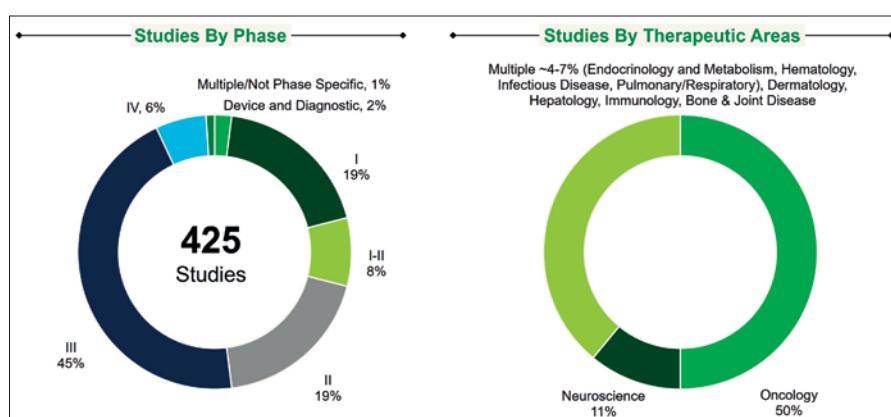


Figure 1. Fortrea's studies in Australia over the past five years (by phase and therapeutic area).

Source: Fortrea internal database. Statistical period: 2019–2024

WHAT HAPPENS WHEN ANTIBIOTICS STOP WORKING?

The rising threat of antimicrobial resistance and how biotechnology is shaping the future.

ANTIMICROBIAL RESISTANCE (AMR) is embedded in the world around us. Routine cuts can spiral into a life-threatening infection, and standard surgeries come with the risk of untreatable complications. As bacteria outsmart existing antibiotics, once-curable conditions can become untreatable, threatening decades of medical progress.

The escalating challenge of AMR

AMR, often referred to as the 'silent pandemic', is already linked to nearly five million deaths each year. The World Health Organization projects that if the problem is left unchecked, annual deaths could reach 10 million by 2050, at a global economic cost approaching US\$100 trillion.

Antibiotic consumption in Australia remains among the highest in the developed world, and resistance among common pathogens – for example, *Escherichia coli* in urinary tract infections – is a growing concern, with some now resistant to last-resort drugs. Antibiotic-resistant infections are linked to longer hospital stays and higher mortality rates, meaning that once-routine infections can again become potentially fatal.

Biotechnology at the frontline of innovation

Addressing this global challenge requires new approaches, and Australian biotechnology company Recce Pharmaceuticals (ASX: RCE) has a portfolio of synthetic anti-infectives designed to work differently from traditional antibiotics. Its leading compound,

RECCE® 327 (R327), has been shown to kill bacteria within minutes rather than hours and, crucially, it remains effective even after repeated exposure.

This innovation has translated into patient outcomes. In a Phase II clinical trial of R327 topical gel (R327G) for acute bacterial skin and skin structure infections (ABSSSI), patients treated with the therapy demonstrated rapid and durable responses. After seven days of treatment, 86 per cent of patients achieved a successful clinical response; and after 14 days, 93 per cent had met the primary efficacy end point. R327G was safe and well tolerated, with no serious adverse events reported across the study. These compelling results have supported Recce's ongoing Registrational Phase III clinical trial in Indonesia, targeting diabetic foot infections, one of the most dangerous and costly complications of diabetes.

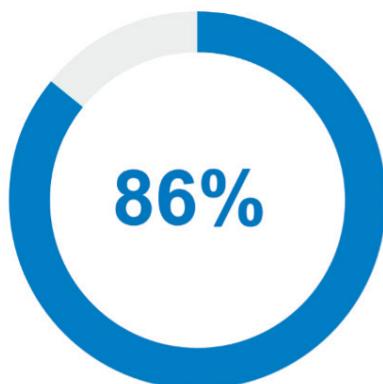
The road ahead

Addressing AMR will require more than just scientific discovery, encompassing responsible antibiotic stewardship, a One Health approach of international cooperation and public awareness. Biotech innovation, such as Recce's new class of synthetic anti-infectives, also offers a unique method of combating this global health threat.

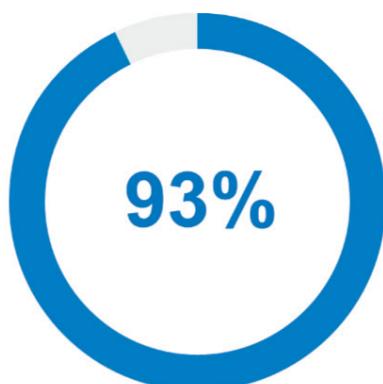
If successful, compounds like R327 and R327G can mark the beginning of a new era in antibiotics, helping to evolve modern medicine and ensure that infections remain treatable for generations to come. 

Successful clinical response

After 7 days of treatment



After 14 days of treatment



Recce Pharmaceuticals

RECCE® 327 Topical Gel Targets a Global Market of Unmet Medical Needs

Novel Australian Technology

First Australian-developed anti-infective approved for Phase 3 clinical trial in Indonesia for Diabetic Foot Infections.

Globally Recognised

Recce's anti-infective compounds recognised by World Health Organization (WHO) for efforts to combat antimicrobial resistance.

The Global Burden of Topical Infections

Antibiotic-resistant topical infections affect millions worldwide each year. Among the most concerning are methicillin-resistant *Staphylococcus aureus* (MRSA) and *Pseudomonas aeruginosa*, which drive longer hospital stays, higher healthcare costs, and increased mortality. Both are classified by the WHO as priority drug-resistant pathogens.

A New Class of Anti-Infectives

RECCE® 327 as a topical gel targets therapeutic indications such as Diabetic Foot Infections and Acute Bacterial Skin and Skin Structure Infections, conditions that cause significant morbidity and mortality worldwide.



Recce Pharmaceuticals (ASX:RCE, FSE:R9Q)

Entering a new phase in our journey to combat antibiotic-resistant superbugs. There remains a crucial need for antibiotics that can address both Gram-positive and Gram-negative pathogens.

Recce's anti-infective compounds have a unique mechanism of action with broad-spectrum capabilities, enabling a rapid response to resistant and mixed bacterial infections.

[LinkedIn](#) [Website](#)



DRIVING INNOVATION: HIGHLIGHTS FROM AUSMEDTECH AND AUSMEDTECH INVEST

AUSTRALIA'S MEDICAL TECHNOLOGY sector took centre stage in May as AusBiotech delivered its flagship medtech events in Sydney. Across three days, AusMedtech 2025 and AusMedtech Invest 2025 drew together innovators, investors, industry leaders, and policymakers from Australia and abroad, underscoring the nation's growing influence in global health innovation. With themes spanning investment flows and intellectual property to regulatory reform, commercialisation pathways, and digital health, the events highlighted the sector's momentum and reinforced AusBiotech's role as a connector and catalyst for growth.

AusMedtech 2025

Australia's premier medical technology conference, AusMedtech 2025, was held in Sydney, New South Wales, from 7–8 May 2025, with the theme 'Innovation to Impact'.

The event brought together close to 500 delegates from across Australia and more than 10 international markets, officially marking it the biggest week in medtech.

Attendees represented sectors including medical devices, diagnostics, digital health, investment, research and government, reflecting the event's reach and influence across the full medtech ecosystem.

AusMedtech was officially opened by New South Wales's Minister for Medical Research, the Hon. David Harris MP. New South Wales's Minister for Industry and Trade and Minister for Innovation, Science and Technology, the Hon. Anoulack Chanthivong MP, launched the NSW Health Research and Innovation Strategy 2025–2030 on the grounds of the conference.

The two-day, industry-led program featured keynote presentations, panel discussions, and interactive sessions covering core themes such as digital health, health system sustainability, clinical trials, investment strategies, regulatory trends, and cross-sector partnerships.

Plenary and breakout sessions examined how medtech innovators can navigate complex regulatory pathways,

AusMedtech 2025 Panel





strengthen local manufacturing and supply chain resilience, and position Australian technologies for global markets.

There were some key program highlights:

- 'A view from the top: shaping the future of medtech through innovation' was a panel session unpacking the future of health care over the next five years, with a focus on innovation in the medtech sector. Chaired by ANDHealth Chair Gavin Fox-Smith, the panel featured Telstra Health Managing Director Elizabeth Koff AM, Medicines Australia Chair Sue MacLeman, Vitrafy Life Sciences Managing Director Kate Munnings, and L.E.K Consulting Managing Partner Stephanie Newey.
- 'Partnering to advance the Australian medtech sector' discussed the critical role of partnerships in the Australian medtech sector, highlighting the fact that we can't do everything alone. Chaired by AusBiotech CEO Rebekah Cassidy, the panel featured Stryker South Pacific President Maurice Ben-Mayor; Cardinal Health ANZ Managing Director Jane Crowe; Becton Dickinson Managing Director ANZ Anelo Cournut; Abbott Regional Director, Government Affairs, Paul Davies; and Baxter International President, Asia Pacific, Steven Flynn.
- 'Regulatory roadmap: Key insights and advice from the TGA and medtech companies' was an update from the Therapeutic Goods Administration (TGA) on what's currently top-of-mind for the sector, both in Australia and globally. Chair Dr James Campbell was joined by TGA First Assistant Secretary, Medical Devices and Product Quality Division, Tracey Duffy; Orthocell CEO and Managing Director Paul Anderson; and Medtronic Senior Director Quality Assurance and Regulatory Affairs ANZ Dr Darren Forrest.

At AusMedtech, AusBiotech also discussed opportunities to optimise Australia's Medical Device Regulatory Scheme with AusBiotech Board member Professor John Skerrit and TGA First Assistant Secretary, Medical Devices and Product Quality Division, Tracey Duffy. It was the start of a conversation about a review to be undertaken by Skerrit in partnership with AusBiotech medtech regulatory committee members and stakeholders. AusBiotech continues to work through the review recommendations with the TGA, members and others across the sector.

With Australia's medtech sector continuing to expand, AusMedtech 2025 demonstrated strong alignment with industry needs, from supporting local commercialisation pathways to navigating regulatory change and fostering connections across disciplines. The conference reinforced its role as a catalyst for collaboration, knowledge exchange, and business growth, helping position Australia as a global leader in medical technology innovation.

AusMedtech 2025 was supported by Host State Partner the NSW Government, sponsors, exhibitors, and the program committee, whose contributions ensured a dynamic and future-focused event.

Save the date for AusMedtech 2026 in Perth: 19–21 May 2026!

AusMedtech Invest 2025

AusMedtech Invest 2025, held on 6 May in Sydney, brought together the nation's most promising medical technology innovators, and an influential mix of Australian and international investors. As Australia's premier investment roundtable dedicated to medtech, the forum underscored the sector's growth potential and its pivotal role in delivering next-generation health solutions.

The program featured expert insights on shifting capital flows, evolving global market dynamics, and the strategic importance of intellectual property in building investor confidence. Set against a backdrop of rising healthcare demand, supply chain challenges and demographic shifts, AusMedtech Invest provided a timely platform for strengthening sector resilience and accelerating commercialisation.

Delegates heard from a distinguished line-up of international and local thought leaders. Dr Nicholas Pachuda from Peptilogics, Neovate Capital, and Precision Life Science Partners, shared global perspectives on scaling breakthrough technologies, while Kylie Frazer of Flying Fox Ventures offered candid advice on the realities of early-stage investment. Elyse Shapiro from Canaccord Genuity delivered valuable analysis on biotechnology and diagnostics markets, equipping attendees with practical intelligence to inform investment decisions.



AusMedtech Student Ambassadors

The program also included a panel discussion on innovation, intellectual property and commercialisation, chaired by Children's Cancer Institute Business Development and Licensing Manager Gorjana Mitic. She was joined by FB Rice Head of IP Advisory Helen Mutimer, Advancell Chief Scientific Officer Dr Simon Puttick, and Brandon Capital Associate Prashanth Rajan. Together, they explored how strong intellectual property strategies underpin investor confidence and enable long-term value creation.

Showcasing emerging innovators

At the heart of AusMedtech Invest were 11 company spotlight pitches, where private and ASX-listed ventures shared their innovations across devices and diagnostics. Each presentation offered investors an early view of opportunities, spanning preclinical development through to late-stage commercialisation.

Companies featured on stage included:

- Convergence Medical
- Wavewise Analytics (formerly Cyban)
- EMVision Medical Devices (ASX:EMV)
- Examin Holdings
- Gelomics
- Haemograph
- High Fidelity Orthopaedics

- Integrant
- Kardiomics
- Navi Medical Technologies
- Venstra Medical.

Collectively, these innovators reflect the breadth and depth of Australia's medtech capability. Their technologies address diverse areas of clinical need from cardiovascular health to imaging and advanced diagnostics, highlighting the sector's ability to improve patient outcomes while building sovereign industry strength.

AusBiotech CEO Rebekah Cassidy emphasised the importance of the event in bridging the gap between innovation and capital.

'With over 900 medtech companies operating in Australia, it's clear the sector is thriving; but growth doesn't happen without capital and investment,' Cassidy said. 'We're proud to build on our strong legacy and commitment to investment, to connect innovators with the capital and connections they need to scale and succeed.'

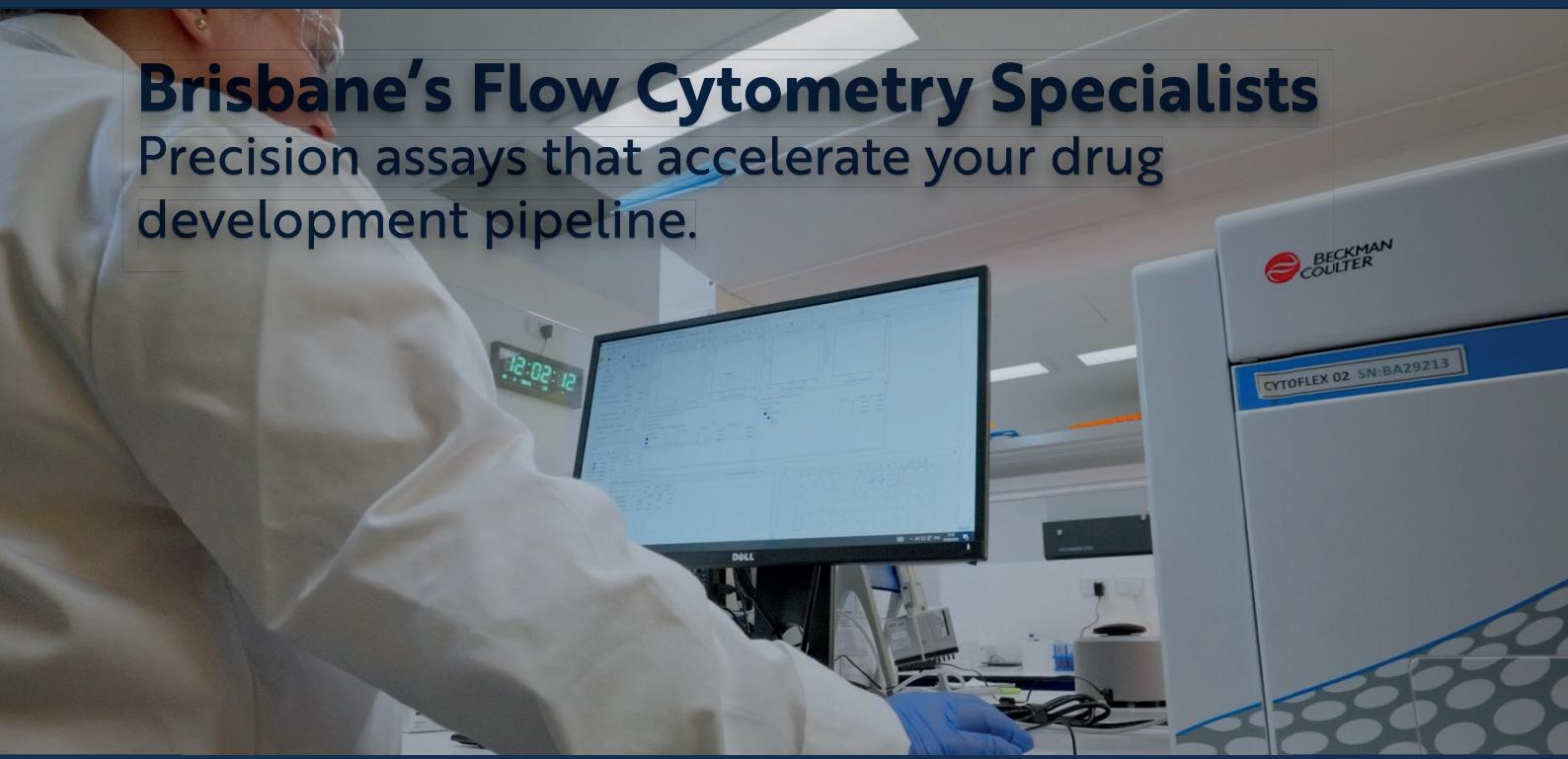
AusBiotech continues to deliver specialised investment forums that empower Australian companies to be competitive on the global stage. Through the AusMedtech Invest 2025 event portfolio, AusBiotech continues to serve as a super-connector linking innovators, investors and strategic partners to accelerate the journey from research to commercialisation.

Special thanks are extended to the Host State Partner, the NSW Government, and to event sponsors FB Rice, Citi, and ASX, whose support enabled the delivery of this year's program. 



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MONASH AND EMERSON COLLABORATE ON STATE-OF-THE-ART mRNA WORKFORCE TRAINING CENTRE

BY DR BRIAN JONG, OPERATIONS AND PARTNERSHIPS MANAGER, MONASH mRNA WORKFORCE TRAINING CENTRE; AND MAKARAND MUJUMDAR, INDUSTRY SPECIALIST – LIFE SCIENCE, EMERSON

AUSTRALIA'S BIOTECHNOLOGY SECTOR has undergone a significant transformation over recent years, driven by the rapid advancement of mRNA technologies. This has accelerated the need to leverage industrial-scale manufacturing technologies while maintaining our leadership in core research. At the heart of this evolution is the Monash mRNA Workforce Training Centre, the nation's first dedicated facility focused on building a skilled workforce for mRNA medicines and vaccine development.

A strategic investment in innovation

Established with a \$10-million grant from the Victorian Government, the centre is a cornerstone of the state's broader strategy to position Victoria as a global leader in mRNA manufacturing and research. Located within Monash University, the centre complements the nearby Moderna manufacturing facility, creating a synergistic ecosystem for innovation and production.

Bridging the skills gap

The centre addresses a critical skills need, ensuring that Australia has the talent pool required to support the burgeoning mRNA sector. Its mission is to build knowledge and skills across the mRNA medicines life cycle, from discovery to development, and support the growth of mRNA manufacturing through hands-on technical training. Beyond the mRNA sector, the centre also works with the wider pharmaceutical industry to address current training needs. The short courses developed and delivered by the centre have been created



with the intent of empowering participants with the knowledge and skills to be industry ready.

Driving economic and scientific growth

The centre is not just a training hub; it's a catalyst for economic development. By equipping professionals with cutting-edge skills, it supports the expansion of Victoria's biotech sector, which already contributes to 60 per cent of Australia's pharmaceutical exports and sustains more than 100,000 full-time jobs.

Moreover, the centre plays a pivotal role in the Asia-Pacific region, training talent from across borders, and fostering international collaboration in mRNA therapeutics and vaccine production.

Enhancing mRNA training with Emerson's Batch Control System

The integration of the bioprocessing equipment with Emerson's DeltaV Batch Control System adds significant value to both the research programs and the trainees by aligning education with real-world, industrial-grade manufacturing technologies. These include:

- centralised, recipe-driven operations
- good manufacturing practice and regulatory compliance
- batch tracking and analytics
- process optimisation.

The Monash mRNA Workforce Training Centre is a strategic enabler of Australia's biotech future. Leveraging the industry-leading DeltaV Batch Control System, it empowers Monash University's training participants with the tools, knowledge and confidence to excel in cutting-edge mRNA manufacturing environments. It transforms theoretical learning into practical expertise that will help Australia build a resilient, future-ready biotech workforce. 



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With Emerson automation software, pharmaceutical companies speed up discovery and production to safely get breakthrough medicines to patients faster than ever before.



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THE EARLY-STAGE INNOVATION FORUM

See you at

AusBiotech
AusMedtech 2026

26, Perth



AusMedtech 2025 ESIF Winner with
AusBiotech CEO and Deputy CEO

FOR ALMOST 40 years, AusBiotech has been supporting the growth of Australia's life sciences sector, connecting researchers, innovators and investors to translate discoveries into real-world solutions. Central to this mission is the Early-Stage Innovation Forum (ESIF), a twice-yearly national platform for emerging innovators.

As part of both the AusMedtech and AusBiotech International conferences, ESIF enables early-stage companies to share bold ideas, gain feedback and build vital networks for commercialisation. It offers the next generation of breakthrough biotechnology, medical technology and digital health companies a unique opportunity to showcase their science in front of investors, industry partners, and clinicians.

Where translation begins

AusBiotech's ESIF has continued to offer early innovators a unique opportunity to gain constructive, real-world insights to help transform promising science into tangible products. The format is deliberately fast-paced: selected applicants deliver short, high-impact pitches, followed by probing questions and live feedback from a panel of experienced industry leaders.

Held at AusMedtech in May and the AusBiotech International Conference in October, the event is the premier national stage for research organisations, universities, hospitals, and pre-Series A companies. The event proves how targeted advice can dramatically shape the commercialisation journey.

For participants, the benefits extend far beyond the pitch. They gain sector-wide recognition and credibility, exposure through AusBiotech's communications platforms, and access to a network of investors and collaborators. For industry and investors, ESIF provides a curated view into the pipeline of science and technologies that will shape the future of health care.

Creating connections and enabling knowledge-sharing is at the heart of AusBiotech's work. Forums like ESIF help to accelerate innovation, but also foster the partnerships needed to bring breakthroughs to patients and strengthen Australia's medtech sector.

AusMedtech 2025 ESIF winner: advancing kidney diagnostics

This year's AusMedtech ESIF winner, Garvan Institute of Medical Research Senior Research Scientist Shanon Ranjit, exemplifies the impact of this platform. Her pioneering work on a liquid biopsy test for the early detection of acute kidney injury stands out for its scientific rigour, clinical relevance and potential to improve patient outcomes.

Acute kidney injury is a common and often underdiagnosed complication in hospitals, particularly following surgery or sepsis. Current diagnostic tools are limited and frequently too

slow to enable timely intervention. Early detection is critical, as delays can lead to severe complications, higher healthcare costs and increased mortality.

Shanon and her team identified an opportunity to address this gap using methylation biomarkers in a liquid biopsy platform. The assay promises to detect kidney damage earlier and more accurately than existing methods, allowing clinicians to intervene before irreversible damage occurs.

'What inspired us was the significant gap in specific, early diagnostic tools for kidney injury and diseases, especially in postoperative patients who face life-threatening complications post surgery,' Shanon explained.

Creating connections and enabling knowledge-sharing is at the heart of AusBiotech's work. Forums like ESIF help to accelerate innovation, but also foster the partnerships needed to bring breakthroughs to patients and strengthen Australia's medtech sector

The path to translation has not been without challenges. 'Translating a molecular concept into a clinically viable test required navigating complex discovery strategies, technical validation, securing ethical approvals, and coordinating pilot studies — all with limited resources,' she said.

Winning ESIF at AusMedtech 2025 was a milestone for Shanon and her team. It was 'a huge validation, not just of the science behind our work, but of its real-world relevance', she said.

ESIF at the AusBiotech International Conference 2024

Each October, as part of Australia's biggest week in biotech, the AusBiotech International Conference features its own ESIF. Last year saw 15 pitches from across the country.

The winners were Pacalis Therapeutics CEO Dr David Bibby, and Dr James Tran of Centron Bio — a spin-out from the Florey Institute of Neuroscience and Mental Health. They highlighted the diversity and promise of early-stage innovation in Australia.

Pacalis Therapeutics: a year of strategic growth

Since securing ESIF recognition in 2024, Pacalis Therapeutics has rapidly emerged as a biotechnology company to watch. Led by Bibby, and working closely with Professor Chris Langmead at Monash University, the Parkville-based company is pursuing novel, small-molecule therapeutics that target some of the most pressing unmet needs in mental health, including depression, post-traumatic stress disorder, and substance use disorders.

On the research and development front, the team is advancing novel programs targeting the serotonergic pathway, with a focus on 5-HT2A agonists and positive allosteric modulator.



AusBiotech 2024 ESIF winner Centron Bio CEO Dr James Tran

The ESIF award has proven catalytic for Pacalis Therapeutics. In the past year, Bibby has been actively engaged across the biotech ecosystem, presenting at AusBiotech events and the Jumar Bioincubator, while building the company's strategic network through the Monash Innovation Hub.

'The past year has been a rewarding experience for Pacalis, opening doors to world-leading laboratories and forging confident partnerships,' Bibby said. 'With a strong scientific foundation and early investor backing, Pacalis Therapeutics is now poised for its next phase of growth: bringing transformative central nervous system (CNS) therapies closer to market.'

With a solid base now established, Pacalis Therapeutics is poised to enter its next phase of development that promises continued innovation and impact.

Centron Bio: accelerating a global mission

Centron Bio, led by CSO Associate Professor Fazel Shabapoor and CEO Dr James Tran, is capitalising on its ESIF recognition to accelerate growth on the international stage. Since being awarded joint first place in 2024, the Florey Institute spin-out has expanded its global footprint in developing next-generation genetic medicines for the CNS. The company's mission is clear: to enable more efficacious and convenient therapies for patients suffering from neurodegenerative diseases.

In the past year, Centron Bio has been welcomed into leading international incubators, including Bayer Co.Lab in Boston and Johnson & Johnson's JLABS in Singapore. It was also selected for MassBioDrive's Spring 2025 cohort and Boston's Science2Startup program.

Centron Bio is advancing both in-house and partnered genetic medicines that

address disease progression at its root cause by modulating disease-driving genes intracellularly and at the RNA level. This tailored approach is designed to provide durable benefits in neurodegenerative diseases, such as Alzheimer's, where current therapies remain limited.

Together, the three most recent ESIF winners — Shanon, Bibby, and Tran — demonstrate the breadth of Australia's life sciences capability. They embody the ambition and translational focus that define the sector

With a near-term focus on first-in-human trials for Alzheimer's, the company is positioning itself as a global leader in CNS and genetic medicine.

A showcase of national capability

Together, the three most recent ESIF winners — Shanon, Bibby, and Tran — demonstrate the breadth of Australia's life sciences capability. They embody the ambition and translational focus that define the sector.

More than a competition, ESIF is a showcase of ideas at their earliest stages, where feedback and connections can make the difference — giving innovators structured opportunities to refine and accelerate their work.

Australia's life sciences sector is critical to the economic resilience and health security of our nation, and supporting the pipeline of emerging innovation is essential. ESIF remains a cornerstone of this effort, ensuring the nation's boldest ideas are given the chance to thrive. 



Where Science Meets Innovation: 360biolabs' Infectious Diseases Centre of Excellence Accelerates Clinical Trial Success

In the race to combat infectious diseases, speed, accuracy, and adaptability are everything. That's why 360biolabs, a BioAgilytix company, is proud to announce the expansion of our ready-to-deploy assay portfolio tailored to support respiratory virus vaccine and therapeutic clinical trials with unmatched efficiency.

Whether you're running early-phase trials or advancing complex, multi-site programs, our off-the-shelf validated assays and integrated immunological and molecular endpoint services provide the depth and flexibility today's vaccine development demands.

Assay Innovation Meets Infectious Disease Expertise

At the heart of this expansion is our state-of-the-art virology and infectious diseases facility in Melbourne, equipped with certified BSL-2 and BSL-2 containment laboratories. Our scientists are deeply experienced in supporting clinical trials targeting a broad spectrum of infectious agents, both endemic and emerging. 360biolabs has supported 225+ infectious diseases clinical studies from 2023 to 2025 and analysed >115,000 clinical samples during this period.

Our expanded services include validated assays for key respiratory viruses providing advanced endpoint analysis for early-phase vaccine trials. We have introduced both live-virus assays plus pseudovirus assays where live-virus is not possible due to containment level or importation regulations.

Key Assay Platforms Now Available Off the Shelf

We've boosted our virology capabilities to include a wider range of fully developed and validated, ready-to-go assays for rapid study start up and accelerated timelines.

- **Cell Culture-Based Assays:** Still a gold standard in virology, cell-based platforms like plaque assays and cytopathic effect (CPE) assays provide direct insights into viral replication.
- **Neutralisation Assays:** Measure the functional ability of neutralising antibodies for assessment of vaccine protection or antivirals to block infection at key viral lifecycle stages.
- **HAI Assays:** Essential for influenza clinical trials, Haemagglutination Inhibition (HAI) assays quantify functional antibodies that prevent red blood cell agglutination, a proxy for immunity.
- **Molecular Virology:** Advanced qPCR and dPCR methods support viral detection and quantification, mutation tracking, vector titre analysis and viral shedding studies.

What's New: Expanded Respiratory Virus Assays

To meet continued requests for clinical trial support, 360biolabs has added new off-the-shelf respiratory virus assays to its service repertoire, including neutralisation titre assessment for RSV A and B, metapneumovirus, parainfluenza, influenza, H1N1, H3N2, B and HAI assays for influenza strains:

- Plaque Reduction Neutralisation Test (PRNT) for metapneumovirus and parainfluenza
- Microneutralisation Test (MNT) for RSV subtypes A and B
- HAI and neutralisation assays for influenza



Pseudovirus Assays for High-Containment Pathogens

Pathogens, for example influenza H5N1 and monkeypox, cannot be cultured safely in Australia due to importation restrictions and biosecurity requirements. To overcome this, we've developed pseudovirus-based assays that mimic whole virus infection without fully replicating. These safe, BSL-2 compliant assays offer powerful tools to measure neutralising antibodies, evaluate vaccine-induced immune responses and accelerate development of pandemic-ready vaccines.

Custom Solutions for Complex Programs

While our off-the-shelf assays offer speed and standardisation, we also specialise in custom assay development for trials with unique targets or endpoints. Our scientists blend expertise in virology, immunology, and molecular biology to deliver bespoke assay solutions tailored to your trial's specific needs.

Integrated Immune Endpoint Support

A comprehensive picture of vaccine efficacy requires more than viral titres. We offer a full suite of humoral and cellular immune assays to support endpoint analysis across all immune response dimensions:

- **Humoral assays:** ELISA: absorbance based and MSD-ECL and IgG, IgM, IgA serology
- **Cellular assays:** ELISpot, Immunophenotyping: standard and spectral flow, and Intracellular cytokine staining (ICS)
- **PBMC services:** Isolation, cryopreservation and storage



A Strategic Edge: Conducting Trials in Australia

Australia's location in the Southern Hemisphere offers a strategic advantage for extending seasonal respiratory virus clinical trials beyond the Northern Hemisphere winter. By shifting trial activity to coincide with the Southern Hemisphere winter, sponsors can avoid seasonal delays and accelerate study completion by up to six months.

“We saved 6 months, recruitment exceeded expectations, and the study cost 40% less than running it in Europe.”

— VACCITECH

Australia is a preferred destination for early-phase clinical trials due to its pragmatic regulatory environment and rapid approval process. The strong R&D tax incentives make conducting clinical trials up to 60% cheaper than in the USA, without compromising on quality. Australia is an OECD country, ensuring data generated in Australia is accepted by global regulatory agencies. A highly skilled and English-speaking workforce simplifies communication and collaboration.

At 360biolabs, we don't just provide data, we deliver insights that drive decisions. Our expanded infectious diseases validate, and advance vaccines and therapeutics that are changing the future of global health.

Whether you're working with a known virus or developing countermeasures against emerging threats, we're ready to help you move forward, faster, smarter, and more confidently.

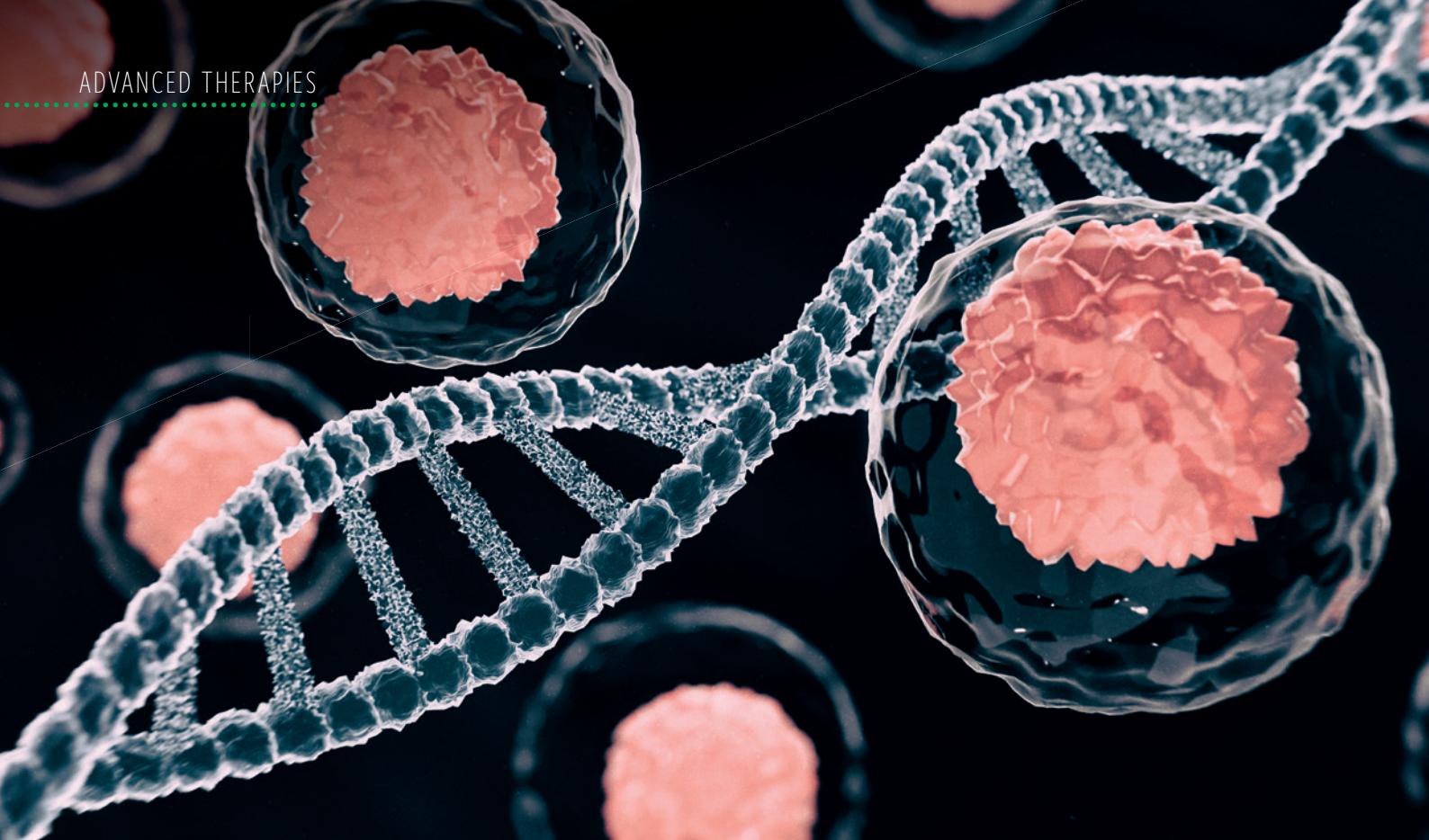
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AUSTRALIA'S ADVANCED THERAPIES SECTOR

BY SILVIO TIZIANI, CHIEF EXECUTIVE OFFICER, CCRM AUSTRALIA

We are at the forefront of a \$50-billion global cell and gene therapy market.

AUSTRALIA STANDS AT a pivotal moment in healthcare innovation, with the cell and gene therapy (CGT) sector offering transformative potential. Globally, the CGT market is set to grow from US\$7.2 billion in 2023 to US\$23.3 billion by 2028, reflecting a compound annual growth rate of 26.4 per cent (BCC Research, 2023). Domestically, the Australian CGT market is projected to reach US\$2.1 billion by 2027, up from US\$855.7 million in 2023, driven by increasing government support, cross-border collaborations, and expanding clinical trial activity (BioIntel360, 2023; IMARC Group, 2024).

These trends highlight both the scale of the opportunity and the urgency for Australia to act decisively. The question is not whether this wave of transformative medicine is coming, but whether Australia will lead the way or risk being left behind (AusBiotech, 2023).

Our nation boasts world-class research institutions, a robust Therapeutic Goods Administration, high clinical care standards, and a growing record in translational science. These strengths position us to play a leading role in developing and delivering

advanced therapies. Yet, without the facilities and systems to support early-phase manufacturing and commercialisation, we risk losing intellectual property, talent, and economic value to better-prepared jurisdictions.

Science in search of scale

The science is here. What we lack is a nationally coordinated effort to translate it into economic, social and clinical outcomes. The advanced therapies sector is complex and capital-intensive, and demands close integration of research, manufacturing, regulatory approval, and commercial pathways. Australia must adopt an ecosystem model at scale to compete internationally.

Success will require moving beyond incremental improvements. To be globally competitive, Australia needs to embed advanced manufacturing technologies, automation and process innovations into our capabilities. Several organisations, including CCRM Australia, are working with research, government, and industry partners to identify, pilot, and integrate such technologies into process development and good manufacturing practice (GMP).

Building capability through collaboration

One example of how collaboration can reshape a sector is the newly funded SMART CRC, a cooperative research centre (CRC)

for advanced manufacturing and regenerative medicine. Recognising a critical gap in national capability, CCRM Australia identified the need for a CRC in this field and initiated the project to establish it. The result is a national initiative that now brings together more than 60 partners, including research institutions and universities, small and medium-sized enterprises, global biotechnology firms, clinical networks, and advanced manufacturers.

The SMART CRC will align research with real-world clinical and commercial needs, strengthen sovereign manufacturing capability, and provide a platform for de-risking innovation. This makes Australian-developed therapies more attractive to investors and better positioned for global markets.

Other groups, including the recently concluded Cell and Gene Catalyst, have been and are advancing talent development, clinical trial readiness, and sector coordination. These efforts highlight a central truth: no single organisation can solve the challenge alone. Progress depends on aligned, sustained collaboration.

Overcoming persistent barriers

Despite strong science, Australia's biotech sector continues to face the 'valley of death' — the gap between early-stage research and commercial success. Many promising therapies stall at preclinical or early clinical stages due to limited capital, infrastructure and coordinated support.

Fragmented policy and investment exacerbates the challenge. While state initiatives have provided valuable support, national alignment is needed. Federal leadership can deliver the scale, certainty and strategic direction required to compete globally.

A national strategic imperative

The Future Made in Australia agenda and National Reconstruction Fund present a chance to make strategic investments in biomanufacturing, process development facilities and incubator programs. These investments could be transformative, creating high-value jobs, retaining intellectual property, attracting clinical trials and strengthening export potential.

Beyond economics, sovereign capability is a matter of resilience and security. The COVID-19 pandemic demonstrated that nations with local manufacturing capacity were better positioned to respond to global supply chain shocks. In advanced therapies, the same principle applies.

The AI and automation shift

Artificial intelligence (AI) and automation are set to reshape advanced therapy development, manufacturing, and delivery. AI can accelerate candidate identification, optimise clinical

trial design and improve manufacturing efficiency. Predictive analytics will support highly personalised treatments, improving patient outcomes and reducing costs.

In GMP facilities, automation enables continuous monitoring, reduces error rates and improves scalability.

This is analogous to how diagnostic pathology laboratories have evolved from essentially manual operations to highly automated, high-throughput environments. The future of advanced therapies will be a hybrid of human expertise and automated systems, with AI supporting complex decision-making.

To succeed in this AI-driven future, Australia must invest in:

1. digital infrastructure to enable secure, efficient data sharing across research, clinical, and manufacturing environments
2. skills development that combines biomedical science with AI and automation expertise
3. regulatory evolution to address new safety, quality and ethical considerations
4. private sector investment alongside government support to commercialise and deploy these technologies.

Seizing the moment

Australia has a track record of global leadership when science, industry, and government collaborate with purpose, as seen in medical devices and digital health. Applying the same ambition to advanced therapies could make us a destination for global innovation and manufacturing.

The opportunity is real, the stakes are high and the time is now.

By building integrated ecosystems, embracing new technologies, and aligning policy with industry needs, we can establish Australia as a leader in the global advanced therapies sector, and ensure the benefits are realised here at home. 

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Silvio Tiziani

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Global Market Access Through Integrated Certification

For medical device manufacturers, achieving international market access requires navigating a complex landscape of regulatory requirements. Multiple audits and overlapping compliance obligations can create significant challenges in terms of time, cost, and resources. By aligning certification strategies under globally recognised frameworks such as **MDSAP, ISO 13485, and the EU MDR**, companies can streamline approvals, reduce duplication, and accelerate access to markets worldwide.

Why Choose DQS?

With decades of experience in the medical device sector, **DQS has developed extensive expertise in conducting combined audits** that integrate MDSAP, ISO 13485, and MDR requirements. Our team of qualified auditors brings in-depth regulatory knowledge and industry insight, ensuring that every audit is both well-organised and comprehensive.

Certification and
audit services on
the basis of:



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

EU-MDR ✓
2017/745

MDSAP: An Integral Pathway to Australian Market Access

The **Medical Device Single Audit Program (MDSAP)** provides manufacturers with a single, comprehensive audit that satisfies the regulatory requirements of **Australia, Canada, Brazil, Japan, and the United States**. This unified approach reduces duplication and offers a practical pathway to global compliance.

By achieving MDSAP certification, manufacturers showcase their commitment to **high-quality processes, robust risk management, and patient safety**. The result is not only faster approval but also greater acceptance across major international markets, reducing the time and cost associated with multiple regulatory submissions.

ISO 13485: A Cornerstone for Contract Manufacturers and Service Providers

ISO 13485 is the internationally recognised standard for medical device quality management systems. It provides the essential foundation for manufacturers, suppliers, and service providers working within the medical device supply chain.

Implementing ISO 13485 also leads to **greater operational efficiency**, as processes are standardised and risks are better managed. This reduces the likelihood of costly nonconformities or product recalls and helps build **long-term client trust**. Beyond compliance, ISO 13485 fosters a **culture of quality** that enhances reputation and competitiveness in a highly regulated industry.

MDR: Strengthening Access to the European Market

The **European Union Medical Device Regulation (MDR 2017/745)** sets one of the world's most rigorous frameworks for medical device approval. Compliance is essential for manufacturers wishing to sell in the European market and reflects a company's ability to meet **stringent safety and performance requirements**.

MDR places strong emphasis on **clinical evidence, traceability, and post-market surveillance**, ensuring that devices remain safe and effective throughout their lifecycle.

For manufacturers, MDR certification opens the door to the entire European market, while also reinforcing their reputation globally as a provider of devices that meet the highest regulatory standards.

Combined Audits: One Assessment, Multiple Approvals

Medical device manufacturers often face the challenge of undergoing separate audits for different standards and regulatory frameworks. A **combined audit** offers a streamlined alternative by assessing a company's **Quality Management System (QMS)** against **MDSAP, ISO 13485, and MDR requirements in one process**.

Key Benefits:

- Reduced Audit Burden & Costs** – Instead of preparing for multiple audits, companies undergo a single, coordinated assessment. This lowers costs, minimises disruption to operations, and frees resources for innovation and growth.
- Faster Market Access** – By achieving compliance across several frameworks simultaneously, manufacturers can enter **multiple global markets more efficiently**. MDSAP enables access to five key countries, MDR opens the European Union, and ISO 13485 provides recognition worldwide.
- Stronger Regulatory Confidence** – A combined audit highlights the maturity and robustness of a company's QMS, which can improve confidence among regulators, partners, and customers alike.

Contact us to learn more about ISO 13485, MDSAP, and CE marking under MDR (EU) 2017/745

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SPATIAL IMAGING PTY LTD: PIONEERING HOMEGROWN MICROFLUIDICS

FOUNDED IN 2023, Spatial Imaging Pty Ltd has rapidly emerged as a trailblazer in Australia's life sciences technology landscape. With its headquarters in Brisbane, the company offers a full spectrum of microfluidics solutions, from hardware and fluidic systems to complete integrated platforms, designed and built locally.

Comprehensive microfluidics expertise

Spatial Imaging possesses deep expertise across the microfluidics spectrum, focusing on precision, reproducibility and automation. Its product portfolio includes:

- smart lipid nanoparticle generators, enabling efficient formulation of lipid-based delivery systems for vaccines, gene therapy and other biomedical applications
- microdroplet and microsphere generators, supporting high-throughput screening, single-cell studies and synthetic biology applications
- integrated control systems, featuring precision pressure controllers, flow sensors, distribution valves, solenoid valves and user-friendly software for automated operation.

These systems allow scientists to produce droplets with unparalleled control over size, uniformity and composition,

unlocking new capabilities in drug delivery research, molecular diagnostics, and biopharmaceutical development.

Collaborative innovation and recognition

Spatial Imaging's commitment to research and innovation is demonstrated through its partnership with The University of Melbourne under Australia's Economic Accelerator – Innovate program. This collaboration highlights the company's credibility and recognition within both academic and industrial circles.

The launch of its new microfluidics brand, Vivoflow, marks a strategic effort to strengthen its market presence, inspire fresh growth and drive recognition of Australian-designed microfluidics technology. Vivoflow is positioned to serve both research institutions and commercial laboratories, offering cutting-edge solutions that meet the evolving needs of life sciences.

Local expertise with global reach

Rooted in Brisbane, Spatial Imaging combines homegrown engineering talent with a global outlook. Its technologies have been successfully exported to key international markets, including Singapore, Mainland China, Hong Kong and Japan. This international adoption underscores both the quality of its microfluidic platforms and the global demand for precise, reliable, and scalable microfluidics solutions.

Looking ahead

As Spatial Imaging continues to solidify its product line, including Vivoflow, the company remains poised for further expansion in both academic and commercial research markets. With patents secured, export momentum building, and award recognition affirming its promise, Spatial Imaging is crafting a new chapter for homegrown life sciences innovation, designed in Brisbane and ready for the world. 



Spatial Imaging's Founder, Yi Liu, and Co-founder, Kenny Wang

NANOINSIGHTS IMAGING

NANOINSIGHTS TECH CO Ltd (referred to as 'NanoInsights') is a leading enterprise in the field of high-end optical microscopy imaging in China. NanoInsights focuses on the innovative manufacturing of high-end, scientific-grade optical super-resolution microscopes and provides revolutionary super-resolution imaging solutions for global scientific research, integrating R&D.

NanoInsights is a high-tech enterprise headquartered in Beijing, China, with branches in Guangzhou, Hefei and Shanghai. The company is also actively expanding into overseas markets, establishing a nationwide and globally radiating R&D and service system.

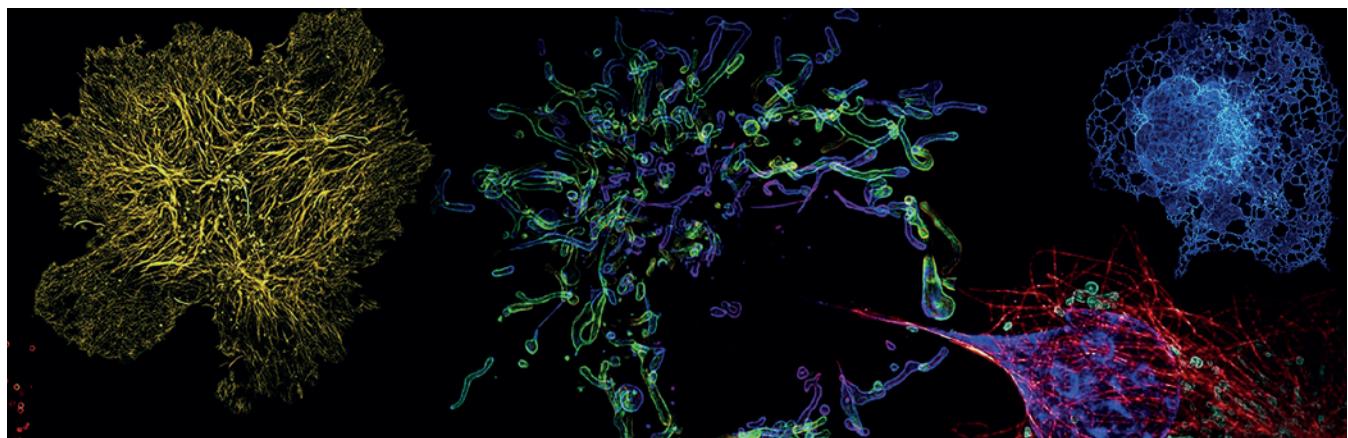
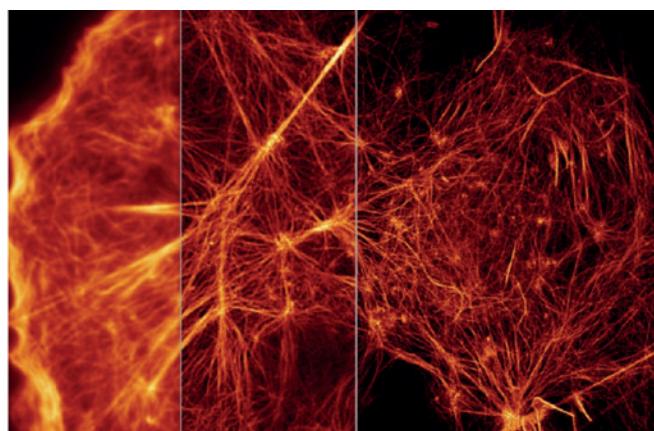
The core products of NanoInsights include the multimodal structured illumination super-resolution intelligent microscope (Multi-SIM), the super-resolution light-sheet microscope (NanoSlice), and the intelligent spinning disk confocal microscope (SpinX), among others. These devices provide strong technical support for fields such as life sciences, materials sciences and basic medicine.

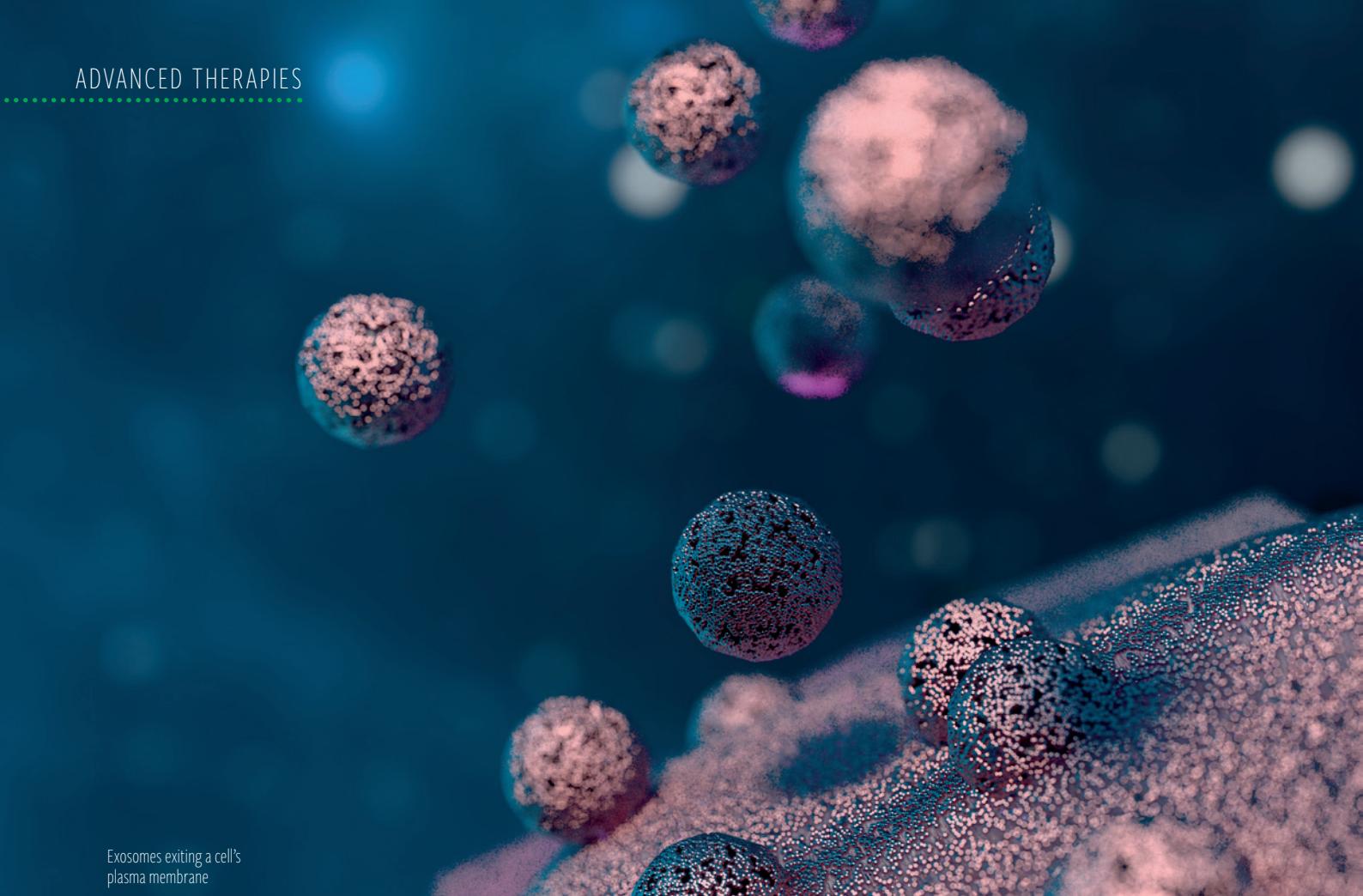
Combining temporal and spatial resolution, Multi-SIM offers all the advantages of a multimodal, intelligent and high-throughput super-resolution microscope. As the first super-resolution microscope system in the world that

realises high-speed and flexible structured illumination through programmable spatial light modulation technology, it integrates multiple super-resolution microscopy modalities, and provides 5-D (X-Y-Z-Time-Colour) super-resolution imaging solutions with excellent performance, and good versatility for multiple research directions.

NanoSlice super-resolution light-sheet microscopy system, through light-sheet illumination, enables high-speed, low-phototoxicity 3D volumetric imaging. The system integrates conventional light sheet, SIM light sheet, and line-scanned light sheet modalities with deep-learning algorithms to achieve 100-nanometre lateral resolution, supporting long-term super-resolution imaging across single cells, multicellular clusters, embryos and other multi-organ organisms, and other specimens.

Founder of NanoInsights Dr Dong Li is an authoritative expert in the field of optical microscopy imaging, and currently holds the position of Xinghua Chair Professor at Tsinghua University. In 2012, he achieved a breakthrough in the resolution limit of structured illumination microscopy, achieving dynamic imaging of living cells at 60 nanometres. In 2018, he developed the grazing incidence structured illumination microscopy (GI-SIM) and reported his work in *Cell*. He also developed the rationalised deep learning rDL intelligent algorithm and promotes the intelligent upgrade of microscopy technology. 





Exosomes exiting a cell's plasma membrane

CAR-EXOSOME THERAPY: A NEXT-GENERATION FRONTIER IN CANCER IMMUNOTHERAPY

BY CHRIS KALLOS, LIFE SCIENCES ANALYST, BRIDGE INVESTMENT RESEARCH

The treatment of cancer has radically transformed in recent decades, particularly with the advent of immunotherapies that harness the adaptive immune system's precision in targeting malignant cells.

AMONG NEW IMMUNOTHERAPIES, chimeric antigen receptor (CAR) T-cell therapy (CAR-T therapy) has received immense scientific and clinical attention. This approach, in which T lymphocytes (T cells) are genetically reprogrammed to express engineered receptors against tumour antigens, has achieved remarkable successes in hematologic malignancies, such as acute lymphoblastic leukemia and diffuse large B-cell lymphoma, in particular.

Despite these high-profile breakthroughs, CAR-T therapy is still encumbered by significant limitations. These include risks

to the patient (unpredictable and life-threatening toxicities, restricted efficacy in solid tumours, and disease escape through immunosuppressive tumour mechanisms), as well as operational challenges (prohibitive manufacturing costs and logistical complexity). These hurdles underscore the urgent need for innovative platforms that preserve the hallmark antigen-directed cytotoxicity of CAR-T cells while eliminating the shortcomings of CAR-T therapy.

Into this breach steps CAR-exosome therapy, a rapidly emerging cell-free immunotherapeutic approach with the potential to revolutionise cancer treatment. By leveraging nanoscale extracellular vesicles that are engineered to carry CARs on their surface, this approach merges the precision of cellular immunotherapy with the scalability and safety profile of an off-the-shelf biologic.

CAR-T therapy: a real breakthrough, but bounded by limitations

CAR-T cells combine an antigen-recognition domain, typically derived from a tumour-directed monoclonal antibody, with T cell-signalling motifs that trigger cytolytic activity upon antigen binding. Simply put, these engineered cells both identify and destroy their target cells. The approach has shown curative potential in certain blood cancers, achieving durable remissions in patients who have few alternatives.

Despite this, the broader clinical impact of CAR-T therapies is limited for a few reasons:

- Immediate potential danger to the patient from severe immune toxicities: Cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome are frequent effects of CAR-T therapy. These unwanted effects can be severe, and often require intensive monitoring and rescue interventions with Interleukin-6 inhibitors or steroids.
- Limited efficacy due to solid tumour resistance and tumour-mediated immunosuppression: Dense stromal barriers and immunosuppressive microenvironments blunt T-cell infiltration and persistence, limiting efficacy beyond hematologic cancers. Additionally, tumour expression of programmed death-ligand 1 (PD-L1) can engage programmed cell death protein 1 (PD-1) receptors on CAR-T cells, inducing T-cell exhaustion and therapeutic failure.
- Failure of ongoing treatment: Host rejection, T-cell senescence and antigen escape can limit the durability of CAR-T therapy, while readministration of this treatment is risky due to immunogenicity.
- Expensive, logically difficult manufacturing: Autologous processes require personalised cell isolation, engineering, and expansion, inflating costs beyond US\$400,000 per dose and slowing delivery.

These problems have sparked intensive efforts to devise next-generation CAR platforms, including CAR-NK cells, armoured CARs, and synthetic biology-driven switches. Yet perhaps the most promising pivot is towards a treatment that completely eliminates the use of live cells, instead harnessing the exosome: nature's smallest communication vehicle.

How exosomes (nature's nanocarriers) represent the next step in cancer treatment

Exosomes are extracellular vesicles, typically 30–150 nanometres in diameter, naturally secreted by virtually all cell types. They transport proteins, RNA, and lipids between cells and play key roles in immune modulation. Importantly, exosomes inherit surface proteins and functional traits from their parent

cells, making them attractive delivery systems for engineered therapies.

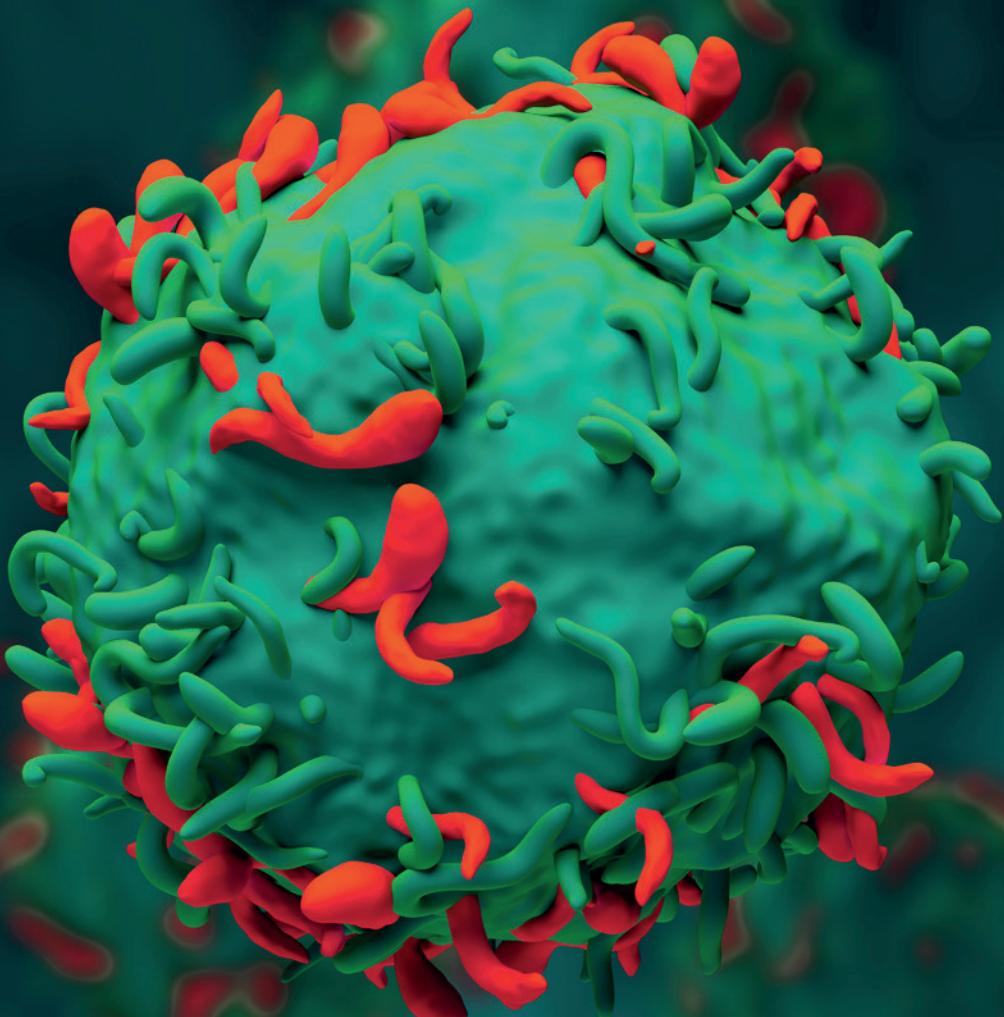
By harvesting exosomes from CAR-T or CAR-NK cells, researchers can generate CAR-exosomes: vesicles that display tumour-specific antigen receptors on their surface. CAR-exosomes can recognise targets and deliver cytotoxic payloads just as well as their cellular progenitors, but are safer and more effective, as well as easier to manufacture.

... exosomes inherit surface proteins and functional traits from their parent cells, making them attractive delivery systems for engineered therapies

Advantages of CAR-exosome therapy: addressing the challenges of CAR-T therapy

CAR-exosome therapy, while still in development, has strong potential to offer the benefits of CAR-T therapy while eliminating the key drawbacks. These benefits include:

- Safer for the patient: Unlike live CAR-T cells, exosomes cannot proliferate or trigger cascade immune overreactions. Preclinical studies demonstrate potent tumour killing without inducing cytokine storms. Their rapid physiological clearance limits long-term adverse effects while permitting flexible dosing schedules.
- More powerful cancer-killing ability with improved tumour penetration and resistance to immune evasion: The nanoscale size of exosomes enables them to permeate into parts of a tumour that are largely impenetrable to bulkier CAR-T cells, such as dense stromal tissues and hypoxic niches. Furthermore, because CAR-exosomes lack PD-1 receptors, tumours that evade T-cell attack by upregulating PD-L1 are unable to suppress CAR-exosome activity. This bypasses one of the key immunosuppressive pathways that tumours typically exploit.
- Continued efficacy in repeat dosing and readministration: CAR-exosomes exhibit low immunogenicity compared to cellular infusions. This provides flexibility for the use of CAR-exosomes in repeat administration, intermittent maintenance dosing, or combination regimens, which are capabilities constrained in current CAR-T approaches.
- More scalable, higher-quality and cheaper manufacturing: As a non-living product, CAR-exosomes can be produced from standardised donor-derived cell lines under controlled conditions, then purified at scale using ultracentrifugation, chromatography, or tangential-flow filtration. This dramatically lowers cost, increases batch consistency and supports an off-the-shelf therapeutic model.



CAR-T cell

Preclinical validation: CAR-exosome therapy shows strong promise

CAR-exosome therapies remain in the early preclinical stage, with current evidence derived primarily from in-vitro studies and murine tumour models. While this data highlights a compelling blend of potency and safety, the approach has yet to progress into IND-enabling studies or first-in-human trials, underscoring that translation into the clinic is still at a very preliminary stage.

In-vitro assays consistently show that CAR-exosomes retain the antigen recognition and targeted cytotoxicity of their parent CAR-T or CAR-NK cells. More importantly, animal studies in murine solid tumour models reveal strong anti-tumour efficacy without evidence of CRS, neurotoxicity, or off-target inflammation. They also display favourable pharmacokinetics, with rapid clearance reducing systemic exposure, but permitting redosing as needed to sustain activity.

These findings suggest that CAR-exosomes may combine the precision targeting and potency of CAR engineering with the dosing flexibility and safety associated with biologics, which is an especially valuable trait for managing heterogeneous or refractory disease burdens.

Challenges and future directions

Despite compelling potential advantages, CAR-exosome therapy remains at an early preclinical stage, and faces critical hurdles to development and deployment:

- Manufacturing needs to become more scalable: While purification techniques are advancing, reproducible large-scale GMP-compliant production of high-purity exosomes requires further refinement.
- Exosome cargos must be standardised: Exosomes carry diverse bioactive molecules beyond engineered CAR proteins. Ensuring consistent loading and avoiding unintended effects will be essential for regulatory approval.
- Challenges around pharmacokinetics and biodistribution must be overcome: Although rapid clearance of exosomes reduces the risk of systemic toxicity, it also limits therapeutic persistence at the tumour site, potentially requiring higher or repeated dosing. Approaches under investigation include engineering long-acting formulations, or anchoring exosomes to biomaterials or carrier cells to prolong circulation time and enhance tumour accumulation.

Continued on page 34



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Who are we?

Alithia Life Sciences is an Australian owned full capability, boutique, clinical research organization (CRO) launched to support and assist pharmaceutical, biotechnology, device companies and institutional research groups undertaking their project in the Australian region and beyond.

What we do?

- Overall management of projects and clinical strategy on behalf of local and international Sponsors from concept to start up and through to close out.
- Biotech executive management and director support provision (local directorship).
- Access to an extensive network of project enabling KOLs and vendors including laboratories and R&D tax experts and Investigational Product depots.
- Clinical research suite: project and site management, site feasibility and selection, selection and management of vendors, monitoring support, trusted data management and biostatistical solutions, local and global medical monitor capabilities.

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Continued from page 32

- Regulatory frameworks need to be developed to oversee this hybrid therapy: As a hybrid between biologics and cell-derived therapies, CAR-exosomes will challenge regulators to define coherent standards for safety, identity, and potency assays.

Notwithstanding regulatory issues, we expect that ongoing advances in exosome biomanufacturing, synthetic biology and vesicle engineering will address the other gaps.

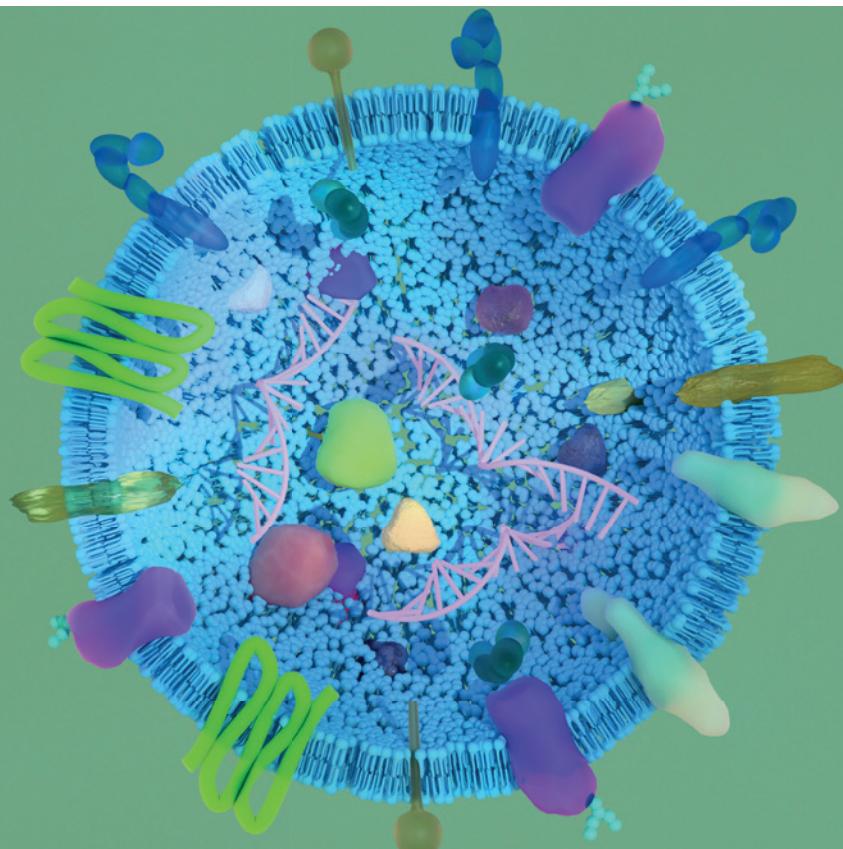
Positioning within the immunotherapy landscape

Over time, CAR-exosome therapy is likely to evolve from a complementary adjunct to CAR-T therapies into a distinct and versatile immunotherapy platform, offering advantages in safety, dosing flexibility, and accessibility across a broader range of tumour settings.

In hematologic malignancies, where CAR-T cells already deliver curative potential, exosomes may serve as safer adjuncts for maintenance therapy or as first-line treatments for patients at risk of severe toxicities. In solid tumours, they offer a new therapeutic class capable of overcoming stromal and immunologic barriers that have defeated conventional CAR-T approaches.

Combination regimens marrying CAR-exosomes with immune checkpoint inhibitors, cytokine adjuvants, or conventional chemotherapy also represent fertile ground for clinical exploration. Strategic partnerships between academic centres and biotechnology firms are beginning to crystallise around these opportunities.

Exosome structure, showing proteins, RNA and lipids



Next steps for CAR-exosome therapy: safer, better and more flexible cancer treatment

The development trajectories of new cancer immunotherapies tend to exhibit a familiar pattern: initial breakthroughs tempered by safety and scalability concerns, followed by iterative innovation to broaden clinical applicability. CAR-T therapies are a good example of this. Though these therapies are transformative, they remain limited by toxicities, manufacturing burdens, and a lack of efficacy in solid tumours.

CAR-exosome therapy represents the logical next stage in the trajectory, as a cell-free platform that retains antigen-specific cytotoxicity while enhancing safety, scalability and resistance to tumour immunosuppression. By merging the biologic simplicity of exosomes with the precision engineering of CARs, this modality holds the potential to transform the accessibility and cost profile of immunotherapy.

While still early in development, the convergence of exosome engineering and CAR technology could mark the beginning of a new therapeutic era in which precision immunotherapy extends far beyond hematologic malignancies, making meaningful inroads into the vast and unmet challenge of solid tumours.

If realised, CAR-exosomes may emerge not just as an incremental improvement, but also as yet another fundamental change in cancer treatment, shaping the future of oncology with safer, more versatile and more broadly applicable therapeutics. 



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ION SETS NEW BENCHMARK FOR LIFE SCIENCES FACILITIES



The Kurraba Group-built ION precinct offers opportunities for collaboration and cost advantages for biotechnology companies.

THE CONSTRUCTION OF ION — a groundbreaking life sciences precinct near Sydney's CBD — will help biotechnology firms to benefit from a new ecosystem of research innovation and commercialisation in the Asia Pacific. Purpose-built for life sciences organisations, the state-of-the-art facility will have lower fit-out costs for biotech firms compared to retrofitted buildings. Access to grant support and venture-capital funding are other potential benefits.

'ION is a game changer for Australia's life sciences sector,' says Kurraba Group CEO and Co-founder Nick Smith, the developer of ION. 'For the first time, the sector will have a master-planned, commercial life sciences precinct near a capital city CBD. The opportunities from this precinct are immense.'

The \$520-million ION project has been years in the making. Kurraba Group, Australia's leading life sciences real estate firm, saw an opportunity to construct life sciences facilities after the 2008-09 global financial crisis.

'There was a big gap here for facilities like ION,' says Smith. 'Sovereign capability in life sciences had become a much bigger issue, particularly after the COVID-19 pandemic. But Australia didn't have enough lab-ready buildings or medical manufacturing facilities to meet demand.'

Another issue, says Smith, is Australian life sciences firms commercialising their intellectual property overseas due to a lack of local facilities or capital. 'We have all this great IP in life sciences, but too much of it goes overseas to get commercialised. It's a lost opportunity for our nation.'

The location of life sciences precincts mostly on or associated with university campuses has been a limitation, says Smith. 'University research precincts play an important role, but collaboration between industry, government and academia through them has been too low. Having a life sciences precinct near the heart of Sydney, not on a university campus, can boost collaboration and commercialisation.'

A landmark facility with a unique offering

Kurraba's flagship ION project is designed to support industry to overcome these limitations and unlock the potential of the Australian

biotech industry. The facility is strategically located in Waterloo, in Sydney's inner south, about three kilometres from the CBD.

Surrounded by leading health, research and academic institutions, ION will be a key part of Sydney's centre of life sciences, says Smith. 'We're going to bring dozens of outstanding life sciences firms to this part of Sydney, and help to develop and expand a thriving innovation and commercialisation ecosystem.'

After several years of planning and approvals, construction on ION is schedule to commence in October 2025, and leasing is already underway. The precinct is due to open in the first quarter of 2028.

Smith says leasing inquiries have exceeded expectations. 'We've had huge interest in getting space in ION across the biotech, agricultural technology and clean energy sectors, and expect to secure a large university as an anchor tenant. The facility offers several substantial advantages.'

The first is space. ION has more than 27,000 square metres of space, making it among the largest precincts of its kind in Australia. 'ION will solve a problem for biotech and other high-growth firms that have struggled for limited space at other facilities,' says Smith.

Design is another attraction. Gensler, a leading global architect in innovation and life sciences environments, designed ION. Its brief: to bring together form, function and flexibility for life sciences firms.

ION has specialist lab-enabled buildings, incubators, Current Good Manufacturing Practice clean rooms, flexible workspaces and other research infrastructure, as well as an eye-catching facade. Every inch of its design has been considered for life sciences firms.

'ION tenants will benefit from the latest design for life sciences buildings and lower fit-out costs,' says Smith. 'It's far costlier to fit out a building not designed for life sciences research than moving into a purpose-built facility.'

Embedded support for tenants is a further attraction. Through Kurraba's venture-capital fund, ION tenants will have access to potential equity funding. Kurraba is also supporting tenants with their grant applications for office fit-outs.

Curated connections to firms within ION, and other organisations in the life sciences precinct, is another advantage. 'We will be more than a landlord,' says Smith. 'We want to embed Kurraba in this ecosystem, and help its tenants to develop new opportunities and grow. This is a unique model in Australia.'

Strong results and a bold future

Smith is pleased with Kurraba's progress since its 2022 launch, and is excited by its future. ION is the largest of three Kurraba projects and the centrepiece of a strategy to develop facilities in Brisbane, Melbourne, Adelaide, and Perth.

'Kurraba's strategy is to build a network of life sciences facilities in Australian capital cities,' says Smith. 'Our goal is to develop a national ecosystem where firms in this network collaborate to advance and commercialise research and development.'



Kurraba is also exploring expansion into Asia, and Singapore is a particular focus. 'We see great potential to develop life sciences facilities in the Asia Pacific, and to connect Australian biotech firms with opportunities from that network.'

Kurraba's strategy is timely. 'In the short term, we're seeing more life sciences firms from America and Europe looking to conduct clinical trials outside of China, in places such as Australia, where regulatory approval is more likely,' says Smith. 'More local life sciences facilities will help to meet that trial demand.'

Longer term, Australia has much ground to make up in life sciences facilities. 'We're at least 20 years behind the United States and 10 years behind Europe,' says Smith. 'Boston alone has five million square metres of space for life sciences companies, dwarfing Australia by about five times.'

Kurraba is well-placed to implement its strategy. Its team has more than 50 years of experience in developing complex projects, having led dozens in Australia and overseas. It also has relationships with leading asset managers here and overseas.

'ION will set a new benchmark for Australian life sciences facilities,' says Smith. 'But it's just the start. Developing life sciences precincts in the heart of industry, not only on university campuses, is the key to research commercialisation and ensuring that exceptional Australian IP is developed locally.'

'We want large and small biotech firms to be part of ION, and encourage them to talk to us to see how the facility can help their business grow.'

For leasing enquires or to learn more about ION and Kurraba Group, visit www.ionwaterloo.com.au.



CHANGING THE COURSE OF CANCER TREATMENT WITH TARGETED ALPHA THERAPY

CONTENT PROVIDED BY ADVANCELL

Radioligand therapy is poised to revolutionise cancer treatment.

ALTHOUGH THE RADIOLIGAND therapy modality has existed for more than 80 years, it gained mainstream traction in the late 2010s following the landmark approvals of two therapies that redefined the standard of care for neuroendocrine tumours and prostate cancer.

These breakthroughs ignited a wave of innovation across the field and drew significant interest from major pharmaceutical companies. In recent years, industry leaders including Novartis, Bayer, Eli Lilly and Company (Lilly), Bristol Myers Squibb, and AstraZeneca have entered the radiopharmaceutical space through a series of high-profile acquisitions totalling more than US\$15 billion.

Today, most radioligand therapies use beta-emitting isotopes, such as lutetium-177 and iodine-131. While these therapies have demonstrated clinical benefit, their relatively low energy and longer-range radiation can limit effectiveness. The next evolution in radiopharmaceuticals is the emergence of targeted alpha therapies, which utilise alpha-emitting isotopes to deliver higher-energy, short-range radiation. This approach offers

greater potency and precision in destroying cancer cells, and a unique immunogenic profile, with the potential to significantly enhance therapeutic efficacy and improve patient outcomes.

Despite the immense potential of targeted alpha therapies, progress has been hampered by a significant bottleneck: the unreliable and limited supply of alpha-emitting isotopes. Current global production can only support treatment for a few thousand patients annually, which is well below the demand needed for large-scale clinical trials and eventual commercial deployment.

AdvanCell turned this barrier into a launch pad.

Founded in 2019 by a team of radiopharmaceutical experts inspired by the transformative potential of targeted alpha therapies, the company was initially ‘isotope agnostic’; however, Lead-212 quickly emerged as the optimal choice, and has since become the cornerstone of its development efforts.

Lead-212 possesses ideal physical characteristics for targeted alpha therapy, making it a highly attractive alternative to other alpha-emitting isotopes, such as Actinium-225. Its higher dose rate, short half-life and simplified decay scheme — with fewer alpha-emitting daughters — offers the potential for an

improved therapeutic index. These characteristics may also position Lead-212 for use in combination with other modalities and in earlier lines of treatment. Moreover, its generator-based production enables sustainable and scalable global production, a critical advantage in meeting the growing demand for targeted alpha therapies.

AdvanCell's proprietary Lead-212 isotope platform underpins the company's isotope production, which is a key competitive advantage in an industry where challenges around isotope supply continue to hinder development efforts.

Developed from inception with scalability and optimised yield in mind, the company's unique generator-based production method enables reliable, in-house daily Lead-212 production. This infrastructure supports the rapidly expanding therapeutic portfolio, and is being further scaled to meet the demands of late-stage development and future commercial deployment. This positions AdvanCell not merely as a player in the field, but also as a true platform company, and a vertically integrated radiopharmaceutical leader controlling the entire value chain, from isotope production to clinical-stage development.

At the core of AdvanCell's therapeutic pipeline is its lead asset, ADVC001, a novel and proprietary prostate-specific membrane antigen (PSMA) combined with Lead-212, currently in Phase I/II clinical trials (TheraPb, NCT05720130), for patients with metastatic prostate cancer. ADVC001 was engineered with the aim to overcome the limitations of other PSMA molecules, while leveraging Lead-212's unique properties to maximise therapeutic index, positioning it as a potential best in class. It is the most advanced Lead-212 PSMA program worldwide, and is currently enrolling in Australia.

Clinical data from the Phase Ib dose escalation TheraPb study of ADVC001 will be presented at the European Society of Medical Oncology (ESMO) 2025 conference, marking a major milestone for both the company and the field, as it will be the first-ever clinical data presented for a Lead-212 PSMA-targeted therapy. The early promising biodistribution imaging data from the trial had already captured the attention of the field, and was featured on the cover of the April 2024 issue of *Journal of Nuclear Medicine*.

Building on its novel lead program, AdvanCell is developing a pipeline of next-generation radiopharmaceutical therapies across multiple solid tumours, focusing on areas of high unmet need where Lead-212 may offer significant advantages over other modalities, and has the potential to change the course of cancer treatment.

AdvanCell's growth and innovation is driven by a world-class team of 90 professionals across Australia and the United States. The company has assembled a group of industry veterans

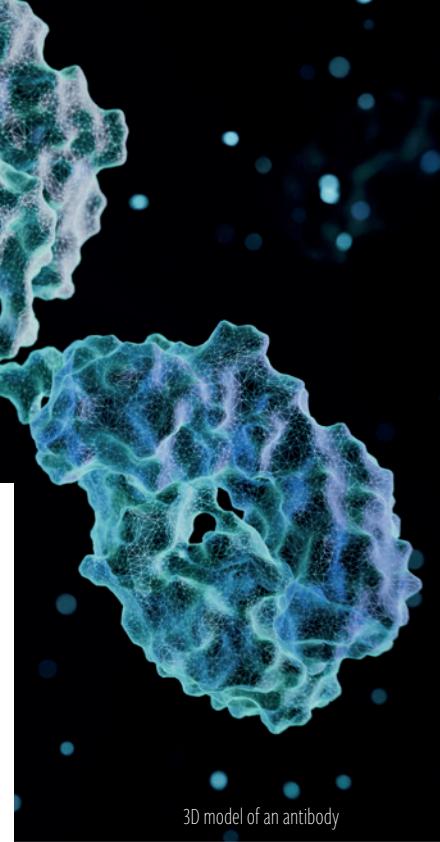
and experienced drug developers whose expertise has been instrumental in shaping the radiopharmaceutical landscape.

AdvanCell secured strong backing from top-tier international biotechnology investors through an upsized and oversubscribed Series C funding earlier this year, raising US\$115 million to accelerate its development and expansion efforts. In parallel, the company expanded a strategic collaboration with Lilly to advance novel targeted alpha therapies, leveraging the company's proprietary Lead-212 technology and infrastructure, as well as Lilly's drug candidate programs.

Most recently, AdvanCell was awarded more than US\$11 million (A\$18 million) in federal funding from the Medical Research Future Fund in Australia. As part of this multi-institutional grant, the company will collaborate with world-leading academics in Australia and globally to develop novel targeted alpha therapy combinations to improve clinical outcomes in prostate cancer.

Looking ahead, the company is deepening its presence in the United States, and enhancing its global manufacturing and development capabilities, which are key steps towards progressing its clinical pipeline and expanding its manufacturing platform technology to achieve its aim to change the course of cancer treatment. 





PROTEIN MODELLING TO SUPPORT IP STRATEGIES

BY KEN SEIDENMAN, FB RICE, AND SIMONA JOHN VON FREYEND, PTNG SCIENTIFIC

Protein modelling is an increasingly powerful discipline in the pursuit of defensive and offensive IP strategies in the commercialisation of protein therapeutics.

OVER THE PAST few years, computing power and developments in protein modelling have begun to offer unprecedented opportunities to explore the tolerance of antibodies or other proteins of commercial interest to mutations in functional domain sequences. These *in silico* methods can aid in the design of libraries of variant sequences that, with increasingly higher hit rates, not only retain original function, but, in some cases, actually improve functional properties of the starting protein or antibody (e.g., binding affinity or target selectivity) despite multiple amino acid substitutions.

In this article, we look at a (de-identified) case study to illustrate the power and commercial implications of these approaches in both defensive intellectual property strategies; for example designing around a patent claim to an antibody of interest, and offensive intellectual properties to obtain *in silico*-supported claims around a potentially broader 'genus' of protein sequences. The latter approach renders design round of such claims using the same *in silico* approaches more challenging to potential commercial competitors.

Protein modelling: the beginnings of a sea change

In 2018, DeepMind's AlphaFold algorithm burst onto the protein structural modelling scene and blew all other predictive tools out of the water with a less than 90 per cent accuracy of the true molecular structure. This level of accuracy is comparable to the atomic level of detail found in traditional crystal structures. AlphaFold (and its increasingly improved incarnations), with the rapidly growing computing power readily available today, offers unprecedented opportunities to accelerate early-stage therapeutics development. It is now possible to use computational structure predictions to design new protein functions, enhance binding affinities, and even design completely *de novo* proteins, including enzymes.

The state of play for protein modelling: a potential challenge for patent protection of protein therapeutics

Travellers on the long protein therapeutic commercialisation journey are well aware of the importance of obtaining patent claims that provide an effective commercial barrier to would-be competitors. In large part, the effectiveness of protein and antibody claims in blocking potential competitors depends on the scope of such claims. In some patent jurisdictions, such as the United States and Australia, the standards, particularly for antibody claims, are very strict and typically require that the scope of a claim to an antibody against a target of interest be limited to antibodies that have the exact same amino acid sequence for all six CDRs. In other words, if a competitor to the patentee develops an antibody that binds to the same target of interest but differs by one or two amino acids in any of the six CDRs, the competitor's antibody would not be covered by the above-mentioned CDR-limited antibody claim.

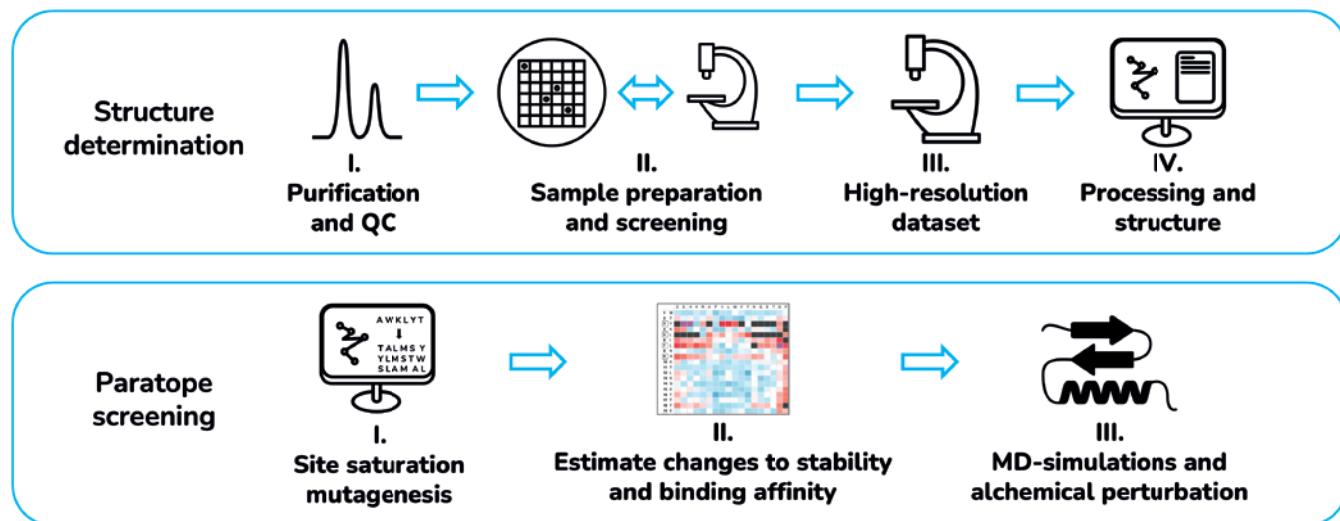
It will be quickly appreciated that the protein modelling approaches now available will drive a progressively rapid and affordable path to 'designing around' protein and antibody patent claims, as computational approaches prove increasingly accurate at predicting amino acid substitutions in a claimed protein to yield (e.g., antibodies that have similar or better binding affinity). We emphasise that this is not merely a hypothetical scenario, as demonstrated by the following de-identified anecdote.



Ken Seidenman



Simona John von Freyend



The protein modelling process

An antibody, a patent claim and a protein modeller

One of us (Simona) and the team at PTNG Scientific worked with a small biotechnology company interested in using an antibody for a promising, novel indication; however, the antibody was protected by an existing patent and the client concluded that generating an antibody variant with one amino acid substitution in each of the CDRs would work around the existing patent protection.

Brute force experimental trial and error testing to identify the relative handful of variants of the claimed antibody that would retain antigen binding despite six CDR mutations was daunting, as there are 64 million possible sequence variations. However, with the help of structural biology and in silico modelling, PTNG narrowed down the candidate set, aiming for functional equivalence, but with enough sequence variation to fall outside of the relevant claims.

In brief, the modelling process (summarised in the accompanying diagram) utilised virtual saturation mutagenesis across all CDR positions in the antibody of interest. Molecular dynamics simulations were then run to assess the impact of each mutation or sets of mutations on the interaction of the CDRs with the target antigen. Perturbation simulations were then applied to double-check binding free energy calculations and further validate tolerated substitution predictions. Only those structures predicted to be stable (via energy scores of the bound complex), and having high affinity to the antigen were then progressed. The biotech company went on to validate, experimentally, the predicted sequences and were able to move forward with the commercial development of their variant antibody, which was not covered by the patent claims for the starting antibody.

Playing offense: design-around proofing in silico

As the above example illustrates, we believe that it will become increasingly important for innovators seeking robust patent coverage of new protein therapeutics (e.g., an antibody to a new therapeutic target) to exploit protein modelling approaches to allow for broader protein/antibody patent claim coverage, particularly in jurisdictions such as the United States that are very strict on allowable sequence variations. The rationale for this

view is at least threefold. First, the use of protein modelling to rapidly identify, *in silico*, will afford the generation of a plausible subset of protein sequence variants to be identified that can be validated experimentally within tractable timelines and budgets, and then incorporated into patent specifications and claims. Second, although it will often not be possible to experimentally test all candidate sequence variants, as the predictive accuracy of protein modelling approaches increases, the patentee incorporating predicted functional sequences into patent claims will be in an increasingly strong position to argue to generally sceptical patent examiners that such claims are justified even when not every single sequence has been experimentally tested. Third, even in the case where a patentee is unable to obtain claims encompassing *in silico*-only sequence variants, the publication of a patent application with such lists of sequences will serve as prior art against patent claims covering sequence variations advanced by potential competitors, which serves as a disincentive to competitors entering that commercial space.

We believe that it will become increasingly important to commercial players interested in developing protein and antibody-based products to reckon with the state-of-the-art in computational modelling by integrating modelling approaches strategically both 'offensively' starting from the research that identifies a protein/antibody with commercial potential to maximise potential patent protection by *in silico* expansion of sequence possibilities, and 'defensively' by using computational tools to design around patent coverage. The most important point is for all actors in the space to be very aware of the potential commercial implications of protein modelling we have outlined here and plan accordingly. In the words of Wayne Gretzky, 'Skate to where the puck is going, not where it has been.'

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CREATING HEALTHIER LIVES: INTEGRATED TESTING, CDMO AND MICROBIAL QUALITY CONTROL FOR THE BIOTECHNOLOGY SECTOR

AUSTRALIA'S BIOTECH INDUSTRY is advancing bold new therapies with global potential, from monoclonal antibodies and vaccines, to cutting-edge cell and gene therapies. As the complexity of products grows, so does the need for robust, integrated support that spans development, manufacturing, biosafety and microbial control.

Charles River Laboratories partners with Australian innovators to navigate the scientific, operational and regulatory hurdles that come with bringing life-changing therapies to market. With a comprehensive global footprint, including a microbiological quality control hub in Melbourne, the company brings proven expertise, scalable platforms, and end-to-end solutions tailored to the needs of both emerging and established biotechs.

Charles River Laboratories supports therapeutic journeys at every stage: from upstream characterisation to downstream release. The portfolio includes:

Biologics testing services

Charles River Laboratories' capabilities include cell banking, viral clearance, impurity profiling, bioactivity, potency testing and stability studies. With more than 40,000 biologics testing reports delivered worldwide, the company's testing ensures confidence in every critical milestone, from clinical batches to global lot release.

Cell and gene therapy contract manufacturing organisation solutions

An integrated contract manufacturing organisation (CDMO) offering spans CGMP plasmid DNA, viral vector development, and autologous/allogeneic cell therapy manufacturing, including T-cells,



NKs, MSCs, and more. Whether you're in early-stage development or preparing for commercial launch, these services are designed to flex with your program's complexity.

Microbiological quality control solutions

Quality control is a cornerstone of safe, compliant production. Charles River Laboratories provides a full suite of microbial solutions:

- Endosafe® bacterial endotoxin testing solutions consist of both Food and Drug Administration-licensed Limulus amebocyte lysate and recombinant cascade reagent products and testing services for rapid and traditional endotoxin detection.
- Celsis® rapid microbial detection methods provide fast, confident and objective results that allow your quality control microbiology team to quickly confirm the presence or absence of microbial contamination in samples using an automated, reagent-based assay.
- Accugenix® microbial identification and strain typing services process more than 620,000 environmental isolates annually, and offer unparalleled accuracy and reliability.

The company's microbial quality control solutions are designed to detect, identify and control microbial risks at every step, supporting everything from raw material inspection to drug product release.

With the combined strength of biologics testing, CDMO services and microbiological platforms, the company is uniquely positioned to reduce complexity and accelerate development timelines without compromising scientific integrity or regulatory compliance.

As Australia's biotech ecosystem continues to expand, Charles River Laboratories remains committed to helping local innovators thrive by providing flexible, reliable and science-driven support, because every moment matters. ☺

To learn more about how we can help fast-track your development journey, visit www.criver.com. To schedule your meeting at Ausbiotech 2025, or to connect with the Charles River team, email contactbiologics@crl.com.



Creating Healthier Lives

Accelerate the development of new therapies for patients who need them most



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Solutions



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Biosafety
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Testing



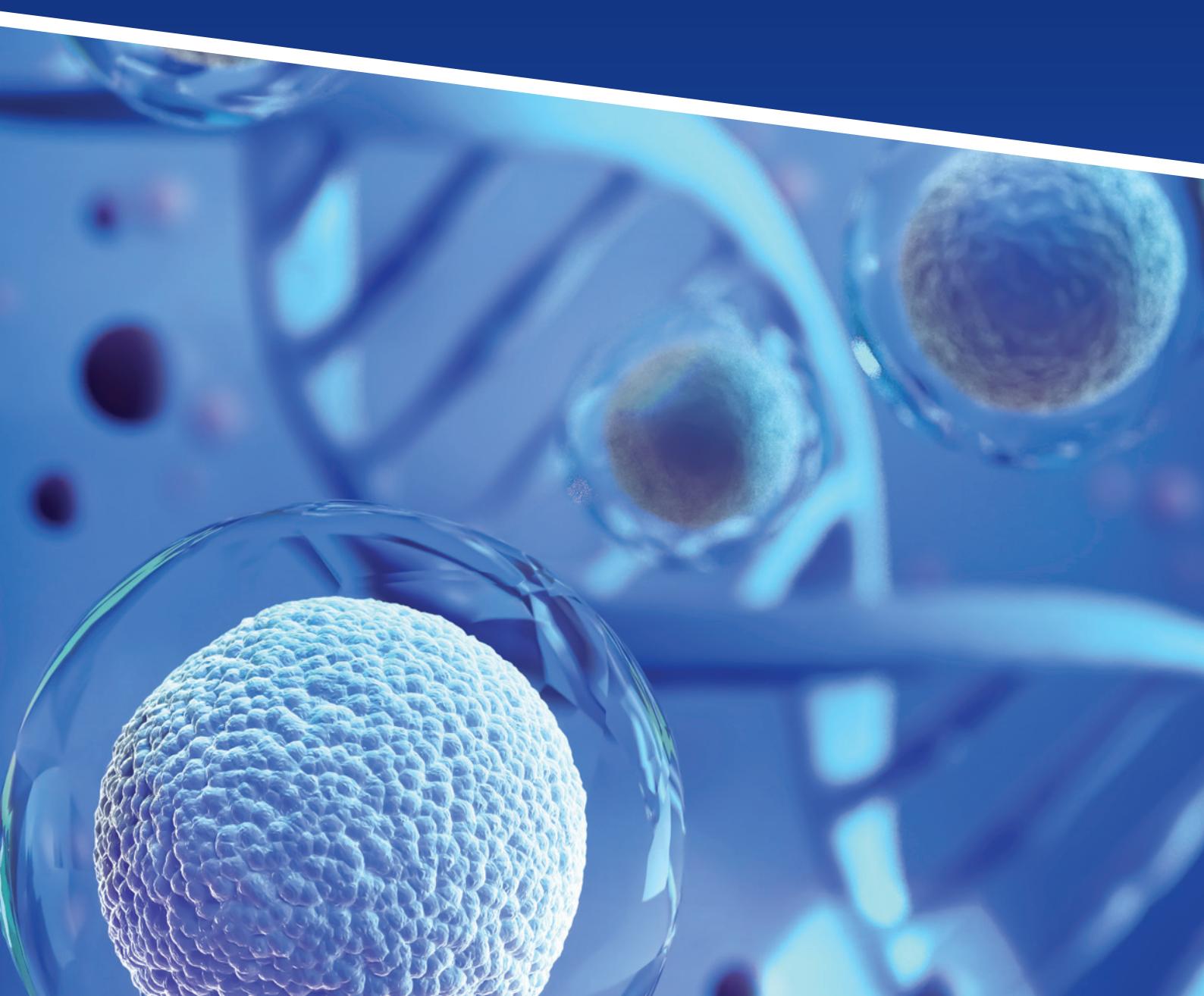
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Cicada x Tech23, 2024

A NEW SYSTEM OF CARE: THE STARTUPS REIMAGINING HEALTH

BY KATJA BEITAT, GROUP EXECUTIVE HEALTH TECH PROGRAMS & INCUBATORS, CICADA INNOVATIONS

The future of health care is being built by mission-led scientists, engineers and founders, working in labs, hospitals, and research centres across Australia. At Cicada x Tech23, the nation's flagship deep tech event, the next generation of healthtech leaders are stepping onto the stage.

FROM PREDICTING PSYCHIATRIC relapse to preventing organ failure, these ventures are laying the groundwork for a healthcare system powered by breakthrough technologies, designed to prevent, diagnose, and intervene earlier and more effectively. They are not driven by short-term returns, but by the ambition to reshape health care as we know it.

From vision to validation

Australia's and many global health systems are under mounting strain. An aging population, the rising burden of chronic disease, and relentless pressure on hospitals and care providers are stretching resources to their limits. These forces have exposed structural gaps that incremental improvements cannot fix. Too often, patients receive care only when it is too late: in the emergency ward or ICU, where costs are highest and outcomes worse.

This new generation of ventures is charting a different course. The aim is to disrupt the traditional way care is provided by creating alternatives to prevent and intervene early, and with precision. While the journey from concept to clinic is often long, requiring years of research, prototyping, validation and regulatory approval, the ultimate goal is to reshape health care itself.

At the forefront is Liora Neurotech, a resident of Cicada's Westmead HealthTech Hub, founded by scientist Naomi Dragt-Velásquez, who combines her background in psychology and neuroscience with lived experience supporting family members with mental illness. Liora is developing a wearable biosensor that continuously tracks a range of biomarkers to give early warning of psychiatric relapse in schizophrenia and bipolar disorder.

In intensive care, Nutromics, co-founded by healthcare consultant turned entrepreneur Hitesh Mehta, is developing a lab-on-a-patch that uses DNA-based biosensors and microneedles to provide real-time molecular monitoring. Instead of delayed lab results, ICU teams can track a patient's molecular profile continuously, aiming to support safer and



Katja Beitat

personalised medication regimes for patients (e.g., Vancomycin, a powerful but risky antibiotic). Backed by \$20 million in funding and validated in early human trials, Nutromics is showing how diagnostics can shift from single snapshots to continuous streams of actionable data.

Pretec Devices emerged after founder Dr Nipanjana Patra, a former astrophysicist, experienced the vulnerabilities of neonatal care firsthand. Her company is developing a monitor that detects IV infiltration in premature babies before it causes lasting damage. By creating a device designed specifically for neonates, Patra is rethinking safety in neonatal intensive care and giving families peace of mind.

And in renal medicine, One Kidney, founded by mechatronics engineer Alur Saguinsin after she lost her father to end-stage kidney failure, is pursuing a fully implantable artificial kidney. Combining personal lived experience with technical expertise in medical device engineering, Saguinsin is working toward a future beyond dialysis machines and scarce donor organs, offering new hope for millions living with kidney disease.

These ventures do not exist in isolation; they follow in the footsteps of Tech23 alumni like dermR Health, whose microneedle patch could reduce the need for biopsies, and Tetratherix, which listed on the ASX in 2025 with a regenerative hydrogel platform for wound care and surgery. Together, they demonstrate how Australian science, driven by bold founders as much as breakthrough technologies, can move from lab discovery to real impact.

A new system of care

Taken together, these ventures are sketching the outline of a healthcare system that intervenes earlier, adapts to each individual, and extends beyond hospital walls into communities and homes. It is a vision of care that is preventive, personalised and proactive.

The path to this future is not simple. Medical innovation demands persistence, long development cycles, and rigorous testing, collaboration and holistic support. Many startups operate for a decade or more before reaching the market. Progress relies on sufficient funding; collaboration with hospitals, clinicians and researchers; and on opportunities for pilot programs and validation studies that bring technologies closer to local procurement and clinical adoption.

This is where Cicada x Tech23 plays a critical role, not only as a showcase, but as a forum that connects founders with the partners, investors, and policymakers who can help bridge the gap between discovery and deployment. Over the past 25 years, Cicada Innovations has supported hundreds of health technology ventures through its incubators, including at the

HealthTech Hub in Westmead and the Bioincubator in Melbourne. By nurturing ventures like Nutromics, dermR Health and Tetratherix, Cicada is helping to transform lab discoveries into global healthcare solutions — proof that Australian healthtech innovation not only scales, but also delivers real patient impact. With more than half of Australia's nationally critical technologies grounded in deep tech, the stakes extend well beyond commercial outcomes to the long-term sustainability of the health system itself.

The future of health care will not be built by institutions alone. It will be shaped by founders who translate science into systems, by investors who are willing to share the risks of early-stage discoveries and development, by governments investing in skills and infrastructure to support scaling and building true pathways to local procurement, by clinicians willing to adopt new tools, and by communities prepared to embrace change. These ventures and the people behind them remind us that innovation is not just about devices, but is also about reimagining how care is delivered. If given the chance, Australia's healthtech innovators could shift health care from crisis response to proactive support, improving outcomes for millions and securing Australia's place as a global leader in medical innovation.



The Nutromics lab-on-a-patch uses biosensors and microneedles to provide real-time molecular monitoring

Bold but Unheralded: How Myrio Therapeutics is Redefining the Future of Immuno- Oncology



The current US based PHOX2B CAR-T cell trial for paediatric relapsed neuroblastoma represents the strongest demonstration to date of Myrio's real-world impact, advancing the company's innovations beyond preclinical promise into meaningful clinical progress.

Myrio Therapeutics, an Australian biotechnology company established in 2009, has long been dedicated to advancing breakthrough therapies while operating under the radar. The company's first-in-human neuroblastoma trial now places Myrio firmly in the global spotlight.

As the trial progresses, Myrio is preparing to expand access to eligible patients internationally by the end of 2025, marking a significant step forward in addressing urgent unmet medical needs. Myrio's antibody technology served as the critical enabler for the development of a PHOX2B-targeting CAR-T, highlighting the transformative potential of its innovation platform.

This milestone underscores the company's commitment to delivering "innovation for global impact," a mission that aligns with AusBiotech's celebration of Australian scientific excellence on the world stage.

Under the leadership of Dr Graeme Wald, CEO, the company, while maintaining research in Australia, has developed global collaborations.

"We are scaling our business through numerous collaborations with elite research institutions. They recognise the skills and technology we bring to allow for collaborations to tackle peptide Human Leukocyte Antigen (pHLA) targets in solid tumours. The fact that we now have a product in clinical trials is a testament to our staff, technology and the collaborations with US institutions."

The company's success stems from a clear scientific philosophy: focus and target novel solid tumour intracellular targets via the pHLA complex.

Our Platform

The heart of Myrio's approach lies in its sophisticated antibody engineering and discovery platform - Retained Display (ReD™). It's the only platform that generates cancer-specific single chain fragment variant (scFv) panels with single-residue resolution. Furthermore, ReD™ is modality-agnostic where the selected scFvs can be developed into various therapeutic solutions, from bispecific T-cell engagers to CAR-T therapies.

Bispecific T-cell engager antibodies are proteins that can bind to two different antigens simultaneously. One arm of the antibody binds to a specific antigen on a cancer cell, while the other arm binds to the CD3 receptor on a T-cell, a powerful immune cell.

CAR-T cells are engineered to express a chimeric antigen receptor (CAR). These receptors are created by fusing a scFv to T-cell signalling domains, giving the engineered T cells antibody-like selectivity combined with potent immune activation.

Myrio's systematic, expeditious approach operates to engineer exquisite T-cell engagers focusing on target specificity early in the preclinical process. This allows for the identification and prioritisation of the safest and most potent antibody candidates, ensuring their discoveries can be translated into globally impactful therapies. Myrio isn't just seeking incremental improvements; it's focused on delivering next generation of pHLA therapeutics that aim for durable, complete clinical benefit and long-term patient survival.

Myrio's technology also addresses a critical challenge in novel immunotherapy: HLA restriction. Unlike other approaches, for example, T cell receptor-like engagers that are limited to a single HLA allotype; Myrio's platform identifies antibodies that bind to cross-presenting alleles with the same epitope. This capability, called "breaking HLA restriction," significantly broadens the patient population eligible for treatment, making therapies more inclusive and accessible.

Myrio's antibody technology

- Enhanced safety at early preclinical stage
- Specificity unrivalled for targeted efficacy
- Optimal stability for performance
- Efficacy maximised for potent clinical response
- Developability for faster timelines
- Half-life extension for improved PK
- Breaking HLA restriction for broad patient coverage
- Flexibility in therapeutic format
- Diversity in binders increase probability of success



Myrio welcomes discussions with interested partners on advancing and commercialising immunotherapies for patients globally.

Enquiries: partnerships@myriotx.com

Stay Connected & to view our pipeline

www.myriotx.com



Our Pipeline

Myrio is advancing 11 programs against high value pHLA targets including mutant KRAS, PRAME, and IGFBPL1 with a focus on assets backed by the strongest mechanistic rationale.

Our IP Strategy

Central to Myrio's progress is a disciplined approach to intellectual property: publish rigorous, peer-reviewed data while protecting the inventions that enable clinical translation. By sequencing public disclosure around tightly managed IP filings, Myrio preserves scientific credibility and fosters open academic exchange. At the same time, this approach secures the freedom to operate and builds commercial foundations needed for long-term development. This duality has made Myrio an attractive partner.

Our Partnerships

Myrio's scientific prowess and translational relevance are validated by its high-profile and published collaborations with leading U.S. clinical and academic institutions. Since 2017, the company has forged strong partnerships with the Children's Hospital of Philadelphia, the University of Pennsylvania, Stanford University, the NIH and NYU, demonstrating a bridge between Australian biotech innovation and world-class U.S. academic centres.

These partnerships are not just symbolic; they are a direct validation of Myrio's technology and potential to deliver meaningful clinical impact. By working closely with luminaries of translational T cell research, Myrio's innovations are applied directly to solving the most urgent challenges in treating solid tumours.

PARTNERING FOR PROGRESS: WHY THE PATIENT'S VOICE BELONGS IN THE TRANSLATIONAL PIPELINE

BY DR AUVRO MRIDHA, DIRECTOR, ADVANCED THERAPIES & TRANSLATION; AND DR DOROTA PAWLAK, CHIEF SCIENTIFIC OFFICER AND DIRECTOR T1DCRN, BREAKTHROUGH T1D AUSTRALIA



Breakthrough T1D's globally coordinated, consumer-informed approach showcases how to fast-track therapies through integrating science and community.

IN MEDICAL RESEARCH, brilliant discoveries stall between the bench and the bedside. This 'valley of death' is costly, risky and slow. Traditional pipelines are fragmented, leading to delayed translation and therapies that fail to meet real-world needs.

For innovators across pharmaceuticals, biotechnology, academia and patient organisations, the goal is shared: accelerate science and deliver outcomes. But to their detriment, the path is rarely aligned.

This is where specialised, disease-focused non-profit organisations like Breakthrough T1D (formerly JDRF) can make a difference. As a leading global funder, we use our capital and expertise to drive the most promising research forward, speed up clinical development, and influence other funders, biotechs, and pharma to make the investments needed to cure, prevent, and better treat type 1 diabetes (T1D).

This model is already driving impact for T1D and offers a blueprint for catalysing innovations across disciplines.

Breakthrough T1D's strategic model

T1D affects 9.5 million people worldwide¹, including more than 140,000 Australians². It requires lifelong insulin therapy and constant glucose monitoring, and carries the risk of life-threatening complications. There is no cure or prevention — yet.

Breakthrough T1D's singular focus is to create a world without T1D. Founded more than 50 years ago by parents determined to change the future for their children, T1D has grown into the largest non-profit funder of T1D research globally.

To date, we've stewarded more than US\$2.5 billion in cumulative research investment in more than 20 countries, with a portfolio spanning basic discovery through to early- and mid-stage clinical trials. Moreover, since its inception in 2016, the T1D Fund, our dedicated venture philanthropy arm, has catalysed more than US\$900 million in private investments towards advancing T1D cures and therapies.

Yet, we know funding alone won't deliver breakthroughs into the hands of the community. That's why our model encompasses public advocacy and patient engagement to move therapies through the pipeline. We:

- include patients and families in setting research priorities
- convene advisory panels to define therapeutic and clinical care needs

- review research protocols and prototypes, ensuring real-world relevance
- connect communities to promote clinical trial enrolment and awareness
- educate industry, governments and regulators about patient needs and upcoming therapies.



Dr Auvro Mridha



Dr Dorota Pawlak

Proof in practice

From basic science to approved therapy

In 2022, the Food and Drug Administration approved the first disease-modifying therapy for T1D, Tzield, which slows T1D progression and delays insulin initiation. We supported Tzield's development from early-stage research through to clinical trials and helped navigate regulatory pathways for its approval. In 2017, the T1D Fund made a strategic investment in Provention Bio and catalysed the therapy's further development. In 2023, Sanofi acquired Provention Bio for US\$2.9 billion, bringing Tzield into the portfolio of a global pharmaceutical leader.

From research to standard of care

For decades, Breakthrough T1D funded independent research to demonstrate the real-world clinical effectiveness and quality-of-life benefits of continuous glucose monitors (CGMs).³ This body of evidence lead to international regulatory approvals and guideline adoption.

Our Access for All campaign, undertaken in collaboration with other peak diabetes bodies, worked to make CGMs accessible in Australia. Through our joint advocacy, staged subsidisation was introduced in 2017, with gradual expansions leading to universal subsidisation in 2022.

This resulted in local CGM uptake increasing from <5 per cent pre-subsidy to over 70 per cent, with CGMs now considered the standard of care.⁴

Growing Australia's clinical capability

The main vehicle for Australian T1D research is Breakthrough T1D's Clinical Research Network. Established more than a decade ago, it has 'put Australia on the map as a leader in T1D research', according to Minister for Health and Aged Care the Hon. Mark Butler MP.

People with T1D sharing their lived experience at Breakthrough T1D's consumer engagement conference, attended by researchers and industry



Breakthrough T1D advocate with Minister for Health and Aged Care the Hon. Mark Butler MP, and Shadow Minister for Health Senator the Hon. Anne Ruston



Thanks to our advocacy, the network has received continued government funding to the sum of \$122 million, enabling us to fund the best and brightest researchers, and push therapies through the pipeline.

The network has doubled the number of T1D trials and studies in the country, with more than 10,000 Australians enrolled and accessing potentially life-changing therapies.⁵

The network is also speeding up trial recruitment and advancing trial design, with the first-ever adaptive T1D trial launched this year, testing multiple therapies simultaneously to expedite outcomes.

Building commercial capabilities

Translation often falters between discovery and commercialisation. To bridge this gap in Australia,

Breakthrough T1D launched the SPARC Program, investing in high-potential projects while providing commercialisation training, mentorship and cross-sector collaboration. Researchers learn how to navigate regulation, intellectual property and business development, creating a pipeline of investor-ready opportunities.

Preparing for the next era of cures

People living with T1D consistently voice their need for therapies that go beyond managing the condition, to address the root cause and ultimately deliver a cure. Advanced therapies that can restore insulin production are the most likely to disrupt T1D care and realise this hope.

Breakthrough T1D has supported foundational research in stem cell-derived islet replacement and immune-modulation, many of which are now in clinical trials. Of these, Vertex and other biotechs are advancing cell therapies towards regulatory approvals.

Together with academia and industry, Breakthrough T1D is working to ensure these therapies can be tested and delivered locally.

A blueprint for biotech collaboration

For decades, disease-focused foundations such as Breakthrough T1D have partnered with industry and governments to share risks, shorten translation timelines, and advance human-centred research.

This isn't only ethical; it's strategic. By embedding patient voices, therapies are designed for the people who will use them, reducing costly missteps and improving market success. It is no surprise that, increasingly, funding bodies and investors are demanding proof of consumer engagement in early-stage development.

Breakthrough T1D's globally coordinated, consumer-informed strategy is a blueprint that proves the patient voice belongs in the translational pipeline.

For the biotech sector, the opportunity is clear: partner with patient organisations to ensure your innovations reach the people who need them. Together, we can bring Australian T1D innovations to the world, and global breakthroughs to Australia. 

End notes

- 1 T1D Index. 2025. Available online: www.t1dindex.org
- 2 National Diabetes Services Scheme, 'Type 1 diabetes data snapshot', August 2025, available online: snapshots.ndss.com.au
- 3 N Engl J Med 2008; 359:1464-76
- 4 Diabetes Care 2022; 45:391-397
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THE FOCUS OF OUR ATTENTION

WHEN BELLBERRY WAS founded in 2004 as a not-for-profit independent provider of human research ethics committee (HREC) services, one of its objectives was to protect the welfare of research participants. Its focus on participants has never wavered.

How does Bellberry do this? First and foremost, through the core work of its 12 HRECs in providing ethical and scientific reviews of human research. When reviewing research submissions, the participant is placed at the centre of the HREC's considerations.

Secondly, as a not-for-profit, Bellberry reinvests the profits it generates into activities that can further promote participant or patient interests.

Bellberry is proud to host CT:IQ, a member-based organisation dedicated to enabling efficient, effective and patient-centred trials. CT:IQ was recognised by ARCS Australia, winning the 2025 ARCS Australian Patient-Centred Award for its work in promoting the voice of the patient or participant in clinical trials.

An example of CT:IQ's work is The InFORMed Project, which has created a participant-centred, simplified, national participant information and consent form template (PICF) for health and medical research in Australia. Previously, participants have described PICFs as overwhelming, long-winded, complex and confusing.

The InFORMed PICF was developed following extensive consultation with healthcare consumers, patients and carers, as well as researchers, research organisations, and plain language experts. You can find it by visiting www.informedpicf.com.au.

In a new initiative, Bellberry is piloting a community and consumer advisory panel (CCAP). The CCAP is made up of consumers and community members with lived experience and expertise in a range of conditions. The panel will be available as a resource for researchers, sponsors, and sites to provide advice and insights into the research design phase.

By involving those with lived experience in the design phase of the research, participant recruitment, engagement and retention is likely to be stronger, and result in more participant-focused study outcomes. To find out more about the CCAP, contact trinaodonnell@bellberry.com.au.

Since 2022, Bellberry has awarded participant engagement grants to conference organisers to place consumer and participant perspectives at the heart of healthcare innovation. This year, Bellberry has awarded grants to four organisations, including the 2026 Australian Frailty Network (through The University of Queensland) for its consumer-led unconference, titled 'Bringing Researchers to the Consumers'. Other organisations supported are the Australian & New Zealand Stroke Organisation; Cancer Institute NSW; and the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine.

Bellberry proudly sponsored AccessCR's 2025 Inaugural Australian Consumer Partnerships in Research Awards showcasing innovation and excellence in partnership activity between researchers and health consumers.

Bellberry is excited to see what's next in supporting participants, patients and health consumers, and is always interested to hear how to do this best. ☺



Some members of Bellberry's consumer and community advisory panel (CCAP): Sarah Lukeman, Shyam Muthuramalingam and Ann Single

De-Risking Early-Stage Biotech: Turning Vision into Venture Capital

Why early commercial thinking, stakeholder alignment, and scenario modeling are your best fundraising tools

Drug development is complex and costly—especially for emerging biotech. IQVIA helps you define a clear product vision and compelling value story to attract investors. From strategy to first-in-human trials, we guide you through three essential steps for success.



Target Product Profile (TPP): A dynamic blueprint that connects clinical goals with commercial vision—driving faster development and unified stakeholder buy-in. While traditionally seen as a static blueprint, the strategic TPP is a dynamic tool, especially valuable for companies pursuing accelerated timelines into first-in-human trials. By enabling early clarity on differentiation, risk tolerance and value drivers, a well-structured TPP empowers teams and stakeholders to align and move decisively while maintaining strategic cohesion.



Clinical Development Plan (CDP): A flexible roadmap that models multiple pathways—balancing cost, risk, and timelines to guide smart decisions and investor confidence. It enables teams to model and compare multiple development pathways, each with distinct timelines, costs, and risk profiles. This flexibility is especially critical for early-stage companies navigating uncertainty and capital constraints. A robust CDP not only guides internal decision-making but also serves as a communication tool for investors, demonstrating the impact of time and cost against regulatory milestones and commercial goals. By integrating real-world data, adaptive trial designs, and go/no-go criteria, the CDP becomes a living document that evolves with the asset, supporting both conservative and accelerated strategies.



Expected Net Present Value (eNPV): A powerful metric that turns uncertainty into opportunity—quantifying strategy to unlock funding and fuel growth. eNPV provides a framework to objectively assess the potential value of that asset at the end of its projected development path. By integrating assumptions around development time, cost, risk, and return across multiple scenarios, eNPV transforms scientific uncertainty into quantifiable investment potential.

Conclusion:

The TPP, CDP and eNPV are not only important to investors, but for alignment of your own development team. It is also the basis for creating the clear product vision that underpins the value of the drug to the patient, the physician and the payer. Creating a realistic and robust value story will improve the chance of successfully funding your development program and gaining approval of your drug. A survey of 100 biopharma executives, conducted by Citeline and IQVIA, found that 83% use a traditional TPP approach focused on regulatory and feasibility factors. 68% develop multiple TPPs per asset. Beyond the base case, developers should define both a minimally viable profile to guide go/no-go decisions and an aspirational target to avoid limiting potential success.

Scan the QR code to access the White Paper that unlocks insights into driving smarter clinical development.



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- 2** *Global. Scalable. Results-driven.* ► IQVIA's expansive global network—active in over 100 countries—delivers comprehensive, full-service support across clinical research and commercial operations. 
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Entomopathogenic fungi as a biocontrol measure for pest insects grows in a petri dish

ACCELERATING IMPACT IN AGRICULTURAL BIOTECHNOLOGY: A STORY OF CONVERGENCE

BY MICHELLE GOLDSMITH, CEO, AGRICULTURE VICTORIA SERVICES PTY LTD

The line between medical biotechnology and agricultural biotechnology is blurring — and that's a good thing.

AS CLIMATE PRESSURES intensify and food systems become more complex, agriculture can no longer rely on conventional tools alone. Some of the most promising breakthroughs are now coming from outside the farm gate — from technologies originally developed for human health.

RNA-based solutions, biosensors, diagnostics, and data platforms are being repurposed for agriculture, addressing challenges from methane mitigation to pest management, and disease and crop resilience. This is not just a case of technology transfer; it's also a shift in how we think about biotechnology itself. The convergence of sectors presents a rare opportunity: dual-purpose solutions with the potential for global impact.

In Victoria, this shift is already underway. Agriculture Victoria and Agriculture Victoria Services are trialling and scaling technologies through a network of five SmartFarms and AgriBio, one of Australia's premier, state-of-the-art agribioscience hubs. This hub-and-spoke model of facilities acts as a real-world testbed for crossover innovation where scientific discovery, practical application and commercialisation intersect to develop impactful solutions.

At the heart of these efforts is a commitment to listening to and learning from the people and organisations who will ultimately use, adopt, and benefit from these innovations. The voices of farmers, growers, industry partners, and government stakeholders bring essential perspectives on what works in practice, what delivers value, and what challenges might stand in the way of adoption. Their input shapes priorities, ensures technologies are fit-for-purpose, and keeps the focus on

delivering solutions that address real needs, rather than chasing purely technical milestones.

Working at Agriculture Victoria's SmartFarms, researchers can adapt vaccine technologies, first developed for humans, to protect crops from pests and diseases without traditional chemical inputs. This approach offers precision and sustainability, targeting only the problem organisms while minimising environmental impact.

Biosensors, originally designed to detect health conditions in humans, are being applied to monitor animal wellbeing in real time. This enables earlier intervention, reduces the spread of disease and can improve productivity by preventing health issues before they escalate. Data platforms are finding dual use, offering insights that can improve both patient outcomes in health care and productivity in agriculture. Whether tracking disease patterns, monitoring soil and plant health, or integrating weather and market data, these platforms help producers make better-informed decisions.

This convergence is not accidental; it is the result of breaking down silos between sectors. When scientists, innovators, policymakers and investors work across boundaries, ideas flow more freely and opportunities for impact multiply. The medical biotechnology/pharmaceuticals sector brings a depth of expertise in precision diagnostics, regulatory navigation and investor readiness; agriculture offers real-world complexity, scale, and an urgent demand for solutions. Together, they create fertile ground for innovation.

The next wave of agricultural breakthroughs could be developed by medical research-trained talent and backed by investors seeking broader impact. It might be a medical diagnostics startup pivoting to livestock health, a biotech company adapting a therapy for plant disease resistance, or a health-data platform repurposed to track environmental conditions affecting crop yields. The common thread is a technology that can serve multiple markets and deliver benefits across sectors.

These kinds of crossovers are often sparked by unexpected conversations or collaborations; when a researcher realises their work could solve a pressing agricultural problem, or when an agricultural business recognises the potential of a health technology to improve farm outcomes. The challenge, and the opportunity, lies in creating the conditions where these connections are more likely to happen and can be developed into practical, scalable solutions.

For Victoria, the opportunity is clear. By leveraging our scientific expertise, commercialisation capability and collaborative networks, we can foster an environment where convergence thrives. Innovators, entrepreneurs and investors — whether

from agriculture, health technologies or beyond — can find fertile ground for exploring the possibilities that this crossover offers.

Convergence is not just about sharing tools; it's also about unlocking new markets, multiplying impact, and delivering solutions that matter. A technology developed to diagnose disease in humans could save an entire crop from a destructive pest. A data analytics platform built to track patient recovery could optimise farm management in real time. Each example illustrates how the benefits flow in both directions, strengthening resilience in agriculture while extending the reach and relevance of health innovations.

The next breakthrough may already be in development in a lab, business or investment portfolio, waiting to find its agricultural application. In the same way, the next leap forward for human health might be born in agricultural research.

If we are serious about meeting the challenges facing agriculture, we must keep encouraging this crossover thinking. The future of farming may depend as much on breakthroughs in medical biotech as it does on discoveries in the paddock. The sooner this reality is embraced, the greater the shared impact will be. 

Entomopathogenic fungi as a biocontrol measure for pest insects grows in a petri dish





NEW TOOLS TO AID DISEASE FIGHT

BY DR JACK RICHARDS, CO-FOUNDER AND SCIENTIFIC DIRECTOR, ZIPI DIAGNOSTICS

ZiP Diagnostics was founded in 2019 with a mission to develop rapid, accurate and low-cost point-of-care diagnostics.

As an infectious disease physician, I've had experience working in Australia and in low-middle income countries. I have seen firsthand the need to develop new high-quality diagnostic tools to enable healthcare professionals to make rapid decisions and improve patient outcomes.

The disruption and supply chain risks during the COVID-19 pandemic made it even clearer that there is a global demand for innovative diagnostic solutions. ZiP is proudly the first Australian manufacturer to ever achieve Therapeutic Goods Administration registration of a molecular point-of-care test platform.

We currently have tests on the market for SARS-CoV-2 and environmental applications. We also have tests for emergency animal diseases (foot-and-mouth disease, lumpy skin disease and African swine fever) in validation studies. These are critical for protecting Australia's livestock industry.

Our integrated test platforms comprise diagnostic assays, cartridges and instruments that are small and portable, and can be used by operators without laboratory training. All significant components are manufactured in Melbourne.

New products in the pipeline

We're developing new products to address critical gaps in global health. Our pipeline includes tests targeting some of the world's most devastating mosquito-borne infections, including dengue fever, chikungunya virus and malaria. With almost 700 million people contracting mosquito-borne diseases annually, this work is particularly urgent.

We're also advancing our world-first rapid diagnostic for scabies and skin co-infections, addressing a major unmet need as scabies affects more than 200 million people

worldwide each year. Our test can detect scabies and identify common secondary bacterial infections within 10–20 minutes.

Additionally, we're expanding into diseases affecting maternal and child health, recognising the critical importance of rapid diagnosis in these vulnerable populations. We're also broadening our menu for animal and environmental diseases, building on our existing capabilities in biosecurity applications.

Growth on the horizon

Australia is exceptionally well-suited for this high-tech industry. We've established robust research and development capabilities alongside domestic manufacturing here in Melbourne. Victoria's concentration of hospital-linked clinical trial networks provides an ideal ecosystem for a company like ours to conduct clinical validation studies.

We have access to Victoria's breadth of highly skilled workers so we can build our own research and development, and advanced manufacturing capability, as well as deliver clinical validation and regulatory approvals, positioning us perfectly for expansion. Our end-to-end capability enables us to rapidly progress products from development to manufacturing, and then through to commercial products.

We have been supported by the Victorian Government to scale our manufacturing capabilities and have shown proven ability to develop, manufacture, and validate diagnostics for multiple disease areas. ZiP is well positioned to grow as we commercialise new products for use in Australia and for export. Our goal is to supply affordable, high-quality products globally while building a sustainable Australian company that contributes to both local prosperity and global health security. 



Dr Jack Richards

Victoria, where government is your partner for success

Melbourne, Victoria is a highly sought-after destination by global and local medical technology, pharmaceutical and agritech companies.

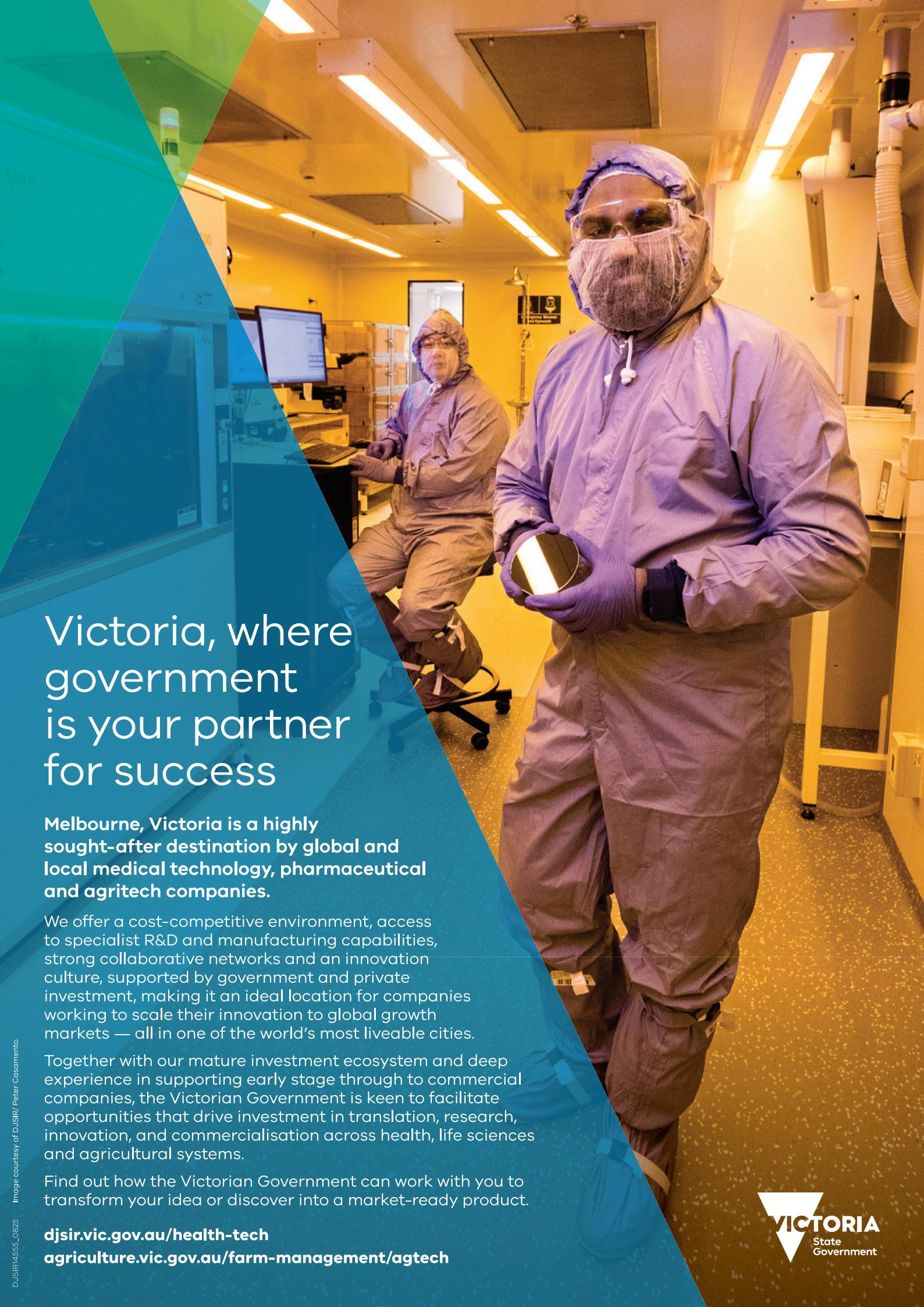
We offer a cost-competitive environment, access to specialist R&D and manufacturing capabilities, strong collaborative networks and an innovation culture, supported by government and private investment, making it an ideal location for companies working to scale their innovation to global growth markets — all in one of the world's most liveable cities.

Together with our mature investment ecosystem and deep experience in supporting early stage through to commercial companies, the Victorian Government is keen to facilitate opportunities that drive investment in translation, research, innovation, and commercialisation across health, life sciences and agricultural systems.

Find out how the Victorian Government can work with you to transform your idea or discover into a market-ready product.

djsir.vic.gov.au/health-tech

agriculture.vic.gov.au/farm-management/agtech



TURNING POTENTIAL INTO IMPACT

LOCATED IN MELBOURNE'S Parkville Precinct, the Monash Institute of Pharmaceutical Sciences (MIPS) is home to a community of more than 500 scientists that seek to catalyse and connect discovery teams with translational resources and expertise to progress new ideas towards commercial and clinical success. In doing so, MIPS has become renowned for its ability to support internal entrepreneurship, and to work with collaborators to maximise the value of their discoveries.

This model has led to multiple spin-out biotechnology companies, and has been the driving force behind working with partners to progress more than 40 novel drug candidates into clinical development.

Infrastructure and support: enabling commercial translation

MIPS research spans the full drug discovery and development pipeline, from early discovery through to real-world evaluation of medicine use. This is supported by cutting-edge platforms encompassing drug screening, medicinal chemistry, lead optimisation and drug delivery, with the ultimate goal of preparing viable drug candidates that are well-positioned for further development and investment.

Medicinal chemistry: turning hits into leads

Central to this is the establishment of several landmark initiatives to bolster Australia's biopharmaceutical ecosystem. One recent example is MedChem Australia, a national initiative established to guide projects through the critical early stages of drug discovery and translate 'hits' into drug candidates with enhanced commercial value. In 2024, MedChem Australia announced its

first six projects from universities and research institutes from four states, addressing unmet needs across a range of diseases.

Advancing the next generation of mRNA

MIPS is also home to multiple mRNA-focused programs, including mRNA Core and CORTx, which have collaborated with national and international research institutes on vaccines and therapeutics for COVID-19, malaria, fatty liver disease, type 2 diabetes, cancer, and tuberculosis. mRNA Core and CORTx are working on a range of projects that collectively have developed more than 600 different candidate mRNA-lipid nanoparticle formulations, laying the foundation for the next generation of mRNA medicines.

Building biotechnology: from basic research to commercial success

In the last five years, Monash University has collectively generated more than 500 invention disclosures, completed 169 new licence deals and created more than 30 spin-out companies that together have raised more than A\$1.5 billion in investment. With the support of Monash Innovation, MIPS has made a significant contribution to the university's research commercialisation success with multiple licence deals and biotech spin-outs stemming from MIPS-led research projects. This includes (but is not limited to) Septerna, Cincera, Seaport Therapeutics, Phrenix, and Pacalis Therapeutics, the latter three of which are helping to address the urgent unmet need for new mental health and neurological medicines. 

MIPS sits within Monash University's world-leading Faculty of Pharmacy and Pharmaceutical Sciences. Discover more about how MIPS can contribute to your pharmaceutical project or business by contacting mips.research@monash.edu.

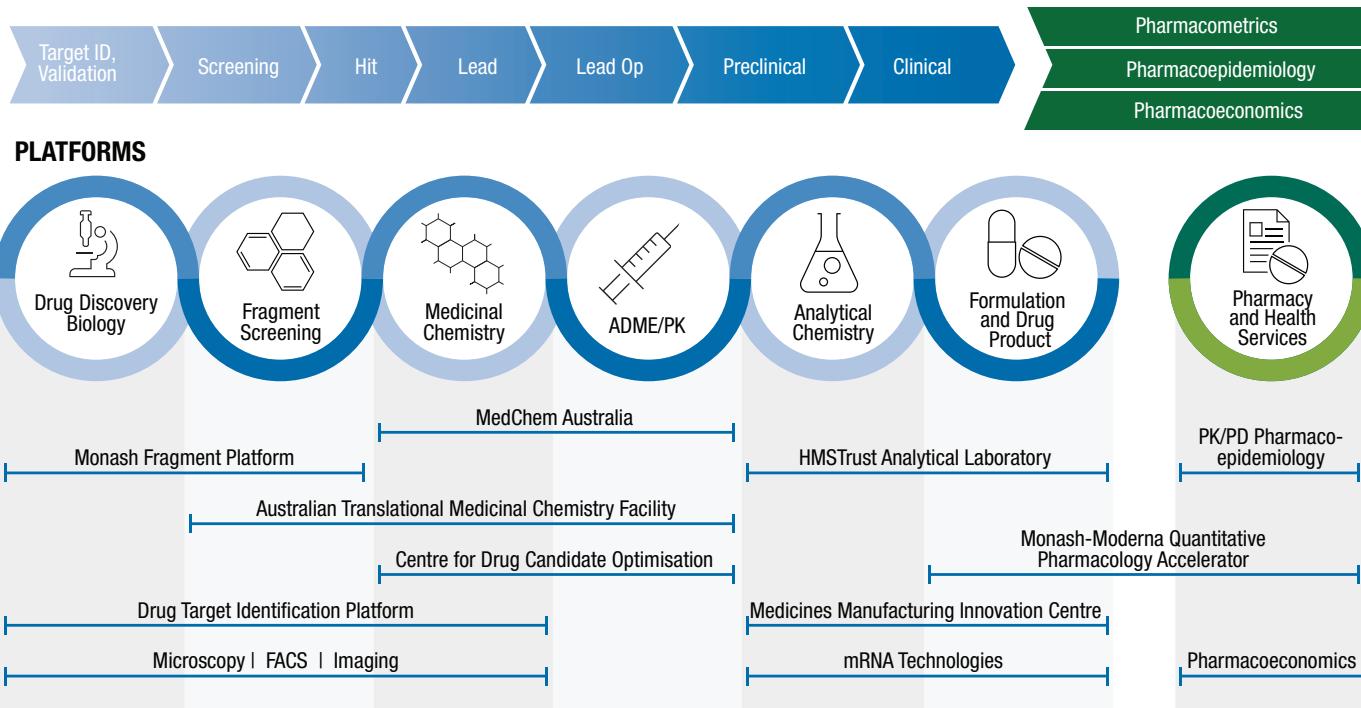




THE MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES (MIPS) IS A DYNAMIC, INNOVATIVE AND HIGHLY COLLABORATIVE CENTRE OF PHARMACEUTICAL SCIENCE RESEARCH AND DEVELOPMENT.

Committed to research translation, we have made major contributions to collaborative drug discovery programs that have progressed more than 40 novel drug candidates into clinical development.

AT A GLANCE: THE MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES



To find out more about MIPS, visit monash.edu/mips

And to discover more about how MIPS can contribute to your pharmaceutical project or business, contact us at: mips.research@monash.edu



AUSBIOTECH CORPORATE MEMBERS

AusBiotech thanks its corporate members for their ongoing commitment, participation and support of the biotechnology community. AusBiotech's substantial contribution to the ecosystem for more than 39 years is testament to the dedication of its 3000-plus members, volunteer committees, Board and business team.

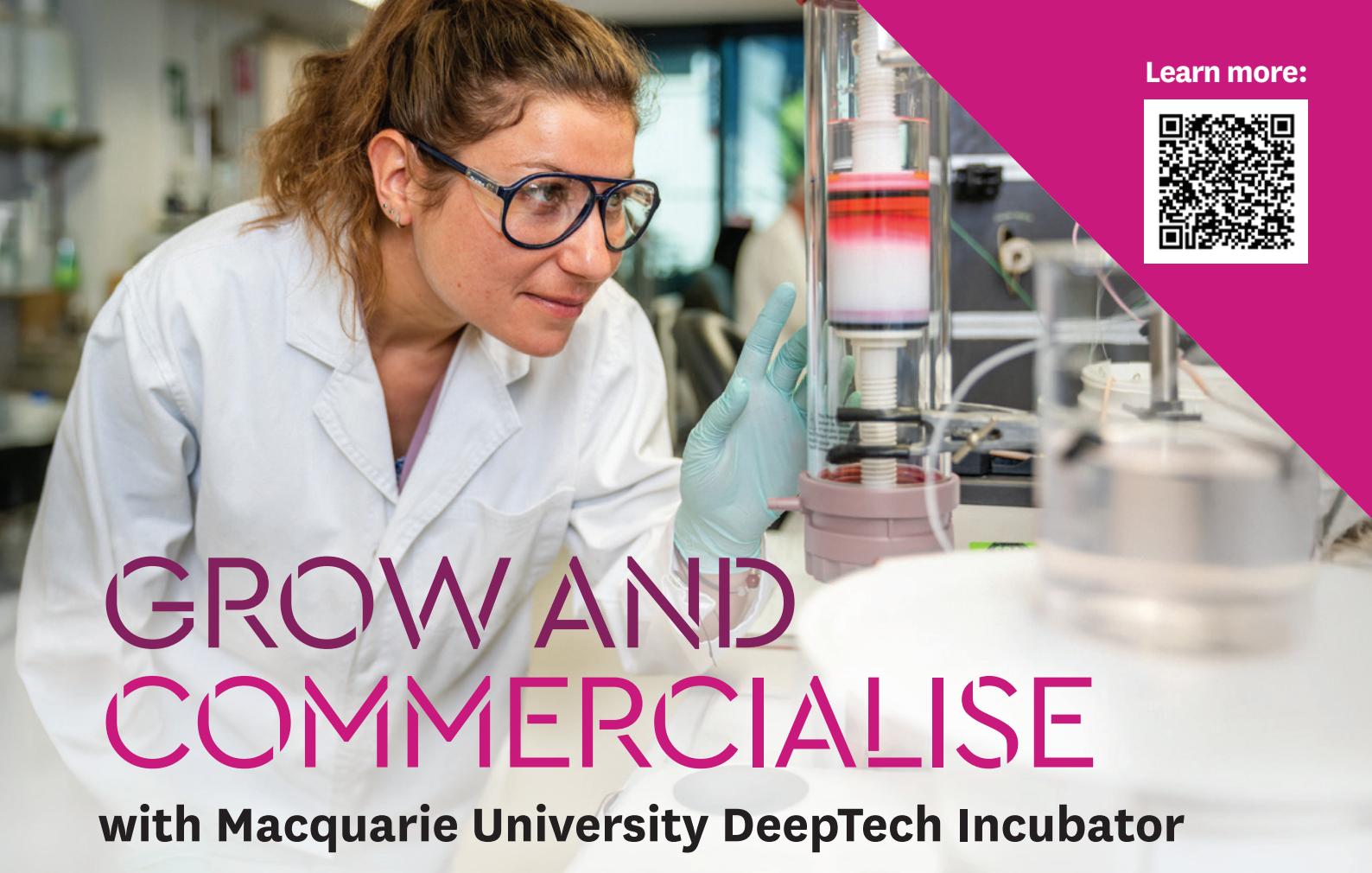
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Learn more:



GROW AND COMMERCIALISE

with Macquarie University DeepTech Incubator

Offering cutting-edge space to support innovators through the “Valley of Death” with access to technical infrastructure, networks, education programs, and services.

“

The DeepTech Incubator was just what my idea needed to prove itself. There is nothing else like this – it's accessible to anyone with a good idea and delightfully quick and easy to commence. The team is amazingly competent and supportive. It's fantastic what they are providing Sydney entrepreneurs and the model for how incubators should be done.

Membership offering:

- Laboratory assets, secure offices, co-working spaces, including new PC2 facility in 2026
- Professional laboratory support and access to education programs
- Discounted consumable and equipment support
- Subsidised membership rates designed for early-stage startup and scaling companies
- Networks of researchers, industry, mentors, investors, and students
- No pre-existing relationship with Macquarie University required
- Triaging into Macquarie University research expertise, services, and equipment
- Located in the heart of Australia's original innovation district Macquarie Park Innovation District - surrounded by medtech and biotech industry



**DEEPTech
INCUBATOR**

Questions or would like more information?

Contact us on incubator@mq.edu.au

Dr Jeremy Henson
ETHyR Biotech

Continued from page 60

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GreenLight Clinical

Specialist CRO,
Built on Partnerships,
Driven by Innovation



ABOUT US

GreenLight Clinical (GLC) is a physician-led, full-service clinical CRO with headquarters in Sydney, Australia. Our dynamic team are located around Australia, the USA and Asia.

At GLC, we specialise in delivering comprehensive early phase clinical trial services in **oncology, ophthalmology, gene & stem cell therapies and medical devices**. With a commitment to speed and precision, we partner with biotech companies to drive innovation and bring life-changing therapies to market faster.

OUR SERVICES



Site Start-up, Monitoring & Project Management



Medical Writing



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Quality Assurance



Medical Monitoring & Pharmacovigilance



Grant Writing & Applications



Medical Device & TGA Product Registration

With our medical expertise and deep industry knowledge, we develop bespoke solutions to streamline development of therapies for patients with unmet needs. We conduct our trials according to ICH/GP guidelines and we also have ISO 9001:2015 accreditation.

Continued from page 62

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– Chair of NeuroScientific Biopharmaceuticals

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ADVANCELL



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AusHealth is Australia's largest self-funded medical research charity. In 2024, it donated \$4.5 million to scientists developing new disease therapies, artificial intelligence-powered clinical solutions and novel healthcare technologies. AusHealth also runs and finances The Accelerator, a research translation hub in Adelaide where entrepreneurs and innovators collaborate on the health technology of tomorrow. AusHealth's charitable works are supported by its three commercial operations: Healthcare Revenue Management Services, Drug & Alcohol Testing Services, and Clinical Coding Services.

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BREAKTHROUGH T1D



Breakthrough T1D (formerly JDRF) is the global leader in type 1 diabetes (T1D) research and advocacy. For more than 50 years, the company has driven every major advancement in T1D care by accelerating breakthroughs across the entire research and development pipeline. The company is working to create a world without T1D through investing in cutting-edge research to prevent, cure, and treat T1D and its complications. Breakthrough T1D is proud to be AusBiotech's first and only community advocacy partner.

Phone: 1300 363 126 | Email: crn@breakthroughT1D.org.au



CELLEO BIOTECH

Celleo Biotech produces intelligent production systems for cell therapy. The company's mission is to enable cell therapies to deliver population-level health outcomes, realising the extraordinary potential of humanity's most powerful therapeutic modality: our cells, augmented. Celleo customers are the world's leading commercial-scale biotherapeutics players, CDMOs and developers of novel therapeutics. They employ Celleo's Intelligent Production Systems for the GMP manufacture of autologous and allogeneic therapies, cell banking, and critical reagent preparation, including viral vectors, and other emerging applications.

Email: celleo@celleo.com | Web: celleo.com



CICADA INNOVATIONS

Cicada Innovations is Australia's leading deep tech incubator. With a 20-year track record of developing ventures focused on the world's most pressing problems and promising opportunities, Cicada's incubators, training, and community are designed to meet the unique needs of deep tech startups. From cutting-edge labs and flexible spaces, to mentors and a network of ambitious peers, Cicada's mission is to help startups grow and make Australia a leader in deep tech innovation.

Email: info@cicadainnovations.com | Web: www.cicadainnovations.com



CMBIO

Cmbio is a global leader in microbiome science and multi-omics research, delivering advanced laboratory services and digital biology solutions for human, animal, and environmental health. Headquartered in Copenhagen, Denmark, and with facilities in the United States, Europe, and the Asia-Pacific region, Cmbio brings together more than 100 experts across microbiology, molecular biology, bioinformatics, metabolomics, and data science. The company has expertise in metagenomics, metabolomics, proteomics, and microbial strain characterisation, including engraftment analysis, as well as GxP-compliant omics services, and regulatory-ready data for clinical and research applications.

Phone: 0428 466 299



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A world leader in the design, manufacture, and validation of passive high-performance isothermal packaging for the transport of pharmaceutical products, EMBALL'ISO is also a pioneer and expert in Reuse and Reverse Logistics services for a sustainable cold chain. Present across four continents, with 12 manufacturing sites (United States, Brazil, France, Germany, England, India, Singapore, Mexico, China, Japan and Vietnam), more than 15 service centres, and collection points in more than 80 countries, EMBALL'ISO optimises global supply chains while ensuring compliance with environmental sustainability goals.

Nicole Roy, Business Development Manager Australia & New Zealand

Phone: 0431 112 840 | Email: nicole.roy@emballiso.com



EVALUATE

Evaluate is an economic consulting practice focused on the funding and regulation of social goods, particularly in health and aging. Evaluate measures the impact of new technologies, including pharmaceuticals, medical devices and other health interventions, and examines whole-of-system questions around public finance, health insurance, tax settings, trade, and intellectual property. Evaluate's partners bring extensive experience in both government and the private sector, in Australia and internationally, including in health, aged care, pharmaceuticals, innovation, research and development, and product analysis.

Alastair Furnival and Catherine McGovern, Partners

Phone: 02 9234 3883 | Email: alastair@evaluate.net.au, catherine@evaluate.net.au | Web: evaluate.net.au



INVETECH

For more than 35 years, Invetech has partnered with health and life science leaders around the world to co-create breakthrough solutions for applications in medical technology, life sciences and cell therapy manufacturing. Leveraging a combination of proven technology platforms and its team's deep domain expertise in core target markets, the company delivers value to clients by helping them realise their most critical product innovation needs, hence swiftly transforming client's and customers' ideas into market-ready medical solutions and vital therapies.

Sarah Phillips

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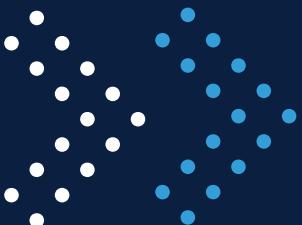
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- Kit assembly for APAC, US & Europe based sites
- Project management services
- Logistics management for kits and samples
- Database management
- Site training
- Logistics management
- Vendor management





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

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
1AD	AdAlta Limited	Drug discovery and development using its technology platform.	\$4.6m	\$0.00	\$0.018	\$0.002	(0.7)	NA	-	-
1AI	Algorae Pharmaceuticals Limited	A biotechnology company focused on developing solutions for Parkinson's disease in Australia.	\$14.3m	\$0.01	\$0.010	\$0.005	(0.1)	NA	-	-
4DX	4DMedical Limited	A software technology company.	\$785.4m	\$1.68	\$2.380	\$0.225	(14.0)	NA	-	-
ACR	Acrux Limited	Transdermal drug delivery platform technology.	\$5.7m	\$0.01	\$0.058	\$0.012	(1.7)	NA	-	-
ACW	Actinogen Medical Limited	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders.	\$88.9m	\$0.03	\$0.042	\$0.019	(0.3)	NA	1.00	-
ADO	AnteoTech Limited	Multi-component coatings for solid phase of immunoassays for biomarker development.	\$62.7m	\$0.02	\$0.037	\$0.007	(0.3)	NA	-	-
ADR	Adherium Limited	Developer of digital technologies to monitor medication use.	\$11.2m	\$0.01	\$0.015	\$0.004	(2.4)	NA	1.00	-
AFP	AFT Pharmaceuticals Limited	Develops, licences and sells a range of medical products globally.	\$242.2m	\$2.31	\$3.160	\$2.150	10.4	22.3	34.00	1.63
AGH	Althea Group Holdings Limited	An independent health technology service provider.	\$17.8m	\$0.02	\$0.054	\$0.018	(1.1)	NA	(1.00)	-
AGN	Argenica Therapeutics Limited	Researches and develops a neuroprotective therapeutic drug in Australia.	\$42.4m	\$0.33	\$0.885	\$0.190	(5.6)	NA	6.00	-
AHX	Apiam Animal Health Limited	iVet technology for real-time animal health monitoring.	\$146.7m	\$0.80	\$0.810	\$0.345	0.5	172.3	(24.00)	2.00
ALA	Arovella Therapeutics Limited	Oromucosal sprays for drug delivery treatment of off-patent drugs.	\$95.7m	\$0.08	\$0.210	\$0.068	(1.3)	NA	2.00	-
ALC	Alcidion Group Limited	Development and licensing of healthcare software products.	\$119.5m	\$0.09	\$0.145	\$0.051	0.1	75.8	-	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
AN1	Anagenics Limited	Clinically validated anti-aging and wellness products.	\$2.5m	\$0.01	\$0.009	\$0.004	(0.3)	NA	-	-
ANN	Ansell Limited	Gloves and protective personal equipment.	\$4,988.4m	\$34.18	\$37.850	\$28.190	108.0	31.8	322.00	77.65
ANO	Advance ZincTek Limited	Manufactures aluminium oxide powder for use in the personal care sector.	\$68.9m	\$1.10	\$1.250	\$0.720	2.0	55.6	42.00	-
ANR	Anatara Lifesciences Limited	Natural, plant-based therapeutics for gastrointestinal diseases.	\$2.3m	\$0.01	\$0.073	\$0.004	(1.0)	NA	-	-
ARX	Aroa Biosurgery Limited	A regenerative medicine company.	\$232.9m	\$0.68	\$0.815	\$0.350	(1.0)	NA	18.00	-
AT1	Atomo Diagnostics Limited	Medical devices for blood-based rapid testing.	\$15.4m	\$0.02	\$0.025	\$0.014	(0.8)	NA	1.00	-
ATH	Alterity Therapeutics Limited	Focuses to commercialise research into Parkinsonian movement disorders.	\$119.7m	\$0.01	\$0.019	\$0.002	(0.2)	NA	-	-
ATX	Amplia Therapeutics Limited	Pipeline of focal adhesion kinase inhibitors for cancer and fibrosis.	\$84.7m	\$0.17	\$0.425	\$0.049	(2.1)	NA	3.00	-
AUA	Audeara Limited	Personalised listening products.	\$4.5m	\$0.03	\$0.058	\$0.019	(1.1)	NA	1.00	-
AVE	Avecho Biotechnology Limited	Consumer and animal health products.	\$22.2m	\$0.01	\$0.009	\$0.001	(0.1)	NA	-	-
AVH	AVITA Medical Inc Shs Chess Depository Interests repr 0.2 shs	Skin regeneration technology for the treatment of wounds.	\$96.1m	\$1.31	\$4.520	\$1.300	(60.8)	NA	(122.00)	-
AVR	Anteris Technologies Global Corporation	Tissue engineering and vaccine development for herpes and HPV.	\$98.6m	\$6.86	\$13.910	\$4.260	(360.3)	NA	280.00	-
AXE	Archer Materials Limited	Integrating graphene in energy, human health and quantum technology.	\$65.0m	\$0.26	\$0.585	\$0.175	(2.7)	NA	7.00	-
AYA	Artrya Limited	Artificial intelligence-powered image-analysis software.	\$250.6m	\$2.13	\$2.400	\$0.250	(18.2)	NA	15.00	-
BCT	Bluechip Limited	Wireless tracking solutions for the health care and life sciences.	\$3.6m	#N/A	\$0.004	\$0.002	(0.5)	NA	-	-
BDX	BCAL Diagnostics Limited	Non-invasive laboratory blood test for the detection of breast cancer.	\$22.3m	\$0.06	\$0.140	\$0.052	(2.0)	NA	2.00	-
BGT	Bio-Gene Technology Limited	Insect control in agriculture and animal health.	\$6.7m	\$0.02	\$0.071	\$0.016	(1.2)	NA	-	-
BIO	Biome Australia Limited	Live biotherapeutics and complementary medicines in Australia and internationally.	\$105.9m	\$0.48	\$0.870	\$0.385	(0.8)	NA	2.00	-
BIT	Biotron Limited	Antiviral drug developer for HIV and hepatitis.	\$4.0m	\$0.00	\$0.021	\$0.002	(0.0)	NA	-	-
BOT	Botanix Pharmaceuticals Limited	Developer of therapeutics for skin diseases including acne, psoriasis and dermatitis.	\$264.8m	\$0.14	\$0.535	\$0.125	(4.7)	NA	3.00	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
BP8	BPH Global Limited	Engages in sourcing, producing, marketing and selling traditional medicines in Australia.	\$2.1m	\$0.00	\$0.006	\$0.001	(0.2)	NA	-	-
BXN	Bioxyne Limited	Gut and immune health probiotic products, including a patented probiotic range.	\$93.4m	\$0.04	\$0.060	\$0.009	0.2	19.2	-	-
CAJ	Capitol Health Limited	Provider of diagnostic imaging services to the Australian healthcare market.	\$413.1m	#N/A	\$0.395	\$0.220	#N/A	NA	(5.00)	#VALUE!
CAN	Cann Group Limited	Research, development and cultivation to facilitate the supply of medicinal cannabis.	\$7.3m	\$0.01	\$0.128	\$0.010	(4.2)	NA	1.00	-
CBL	Control Bionics Limited	Wireless wearable electromyography.	\$10.3m	\$0.04	\$0.088	\$0.025	(2.3)	NA	-	-
CDX	CardieX Limited	Digital solutions for large-scale population health disorders with significant market scale.	\$16.0m	\$0.03	\$0.171	\$0.027	(3.7)	NA	1.00	-
CGS	Cogstate Limited	Diagnosis and therapeutic products for neurodegenerative diseases.	\$301.0m	\$1.77	\$1.880	\$0.860	9.2	18.9	31.00	2.00
CHM	Chimeric Therapeutics Limited	Chimeric antigen receptor T cell therapy drugs for solid tumours.	\$11.4m	\$0.00	\$0.016	\$0.002	(0.8)	NA	-	-
CLV	Clover Corporation Limited	Science-based oil products to the medical food market for infants and children.	\$90.2m	\$0.54	\$0.600	\$0.335	2.7	19.9	40.00	1.50
CMB	Cambium Bio Limited	Stem cell technologies to develop a portfolio of novel cell-based therapies.	\$11.8m	\$0.52	\$0.680	\$0.190	(32.0)	NA	(3.00)	-
CMP	Compumedics Limited	Diagnosis of sleep disorders, neurodiagnostics solutions and brain research.	\$57.7m	\$0.30	\$0.360	\$0.240	(0.7)	NA	4.00	-
COH	Cochlear Limited	Manufacture and sale of cochlear implant system for impaired hearing.	\$19,546.4m	\$298.88	\$323.000	\$246.140	594.3	50.5	2,217.00	425.00
CSL	CSL Limited	Development, manufacture and marketing of pharmaceutical and diagnostic products.	\$101,821.1m	\$209.94	\$304.990	\$205.820	957.6	22.3	1,647.00	424.56
CSX	CleanSpace Holdings Limited	Respirators and related products.	\$62.6m	\$0.80	\$0.880	\$0.305	(0.6)	NA	24.00	-
CT1	Constellation Technologies Limited	Internet of Things product development.	\$2.2m	\$0.00	\$0.003	\$0.001	-	NA	-	-
CTE	Cryosite Limited	Collection, processing and long-term storage of blood stem cells.	\$42.0m	\$0.86	\$0.950	\$0.660	3.9	22.3	5.00	7.00
CU6	Clarity Pharmaceuticals Limited	Radiopharmaceutical company.	\$1,153.0m	\$3.10	\$8.975	\$1.430	(9.5)	NA	28.00	-
CUV	Clinuvel Pharmaceuticals Limited	Developer for treatment of UV-related skin disorders.	\$541.3m	\$10.80	\$15.990	\$9.410	72.2	15.1	477.00	5.00
CYC	Cyclopharm Limited	Manufacturer and distributor of radiopharmaceuticals for imaging technology.	\$94.5m	\$0.85	\$2.500	\$0.830	(12.1)	NA	27.00	-
CYP	Cynata Therapeutics Limited	Stem cell and regenerative medicine platform technology.	\$45.1m	\$0.19	\$0.285	\$0.140	(5.4)	NA	2.00	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
DVL	dorsaVi Limited	Motion analysis device technologies for clinical, elite sports, and occupational health and safety.	\$50.6m	\$0.05	\$0.053	\$0.006	(0.3)	NA	-	-
DXB	Dimerix Limited	Drug discovery platform, receptor-heteromer investigation technology.	\$294.1m	\$0.49	\$0.785	\$0.300	(2.4)	NA	(1.00)	-
EBO	EBOS Group Limited	Distributor of healthcare products.	\$5,463.6m	\$26.88	\$38.230	\$26.880	109.7	25.1	(417.00)	113.50
EBR	EBR Systems, Inc. Shs Chess Depository Interests Repr 1 Sh	Implantable systems for wireless tissue stimulation.	\$512.7m	\$1.14	\$2.080	\$0.820	(18.2)	NA	11.00	-
ECS	Ecs Botanics Holdings Limited	Medicinal cannabis products.	\$7.8m	\$0.01	\$0.021	\$0.006	(0.4)	NA	3.00	-
EMD	Emyria Limited	A cannabinoid medicine for treating patients with mental health disorders.	\$30.6m	\$0.05	\$0.058	\$0.021	(0.7)	NA	-	-
EMV	EMvision Medical Devices Limited	Commercialisation of imaging and diagnostic technology products.	\$189.0m	\$2.21	\$2.240	\$1.630	(4.1)	NA	17.00	-
EOF	Ecofibre Limited	Controlling specific parts of the hemp value chain in targeted geographies.	\$7.6m	#N/A	\$0.057	\$0.015	(4.1)	NA	(1.00)	-
EYE	Nova Eye Medical Limited	Surgical devices for the treatment of glaucoma.	\$39.9m	\$0.14	\$0.200	\$0.086	(3.7)	NA	3.00	-
FGH	Foresta Group Holdings Limited	Natural and renewable pine chemical and wood pellet manufacturing.	\$29.2m	\$0.01	\$0.015	\$0.003	(0.1)	NA	-	-
FPH	Fisher & Paykel Healthcare Corporation Limited	Respiratory care, acute care, surgery and the treatment of obstructive sleep apnoea.	\$20,195.5m	\$34.39	\$35.770	\$29.080	58.6	58.4	258.00	45.49
FRE	Firebrick Pharma Limited	Nasal spray treatment for the common cold.	\$17.7m	\$0.07	\$0.100	\$0.051	(1.3)	NA	1.00	-
GLH	Global Health Limited	Digital health solutions for the healthcare sector.	\$7.6m	\$0.13	\$0.160	\$0.051	(1.5)	NA	(6.00)	-
GSS	Genetic Signatures Limited	Molecular diagnostics company.	\$59.1m	\$0.26	\$0.735	\$0.260	(10.8)	NA	22.00	-
GTG	Genetic Technologies Limited	Molecular diagnostics specialising in women's health.	\$52.1m	\$0.04	\$0.043	\$0.038	(7.1)	NA	(1.00)	-
HCT	Holista Coltech Limited	Development and commercialisation of food ingredients and ovine collagen.	\$35.2m	\$0.11	\$0.110	\$0.007	0.2	45.7	(1.00)	-
HIQ	HitIQ Limited	Concussion management technology.	\$10.4m	\$0.02	\$0.050	\$0.012	(1.3)	NA	-	-
HMD	HeraMED Limited	Fetal heartbeat monitors and other pregnancy monitoring.	\$37.5m	\$0.04	\$0.038	\$0.006	(0.5)	NA	-	-
HXL	Hexima Limited	Plant-derived proteins and peptides for applications as human therapeutics.	\$2.2m	\$0.01	\$0.019	\$0.012	(0.3)	NA	-	-
HYD	Hydrix Limited	Hydrix Limited provides product design, engineering and regulatory services.	\$4.4m	\$0.02	\$0.032	\$0.010	(1.1)	NA	(2.00)	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
IBX	Imagion Biosystems Limited	Detection and localisation of cancer.	\$8.1m	\$0.03	\$0.080	\$0.011	(1.1)	NA	(2.00)	-
IDT	IDT Australia Limited	Manufacturer of pharmaceuticals and clinical trial management services.	\$27.9m	\$0.07	\$0.130	\$0.055	(1.9)	NA	5.00	-
IIQ	Inoviq Limited	Non-invasive diagnostic tests for early detection of cancer.	\$44.1m	\$0.40	\$0.690	\$0.345	(6.2)	NA	7.00	-
ILA	Island Pharmaceuticals Limited	Preventive or therapeutic drugs for viral infections.	\$72.3m	\$0.29	\$0.305	\$0.070	(2.3)	NA	3.00	-
IMC	Immuron Limited	Oral immunotherapy products.	\$18.2m	\$0.07	\$0.110	\$0.054	(1.7)	NA	3.00	-
IMM	Immutep Limited	Developer of novel immunotherapy agents treatments for cancer.	\$337.6m	\$0.23	\$0.415	\$0.223	(4.2)	NA	11.00	-
IMU	Imugene Limited	Developer of HER-2+ gastric and breast cancer immunotherapies.	\$79.9m	\$0.27	\$1.870	\$0.245	(31.6)	NA	6.00	-
IPD	Impedimed Limited	Diagnostic devices for lymph oedema, muscle wasting.	\$81.4m	\$0.04	\$0.068	\$0.026	(1.2)	NA	-	-
IRX	InhaleRx Limited	Medical diagnostic and monitoring technology using smartphones.	\$8.3m	\$0.04	\$0.050	\$0.018	(0.8)	NA	-	-
IVX	Invion Limited	Developer of treatments for inflammatory diseases.	\$10.3m	\$0.12	\$0.430	\$0.078	(12.2)	NA	-	-
IXC	Invex Therapeutics Limited	Exenatide as an efficacious treatment for neurological conditions.	\$7.3m	\$0.10	\$0.105	\$0.059	(0.6)	NA	1.00	-
LDX	Lumos Diagnostics Holdings Limited	Diagnostic test solutions to help healthcare professionals.	\$110.3m	\$0.15	\$0.155	\$0.019	(1.5)	NA	-	-
LGP	Little Green Pharma Limited	Medicinal cannabis products.	\$38.2m	\$0.13	\$0.165	\$0.077	1.1	11.8	24.00	-
M7T	Mach7 Technologies Limited	Imaging IT solutions, 3D printing and holographic projection provider.	\$72.8m	\$0.31	\$0.570	\$0.280	(2.6)	NA	10.00	-
MAP	Microba Life Sciences Limited	Microbiome testing and analysis services for clinicians.	\$53.0m	\$0.09	\$0.325	\$0.082	(3.3)	NA	3.00	-
ME1	Melodiol Global Health Limited	Medical cannabis products.	\$1.1m	\$0.00	\$2.700	\$0.001	#N/A	NA	-	#VALUE!
MEM	Memphasys Limited	Cell and protein separation systems.	\$9.9m	\$0.01	\$0.011	\$0.003	(0.2)	NA	-	-
MSB	Mesoblast Limited	Commercialisation of adult stem cell technology.	\$2,867.1m	\$2.24	\$3.370	\$0.915	(13.1)	NA	5.00	-
MVF	Monash IVF Group Limited	Assisted reproductive technologies, genetic testing and ultrasound services.	\$270.8m	\$0.70	\$1.290	\$0.538	6.4	11.0	(11.00)	5.10
MVP	Medical Developments International Limited	Medical and veterinary equipment including pain management and resuscitation.	\$65.3m	\$0.58	\$0.940	\$0.395	0.1	712.5	30.00	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
MX1	Micro-X Limited	Mobile X-ray imaging systems for medical applications.	\$61.4m	\$0.09	\$0.102	\$0.039	(2.3)	NA	1.00	-
MYX	Mayne Pharma Group Limited	Oral drug delivery systems.	\$373.7m	\$4.60	\$7.310	\$4.020	(118.6)	NA	169.00	-
NAN	Nanosonics Limited	Ultrasound probe disinfection – trophon device.	\$1,165.9m	\$3.84	\$5.180	\$2.880	6.8	58.7	56.00	-
NC6	Nanollose Limited	Plant-free cellulose for use in the food and medical industries.	\$18.6m	\$0.06	\$0.085	\$0.016	(0.7)	NA	-	-
NEU	Neuren Pharmaceuticals Limited	Therapies for brain injury, neurodegenerative and neurodevelopmental disorders.	\$2,551.0m	\$20.20	\$20.825	\$8.610	116.8	17.8	248.00	-
NGS	Nutritional Growth Solutions Limited	Pediatric protein supplements in the United States and internationally.	\$4.3m	\$0.02	\$0.053	\$0.017	(3.3)	NA	-	-
NOU	Noumi Limited	Plant-based beverages, and dairy and nutritional ingredient.	\$43.0m	\$0.16	\$0.310	\$0.105	(54.1)	NA	(142.00)	-
NOX	Noxopharm Limited	Radiotherapy.	\$27.5m	\$0.09	\$0.150	\$0.043	(1.7)	NA	-	-
NSB	Neuroscientific Biopharmaceuticals Limited	Neurodegenerative diseases through preclinical studies of patented technologies.	\$54.9m	\$0.17	\$0.260	\$0.033	(1.3)	NA	3.00	-
NTI	Neurotech International Limited	Neurological conditions. Flagship device is Mente Autism.	\$16.8m	\$0.02	\$0.074	\$0.012	(0.6)	NA	-	-
NUF	Nufarm Limited	Crop protection and specialist seed company.	\$881.0m	\$2.30	\$4.210	\$2.085	(12.2)	NA	269.00	-
NXS	Next Science Limited	Next Science Limited is a medical technology company.	\$42.4m	\$0.15	\$0.225	\$0.055	(7.6)	NA	(1.00)	-
NYR	Nyrada, Inc. Shs Chess Depository Interests Repr 1 Shs	A preclinical-stage drug development company.	\$68.1m	\$0.29	\$0.370	\$0.051	(2.2)	NA	2.00	-
OCC	Orthocell Limited	Soft tissue cellular therapies for restoration of tendon and cartilage injuries.	\$282.0m	\$1.15	\$1.790	\$0.405	(3.8)	NA	8.00	-
OIL	Optiscan Imaging Limited	Real-time digital microscopic imaging for medical applications.	\$71.0m	\$0.09	\$0.199	\$0.077	(0.8)	NA	1.00	-
ONE	Oneview Healthcare PLC Chess Depository Interests repr 1	Software platform for patients in hospital and aged care facilities.	\$175.8m	\$0.23	\$0.375	\$0.210	(2.5)	NA	2.00	-
OPL	Pathkey AI Limited	Artificial intelligence-assisted technologies improve to healthcare design, development and delivery.	\$7.9m	\$0.03	\$0.036	\$0.013	(0.8)	NA	-	-
OPT	Opthea Limited	Developer of novel therapy OPT-302 for treatment of eye diseases.	\$820.8m	\$0.60	\$1.165	\$0.575	(20.5)	NA	(23.00)	-
OSL	Oncosil Medical Limited	Beta radiation into a pancreatic tumour.	\$30.1m	\$1.60	\$6.000	\$0.800	(138.2)	NA	76.00	-
PAB	Patrys Limited	Developing novel antibody therapies for a range of oncology.	\$6.9m	\$0.00	\$0.005	\$0.001	(0.1)	NA	-	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
PAR	Paradigm Biopharmaceuticals Limited	Pentosan polysulphate sodium for the treatment of inflammation.	\$104.9m	\$0.26	\$0.660	\$0.165	(6.0)	NA	8.00	-
PCK	PainChek Limited	Smartphone app to provide pain assessment.	\$90.7m	\$0.04	\$0.060	\$0.024	(0.4)	NA	-	-
PEB	Pacific Edge Limited	Pacific Edge Limited is a cancer diagnostic company.	\$132.9m	\$0.13	\$0.180	\$0.050	(3.4)	NA	3.00	-
PER	Percheron Therapeutics Limited	Novel antisense pharmaceuticals in Australia.	\$9.8m	\$0.01	\$0.140	\$0.005	(1.7)	NA	92.00	-
PGC	Paragon Care Limited	Provider of medical equipment, devices and consumables.	\$546.3m	\$0.33	\$0.590	\$0.315	1.2	26.6	(7.00)	-
PIQ	Proteomics International Laboratories Limited	Focused on proteomics.	\$52.4m	\$0.32	\$0.885	\$0.280	(6.0)	NA	8.00	-
PME	Pro Medicus Limited	Provider of radiology information systems and diagnostic imaging.	\$31,175.6m	\$298.30	\$336.000	\$155.830	110.3	271.6	226.00	47.00
PNV	Polynovo Limited	Developer of biodegradable polymers for use in medical devices.	\$956.8m	\$1.39	\$2.680	\$0.930	0.8	273.7	11.00	-
PTX	Prescient Therapeutics Limited	Developer of anti-cancer drugs. Lead drug candidate is PTX-200.	\$42.1m	\$0.04	\$0.063	\$0.037	(0.9)	NA	1.00	-
PYC	PYC Therapeutics Limited	Intracellular biological therapeutics.	\$720.3m	\$1.24	\$2.089	\$0.950	(10.1)	NA	11.00	-
RAC	Race Oncology Limited	Development of chemotherapy drug Bisantrene for cancer.	\$291.9m	\$1.68	\$1.940	\$0.920	(2.8)	NA	8.00	-
RAD	RadioPharm Theranostics Limited	Radiopharmaceutical and nuclear medicine products.	\$68.6m	\$0.03	\$0.042	\$0.019	(1.6)	NA	-	-
RCE	Reece Pharmaceuticals Limited	Synthetic antibiotics to address the threat of antibiotic resistance.	\$138.8m	\$0.48	\$0.565	\$0.275	(9.0)	NA	(2.00)	-
RGT	Argent Biopharma Limited	Medicines targeting immunology and neurology worldwide.	\$8.3m	\$0.11	\$0.570	\$0.068	(31.2)	NA	-	-
RHT	Resonance Health Limited	Non-invasive medical imaging software services.	\$15.5m	\$0.03	\$0.068	\$0.032	(0.4)	NA	-	-
RHY	Rhythm Biosciences Limited	Affordable blood test for the early detection of colorectal cancer.	\$27.4m	\$0.09	\$0.210	\$0.047	(1.4)	NA	1.00	-
RMD	ResMed Inc. CHESS Depositary Interests on a ratio of 10 CDIs per ord.sh	Equipment for diagnosis and management of sleep-disordered breathing.	\$24,446.2m	\$42.20	\$45.250	\$32.040	146.8	28.6	-	33.74
SDI	SDI Limited	Manufacturing and marketing of specialist dental materials.	\$104.6m	\$0.88	\$1.250	\$0.800	10.2	8.6	58.00	3.40
SDV	SciDev Limited	Offers coagulants, flocculants in powder and liquid form.	\$59.9m	\$0.32	\$0.660	\$0.255	(0.5)	NA	13.00	-
SHG	Singular Health Group Limited	Singular Health Group Limited is a medical technology company.	\$92.9m	\$0.31	\$0.420	\$0.078	(2.7)	NA	4.00	-

ASX	Issuer Name	Principal Activity	Market Cap	Close Price	Year High	Year Low	EPS (cents)	PER	Asset Backing (cents)	DIV (cents)
SHL	Sonic Healthcare Limited	Laboratory medicine/pathology, radiology/diagnostic imaging.	\$11,219.2m	\$22.70	\$29.350	\$22.630	107.0	21.5	(269.00)	107.00
SNT	Syntara Limited	Blood-related cancers.	\$39.2m	\$0.02	\$0.095	\$0.024	(0.5)	NA	1.00	-
SOM	Somnomed Limited	Sleep apnoea.	\$163.6m	\$0.75	\$0.850	\$0.240	(1.6)	NA	11.00	-
SPL	Starpharma Holdings Limited	Developer of dendrimer products.	\$52.3m	\$0.13	\$0.145	\$0.082	(2.4)	NA	5.00	-
TD1	Tali Digital Limited	Cognitive training program for children with attention difficulties.	\$4.7m	\$0.00	\$0.002	\$0.001	(0.0)	NA	-	-
TLX	Telix Pharmaceuticals Limited	Molecularly-targeted radiation.	\$4,677.2m	\$13.82	\$31.980	\$13.455	5.0	273.1	(104.00)	-
TRI	TrivarX Limited	A health technology company.	\$6.8m	\$0.01	\$0.024	\$0.007	(0.2)	NA	-	-
TRJ	Trajan Group Holdings Limited	Concussion management technology in Australia.	\$121.1m	\$0.80	\$1.310	\$0.675	(2.9)	NA	12.00	-
TRP	Tissue Repair Limited	Advanced wound healing products.	\$18.1m	\$0.30	\$0.485	\$0.165	(7.0)	NA	23.00	-
TRU	TruScreen Group Limited	Cancer detection devices and systems.	\$12.0m	\$0.02	\$0.033	\$0.015	(0.4)	NA	-	-
UBI	Universal Biosensors, Inc. Shs Chess Depository Interests US Prohibited repr 1 sh	Specialist medical in-vitro diagnostic tests.	\$4.2m	\$0.01	\$0.160	\$0.012	(5.9)	NA	6.00	-
UCM	Uscom Limited	Non-invasive medical devices in the field of cardiac.	\$2.9m	\$0.01	\$0.045	\$0.011	(1.8)	NA	-	-
VBS	Vectus Biosystems Limited	Drug discovery and development company.	\$3.9m	\$0.07	\$0.089	\$0.037	(3.3)	NA	-	-
VIT	Vitura Health Limited	A medicinal cannabis company.	\$44.4m	\$0.07	\$0.135	\$0.057	0.5	12.2	1.00	-
VLS	Vita Life Sciences Limited	A pharmaceutical and healthcare company.	\$134.7m	\$2.45	\$2.480	\$1.620	16.6	14.8	89.00	10.00
WNX	Wellnex Life Limited	Health and wellness products with scientific and nutritional benefit.	\$15.6m	\$0.23	\$0.997	\$0.210	(23.0)	NA	(56.00)	-
WOA	Wide Open Agriculture Limited	Regenerative food and agriculture company.	\$9.2m	\$0.01	\$0.038	\$0.004	(1.3)	NA	1.00	-
XRF	XRF Scientific Limited	Manufacturer and marketer of instrumentation.	\$310.3m	\$2.18	\$2.330	\$1.430	7.4	28.7	31.00	3.90
ZLD	Zelira Therapeutics Limited	Medical cannabis for a variety of ailments.	\$4.5m	\$0.38	\$0.920	\$0.345	(31.6)	NA	75.00	-

Data current at 11 September 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.

This quarter's top ASX healthcare sector performers

ASX Code	Company Name	Closing Price	Quarter Return %
4DX	4DMedical Limited	\$1.68	458.3%
LDX	Lumos Diagnostics Holdings Limited	\$0.15	367.7%
HMD	HeraMED Limited	\$0.04	300.0%
ADO	AnteoTech Limited	\$0.02	228.6%
IBX	Imagion Biosystems Limited	\$0.03	200.0%
NSB	Neuroscientific Biopharmaceuticals Limited	\$0.17	194.6%
DVL	dorsaVi Limited	\$0.05	181.3%
AYA	Artrya Limited	\$2.13	176.6%
ATX	Amplia Therapeutics Limited	\$0.17	150.0%
NXS	Next Science Limited	\$0.15	113.2%
CMB	Cambium Bio Limited	\$0.52	110.2%
AHX	Apiam Animal Health Limited	\$0.80	99.4%
CSX	CleanSpace Holdings Limited	\$0.80	97.5%
ANR	Anatara Lifesciences Limited	\$0.01	83.3%
MX1	Micro-X Limited	\$0.09	80.4%
EMD	Emyria Limited	\$0.05	76.9%
HCT	Holista Coltech Limited	\$0.11	75.0%
AVE	Avecho Biotechnology Limited	\$0.01	75.0%
BXN	Bioxyne Limited	\$0.04	72.0%
GLH	Global Health Limited	\$0.13	71.1%
1AI	Algorae Pharmaceuticals Limited	\$0.01	70.0%
TRP	Tissue Repair Limited	\$0.30	66.7%
OSL	Oncosil Medical Limited	\$1.60	60.0%
RCE	Recce Pharmaceuticals Limited	\$0.48	57.4%
FGH	Foresta Group Holdings Limited	\$0.01	57.1%
VBS	Vectus Biosystems Limited	\$0.07	52.1%
NYR	Nyrada, Inc. Shs Chess Depository Interests Repr 1 Shs	\$0.29	50.0%
NEU	Neuren Pharmaceuticals Limited	\$20.20	46.8%
ANO	Advance ZincTek Limited	\$1.10	44.7%
ILA	Island Pharmaceuticals Limited	\$0.29	42.5%

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This year's top ASX healthcare sector performers

ASX Code	Company Name	Closing Price	Year Return %
AYA	Artrya Limited	\$2.13	622.0%
NYR	Nyrada, Inc. Shs Chess Depository Interests Repr 1 Shs	\$0.29	418.2%
HCT	Holista Coltech Limited	\$0.11	356.5%
NSB	Neuroscientific Biopharmaceuticals Limited	\$0.17	334.2%
ATH	Alterity Therapeutics Limited	\$0.01	333.3%
DVL	dorsaVi Limited	\$0.05	309.1%
4DX	4DMedical Limited	\$1.68	303.6%
LDX	Lumos Diagnostics Holdings Limited	\$0.15	281.6%
ILA	Island Pharmaceuticals Limited	\$0.29	280.0%
SHG	Singular Health Group Limited	\$0.31	276.5%
FGH	Foresta Group Holdings Limited	\$0.01	266.7%
AVE	Avecho Biotechnology Limited	\$0.01	250.0%
BXN	Bioxyne Limited	\$0.04	207.1%
NC6	Nanollose Limited	\$0.06	161.4%
OCC	Orthocell Limited	\$1.15	160.2%
MSB	Mesoblast Limited	\$2.24	142.2%
CGS	Cogstate Limited	\$1.77	90.5%
PME	Pro Medicus Limited	\$298.30	89.7%
SOM	Somnomed Limited	\$0.75	76.5%
CMB	Cambium Bio Limited	\$0.52	71.7%
CSX	CleanSpace Holdings Limited	\$0.80	68.4%
ATX	Amplia Therapeutics Limited	\$0.17	68.3%
MX1	Micro-X Limited	\$0.09	65.8%
HMD	HeraMED Limited	\$0.04	63.6%
PEB	Pacific Edge Limited	\$0.13	60.5%
XRF	XRF Scientific Limited	\$2.18	56.5%
OPL	Pathkey AI Limited	\$0.03	52.9%
ANO	Advance ZincTek Limited	\$1.10	52.8%
LGP	Little Green Pharma Limited	\$0.13	48.8%
CLV	Clover Corporation Limited	\$0.54	48.2%

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