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Australasian BioTechnology

The journal of AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Enabling biotech patents in an AI-enabled world

Industry-first ESG guide for small biotechs

The future of drug discovery using next-generation technologies

Back to the future: AusMedtech 2023

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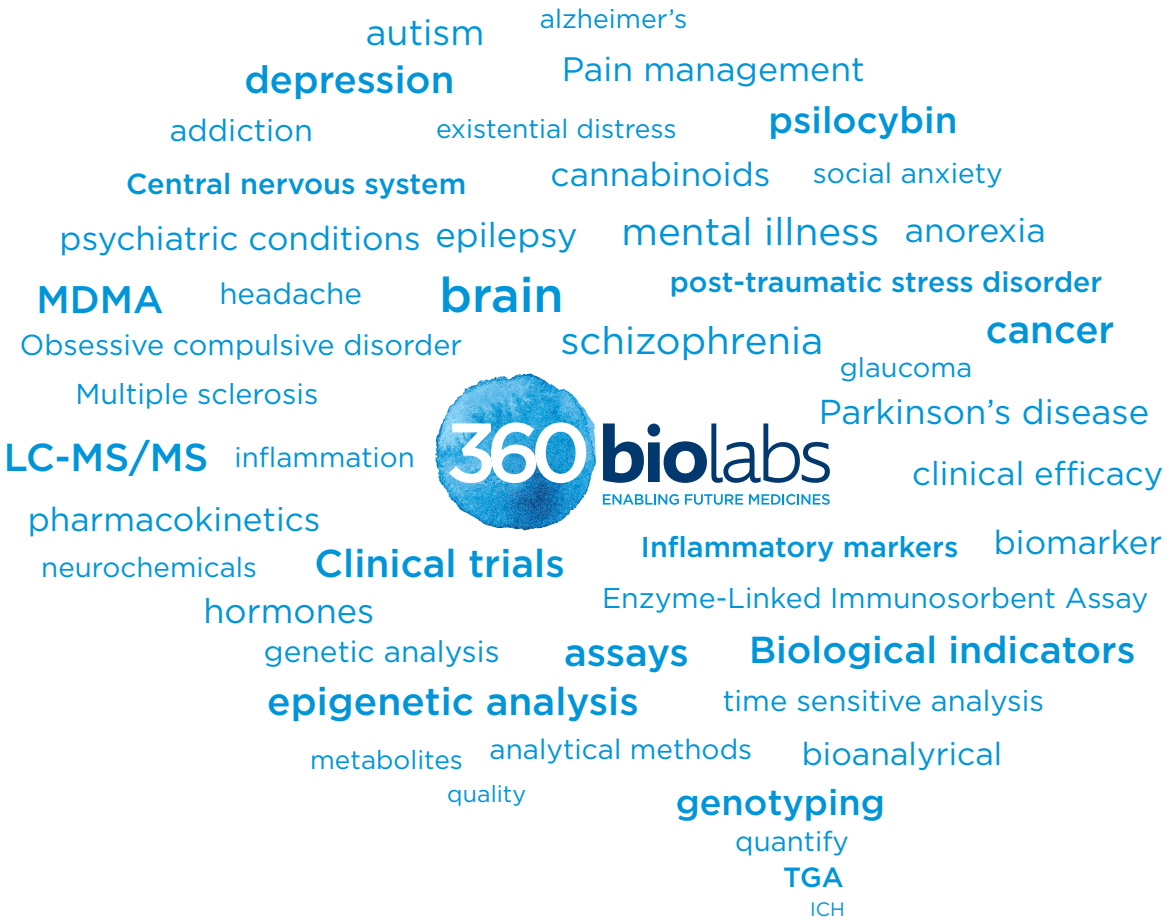

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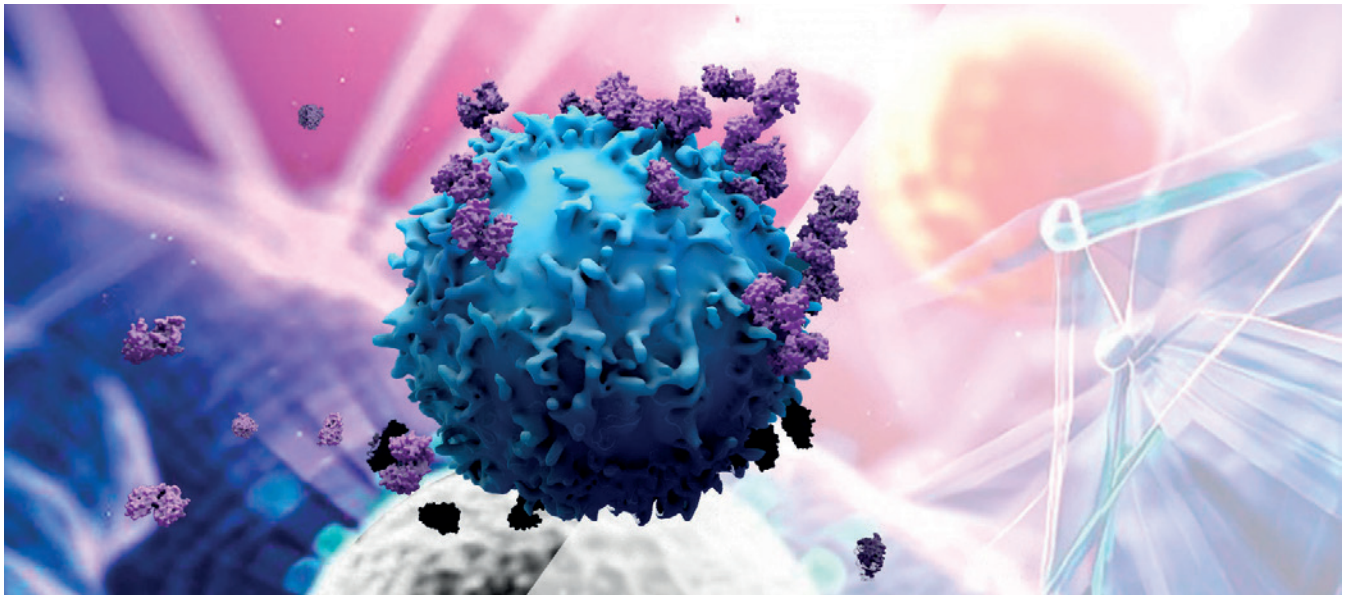

PIONEERING A NEW ERA OF IMMUNO-ONCOLOGY

Agilex has extensive experience developing and validating ligand-binding assays for specific immuno-oncology therapeutics.

FROM ANCIENT EGYPT to the early 19th century, there have been multiple anecdotal reports of tumours disappearing spontaneously. These typically occurred after an infection with a concomitant high fever. As early as 1863, Rudolf Virchow, a German pathologist, began investigating the connection between tumours and inflammation. Working in his lab, Virchow observed that neoplastic tissues were often decorated with leukocytes of the immune system.

Since the dawn of the new millennium, the field of immuno-oncology has made exponential strides in its overall efficacy as a form of cancer treatment. Unsurprisingly, Agilex Biolabs has been at the forefront of this critical research, consistently providing key scientific support to enable clients in the drug development arena to make groundbreaking contributions to the field.

Nearly 50 years ago, signal transducer and activator of transcription inhibitors – which control tumour function and the regulation of those pathways – provided the key to immunotherapeutic drugs. Interferon Alpha was one of the first immunotherapeutic drugs approved by the United States Food and Drug Administration (FDA) for clinical use in cancer.

The effect was one of inhibiting cell function, cell division, or cell proliferation; however, many of these early drugs had a non-specific effect, meaning that they would inhibit cell proliferation in a global manner. They most often took out healthy cells as they destroyed cancerous ones.

Thankfully, over the years, immuno-oncology therapeutics have become more refined and targeted. They've moved to monoclonal antibodies, which are targeted against specific cell-surface proteins. Simply stated, they attack cancer cells without damaging healthy body tissue.

During these past two decades, in particular, there has been a major shift in the traditional approach to systemic anti-cancer therapy. Cytotoxic chemotherapy consisted of chemicals that

targeted any dividing cell, including healthy ones. In contrast, immuno-oncology earns its success by using the body's immune system to specifically eliminate cancer cells. Since immuno-oncology's inception, researchers have worked to identify the many complex signalling pathways and targets. This has led to the development of various immunotherapy agents that modulate the immune response to cancer.

Today, there are numerous FDA-approved immunotherapies available, including checkpoint inhibitors. The field has gone from using something of a generic approach to developing new treatments that include more customised and individualised methodologies. Clearly, immuno-oncology has moved from a theoretical concept to a successful clinical treatment for cancer patients through developments in identifying targets in the immune system.

For their part, researchers at Agilex Biolabs have been at the forefront of these new techonologies in cell gene therapy, developing assays for novel drugs for targeted immuno-oncology diseases. Additionally, immunomodulator therapies, including what could be described as self-targeted immuno-oncology programs, have increased considerably over the last decade. As drug development has increased over the last decade in this area, Agilex has seen a concomitant change in the type of technologies that are used for developing and validating assays.

Agilex now has extensive experience developing and validating ligand binding assays for specific immuno-oncology therapeutics. Some of these might target cell-surface receptors on immune cells or cancer cells. These might include bispecific antibodies that have a dual mode of action – targeting the immune cell population, as well as a cell within the cancer population within the tumour itself.

At Agilex, the choice of platform depends largely on the molecule itself. If it's a small-molecule drug that targets the intracellular signal transduction pathway (for example, modulated to inhibit tumor progression), Agilex scientists might use liquid chromatography mass spectrometry. Agilex experts might use a ligand binding assay if it's a larger peptide, a monoclonal antibody or a bispecific or antibody-drug conjugate (ADC). Generally, with the fusion of both a small and a large molecule with a chemical linker for ADC drug programs, Agilex researchers might use both platforms. The choice of platform is always driven by the drug.

With development funding at a premium, project sponsors rightly ask whether the developed drug is actually having the desired effect. Agilex is curious about this as well. Is the drug modulating a cell population? Is it modulating the immune function? Questions such as these inform every step of the development process.

The scientists at Agilex can perform a variety of pharmacodynamic assays. These techniques allow Agilex to elaborate on specific immune cell populations present within the patient. Agilex's researchers can then determine how the drug actually functions in these populations. Is the drug activating specific pathways within the cell? Is it causing cells to proliferate? Flow cytometry becomes a powerful tool for the team to determine overall efficacy.

With well over two decades of experience, Agilex has intentionally moved into a new era of immuno-oncology through its ongoing acquisition of scientific expertise and state-of-the-art technology. These strategic investments have allowed Agilex to approach projects with flexibility and agility, delivering solutions that are both on point and on time. Agilex's clients are often looking for a lab with a track record of being able to develop new projects (or rescue stalled ones) within constrained time frames ahead of a clinical trial.

In today's clinical trial landscape, most clients are looking for a one-stop shop. Project sponsors have grown increasingly averse to splitting their programs across multiple labs. Agilex scientists are by far the greatest asset. Agilex's teams stay abreast of cutting-edge technology and research by attending immuno-oncology conferences and events around the world. Its researchers comprise scientists that stand at the forefront of the latest technologies and techniques. Equipped with the latest information, instrumentation and innovations, Agilex has the breadth of experience necessary to solve complicated problems, rescue complex projects from other labs and develop customised assays.

Having the expertise and facilities to develop workable assays is one thing – rescuing stalled projects is a high-value ability – but combining those strengths with a proven ability to deliver those assays on time puts Agilex ahead of its competitors. In 2023, Agilex is perfectly poised to lead in this new era as a science-first, science-driven bioanalytical company.

Contact one of the project specialists today to discuss your company's needs, time line, and desired outcomes. For more information, visit www.agilexbiolabs.com.

CEO REPORT

BY LORRAINE CHIROIU, CEO, AUSBIOTECH

Momentum continues for our sector as we see a record-breaking year of AusBiotech and AusBiotech-led event attendance, and progress on important policy to support the sector's success.

OVER THE PAST six months, Australia's world-class capabilities have been appropriately front and centre. Australia's position in the global biotech ecosystem is stronger than ever, and key policy work currently underway locally will continue to support that success. As the voice of the industry, we are proud to champion advocacy and proactively position Australia's life sciences industry as a leader on the world stage.

We are extremely proud to have launched a number of resources for the sector over the past six months – including the Australian Life Sciences Incubator and Accelerator Programmes, A Practical Guide to ESG for Australian Life Sciences Companies, and the National Cell and Gene Manufacturing Blueprint – after many months of collaborative development with industry leaders and AusBiotech members. Read more about these below, with full articles on the ESG guide on page 52, and the National Cell and Gene Manufacturing Blueprint on page 30.

AusBiotech has also been particularly active on the policy and advocacy front, formally responding to a number of consultations on behalf of the sector, including those on the coordination of the Medical Research Future Fund (MRFF) and the Medical Research Endowment Account (MREA), managed by NHMRC, and the Industry Growth Program, as well as engaging with federal industry and health ministers, and a number of one-on-one meetings, virtual webinars, and policy round tables with departments.

Since the $392.4-million Industry Growth Program was announced in the May federal budget, AusBiotech has been engaging with the Department of Industry, Science and Resources to ensure that the policy design takes the unique characteristics of the biotechnology industry into account. This is important because the program aims to support Australian small and medium-sized enterprises (SMEs) and startups to commercialise ideas, and grow operations. The Industry Growth Program will be aligned with the federal government's National Reconstruction Fund (NRF) priorities, positioning SMEs to seek potential funding through the NRF, or gain other investment interest.

AusBiotech was pleased to see the long-awaited National One Stop Shop for clinical trials consultation report released by the Australian Commission on Safety and Quality in Health Care in June, revealing five key recommendations for implementing a single, national clinical trials platform. Providing a public interface for the community and establishing enduring cross-jurisdictional governance arrangements for platform management are among a handful of recommendations to support the implementation of the National One Stop Shop.

Lorraine Chiroiu

AusBiotech has supported the concepts of a National One Stop Shop and a National Clinical Trials Front Door since they were mooted, through national speaking opportunities, formal submissions, and its ongoing discussions with ministers and departmental staff.

It was also very positive to see the Therapeutic Goods Administration (TGA) confirm that the Clinical Trials Notification (CTN) and Clinical Trials Approval (CTA) pathways for medical devices will remain unchanged, following consultation on 'proposed changes for clinical trials of medical devices'. AusBiotech has been vocal about the proposed regulatory changes, engaging with key decision-makers at a regulatory and policy level on behalf of industry, and working with members to develop a position for an industry-led submission.

The TGA recommended that medical devices be included in the current GCP Inspection Program, which historically only covered medicines and biologicals in Australia. The industry is very supportive of the TGA's risk-based regulatory approach, where regulation is commensurate with the risks posed by the therapeutic good to best protect and advance public health. We laud the TGA for its collaborative approach in working with industry to produce the best outcome for Australia and Australians. Thank you to AusBiotech's Clinical Trial Advisory Group, AusMedtech Advisory Group and AusMedtech Regulatory Affairs Advisory Group for contributing to these advocacy activities over the past 12 months.

World-first ESG guide for biotechs launched

It was a landmark achievement to launch A Practical Guide to ESG for Australian Life Sciences Companies, after more than a year of development with industry leaders. The guide is a world-first for the biotech sector, with Australia being the first nation to develop a guide to environmental, social and corporate governance (ESG) specifically for biotechnology SMEs.

The ESG guide has been designed to be a pragmatic and easy-to-use ESG resource for biotechs – in particular for SMEs – and was developed to support Australian life sciences companies navigating their ESG reporting and build reporting capabilities.

AusBiotech decided to develop the guide to increase the attractiveness of Australia's business environment to international and local investors and collaborators, as part of AusBiotech's

broader mission to increase and diversify investment into the Australian biotech sector via its investment program.

Developed with the support of the AusBiotech ESG Working Group – comprised of investors, life sciences companies and experts – the ESG guide enables a consistent approach to proactively identifying and reporting on key ESG factors that are particularly relevant to life sciences companies.

The ESG guide is designed to be a reference for company executives and boards to highlight the importance of establishing ESG programs, understand the materiality of factors specific to the life sciences industry and their own individual company, initiate a process to assess strengths and gaps, and provide a starting point for implementation and communication. It is also intended to be a useful resource for investors to understand the priority ESG considerations for life sciences companies as criteria for assessing their ESG credentials.

Australia's life sciences industry currently boasts over 1400 companies undertaking research and development, the majority of which are SMEs; however, with 93 per cent of small cap companies in Australia currently not reporting on ESG, there exists an opportunity for companies to differentiate themselves within the market and in the eyes of potential investors. This guide intends to build reporting capabilities within life sciences companies as part of AusBiotech's broader mission to increase and diversify investment into the Australian biotech sector via its investment program.

Cell and Gene Manufacturing Blueprint launched

There is an untapped opportunity for Australia to be a regional hub in the Asia-Pacific region for cell and gene (C&G) manufacturing, yet we face a number of barriers. These include quality control processes, infrastructure and large gaps in the people-based capability for manufacturing. Unlocking Australia's opportunities requires a much better understanding and coordination of our capabilities and addressing where the gaps lie. There are an increasing number of C&G technologies being developed globally; however, Australia has lacked the shared vision, policy, coordination and infrastructure to seize the opportunity.

To help realise Australia's cell and gene potential, AusBiotech commissioned the National Cell and Gene Manufacturing Blueprint to outline an industry-developed strategic approach for Australia to expand its sovereign C&G manufacturing capabilities and capacity, and become a regional C&G manufacturing hub. The blueprint also provides a shared, forward-looking vision for manufacturing C&G products in Australia; outlines where we are now as a country; and recommends a blueprint of implementation strategies for manufacturing C&G products locally.

Funded by the Victorian Government's Australian Medtech Manufacturing Centre, this project builds on the manufacturing report and strategic road map developed under the 2021–2022 AusBiotech-led Regenerative Medicines Consortium Project. Read more about the blueprint on page 30.

AusBioNSW takes next step

We are thrilled to have appointed Dr Robyn Lindner to lead operations for AusBioNSW, the peak industry membership body for New South Wales, launched by AusBiotech last year. An accomplished scientist and partnership executive, Lindner (BSc (Hons), PhD, GDM, GAICD) brings with her more than 25 years' experience in life sciences, spanning appointments in academia, medical research, biotechnology and the public health sector.

Lindner is an experienced strategic partnerships and executive leader, with a track record in establishing and driving effective business partnerships and stakeholder relationships. In her role as General Manager, she will be responsible for promoting and facilitating AusBioNSW activities, including state ecosystem growth and engagement, policy and advocacy, and strategic projects in New South Wales. Lindner's remit is broad, with her responsibilities including building business development and commercialisation capabilities in New South Wales; driving initiatives to attract investment, and grow innovation and trade in New South Wales; and developing programs that strengthen New South Wales–based companies' ability to commercialise and grow investment, so as to create jobs and growth for the state.

AusBioNSW was established in March 2022 to foster local connection and promote New South Wales organisations doing business in, and with, the local, national, and global life sciences economy. AusBioNSW is backed by AusBiotech's national representation on advocacy activities, membership services, events and networks – and, for AusBiotech members in New South Wales, no additional membership subscription is required.

We look forward to sharing more about AusBioNSW's industry-developed vision after engaging with members across the state.

Record-breaking attendance at AusBiotech events

We are extremely proud to see our international, national and state-based events continue to break records, with AusMedtech 2023 and BIO 2023 attracting the largest number of delegates to date.

Held this year in Adelaide from 24–25 May, AusMedtech 2023 hosted 430 registered attendees from across the medical technology sector, representing 12 different countries, including China, India and the United States. The 16th annual

AusMedtech 2023

AusMedtech national conference, created by industry for industry, included more than 100 local and international speakers across 28 sessions, with inspirational keynotes from industry leaders, and panel sessions on the latest medtech advancements and trends. Read more about AusMedtech's biggest conference to date on page 72.

Complementing the informative keynotes and panels, the AusMedtech Early-Stage Innovation Forum rapid-fire pitch event featured presentations from Australia's local research institutes, universities, hospitals, and pre-Series A companies in the areas of medical devices and diagnostics, digital health, and enabling technologies. Read more about the Best Translational Research Project from QIMR Berghofer that took away the top spot on page 74.

Back to BIO

The highly popular Australian Pavilion was back at BIO Boston this year, attracting Australia's largest-ever BIO delegation to date. The Australian delegation saw a number of state governments, the Australian Ambassador to the United States, state ministers, more than 170 companies and 430 delegates standing united at the BIO International Convention.

As the national voice of the Australian biotech community, AusBiotech has led the Australian delegation to BIO and hosted the pavilion for more than 10 years. Australia's largest delegation at the world's largest and most influential global life sciences conference highlights industry's commitment to fostering global collaborations and partnerships.

Supported by MTPConnect, Austrade, CSIRO and state governments (the New South Wales, South Australian, Victorian, Queensland and Western Australian governments), the pavilion showcased Australia's world-class capabilities to promote the strength of our national life sciences sector.

Register now for the biggest week in biotech

We're off to Brisbane this year for Australia's premiere life sciences conference. AusBiotech 2023 will unite life sciences executives, decision-makers and enablers to learn, share, discuss and collaborate over the latest research, innovations, ideas, and trends from 1–3 November at the Brisbane Convention and Exhibition Centre.

The diverse, high-calibre program with renowned speakers will cover the latest trends, technologies and research, and include topics such as IP strategy; navigating regulatory frameworks in key markets; collaborating with First Nations communities; creating effective relationships with investors; game-changing new technologies, and much more. In addition to the jam-packed program, there will be plenty of opportunities to network, connect and foster relationships with key industry players.

This year, AusBioInvest 2023, Australia's premier life science investment event, will be hosted in Melbourne on 30 October. This is your opportunity to explore the extraordinary world of biotech investing. Learn from global and local investors as they share insights on trends, market conditions and drivers; hear the authoritative views of industry leaders at the frontier of health and biomedical innovation; and gain market-moving updates from company executives developing breakthrough technologies.

Register now at www.ausbiotechnc.org and www.ausbiotechinvestment.com.au

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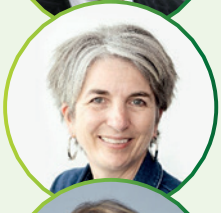

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PIONEERING THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE

An Australian biotech company is advancing a new class of synthetic anti-infectives that can be used against a broad range of bacteria, including superbugs, without contributing to drug resistance.

In recent years, several reports, including those from the Centers for Disease Control and Prevention and the United Nations, have discussed an impending crisis: antimicrobial resistance (AMR). This is resulting from the overuse of antimicrobials and contributes to the development of multidrug-resistant bacterial species, often referred to as 'superbugs'.

One of the most significant complications from AMR is sepsis, a life-threatening inflammatory response to infection that spreads through the body. Urinary tract infections (UTIs), which occur when bacteria enter the urethra and infect the urinary tract, account for up to 30 per cent of sepsis cases when unresponsive to treatment.

Not only is there a substantial need for novel antibiotics to treat drug-resistant infections, but these new therapies must also not contribute to or perpetuate resistance.

A 'resistance resistant' approach

Recce Pharmaceuticals (ASX: RCE, FSE: R9Q) is rising to the challenge by developing a new class of synthetic anti-infectives that can be used against a broad range of bacterial infections.

Recce's lead anti-infective candidate, RECCE® 327 (R327), is a synthetic polymer designed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria, including their multidrug-resistant superbug forms. R327 uses a unique mechanism of action targeting the energetics of the bacterial cell, enabling rapid cell death.

A compelling safety profile

Recce announced positive safety data from a Phase 1 trial evaluating R327 as an intravenous therapy, demonstrating it to be safe and well-tolerated in healthy volunteers, with no reports of serious adverse events or deaths.

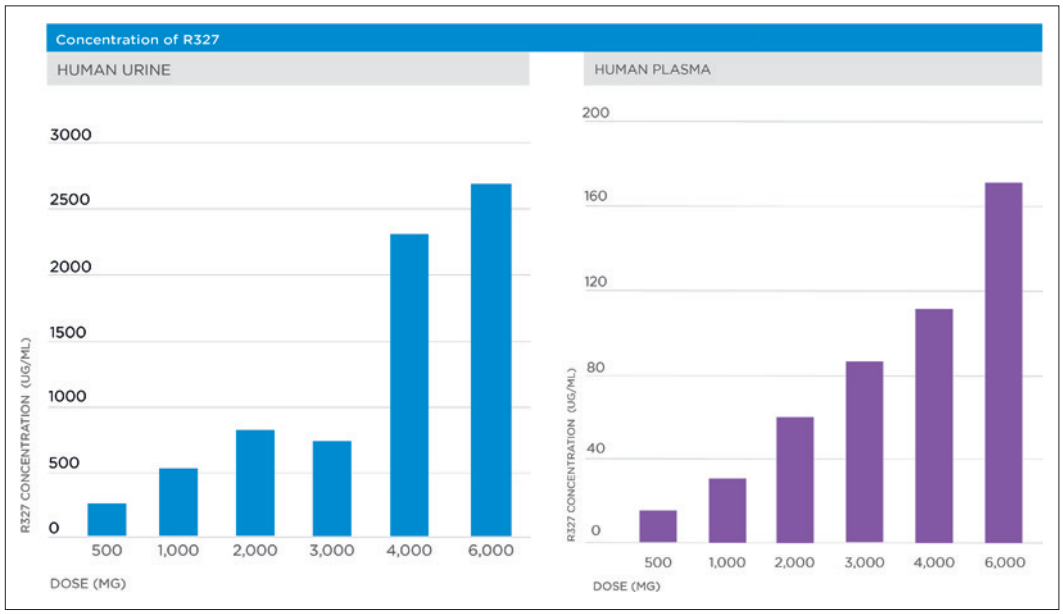
Key takeaways from the Phase 1 study

- All volunteers demonstrated no significant changes in haematology, coagulation, chemistry, urine analysis, vital signs, electrocardiogram or cardiac telemetry parameters.
- R327 displayed a compelling profile for a potential UTI and sepsis drug candidate, demonstrating a consistent and proportional linear increase across the dosage cohorts, with no spikes in drug concentration.
- R327 demonstrated a dose-dependent concentration in urine and plasma, with urine concentrations being up to 21-fold higher than in plasma and the main route of excretion via the kidneys.

The Phase 1 study supports the potential of R327 as a first-line treatment for patients with sepsis and other infections. The study also suggests the potential of R327 to treat both complicated and uncomplicated UTIs, given the results found in the urine and plasma.

Pushing forward

By advancing a new class of anti-infectives that don't contribute to drug resistance, Recce is well positioned to continue its path towards combatting AMR and tackling the historical lack of innovation in antibiotic drug development.



Concentration of R327 in human urine and plasma

Revolutionising the Traditional Approach to Medicine

Recce Pharmaceuticals Ltd (ASX:RCE, FSE:R9Q)

is a clinical stage biotech company with a new class of unique and innovative synthetic anti-infectives in multiple Phase I and Phase II clinical opportunities. Recce aims to address the global health threat of antimicrobial resistance, by revolutionising the existing treatment paradigm.

- Not derived from nature, **no preformed natural superbugs**
- **Purposely designed to overcome the hypercellular mutation of bacteria**, including superbug forms
- **Broad spectrum capability** - Maintains activity with repeated use
- Unique **Mechanism of Action**

Sepsis

UTI

Burn Wounds

Diabetic Foot Infections

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Recce Pharmaceuticals

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30 Oct 2023 | Melbourne, Australia

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Learn from global and local investors as they share insights on trends, market conditions and drivers, hear the authoritative views of industry leaders at the frontier of health and biomedical innovation, and gain market-moving updates from company executives developing breakthrough technologies.

This is your opportunity to explore the extraordinary world of biotech investing. Discuss the fundamentals of life sciences investing, meet potential co-investors, and gain exclusive insights that help you in confidently building a diversified life sciences portfolio.

Australia's premier life sciences investment conference, AusBioInvest, is designed to drive investment outcomes and foster collaboration in life sciences and medical research.

Qualified investors are eligible to receive a complimentary pass to attend AusBioInvest 2023.

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THE FUTURE OF DRUG DISCOVERY USING NEXT-GENERATION TECHNOLOGIES

BY DR CHRISTOS PAPADIMITRIOU, CEO, TESSARA THERAPEUTICS

Drug development has traditionally relied heavily on preclinical animal testing

Preclinical drug development is on the cusp of a major change, driven by the confluence of emerging technologies and an increasing focus on environmental, social, and governance concerns. This change is being accelerated by significant regulatory changes, spearheaded by the US Food and Drug Administration.

DRUG DEVELOPMENT HAS traditionally relied heavily on preclinical animal testing, despite the stark reality that more than 90 per cent of drug candidates entering clinical trials fail[1] due to issues of toxicity or poor efficacy that were not present in the animal model. The lack of predictive power in animal testing has significantly hampered our ability to bring new therapies to market. Additionally, animal testing is resource-intensive and time-consuming, and raises ethical concerns. Promisingly, emerging technologies, such as 3D organotypic systems,

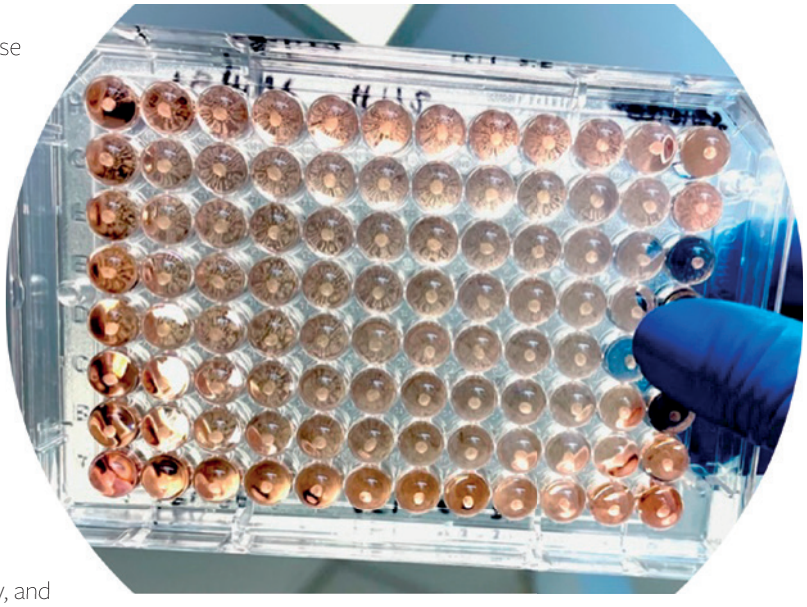
Dr Christos Papadimitriou

1 Sun D, Gao W, Hu H, Zhou S (2022), 'Why 90% of clinical drug development fails and how to improve it', Acta Pharm Sin B, doi: 10.1016/j.apsb.2022.02.002

are demonstrating their capacity as robust and effective non-animal models, offering a new avenue to revolutionise drug development.

3D organotypic culture systems

In contrast to traditional animal models, 3D organotypic culture systems present an innovative and human-relevant, non-animal alternative for preclinical testing. 3D organotypic culture systems are artificially grown 3D cell cultures or tissues that resemble an organ and its physiology. Thus, these technologies can provide a human-specific platform to improve the predictive power of drug testing, and may hold the key to both reducing the number of clinical trial failures and expediting the drug development time lines. Additionally, 3D organotypic models address environmental, social and governance (ESG) concerns, and offer a sustainable approach to medical research. The sophistication of organotypic systems is advancing quickly, and includes micro-tissues, 3D organ-on-a-chip, micro-physiological systems, and organoids.



A 96-wellplate of RealBrain 3D micro tissues

Regulatory changes: embracing a new era of non-animal testing

Significant regulatory changes are occurring in recognition of the growing capabilities of emerging technologies and the limitations of traditional animal models. In December 2022, the US Government passed the FDA Modernization Act 2.0, which eliminates the requirement for animal testing under the Federal Food, Drug and Cosmetics Act. This legislative change enables drug developers to adopt human-relevant approaches, including organotypic systems, and computer models using artificial intelligence (AI) and machine learning in lieu of animal models. Thus, this legislative change marks the start of a new era in which drug development can occur without animal testing. Other jurisdictions – including India, Canada and South Korea – have already followed with similar legislative changes, and more are expected.

Sector response

The broader life sciences sector is increasingly committed to reducing animal testing and adopting non-animal models in the drug development process. Funding and regulatory agencies, such as the National Health and Medical Research Council (NHMRC) and the European Medicines Agency, have announced their commitment to applying the 3R principle (replace, reduce and refine) to their processes. Additionally, most major pharmaceutical players – including GSK, AstraZeneca, Johnson & Johnson and Roche – have also publicly announced their commitment to the 3R principle, and in integrating emerging technologies into their drug development activity.

Roche, in particular, is strongly backing the adoption of 3D organotypic models, and earlier this year opened an organoid research institute that will house 250 scientists and bioengineers over the next four years.

Recent merger and acquisition activities in the area include Molecular Devices' acquisition of Cellesce, and the merger of MatTek and Visikol. Gerrit Schulte, the Head of ZEISS Ventures, who invested in InSphero, expressed optimism about the market's attractiveness, stating that it is experiencing new tailwinds with the implementation of the FDA Modernization Act.

The Australian context

Globally, Australia is known for being among the largest users of animal models in medical research. In 2009, it was estimated that 9.5 million animals were used for scientific purposes.[2]

In 2019, the NHMRC published an information paper titled, 'The implementation of the 3Rs in Australia'. This report found that Australian scientists had a lower awareness and knowledge of the 3R principle compared to their international counterparts; however, significant steps are being made in reducing the use of animal models and integrating emerging technologies. The Australian Government has recognised the potential for non-animal models – not just in medical research, but in other industries, like industrial chemical testing – and commissioned a report into the opportunity. Australia also has several world-leading research groups, and companies developing or enabling powerful 3D organotypic culture systems.

2 Humane Research Australia (2013b), 'Statistics of Animal Use in Research and Teaching in Australia', www.humaneresearch.org.au/statistics_2013/

Continued on page 16

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Continued from page 14

RealBrain® technology

At Tessara, we are focused on pushing the boundaries of non-animal technologies to help them gain market traction, and widespread industry acceptance and adoption. Our mission is to transform how drug discovery, development and toxicity assessment is conducted for neurological conditions through our powerful RealBrain® platform.

Tessara's RealBrain technology generates 3D neural cell–based models (or mini brains) that closely replicate the physiology and function of the human brain. We have two validated brain models: the ArtiBrain™, which accurately mimics a 'healthy' version of the human brain; and the ADBrain™, which emulates the sporadic version of Alzheimer's that accounts for more than 90 per cent of all Alzheimer's cases.[3] We also have a pipeline of models to address the largest unmet needs in neuroscience and in areas where animal models are poor predictors of human responses, such as neurodevelopment, traumatic brain injury and glioblastoma (brain cancer).

Neurological disorders are the leading cause of disability, and are the second most common cause of death worldwide. The socio-economic burden of neurodegenerative disorders is also increasing with the world's aging population. In Australia, dementia (Alzheimer's disease being the most common form) is the leading cause of death in women.[4] The impact of neurological diseases is also compounded by the approximately 95 per cent clinical failure rate of neurological drugs.[5] For Alzheimer's disease, 99.6 per cent of drug candidates[6] have failed to show efficacy in human clinical trials. We want to address this.

Tessara's RealBrain Drug Screening Platform enables the pharmaceutical, biotech and contract research organisation industries to discover and develop safer, more effective treatments for neurological diseases. Our human brain micro-tissues are perfectly engineered for target validation, lead optimisation and efficacy studies, allowing for early detection of neurotoxicity and therapeutic efficacy. The result? Drug developers can save valuable time, and research and development costs, while simultaneously boosting the success and value of their drug development programs.

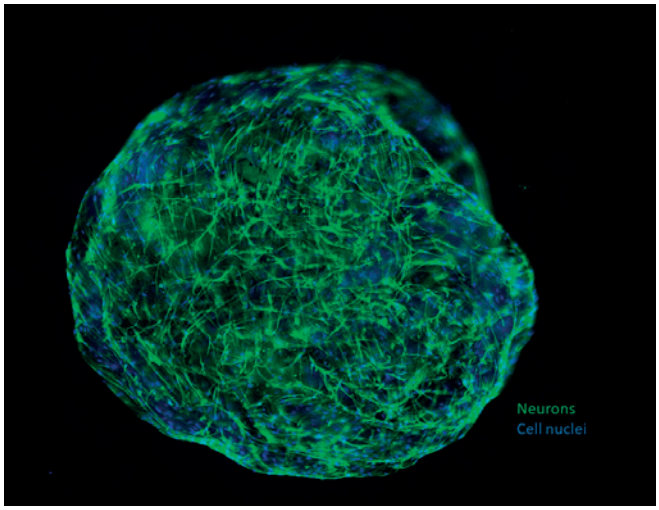
By identifying the safest and most effective therapeutic candidates early in the process, we maximise the likelihood of identifying successful therapeutic candidates. Especially when our micro-tissue technology is combined with AI and imaging applications, we can get an unparalleled understanding of how treatments impact neural plasticity and function. Advantages of our RealBrain 3D technology over traditional methods include:

- fast production and maturation time frames (three weeks)
- high relevance to the human brain
- optical clarity, efficiently, and easily enabling continuous and simultaneous observation of hundreds of drugs and their effects on a neural network, and new insights into the mechanisms of neuroplasticity modulation
- simple and highly reproducible manufacturing processes, providing scalability and reliability.

Tessara is currently scaling up manufacturing and commercial operations, and upon completion, we will commercially launch our RealBrain technology to the Australian and global neurology research community.

We have now entered a new paradigm where animal testing is no longer required as part of the drug discovery process. This transformative shift is being empowered by emerging technologies that address ESG concerns, and make the drug discovery process more efficient and effective, ushering in a new era in which the biotech community will have powerful tools to bring new therapies to the market.

Learn more about alternatives to animal testing models in biomedical research at the AusBiotech 2023 panel session, 'Animal model alternatives: the future of drug screening is driven by human biology', on Friday 3 November in Brisbane, Queensland.



A Tessara micro-tissue image

3 Masters CL, Bateman R, Blennow K, Rowe CC, Sperling RA, Cummings JL (2015), 'Alzheimer's disease', Nat Rev Dis Primers, doi: 10.1038/nrdp.2015.56

4 Australian Institute of Health and Welfare, 'Dementia in Australia, Deaths Due to Dementia', www.aihw.gov.au

5 Dowden H, Munro J (2019), 'Trends in clinical success rates and therapeutic focus', Nat Rev Drug Discov, doi: 10.1038/d41573-019-00074-z

6 Mohs RC, Greig NH (2017), 'Drug discovery and development: role of basic biological research', Alzheimers Dement (N Y), doi: 10.1016/j.trci.2017.10.005

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MODERN RESEARCH TOOLS RELIEVING THE BURDEN OF PHYSICAL EXPERIMENTS

BY JONATHAN KRIEGER, INDUSTRIAL SOFTWARE PRE-SALES; AND MAKARAND MUJUMDAR, INDUSTRY SPECIALIST – LIFE SCIENCE, EMERSON AUTOMATION SOLUTIONS

LAB RESEARCH IS a resource-intensive undertaking. There are tools available to lessen the load of materials and time consumed when advancing programs through their pilot phases and towards large-scale production. The limitations of data collection through physical experimentation are a clear bottleneck in the industry, and modern solutions – such as simulation and multivariate analysis – are paving the way forward.

Current challenges in the research lab

Research is the systematic collection and investigation of data with the aim of deriving conclusions about the interaction of components. The feedstock of research is data, and traditionally, these numbers and figures are obtained by running calculations or physical experiments in labs. This arrangement absorbs a significant amount of time and resources. Collecting and processing data has traditionally been the limiting factor to progressing a scientific exploration, but we are no longer constrained by the physical world.

Imagine that you are analysing the results of your latest experiment. You are plotting trends on Excel and running regressions, trying to find relationships between specific variables to inform the design of future experiments. Any insights you obtain are jotted down in a workbook or stored in your mind to be recalled later. In isolation, this is a well functioning system that has enabled you to continuously derive information from your research to push it forward.

What happens to this scenario when tomorrow's experiment contradicts the previously obtained knowledge that you locked into your mind? The notes you made yesterday seem to lack detail, and perhaps your graphic regression was too simplistic, overlooking other interacting parameters. The best way forward seems to be to re-run yesterday's trials and analyse the fresh data. Months down the track, your direction of research is progressing, and you must submit results and documentation to secure ongoing resources. You are overseas for a family trip and your colleague is assisting in the submission process. They can't find the third notebook that you reference in your equations, and they are struggling to interpret the screenshots of graphs you developed weeks ago. These scenarios can be avoided with the effective use of digital tools.

Accelerating research with the help of simulation

Process modelling has reached a level of utility that cannot be disregarded. The ability to simulate processes based on mechanistic modelling means that researchers can take necessary iterations of experiments from the physical world to the digital world. The use of these tools will help labs save time and money, while also reducing the amount of waste generated during experiments.

Jonathan Krieger

Makarand Mujumdar

Furthermore, industry regulators are supporting the use of simulation outcomes as a major component of the verification/validation process. Aspen Plus™ is one such tool that can utilise both first principles modelling and machine learning algorithms to maximise the pertinence of results. Our understanding of the physical world can only be modelled up to a point, capturing primary and secondary interactions of variables. Artificial intelligence (AI) can be incorporated into so-called 'hybrid' models to produce an understanding of the tertiary reactions taking place.

Aspen Plus™ simulation software offers out-of-the-box simulation for research, process optimisation and building digital twins. Use cases include optimising fermenters and bioreactors, particle size distribution, and solvent optimisation. AI Model Builder and Aspen Custom Modeler are available for complex processes, such as tangential flow filtration. Research and development (R&D) labs work on tight budgets and time lines. Using simulation can allow researchers to run

an experiment many magnitudes faster than in the physical world. They can automatically step through a range of input parameter values or conditions to produce results with zero material waste. Conclusions of interest can be subsequently validated with a physical experiment, and research can continue with minimal delay.

Making sense of the data with multivariate analysis

Pharma and biotech processes are typically multivariate in nature. Most statistical process control systems rely on univariate methods, which only look at variables in isolation, one at a time. The use of multivariate data analysis tools can lead to powerful research discoveries. They can also be utilised as a valuable documentation and information transfer instrument. Detailed analysis can be stored and manipulated in files for multiple researchers to interact with. Aspen Unscrambler™ can help model the complex interaction of parameters to generate more awareness of a given process or reaction. Relationships between variables can be found in this way that a human was unlikely to uncover with simplistic statistical analysis. These insights are digitally stored within a file location, providing a channel for researchers to communicate and interrogate their perceptions of this new information. With the security of data in a digital form, experiments will no longer be subject to the risk of information loss.

When experimental research progresses from preliminary stages, a need arises to monitor the process in real time. The offline models developed by Aspen Unscrambler™ can be implemented online with tools like Aspen Process Pulse™ for continuous improvement monitoring, or even to perform closed-loop control.

Let's talk about process analytical technology

In a conventional manufacturing facility, lab analysis is conducted to check the quality at any defined step by real-time manual sampling. This process is susceptible to human error, risk and delay, and can become a manufacturing bottleneck that causes scheduling impacts. Today's digital technologies have enabled manufacturers to automate and improve this process, reducing the amount of rework. The offline chemometric models using multivariate statistical analysis generated by Aspen Unscrambler™ can be implemented online with tools like Aspen Process Pulse™ and Emerson DeltaV™ spectral process analytical technology (PAT) to observe variables such as cell growth, metabolite production, and nutrient consumption.

This real-time analysis allows for early detection of deviations, and can automatically adjust conditions to optimise quality parameters and other goals of the experiment. The software can predict that the product of an experiment or process is going to resolve in an undesirable state, and then implement control changes to prevent this from occurring. This technology empowers labs and manufacturing operations to have more control over the quality of their products. It can also prevent an entire batch from becoming off-spec. PAT is also an enabler for transitioning from batch to continuous manufacturing.

Conclusion

The tools discussed in this article are forever improving and expanding into new realms of possibility. A key theme is that the knowledge embedded within these simulation and PAT tools can be transferred as you progress to further trial stages. They have the capability to integrate with real-life pilot-scale and commercial plants. This digital transformation within research labs will not only bring efficiency and speed, but it can also empower research to be more sustainable. Reducing the number of physical experiments is the key to accelerate research, and minimise wastage of precious materials and time.

AusBiotech's Biotechnology Blueprint 2022–23 mentions that 'a key foundation of the biotechnology industry is R&D'. In Australia, the R&D sector represents almost 75 per cent of the life sciences industry. Adopting modern research tools will be one of the key steps in maintaining our global leadership.

For more information, email the authors at jonathan.krieger@emerson.com and makarand.mujumdar@emerson.com.

Australian Clinical Trials Alliance

Australian Clinical Trials Alliance: Fostering global collaborations for efficiency and impact in clinical trials

ACTA International Clinical Trials Symposium: 27 – 29 November, Park Hyatt Melbourne

The Australian Clinical Trials Alliance (ACTA) is the national peak body supporting and representing networks of clinician-researchers conducting investigator-initiated clinical trials, maintaining clinical quality registries, and operating clinical trial coordinating centres within the Australian healthcare system.

The ACTA International Clinical Trials Symposium is a highly anticipated event that brings together leading experts, clinical trialists, researchers, and professionals worldwide to discuss and share insights on the latest advancements in clinical trials. With a focus on efficiency and impact, this Symposium plays a crucial role in shaping the future of health in Australia and across the globe.

PROGRAM OVERVIEW:
The Symposium offers a comprehensive program that covers a wide range of topics relevant to clinical trials. The event aims to foster knowledge exchange, promote best practices, and address the challenges researchers and stakeholders face in conducting clinical trials. The program includes local and international keynote speakers, panel discussions, workshops, interactive sessions, and networking events, ensuring a diverse and engaging experience for all attendees.

SPEAKERS AND EXPERTISE:
The Symposium boasts an impressive lineup of renowned local and international speakers who are experts in their respective fields. These speakers bring a wealth of knowledge and experience, enriching the Symposium with their unique perspectives.

The Symposium's speakers include distinguished clinicians, researchers, sector leaders, regulatory authorities, and consumer advocates. Their expertise spans various areas, such as clinical trial design, data management, ethics, consumer engagement, and regulatory frameworks. By bringing together such a diverse group of speakers, the Symposium ensures a well-rounded approach to addressing the challenges and opportunities in clinical trials.

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One of the key strengths of the ACTA International Clinical Trials Symposium is its emphasis on collaboration and networking. The Symposium provides a platform for attendees to connect with like-minded professionals, fostering partnerships that can drive advancements in clinical trials. Participants can exchange ideas, share best practices, and explore potential collaborations that can accelerate the translation of clinical trials into improved patient health outcomes.

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LOCAL AND INTERNATIONAL KEYNOTE SPEAKERS:

Commissioner Robert Califf, U.S. Food and Drug Administration (FDA)

Prof Lucy Chappell, Chief Scientific Adviser to the UK's Department of Health and Social Care (DHSC), and CEO of the National Institute for Health and Care Research (NIHR)

Prof Tony Lawler, Deputy Secretary, Health Products Regulation Group (incl. the TGA)

The Hon. Mary-Anne Thomas, Victorian Health Minister

John Eikelboom, Prof of Medicine at McMaster University, Canada

Louise Bowman, Prof of Medicine and Clinical Trials, University of Oxford, UK

Paula Williamson, Prof of Biostatistics at the University of Liverpool, UK

Dr Scott Berry, President and Senior Statistical Scientist, Berry Consultants, Austin, Texas

Prof Andrew Wilson, Co-Director of the Menzies Centre for Health Policy and Economics

***Please check the event website for continued updates on speakers and the program**

CREATING AN INDUSTRY – SMALL BIOTECH AND THE RNA REVOLUTION

BY DR GISELA MAUTNER, CEO AND MANAGING DIRECTOR, NOXOPHARM

The consequences of the COVID-19 pandemic will be felt for decades to come, but can Australia's biotech industry gain from them in meaningful ways? That is a crucial question as the health and economic shocks of the past three years recede, and we now look ahead to what comes next.

IN A WAY, the situation today is like the immediate aftermath of a major conflict. There has been extensive suffering, but we are also left with interesting technologies, the development of which has been quicker than expected. While World War II saw huge advances in everything from radar to jet propulsion, one of the pandemic's legacies will be an acceleration of mRNA technology and a public grasp of its potential.

Despite some naysayers, there is today a comprehension among the public that the COVID-19 vaccines were developed quickly as a result of a major medical breakthrough. This understanding implies a general bedrock of public support – a social licence – for future investment of taxpayer dollars into lifesaving mRNA technologies that, according to some predictions, could have an immense impact on health care. The consensus further implies that the public will accept government expenditure on mRNA research and development because it is expected to result in significantly better health outcomes. And that is exactly what is happening.

At a speed that may have surprised seasoned observers of public bureaucracies, we are seeing governments springing into action. They are doing this for many reasons: to secure local supply chains of important medicines, to mitigate risk, to invest in promising new research with public health benefits, and to create commercially valuable new intellectual property, jobs, and skills.

This is why in Australia, we are now seeing an mRNA vaccine manufacturing facility in Melbourne, a global mRNA vaccine hub and research centre in Brisbane, and a new RNA pilot manufacturing facility in Sydney. Those are just some major initiatives among many, and they are all welcome developments ensuring this country has the medicines and vaccines it needs for a range of future circumstances, and does not need to wait to import urgently needed vaccines from overseas.

Dr Gisela Mautner

There is a great economic opportunity here, too, as there always is whenever new technologies emerge. Whether it's railroads, home computers or artificial intelligence, new technology means new companies, new leaders, and new products that deliver value at a national or even global scale – and Australia is well-placed to capitalise on this.

Substantial government-backed initiatives are often happy hunting grounds for the largest companies in their fields, as they have the scale, resources and reputations to be trusted partners. Governments themselves are risk-averse, so will often choose the 'safest' names to partner with for both competence and reputational reasons. This is generally good because we need these new facilities to be built by skilled and experienced professionals.

But there is also a danger that governments potentially overlook the best and most promising research, which is often done by small companies, and that those small companies risk being sidelined from centrepiece initiatives. It is not just a risk in biotech, of course, as the same dynamic often occurs in areas like defence, civil engineering, media and financial services. However, what is notable and distinct about this moment in the biotech industry is the nature of the technology itself. By historical standards, mRNA technology is still fairly new on the scene, and even more of a newcomer when considered in terms of its real-world application at the global scale – that is a recent phenomenon.

The development of wider RNA technologies over the coming years will, by nature, be unpredictable. Companies large and small are working in this space but, given the relative novelty of RNA, Australian companies have a real opportunity to become significant players in developing new RNA-based vaccines and therapeutics. Specialised companies are more agile, and the improved vaccines of the future will likely require inputs from a variety of companies focusing their efforts on specific features of RNA-based therapeutics, such as reactogenicity, immunogenicity, and targeted delivery or product stability, among others. The next breakthrough could come from anywhere – so why not from an Australian company?

As the area is in its infancy, we also do not yet know all the issues that will arise. Keeping the investment broad helps with de-risking, as there would be multiple players and ideas in the field, meaning that should an issue arise, there are Australian companies already working in the space allowing fast acceleration of solutions.

At Noxopharm, we are one of those smaller players, having developed an mRNA vaccine enhancer designed to mitigate vaccine side effects. In the RNA space, we are not neutral observers, but rather are exploring the leading edge of RNA technology via ultra-short oligonucleotides with our partners at the Hudson Institute of Medical Research in Melbourne. We have a product we are actively looking to commercialise, and therefore have a keen interest in how the local industry develops as a whole, and how we as a country make the most of this once-in-a-generation opportunity.

The recent mRNA infrastructure announcements clearly demonstrate that larger companies have built constructive relationships with governments, and that is as it should be at this early stage. There is a risk, though, that in the future, policymakers will only view the growing industry in terms of those businesses, and not the wider group of smaller companies who are also active in RNA. Again, to look at other industries, it is not uncommon to hear defence small and medium-sized defence enterprises (SMEs) or innovative tech startups grumble that 'the system' at a national level, and its associated rules, are heavily biased towards the entrenched industry heavyweights.

How do we prevent that outcome in this case and create the largest possible playing field for all participants? The challenge for the future is to link the large infrastructure projects and government-level strategy to a network of companies feeding new ideas into the wider ecosystem.

This is easier said than done, and has already become a focus for several organisations. The Australian Government asking for stakeholder input into the National RNA Sector Development Plan is a helpful initiative. Other associated measures that could also be taken include, for example, specific tax incentives for smaller companies, alongside other motivations to encourage participation in the mRNA space, in areas from intellectual property (which, when spread across numerous companies, will help sustain a healthier ecosystem and economy), to various fee structures.

There could be more top-down encouragement of collaboration agreements between large companies and small, perhaps even mandated in certain projects, as well as clearly defined communication channels between SMEs, larger participants, and governments. There are also opportunities to strengthen overseas market access, carrying on Austrade's good work, as well as promoting greater links between small business and academia.

AusBiotech will no doubt continue to play a central role in representing the interests of its members at the highest levels, and promoting practical ways of helping the ecosystem grow. Creating a framework in which smaller local participants can genuinely thrive would help governments of all persuasions create a positive return on their investments, and deliver valuable economic growth in what could well turn out to be a new golden age of medicine.

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UNIVERSITY–BIOTECH COLLABORATION PROVES VITAL TO BUSINESS GROWTH

RAISING CAPITAL, CONDUCTING clinical trials, developing technology and navigating rising costs – these are the challenges that biotechnology companies face every day. The University of South Australia (UniSA) understands that business success often relies on strategic collaboration. That is why UniSA is committed to helping businesses across the life sciences sector to develop and scale.

This commitment has culminated in the creation of the UniSA Enterprise Hub, a single entry point for businesses to collaborate with leading researchers, and gain access to world-class technology and facilities.

UniSA has more than 30 research institutes, centres and concentrations that are dedicated to solving industry challenges. UniSA also licenses research-backed technology and intellectual property. By connecting businesses with these university resources, the UniSA Enterprise Hub is brokering industry solutions.

Improving the performance of implantable medical devices

UniSA works with businesses across the life sciences sector, including world-leading medtech company TekCyte. Central to UniSA's partnership with TekCyte is the Future Industries Institute (FII), one of the university's key hubs of research innovation. These UniSA researchers are experts in their field, specialising in high-tech manufacturing and medical technologies. TekCyte's team has been able to draw on this expertise while pioneering its world-leading surface-coating technologies.

The company, which operates within UniSA's FII, utilises the university's state-of-the-art manufacturing facilities, while leveraging the university's capabilities in additive manufacturing; multi-layer thin film coating systems; coatings for real-world applications; and the design, fabrication and testing of microfluidic devices.

TekCyte CEO Dr Tony Simula says that the collaboration with UniSA, and its FII, has allowed his company to rapidly develop its drug-free medical device coating, BIOINVISIBLE™, to a point that it is now ready for commercial manufacturing.

'We have been able to draw on the capabilities of UniSA, and its FII, to gain unparalleled access to research, multidisciplinary expertise and state-of-the-art facilities,' Simula says.

'Our continued collaboration with UniSA has allowed TekCyte to improve the process for applying BIOINVISIBLE™ to a variety of implantable medical devices, like an arterial stent, which ultimately could lead to improved clinical and patient outcomes.

'To make that transition possible, TekCyte is now seeking expressions of interest of investment in funding the expansion of its coating development operations.'

The success story of TekCyte is a testament to the power of collaboration between industry and universities.

Find the UniSA team at this year's AusBiotech event. UniSA knows that successful biotechnology ventures rely on strong partnerships. Collaborating with UniSA will support your journey and make your business unstoppable. Get access to world-leading experts, research and technology now. To connect with UniSA or to learn more, visit unisa.edu.au/enterprisehub.

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COULD PSYCHEDELIC MEDICINES BREAK A 50-YEAR DROUGHT ON NEW TREATMENTS FOR MENTAL ILLNESS?

BY PROFESSOR CHRIS LANGMEAD, DIRECTOR OF THE NEUROMEDICINES DISCOVERY CENTRE, MONASH UNIVERSITY

On 1 July this year, Australia became the first country in the world to allow specifically authorised psychiatrists to prescribe psychedelic medicines for the treatment of certain mental health conditions.

THE LANDMARK DECISION by the Therapeutic Goods Administration (TGA) approved the use of 3,4-methylenedioxymethamphetamine (MDMA, the active ingredient in ecstasy) and psilocybin (the active ingredient in magic mushrooms) for the treatment of post-traumatic stress disorder (PTSD) and treatment-resistant depression, respectively.

Many experts were surprised by the timing of the authorisation of psychedelic medicines, with some questioning the sufficiency of evidence; however, while most agree more research is critical, some scientists see the TGA decision as a 'cautiously optimistic' opportunity to build on the mounting (and promising) evidence emerging in the field.

Professor Chris Langmead

For researchers from Monash's Neuromedicines Discovery Centre, the ultimate goal is to develop a new generation of precision psychiatric medicines that are quick to act, require minimal dosing, have few side effects and are effective for long periods of time.

Changes to the classification of MDMA and psilocybin is an opportunity to pave the way towards breaking a 50-year

The Monash Institute of Pharmaceutical Sciences research team

drought in the development of new, safe and effective medicines for a range of difficult-to-treat mental health conditions, and significantly improve the lives of the nearly five million Australians[1] living with a mental health condition.

Why MDMA and psilocybin?

The TGA states that the decision to reclassify psilocybin and MDMA from Schedule 9 (Prohibited Substances) to Schedule 8 (Controlled Drugs) 'acknowledges the current lack of options for patients with specific treatment-resistant mental illnesses'.

Currently, clinical guidelines for PTSD and treatment-resistant depression recommend a combination of talk therapy and antidepressants, such as selective serotonin reuptake inhibitors, as first-line treatments; however, these medications are based on science that is more than 50 years old, and for a number of people they are simply not effective.

As a result, the past decade has seen a revival of interest in the potential of psychedelics, such as psilocybin and MDMA, as fast-acting and potentially more effective treatments when delivered in conjunction with supportive psychotherapy. These neuro medicines act differently to current medicines. Psilocybin, for example, switches on serotonin 2A receptors in the brain, activating previously dormant pathways and increasing connectivity between different regions of the brain, which, in turn, enables patients to become more receptive to psychotherapy.

And the evidence backs this up. A recent Phase 3 clinical trial into the use of MDMA for severe PTSD, published in *Nature Medicine*, found 'MDMA-assisted therapy to be highly efficacious in individuals with severe PTSD, and treatment is safe and well-tolerated, even in those with comorbidities'.

Likewise, one of the many clinical trials into psilocybin – published recently in *The Lancet* – found a single, moderate dose of psilocybin significantly reduced depressive symptoms in patients with major depressive disorder, compared to a placebo, for at least two weeks. No serious adverse events were recorded; however, larger, multi-centre clinical trials with longer follow-up periods are required to better assess safety and efficacy.

On 25 July, *Nature Medicine* also published results from a Phase 1 clinical trial led by the University of California, which found a single dose of psilocybin, administered alongside psychological support, is a safe and acceptable treatment for patients with anorexia nervosa, and may decrease eating-disorder behaviours in a subset of patients.

Health economics and accessibility[2]

Despite the potential of psilocybin and MDMA for the treatment of certain mental health conditions, there are still major issues to tackle in order for the TGA's reclassification to benefit those most in need.

1 https://www.abs.gov.au/statistics/health/mental-health

2 Content in this section has been drawn from an article at The Conversation, which was co-authored by Professor Chris Langmead (https://theconversation.com/the-tricky-economics-of-subsidising-psychedelics-for-mental-health-therapy-201462)

Monash Institute of Pharmaceutical Sciences neuromedicines researcher in the lab

One of the biggest issues is cost, which is estimated to come in at around $20,000 to $30,000 for the medication and therapists' time, instantly excluding the vast majority of the population from being able to access such treatment.

This raises questions around whether psychedelic medicines will be publicly subsidised, given the lack of data about their cost-effectiveness compared with other treatments. A subsidy for the psilocybin/MDMA component would require a detailed submission to the Pharmaceutical Benefits Advisory Committee explaining how the medicine will be prescribed, as well as its effectiveness, safety and cost-effectiveness compared with current alternatives.

Submissions must also include budget impact analysis – that is, how much it will cost if the medicine is listed on the Pharmaceutical Benefits Scheme. To date, there is only one published study on psilocybin's cost-effectiveness, and three on MDMA – all on its use to treat PTSD. All three studies conclude that MDMA-assisted therapy is a potentially cost-effective treatment for people with chronic and severe PTSD.

However, the modelling assumes that the effects of MDMA-assisted psychotherapy taken from clinical trials of relatively short durations (with maximum follow-up of 18 weeks) will extend for 10 to 30 years, which may be overly optimistic. The data was also based on treatment patterns and costs from the United States, which differ from those in Australia.

The upshot of all this means that, in clinical practice, Australia is still a way off offering a public subsidy for these psychedelic treatments for certain mental health conditions.

What could a mental health treatment look like in 10 years?

For researchers at the Neuromedicines Discovery Centre, the aim is to develop new drugs by exploring how chemical compounds found in medicines such as MDMA and psilocybin interact with the brain.

The team is researching how to harness some of the extraordinary advantages associated with psychedelic substances in medicines that might be more consistent and cost effective.

This could include developing medicines that have 'psilocybin like' effects, but that are much shorter-acting (a psilocybin session can last between six and eight hours), or possibly even medicines that have similar effects to augment psychotherapy, but that are devoid of a subjective psychedelic experience and could be taken at home, without clinical supervision.

The ultimate goal is to find 'antibiotics for the mind'. To do this, the Neuromedicines Discovery Centre is forming a joint venture with The University of Melbourne and The Florey Institute of Neuroscience and Mental Health to strive to find better treatments for mental health conditions by propelling new medicines – from drug discovery and development, through to clinical trials, and into the public policy arena.

The TGA has granted Australia a once-in-a-generation opportunity; it is now time to seize it.

Hear Professor Chris Langmead and other experts discuss Australia's role in developing psychedelic-based mental health treatment during the AusBiotech 2023 panel session, 'Australia leading the way: next-generation mental health treatments', on Wednesday 1 November in Brisbane, Queensland.

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NATIONAL BLUEPRINT OUTLINES ROAD MAP FOR AUSTRALIA TO BECOME REGIONAL C&G MANUFACTURING HUB

BY AUSBIOTECH

AusBiotech's newly launched National Cell and Gene Manufacturing Blueprint provides a unified approach to expanding sovereign cell and gene manufacturing capabilities and capacity in Australia.

FOR INDUSTRY, THE National Cell and Gene Manufacturing Blueprint presents an opportunity to shape the field for the future, and to build a sustainable and growing ecosystem that attracts and supports local and international operators. For government, it presents an opportunity to strategically invest and therefore maximise the socio-economic potential of cell and gene (C&G) manufacturing, including job creation and healthcare outcomes. In order to take full advantage of the opportunity, timely buy-in and investment from government is critical.

C&G medicines are a new frontier in medicine, having already demonstrated lifesaving and life-changing results for patients with rare diseases and cancer, and showing promise in addressing additional, more common conditions. C&G products (which include C&G therapies) involve delivering complex biological components. These therapies can address the root cause of diseases, and single treatments are already producing long-lasting and life-changing results for patients with rare diseases and cancer.

The global C&G industry has developed apace in recent years and is only accelerating. With nine C&G products approved in Australia, and the US Food and Drug Administration on track to meet its 2019 prediction of 10–20 approvals per year by 2025, the demand for the growing and diversifying suite of therapies is high. While the initial scientific challenges of C&G products have been overcome, the manufacturing and delivery requirements remain complex and diverse, with the increasing number of therapies pushing global manufacturing capabilities and capacity to the limit.

As the global C&G industry continues to develop, Australia risks missing out on the opportunity and benefits that C&G manufacturing provides to the Australian economy and healthcare system, including for patients in desperate need of novel therapies. Given Australia's advanced manufacturing scene and healthy biotechnology ecosystem, there is an opportunity for Australia to be a regional hub in the Asia-Pacific region, and known for leading C&G research, clinical trials, translational know-how and manufacturing capabilities.

Unlocking these opportunities requires much better understanding and coordination, while addressing the gaps in capacity and capabilities. To provide a road map forward, AusBiotech commissioned the National Cell and Gene Manufacturing Blueprint to outline an industry-developed strategic approach for Australia to expand its sovereign C&G manufacturing capabilities and capacity, and become a regional C&G manufacturing hub.

The blueprint also provides a shared, forward-looking vision for manufacturing C&G products in Australia, outlines where we are now as a country, and recommends a blueprint of implementation strategies for manufacturing C&G therapies locally.

The Australian C&G manufacturing space is highly active. The blueprint updated AusBiotech's 2021 Australia's Regenerative Medicine Manufacturing Capacity and Capability report, which identified 11 companies with a total footprint of 3700 square metres across 49 clean rooms. This footprint has since grown, with five of those companies reporting facility expansions or increased capabilities, and a further three new companies reporting manufacturing space.

AusBiotech CEO Lorraine Chiroiu says, 'This report is an opportunity to harness Australia's role in the global cell and gene ecosystem, and to ensure that we are coordinated and best placed as a nation to be involved in, and benefit from, these life-changing therapeutic approaches now and into the future. In order to secure Australia's position as a critical hub for C&G manufacturing,

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Continued from page 32

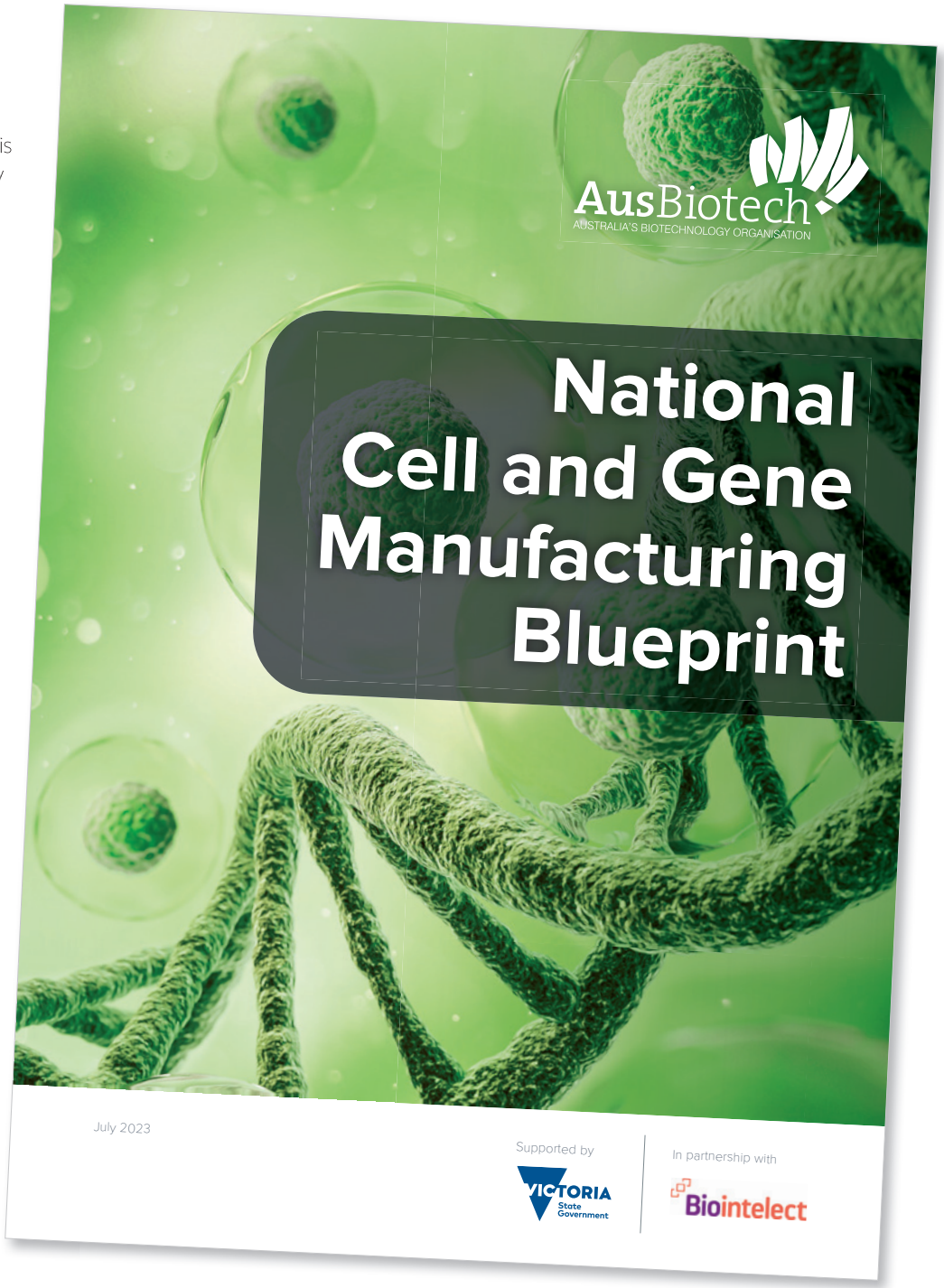
timely government support and funding is essential to fully realising the opportunity lying in front of us.'

The blueprint was developed with both industry and government in mind, outlining recommendations on how Australia's ecosystem can work together to develop the necessary workforce, expertise and infrastructure to position Australia as a regional leader, and deliver a new generation of medical treatments.

Eleven key recommendations to support local C&G manufacturing have been identified in order to overcome four key challenges:

- Challenge 1: Addressing critical and growing skills gaps in C&G manufacturing.
- Challenge 2: Building critical mass in Australia's C&G manufacturing ecosystem.
- Challenge 3: Optimising Australia's contributions to the C&G product pipeline.
- Challenge 4: Tracking and guiding industry growth.

Supported by the Victorian Government's Australian Medtech Manufacturing Centre, the blueprint was developed by AusBiotech, the Cell and Gene Manufacturing Taskforce, and project partner Biointelect.



The blueprint addresses five key areas outlined in the Strategic Roadmap for the Regenerative Medicine Sector: workforce skills development, long-term investment opportunities, strengthened collaboration across the value chain, capability across the value chain, and clear market access pathways aligned with leading global markets.

AusBiotech is encouraged to see the blueprint being taken up by both industry and government, and looks forward to working with stakeholders across the life sciences value chain to implement blueprint recommendations that support Australia's growing C&G capabilities.

Thank you to the individual contributors and the Cell and Gene Manufacturing Taskforce, comprised of Guillaume Herry (AcuraBio), Ian Wisenberg (BioCina, Bridgewest Group), Silvio Tiziani (CCRM Australia), Jennifer Hollands (Cell Therapies Pty Ltd), Susie Nilsson (CSIRO), Margret Schuller (NSW Stem Cell Network), and Heather Donaghy (Therapeutic Innovation Australia).

Listen to industry leaders discuss the National Cell and Gene Manufacturing Blueprint during the AusBiotech 2023 panel session, 'A national plan for leading APAC's cell and gene manufacturing', on Friday 3 November in Brisbane, Queensland.

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GOLD COAST HEALTH AND KNOWLEDGE PRECINCT EMERGES AS MEDICAL TRAINING AND TRIALS HUB

WITH WORLD-FIRST FACILITIES, a rapid post-COVID expansion of biomedical capability and new developments, the Gold Coast Health and Knowledge Precinct (GCHKP) is fast emerging as an Asia-Pacific hub for medical technologies.

Director Craig Rowsell says GCHKP's recent biotech surge and $250 million invested in new buildings within the Lumina commercial cluster furthers GCHKP's standing as Queensland's leading innovation district.

'We're a young precinct, but our offering has rapidly matured, just as private investment is creating the infrastructure to sustain growth,' says Rowsell.

Leading the capability growth is the NeuTex Image-guided Surgery, Training and Robotics Centre – the world's only facility of its kind located outside a hospital and dedicated to training, and research and development (R&D).

Opened in partnership with global healthcare company Philips, NeuTex attracts international specialists to learn the latest neurovascular procedures and trial new devices.

'If you really want to amplify the number of people who get trained in this technology, [GCHKP] is the type of place you want to do it at as a key Asia-Pacific hub,' says Dr Atul Gupta, Philips's Chief Medical Officer for Image-Guided Therapy.

Built around Philips's multimillion-dollar Azurion image-guided therapy platform, NeuTex innovates using personalised anatomical models 3D-printed in the GCHKP's Advanced Design and Prototyping Technology Institute at Griffith University.

'We're expanding R&D in the neurovascular field while broadening training in other surgical specialties, such as cardiovascular,' says NeuTex Co-founder Dr Hal Rice. 'We're looking to a future of artificial intelligence- and robotics-enabling remote procedures, virtually anywhere in the world.'

Together, Rice and colleague Dr Laetitia de Villiers (pictured) have conducted the largest case load of robotic aneurysm repairs globally.

GCHKP has also rapidly grown its clinical trials offering, including world firsts. Griffith University's Clinical Trial Unit (CTU) has doubled its capacity in 18 months. Gold Coast Health's CTU is currently managing 47 trials, involving 562 patients across 24 clinical departments, while Gold Coast Private Hospital is also active.

Griffith's CTU has successfully conducted more than 50 trials across phases 1 to 4 and various disease states, including rare diseases and healthy volunteer trials. Its commercial client list includes global pharma firms, and the bioscience and nutraceutical industries.

'The CTU team is passionate about advancing clinician–academic partnerships, and we're currently supported by 12 Gold Coast University Hospital clinicians across nine trials,' says Director Evelin Tiralongo.

GCHKP is also home to Griffith's Institute for Glycomics, a flagship research institute that attracts more than $15 million in annual research income.

Technologies include a vaccine candidate for streptococcal A, a sepsis drug candidate, a gonorrhoea vaccine candidate and a viral-induced arthritis drug. License agreements are in place with biotechs in Australia, Switzerland and China.

The Institute for Glycomics and Griffith's CTU are central to Griffith's partnership in the $280-million Translational Science Hub, which was established with leading global pharma Sanofi, along with partners The University of Queensland and the Queensland Government.

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INTRODUCING AUSTRALIA'S POWERHOUSE FOR INNOVATIVE BIOTECH VENTURES

BY DR ANDREW NASH, CHIEF SCIENTIFIC OFFICER, CSL; PROFESSOR ALAN COWMAN AC, ACTING DIRECTOR, WEHI; AND PROFESSOR MARK HARGREAVES AM, ACTING DEPUTY VICE-CHANCELLOR (RESEARCH), THE UNIVERSITY OF MELBOURNE

With a mission to connect early-stage and scaling biotech ventures with the support they need to progress discoveries towards real-world treatments and therapies, a world-class biotech incubator in Melbourne aims to build a critical mass of scientists with the knowledge and confidence to run successful biomedical ventures – and the power to influence and impact global health outcomes.

Jumar Bioincubator General Manager Camille Shanahan

AUSTRALIA IS A pre-eminent centre for original biotechnology-focused research. The Melbourne Biomedical Precinct alone, just north of Melbourne's CBD, contains numerous leading hospitals, medical research institutes and universities, and attracts almost 25 per cent of Australia's competitive biotech research funding.[1] In general, however, Australian universities and public research organisations spin out far fewer startups per $100 million of research expenditure than UK, Canadian and US peers.[2]

Overseas experience clearly demonstrates the value of incubation in overcoming barriers to biotech commercialisation, providing the services that emerging companies need to succeed, including physical facilities, support services and coordination, education and training, industry and investor connectivity, and building biotech business skills and acumen. In fact, startups that receive incubator support are 85 per cent more likely to reach the five-year mark compared to a survival rate of 30–50 per cent of standalone startups over the same time period.[3]

1 Melbourne Biomedical Precinct, www.melbournebiomed.com/the-melbourne-biomedical-precinct-office/faqs/ (accessed July 2023)

2 Commonwealth of Australia (2017), 'Australia 2030: Prosperity Through Innovation; Australian Government Department of Industry, Innovation and Science, National Survey of Research Commercialisation', DIIS, Canberra, www.industry.gov.au/data-and-publications/australia-2030-prosperity-through-innovation

3 European Commission Enterprise Directorate General (2002), 'Benchmarking of Business Incubators', Resource document: Centre for Strategy and Evaluation Services

Integration of best-in-class biotech incubators into high-quality biomedical ecosystems is as critical to success as the infrastructure and services provided internally to residents. There is a lack of suitable, affordable incubation wet lab infrastructure, particularly in Melbourne's Biomedical Precinct, which is the ideal location for startups to capitalise on the investments already made in the precinct. With the relocation of CSL's global headquarters to Melbourne's CBD, a fantastic opportunity to establish an incubator co-located with CSL emerged, and a partnership was formed to establish Jumar Bioincubator.

An incubator to nurture Australian biotech ventures

Three of Victoria's distinguished entities spanning industry, research and academia – CSL, WEHI and The University of Melbourne – collaborated, with a shared vision to put Melbourne on the map as a globally recognised hub for biotech translation and commercialisation. Jumar Bioincubator complements the precinct's existing reputation for world-class medical research in infectious diseases and immunology, neurosciences, cancer, child health and healthy aging.

With backing from innovation investor Breakthrough Victoria and the appointment of experienced operator Cicada Innovations, the partnership's unrivalled legacy and experience in the Australian biomedical landscape sets the foundations for what's possible for the next generation of biotech startups.

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Jumar Bioincubator will connect early-stage and scaling biotech ventures in areas such as pharmaceuticals, diagnostics, medical devices, digital health, bioinformatics, and health-oriented artificial intelligence with the state-of-the-art facilities, infrastructure, and support needed to progress discoveries towards real-world treatments.

Jumar Bioincubator's name was inspired by the word 'jumar', which refers to a mountaineering technique by which climbers receive the support necessary to efficiently scale and speedily ascend challenging mountains. By providing a first home for aspiring biotech ventures, Jumar Bioincubator similarly aims to help biotech entrepreneurs to ascend and scale the heights of their industry.

Operated independently by Cicada Innovations, Jumar Bioincubator will be led by General Manager Camille Shanahan. Shanahan has more than 15 years of clinical, scientific, and commercialisation experience in the biopharma sector, with a particular focus on the translation of medical research into clinical application.

'By connecting young companies to all the practical support they need to overcome early challenges, we hope to steward the creation of a thriving biotechnology ecosystem – bringing local talent, innovative ideas and commercial prowess together to solve real-world problems and deliver real-world impact,' says Shanahan.

Made possible with cash and in-kind contributions of approximately $45 million over 10 years from its founding partners – CSL, WEHI, and The University of Melbourne – as well as an initial investment of $25 million from Breakthrough Victoria, Jumar Bioincubator will be able to accommodate up to 40 early-stage biotech companies.

The incubator will facilitate research commercialisation and innovation translation by providing biomedical scientists and researchers with access to the knowledge and skills needed to run successful biomed and biotech companies. The incubator will include:

- specialist facilities at startup-friendly prices, including self-contained laboratories enclosed in physical containment (PC2) wet labs and support facilities, office spaces, and

access to bulk purchasing power to enable savings on laboratory consumables

- preferential access to the unique platform technologies of WEHI and The University of Melbourne, as well as reliable facilities management and curated activities
- the ability for biotechs to retain 100 per cent of their intellectual property and have no equity ties to the three founding partners
- training, education, and facilitated introductions to venture capitalists, and clear separation of academia from innovation translation/research commercialisation, to help residents refine and advance their commercial focus
- unique access to partner institutions, leading hospitals, universities and research institutes within the biomedical precinct, enabling collaboration, learning, and connections
- a strong brand presence and unique pedigree, making the incubator a magnet for talent, investors, and capital.

Enhancing connectivity

Located on two floors within CSL's new Global Headquarters and Centre for R&D, and in the heart of the world-leading Melbourne Biomedical Precinct, Jumar Bioincubator residents will work alongside some of Australia's most distinguished entities spanning industry, research, and academia, enabling opportunities for peer collaboration, learning, and sharing of ideas.

Breakthrough innovation happens at the intersection of different fields, experience and disciplines, and Jumar Bioincubator will create the environment to share knowledge, new ideas, and innovation – a hallmark of the best incubators around the globe.

Jumar Bioincubator is now calling for innovative early-stage Australian biotechs to take up residency in its much-awaited Melbourne facility.

Biotech startups interested in residency are encouraged to submit expressions of interest at www.jumarbio.com.

PRECISE GAS CONTROL FOR BIOREACTORS AND FERMENTERS

WHETHER IN A research laboratory or a pilot production plant, the reproducibility of the fermentation process is a crucial aspect of the application of bioreactors and fermenters in bioprocessing. As essential tools used in various industries, including pharmaceuticals, biotechnology, and food and beverage, bioreactors and fermenters grow and cultivate microorganisms or cells under controlled conditions. The goal is to reliably produce valuable products like proteins, enzymes, antibiotics, biofuels, and other biotechnological products.

Fermentation requires the help of biocatalysts, such as enzymes or cells, and depends on optimum temperature conditions (usually 35–37 degrees Celsius). Precise control of the process also requires accurate supply of up to four gases: oxygen, nitrogen, carbon dioxide and air. Oxygen and carbon dioxide drive the growth process, while pure nitrogen controls growth rate. Air can serve as an all-purpose gas when no specific gas supply is required.

Conventional solutions for the control of gases have involved rotameters (mechanically acting floating flow meters) that require precise calibration and only work at the pressure and temperature to which they have been set.

While rotameters are simple and cost-effective flow control devices for some applications, they may not be the best choice for precision gas control in sophisticated and automated processes. For high accuracy and reliable gas flow control, mass flow controllers (MFCs) offer greater precision and overall cost savings of up to 35 per cent, with benefits including better accuracy, wider flow ranges, digital communication, and higher resistance to external factors, such as pressure and temperature variations.

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Bürkert can also customise modular gas mixing units to suit specific applications. The units are configured according to specifications using the space-saving 8741 and 8742 MFCs arranged side by side, including valves. The units are supplied pre-tested for tightness, pressure and correct electrical operation. A customised assembly saves on installation costs, simplifies engineering of the bioreactor or fermenter, and does not require the ordering and storage of numerous individual parts.

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BREAKING BARRIERS IN BIOTECH: MICROBA LIFE SCIENCES' UNCONVENTIONAL INTELLECTUAL PROPERTY JOURNEY

BY DR KYLIE ELLIS, HEAD OF RESEARCH PARTNERSHIPS, MICROBA LIFE SCIENCES

It is widely accepted that you need strong, protectable intellectual property to build a successful biotech company; however, as the biotech industry adapts to modern tools for discovery and strives for market differentiation, that path may not always be the best, or even an available option. Microba Life Sciences is one company whose journey to advance health care began with a non-traditional IP strategy.

MICROBA IS A Brisbane-based, ASX-listed biotech company (ASX: MAP) dedicated to advancing health through precision microbiome science. The company was founded in 2017 with unique bioinformatic technology developed from the science of its pioneering founders at The University of Queensland to measure the microbiome with superior resolution and accuracy. The founding vision was to leverage that core bioinformatic technology to create value across multiple markets where microbiome analytics and outcomes could be applied to improve human health, including consumer health, health care, and diagnostic and therapeutic applications. To execute that plan, Microba needed to take an agile view of its intellectual property (IP) development and protection strategies.

Software at its core

The first phase of Microba's development journey focused on leveraging its bioinformatic technology to create a microbiome Analysis Platform for consumers, clinicians and research applications. The second phase required the development of a Discovery Platform, including a large databank of microbiome and associated health metadata that could be mined to identify novel therapeutic candidates with a more traditional biotech development pathway.

Since the bioinformatic technology is a software solution, there were several challenges to achieving IP protection in Phase 1. First, patenting requires disclosure of the invention in sufficient detail to reproduce it. Once disclosed, copycats have access to the invention, which they could implement into their own products, or design around to avoid patent infringement. If infringement did occur, it would be difficult for an innovator to detect or demonstrate because software is usually hidden from external markets. Since a patent is only useful if you are willing and able to enforce it, the challenge of identifying infringers is an important one. Microba, therefore, determined that it was a preferable strategy to keep its bioinformatic technology a trade secret.

Trade secrets also come with challenges. They require strict confidentiality and access provisions within organisations, along with training programs to ensure those secrets are kept secure. Further, as a science-led organisation, Microba had to determine how and whether it could benchmark its tools in research publications while maintaining commercial advantage. Ultimately, the company was able to maintain its competitive advantage while publishing the tools' superior performance in a scientific journal with sufficient detail to satisfy peer reviewers and promote the technology.

Investing in IP

For investors, the strength of a patent portfolio is critical in the evaluation of a company as it enables the commercial exploitation of the unique IP. So, how does a company with exceptional software assets and a bold vision for commercial impact attract investment and growth when patenting its core IP would disclose key secrets? For Microba, it was critical to first define its long-term vision and path to impact, then to find the team and investors who believed in the outcome to fund and execute the plan, without the need to patent the originating IP. For other companies navigating this question, it is worth expanding beyond the focused biotech investors to those familiar with technology and scalable commercial solutions to find supporters aligned with your vision.

Professor Ian Frazer AC, Deputy Chairman; Dr Luke Reid, CEO; and Professor Gene Tyson, Co-Founder, Microba

Establishing commercial value

The first commercial deployment of the Analysis Platform IP was in leveraging the precision measurement technology for a consumer market to assess their unique microbiome and its effect on health. At the time, consumer-led microbiome profiling was emerging, and Microba was the first to the Australian market with the advantage of thorough and accurate reporting for its users.

Following success in the consumer market, the company then expanded its technology into health care, where Microba has now launched three distinct microbiome testing products for clinicians. Microba offers the most comprehensive and intuitive gastrointestinal testing solution, including diagnostic assays and strong evidence-based interventions to advance the clinical application of microbiome testing. Microba now aims to become embedded as a routine part of health and disease management. With strong partnership and distribution networks, the company has access to distribute its tests across 35 countries, and is currently operational in 13 across the world.

In the global research market, Microba saw an opportunity to use its precision measurement technology to enable more robust and reproducible microbiome discoveries, leading to higher-impact microbiome-targeting products to improve human health. The Research Services division works with academic researchers, consumer health, nutrition and food, biotechnology and pharmaceutical companies around the world to enable cutting-edge research initiatives across microbiome discovery, clinical trials and new product testing.

Emerging biotech

The development of novel therapeutics has long been Microba's master strategy, made possible from the development and utilisation of its Discovery Platform and databank.

In its relatively short life span, Microba has established three therapeutic programs spanning inflammatory bowel disease (IBD), immuno-oncology and autoimmune diseases. Its primary therapeutic candidate, MAP 315, entered clinical trials in 2023, and presents an opportunity to improve the current standard of care and treatment for millions of people suffering from the debilitating effects of ulcerative colitis, a form of IBD. Microba now has a unique, demonstrated platform for rapid therapeutic discovery that can be applied to future disease programs, both independently and in partnerships.

These discoveries, derived through the artificial intelligence–supported analysis of the company's databank and from its therapeutic programs, have generated a wealth of novel, protectable IP that is central to Microba's IP strategy, and will support future commercialisation of developed assets. Key to this has been working in partnership with a team of attorneys to develop a strong patent portfolio that is well aligned with Microba's long-term business goals.

Microba's journey has relied on strong technology and a world-class team of scientists, innovators, and investors with a belief in what differentiated, but unpatented, IP could achieve. Today, Microba continues to execute its commercial strategy and is now a clinical-stage company with products in several international markets, an international bench of investors, strong established commercial partnerships with global leaders, and a healthy portfolio of drug assets and associated patents.

Embracing risk with vision, passion and dedication has allowed Microba to reach this point, where it now has a unique platform for rapid, repeatable discovery, and is recognised for challenging the traditional biotech pathway.

Creating knowledge that transforms lives

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2023 GLOBAL BIOPHARMA RESILIENCE INDEX

How has the biopharma industry evolved over the past two years, and where should it look to improve?

WHILE THE IMMEDIATE shock of the COVID-19 crisis has faded, the spotlight on the global biopharma industry has not. There are many exciting areas where recent progress has the potential to transform lives, and the heightened threat of new pandemics and antimicrobial resistance means we may soon be looking to biopharma to save us again.

The rapid deployment of mRNA vaccines in response to COVID-19 catalysed a new era in vaccinology, and reignited interest in nucleic acid therapies. Artificial intelligence–enabled research is accelerating therapeutic development, with the opportunity to radically improve patient outcomes. Breakthroughs in cell and gene therapies have the potential to prevent, treat, and even cure genetic diseases.

Despite these breakthroughs and opportunities, sustained high growth is not a certainty for the industry. The emergency funding boost of 2020 and 2021 has fallen away, with financing for small and mid-sized biotech firms in novel therapeutics pulling back in 2022[1]. The funding landscape remains challenging in 2023. The cost of capital, economic insecurity, talent shortages, regulatory challenges and disruption all continue to affect the sector. Furthermore, Cytiva's latest research shows that the pandemic accelerated progress in aspects of the industry where biopharma firms have direct control (such as manufacturing), but ensuring collaboration between government, academia and the industry remains challenging. The knock-on effect may jeopardise long-term improvement in patient outcomes.

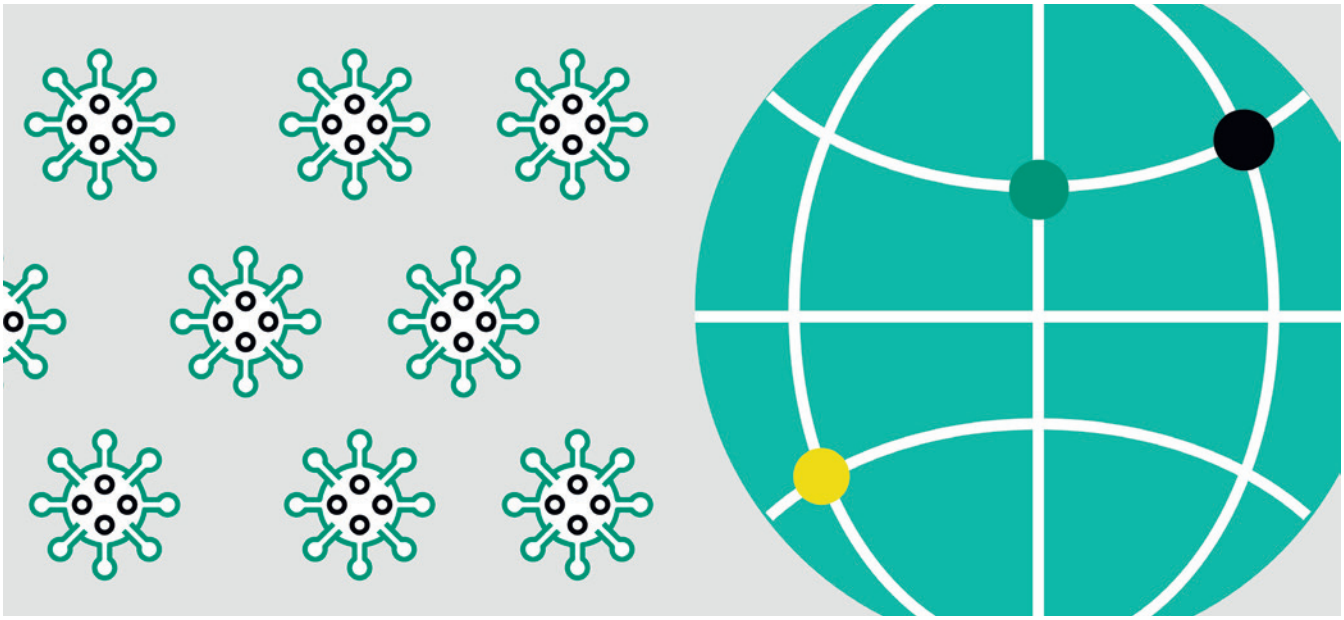
To assess the strength of the global industry in these turbulent times, Cytiva created the Global Biopharma Resilience Index. Introduced in 2021, the index scores and ranks countries on five factors:

1. supply chain resilience
2. talent pool
3. research and development (R&D) ecosystem
4. manufacturing agility
5. government policy and regulation.

The 2023 Index is based on data from a survey of 1250 pharma and biopharma executives across 22 countries. Countries are scored on a scale of zero to 10, where zero reflects the worst performance and 10 denotes best practice (for more information on the methodology, please see page 38 of the full report). The overall score for each country indicates the strength of its biopharma industry.

In addition to survey responses, this year Cytiva has incorporated additional data into the index – including R&D activity and drug-approval time frames – to provide a more in-depth and accurate overview of the industry.

1 Ramko R and Singhania A, 'Financing For Emerging Biotechs: Recent Trends & Predictions For 2023', Bioprocess Online, www.bioprocessonline.com/ doc/financing-for-emerging-biotechs-recent-trends-predictions-for-0001 March 6, 2023



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INDUSTRY-FIRST ESG GUIDE FOR SMALL BIOTECHS

BY NICOLE BITTAR, INNOVATIONAUS

Helping companies see the benefit of being commonly understood is the essence of ensuring a comparable environmental, social and governance practice for biotechs and medtechs. This provided the impetus for AusBiotech's development of the world-first guideline: A Practical Guide to ESG for Australian Life Sciences Companies.

AUSBIOTECH CHIEF EXECUTIVE Officer Lorraine Chiroiu says that being comparable means that investors can see what company A is doing around environmental, social and governance (ESG), and are able to determine how company B's actions compare to that. From an investment perspective, Chiroiu was alerted to 'an explosive growth of venture capitalist–led ESG reporting guidelines'.

Two major levers emerged: the legislation for values alignment, and mandating potential for global governments. Even more tellingly, the available resources were disparate and not specific to either the sector or small and medium-sized enterprises (SMEs). This was critical to AusBiotech seizing the reins for the guide's development, given that the majority of the Australian sector is in the SME category, with most pre-revenue and often preclinical in nature.

'They're early-stage organisations that don't necessarily have the internal resources for a dedicated person to be working on their ESG,' Chiroiu says.

A divergence between large companies with ESG resources and their reporting capability, and the capabilities of small companies, was the desired outcome.

'It was very important for us to empower SMEs in the (biotech) sector who are heavily dependent on investment and venture capital to start their ESG journey,' Chiroiu says.

That's because ESG is about a shared set of values, which has become increasingly important on two levels: one is the need for a common parameter to understanding corporate behaviour; the other is society's expectation of organisations as they grow and develop, Chiroiu adds.

'This is particularly important to investors who, for many years, have sought to place their investments where there is societal good, or at least ethical behaviour. That starts with the best use of their funds for corporations, but flows on to ensuring they are supporting behaviours that align with their broader values.'

Continued on page 54

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Founder and Director

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SCAN ME

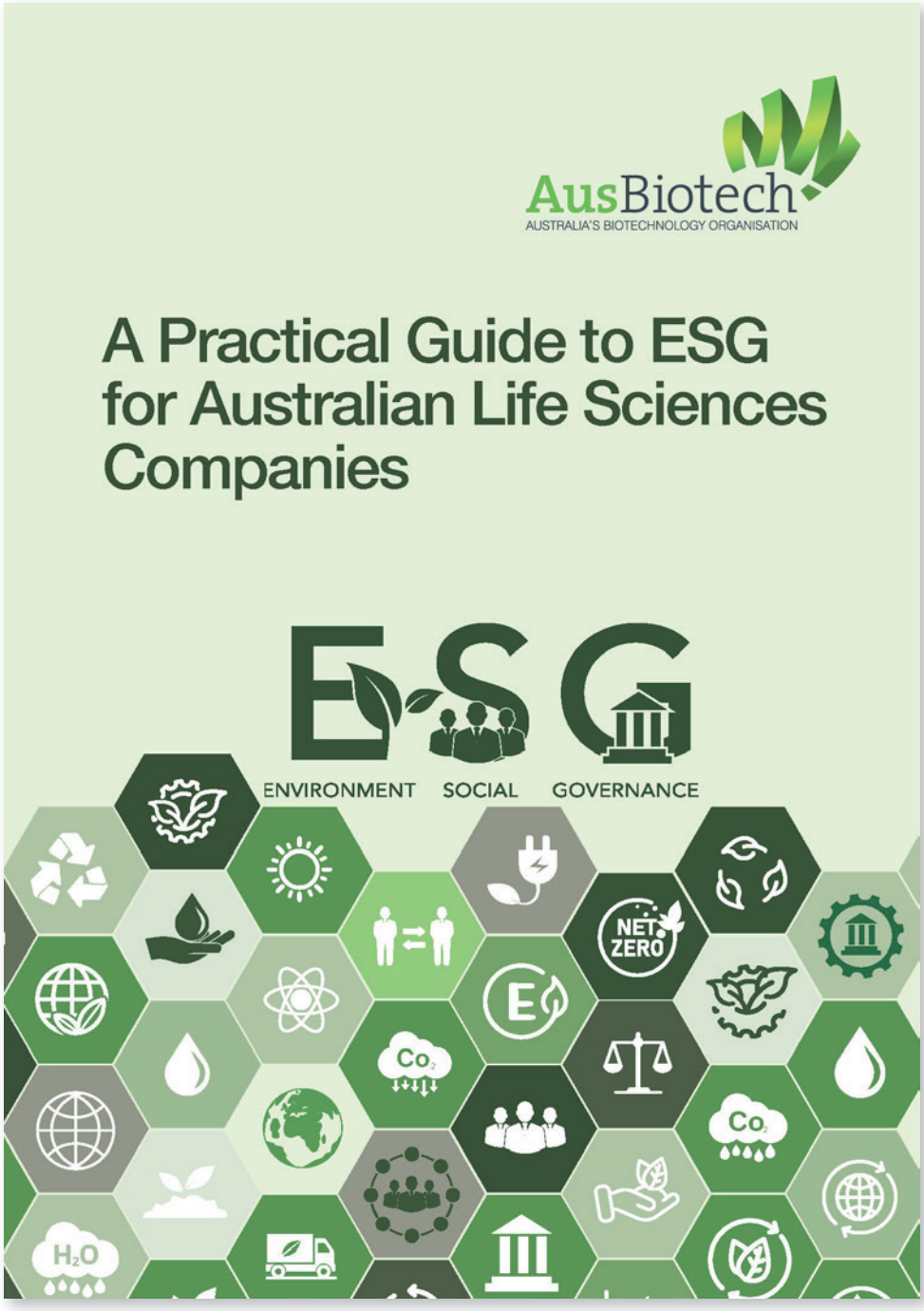
Continued from page 52

AusBiotech's ESG guide found that 93 per cent of small capitalisation companies in Australia are not reporting on ESG, and are therefore missing out on opportunities to differentiate themselves within the market, and in the eyes of potential investors and other stakeholders.

'This is not an easy journey to start for small companies, and starting anywhere along the continuum is a good thing to do,' Chiroiu says.

The culmination of 12 months' expert input from large companies, consultancies and SME biotech companies, the guide covers the gamut of implementing an ESG strategy.

Key areas include climate change, energy and waste reduction initiatives, consumables and natural resources use, pharmaceuticals in the environment, sustainable workplace initiatives, and emissions reduction. Measurable metrics and tools also help to put theory into practice.



'During the consultation process, the consensus was that [the guide] was an excellent resource that was going to be very supportive of the industry. And then, through my work at an international level, I discovered that it was going to be a world first,' Chiroiu says.

'Furthermore, the worldwide SME biotech space is very interested in this Australian-led resource because it's applicable across jurisdictions.'

AusBiotech emphasises that irrespective of the level of ESG maturity within a company, a commitment to even the smallest improvements can have a significant impact.

'I hope the guide will help each and every biotech company start its ESG journey and progress along the development guidelines to the exemplars of the larger companies in our sector, like Cochlear and CSL,' Chiroiu says. 'But I'd also like to see ESG reporting that is comparable between organisations.'

Learn how to implement an ESG framework into your company strategy during the AusBiotech 2023 panel session, 'The why and how of ESG: embedding reporting and action within business strategy', on Wednesday 1 November in Brisbane, Queensland.

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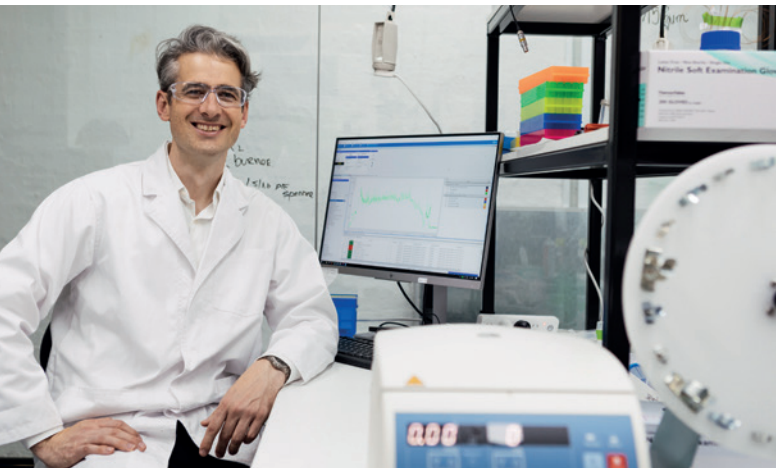
IONOPTICKS: PIONEERING THE FUTURE OF PROTEOMICS RESEARCH

THE FIELD OF proteomics, concerned with the study of proteins, and their identification and functions, has undergone a transformative awakening in recent years. Through significant technological advancements, the applications for proteomics are set to experience rapid expansion over the next decade. Central to this transformation is the emergence of IonOpticks and the ultra-high-performance liquid chromatography columns it produces. IonOpticks' commitment to pushing boundaries has profoundly impacted the field, unlocking the true potential of mass spectrometry research by setting new benchmarks for sensitivity, reproducibility and throughput.

Historically, access to high-performing chromatography solutions was akin to an artform known by an elite few. The discipline was notorious for high barriers, with failure rates and poor reproducibility hampering research efforts – requiring deep technical knowledge of the operator to continually troubleshoot. Despite this, the advantages to nano- and micro-flow liquid chromatography–mass spectrometry (LC-MS) was undeniable, so it became the mission of IonOpticks to overcome the technical challenges, and deliver chromatography solutions that facilitate and inspire a new era in medical research. This included the key growth areas of single-cell workflows, bioprocessing and clinical proteomics leveraging nano- and micro-flow LC-MS.

IonOpticks specialises in the design and production of advanced packed emitter columns for mass spectrometry. Through years of product research and development, it has perfected the Aurora Series nano-flow liquid chromatography columns that empower researchers to achieve unparalleled resolution and sensitivity in their experiments. Each product is a harmony of advanced technology, rigorous testing, and a commitment to quality – enabling users to delve deeper into their samples than ever before.



Dr Jarrod Sandow, Head of Product Development, IonOpticks

The 'user-first' approach to the design of IonOpticks' products has been honed to meet the needs of modern-day proteomics laboratories, with simple plug-and-play formats and innovative heating solutions housing the most advanced chromatography columns available. The unique design of the Aurora Series columns eliminates all pre- and post-column dead volumes, enhancing sensitivity and depth of coverage. These columns are acclaimed for delivering the highest protein and peptide identifications per run, consistent reproducibility, spray stability, high throughput, longevity and pressure tolerances exceeding even the most powerful liquid chromatography systems.

With the recent introduction of its Aurora TS and SX ranges, IonOpticks has expanded the direct compatibility of its Aurora Series products to include the EASY-Spray and Nanospray Flex sources by Thermo; the OptiFlow Turbo V source by SCIEX; and the CaptiveSpray and CaptiveSpray 2 sources by Bruker. Collectively, these cater to about 80 per cent of the proteomics market.

The introduction of the Aurora TS and SX ranges has significantly expanded the accessibility for researchers to improve their experiments by incorporating IonOpticks columns into their existing workflows. The democratisation of top-tier chromatography for more researchers means even smaller laboratories can access elite results from their existing mass spectrometers, enabling deep discovery and driving innovation at all levels.

A testament to IonOpticks' class-leading performance is the widespread adoption of its products. From academia to industry, pharmaceutical powerhouses to budding biotech ventures, IonOpticks products have been a force multiplier in accelerating proteomics research. While it's not just about numbers, they do paint a striking picture, with 16 of the world's top 20 pharmaceutical companies relying on IonOpticks columns.

Beyond the realm of pharma, the most distinguished names in proteomics research globally vouch for IonOpticks products, speaking volumes about its performance and quality. Since establishment in 2017, IonOpticks have experienced the fastest rate of growth in journal publication method citations than any other column manufacturer in the class. Within just six years of operation, IonOpticks is on track to be the most cited column manufacturer for proteomics workflows in 2023.

At IonOpticks, it's not just about leading the race – it is also about ensuring that the entire proteomics community progresses together. Through relentless innovation, an uncompromising approach to quality, and a vision to make advanced proteomics accessible to all, IonOpticks is setting the stage for a brighter, more knowledgeable future.

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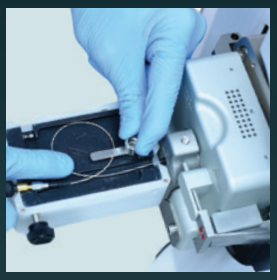

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NAVIGATING THE FUTURE: PREDICTIONS AND POTENTIALS OF AUSTRALIAN BIOTECHNOLOGY

BY PROFESSOR IAN FRAZER

I received a letter recently from a science teacher in a local school where I had run a demo of human papillomavirus vaccine manufacture in 2009. One of the Year 11 students who participated in that demo recently graduated with a PhD, and is now working at CSIRO on new technologies for vaccine development. The teacher's letter, and a coincidentally timed request to speak at AusBiotech this year, prompted me to reflect on what we're doing right and wrong in this country as we aim to grow a healthy local biotech industry.

THE RECENT COVID-19 pandemic has raised awareness in Australian academia, and in government, of the role that the Australian biotechnology industry must be able to play in future years to ensure that our current health challenges, and the next pandemic infection, can be met by appropriate local responses from industry and government. This is necessary to not only ensure Australia's future health, but to also contribute to our national prosperity.

While the immediate post-pandemic focus has been on expanding our vaccine manufacturing capacity, the future agenda will need to be broader. To meet this need, there will be a requirement for appropriate talent and capacity along the entire pathway from scientific research through to the marketing of deliverable product.

Professor Ian Frazer

We will also require an environment sufficiently resourced, and a population sufficiently educated, to ensure that we can respond to not only Australia's needs, but also to those of our neighbouring nations. What part of this agenda can we meet currently, and what are the challenges that hinder our progress towards achieving the rest?

What are our assets?
In Australia, we have:

- a high-quality tertiary education system
- a culturally diverse workforce, bringing different perspectives and skills
- a relatively stable government and administration, with a commitment to economic growth.

What are our challenges?
We need:

- more emphasis in schools on STEM education, and on bioscience product development as a career, to meet our need for a future smart workforce
- to overcome our limited capacity to build a market reach that extends beyond our island population by resolving our geographically and commercially fragmented biotechnology industry.

What should we be doing?
We should:

- advance promotion of careers in biosciences and technology within the education system by rewarding STEM teachers, and by creating more secondary school classroom/tertiary education/industry engagement opportunities
- develop more user-friendly but more financially and technically ruthless state-based industry development assistance programs
- encourage the federal government to further commit to promoting and marketing 'brand Australia' biotechnology across the major nations in our geographical region.

While it's hard to determine the impact, we appear, as a country, to be too fragmented geographically to achieve competitiveness internationally. California has three major bioscience hubs centred on a geographically distributed single major academic institution. Queensland alone has 12 universities, located in about six different regions, and the 'tyranny of distance' stands to defeat collaborative efforts within the biotech industry and academia.

We're also internally competitive, with too many institutions chasing limited research and development dollars, too many small industries chasing limited state and federal government support, and with insufficient independent (international) expert advice on the utility and commerciality of the organisations seeking support.

Further, we lack investment and superannuation industries willing to spread their bets across a range of risks, as seen more effectively in the United States. As a consequence, potential winners are under-supported and, conversely, it is likely that losers are not encouraged to die gracefully.

Each of these problems appear to be fixable, if there is a collective will to achieve; but creating change will require leadership within government and industry, and will be inspired by a collective belief that we can and must make use of our considerable talent and resources to achieve a place for Australia in an increasingly competitive world.

Emeritus Professor Ian Frazer will present the AusBiotech 2023 Millis Oration, 'Navigating the future: predictions and potentials of Australian biotechnology', in Brisbane, Queensland on Thursday 2 November. Named in honour of Emeritus Professor Nancy Millis's contribution to the industry, the Millis Oration, held annually at the national AusBiotech conference, is proudly supported by CSL.

Australia should promote careers in biosciences by creating more secondary school classroom engagement opportunities

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ENABLING BIOTECH PATENTS IN AN AI-ENABLED WORLD

BY KEN SEIDENMAN, SENIOR ASSOCIATE, FB RICE

Recently, court law seems to have adopted a stricter interpretation of the standard for enablement of broad claims in patents covering biotherapeutics. In parallel, rapid improvements in artificial intelligence (AI) tools are aiding the design of whole classes of antibodies and proteins, with increasing reliability and success. The thoughtful combination of AI–based predictive tools and strategic experimental validation could potentially enable more targeted but sufficiently broader biotech patent 'genus' claims, even in the face of a stricter interpretation of the patent enablement standard.

MANY BIOTECHNOLOGY AND pharmaceutical patents include so-called 'genus' claims directed to a broad class of molecules defined around a limited number of working examples. Typically, the number of molecules/embodiments covered by such genus claims far exceeds the number that were made and tested (i.e., shown to be 'enabled' in patent terms) or would be likely to be made and/or tested in practice.

On the other hand, a claim limited to literally only the antibodies or proteins actually tested and shown to work would, in many cases, provide an ineffective commercial barrier to the patentee's competitors, who could quickly 'design around', with just a few changes, the few claimed embodiments. Competitors could thereby realise the benefit of the patentee's disclosed invention while avoiding infringement of the patentee's claims. The tension between these considerations is a continuing theme in patent law, which is well illustrated by the recently decided *Amgen Inc. v Sanofi* case at the Supreme Court of the United States (SCOTUS).

Amgen Inc. v Sanofi – a stricter enablement standard for genus claims?

Amgen's genus claims (in US patents 8,829,165 and 8,859,741) related to a class of antibodies based on their functions: 1) binding to specific amino acid residues on a target ligand protein (PCSK9); and 2) blocking PCSK9 from binding to low-density lipoprotein receptors. In the patent at issue, Amgen identified the amino acid sequences of 26 antibodies that perform these two functions, and depicted the 3D structures of two of these 26 antibodies. In its efforts to enable claims far broader than the 26 exemplified antibodies, Amgen offered scientists two methods: 1) a so-called 'road map', which directs scientists to generate antibodies and then test whether the antibodies achieve the functional features recited in the claims (i.e., how to go about screening for additional members of the genus); and 2) the use of 'conservative substitutions' to replace select amino acids in the antibody with other amino acids having similar properties, and then test the resulting antibody to see if it also achieves the claimed functional features.

In no uncertain terms, SCOTUS stated that these approaches typically presented in many biotechnology patent applications 'amount to little more than two research assignments', leaving a scientist to engage in 'painstaking experimentation' to see what works. In the court's view, 'that is not enablement. More nearly, it is a hunting licence'.

Notwithstanding the difficulty involved in showing that each and every member of a claimed class is enabled, the court held that 'if a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable'.

Ken Seidenman

Drawing a better road map in silico

The rapid progress of computational methods in the ability to predict the structure and function of antibodies and other proteins ever more accurately from just their sequences promises a paradigm shift. It is increasingly possible to 'mine' vast sequence spaces efficiently to yield more focused and claimable genuses of in silico–vetted sequences predicted to correspond to functional antibodies or proteins. In effect, the strategic application of artificial intelligence AI-driven platforms could provide a far more reliable road map to the location of many or most of all functional embodiments within a far broader genus of possible antibody or protein sequences.

Such AI-enabled focused genuses would likely still be broad enough to present an effective barrier to design-around by competitors seeking to leverage the invention while avoiding patent claims. Importantly, as discussed below, patent claims to such genuses should be reasonably considered to be enabled across their full scope and not, as cautioned by SCOTUS, a mere 'hunting licence'.

AI – a potential game-changer for enabling genus claims for biotherapeutics

Increasingly sophisticated developments in the application of AI deep learning neural networks (DLNNs) to infer protein sequence-structure/function relationships are rapidly driving the evolution of a new paradigm to support the enablement of sequence/structure-based genus claims. The availability of rapidly expanding protein sequence and structure databases to train DLNNs is certainly accelerating progress in this area.

Among the notable milestones in the development of these AI platforms is the arrival of DeepMind's AlphaFold and AlphaFold2[1] AI deep learning–based protein structure prediction software. Building off the success of AlphaFold2, a similar approach has been applied specifically to antibody structure prediction (e.g., ABody Builder2).[2] Machine learning approaches have been used recently to efficiently model the 3D-antibody-antigen binding interactions of 6.9 million heavy chain complementarity determining region sequences to 159 antigens (one billion antibody-antigen binding

1 Jumper et al., (2021), 'Highly accurate protein structure prediction with AlphaFold,' *Nature*, 596:583-589

2 Abanades et al., (2023), 'ImmuneBuilder: Deep-Learning models for predicting the structures of immune proteins,' *Communications Biology*, 6:574

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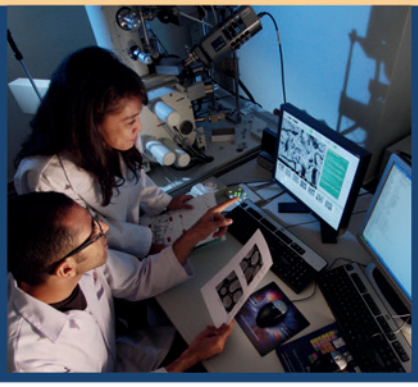

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pairs), as demonstrated for the Absolut! simulation framework.[3] Importantly, these tools are being combined with methods to optimise searching in otherwise hopelessly large sequence spaces (e.g., using techniques such as Bayesian optimisation to efficiently hone in on sequences of antibodies that will match or exceed the binding affinity of a starting antibody).[4]

Another promising approach to sequence diversification and optimisation of antibodies is to generate an initial set of antibodies (containing single mutations) to generate a training set of binding and non-binding sequences to develop a DLNN able to predict specific antigen-binding antibody sequences with high accuracy.[5]

3 Robert et al., (2021), 'Unconstrained generation of synthetic antibody-antigen structures to guide machine learning methodology for real-world antibody specificity prediction,' bioRxiv, p. 2021

4 Akbar et al., (2023), 'Toward real-world automated antibody design with combinatorial Bayesian optimization,' *Cell Reports Methods* 3, 100374

5 Mason et al., (2021), 'Optimization of therapeutic antibodies by predicting antigen specificity from antibody sequence via deep learning,' *Nature Biomedical Engineering*, 5:600-612

Large-scale sequencing of human antibody repertoires and the availability of the sequences in databases, such as the Observed Antibody Space, is also facilitating the humanisation and developability of candidate therapeutic antibody sequences using deep learning platforms such as BioPhi.[6] Not surprisingly, machine learning approaches are also being implemented for other types of proteins (e.g., enzymes) to identify sequence variants that increase catalytic activity, stability, solubility, and/or substrate specificity.[7]

More recently, generative AI approaches have been used to design antibodies and proteins de novo – a so-called 'zero shot' design rather than as variations from a pre-existing antibody or protein.[8, 9] Indeed, this approach underlies the business model of emerging biotechnology companies, such as Absci, which are developing antibodies and other biologics starting from purely in silico–generated protein designs. In fact, generative AI methods have recently been applied to the problem of small-molecule drug design, as exemplified by the whimsically named Drug-GPT.[10]

Potential implications for biotechnology patent protection

While it is still too early to appreciate the full implications of AI-supported platforms to obtain genus claim coverage for antibodies and proteins, there is little doubt that such tools can be used to great effect to leverage a small set of starting sequences/structures to define large, AI-selected genuses of functional variants. Over the next few years, we are likely to see a great increase in the use of AI-based approaches to enhance and broaden the patent protection of antibodies and other biologics, and potentially small drug molecules.

Biotechnology innovators and patent practitioners alike would do well to explore the wealth of increasingly sophisticated AI platforms available, and devise sensible strategies to apply them, where relevant, to potentially support the enablement of sufficiently broad claims. Before making use of any AI-based platforms, particularly ones available on web servers, it will be critical for patentees to ensure that data confidentiality and ownership are maintained.

Hear Ken Seidenman and other experts discuss the impact of AI on biotech patents during the AusBiotech 2023 panel session, 'What does AI and machine learning mean for our innovators' IP?', on Thursday 2 November in Brisbane, Queensland.

6 Prihoda et al., (2022), 'BioPhi: A platform for antibody design, humanization and humanness evaluation based on natural antibody repertoires and deep learning,' MAbs, 14(1): 2020203

7 Shin et al., (2023), 'Protein design and variant prediction using autoregressive generative models,' *Nature Communications*, doi.org/10.1038/s41467-021-22732

8 Shanehsazzadeh et al., (2023), 'Unlocking de novo antibody design with generative artificial intelligence,' bioRxiv, doi.org/10.1101/2023.01.08.523187

9 Watson et al., (2023), 'De novo design of protein structure and function with RFdiffusion,' *Nature*, doi.org/10.1038/s41586-023-06415-8

10 Li et al., (2023), 'DrugGTP: A GPT-based strategy for designing potential ligands targeting specific proteins,' bioRxiv, doi.org/10.1101/2023.06.29.543848

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DEVELOPMENT TO COMMERCIALISATION, AND BEYOND

CONTRACT DEVELOPMENT AND manufacturing organisations (CDMOs) play a crucial role in supporting the pharmaceutical and biotech industries by providing expert solutions for drug development, manufacturing, and clinical trials. To ensure a robust supply chain when partnering with a CDMO, it is vital that your preferred CDMO has global reach, together with flexible, scalable solutions to support your trial – from early phase through to commercialisation.

The importance of a CDMO's scalability and global capabilities cannot be underestimated. Key considerations include:

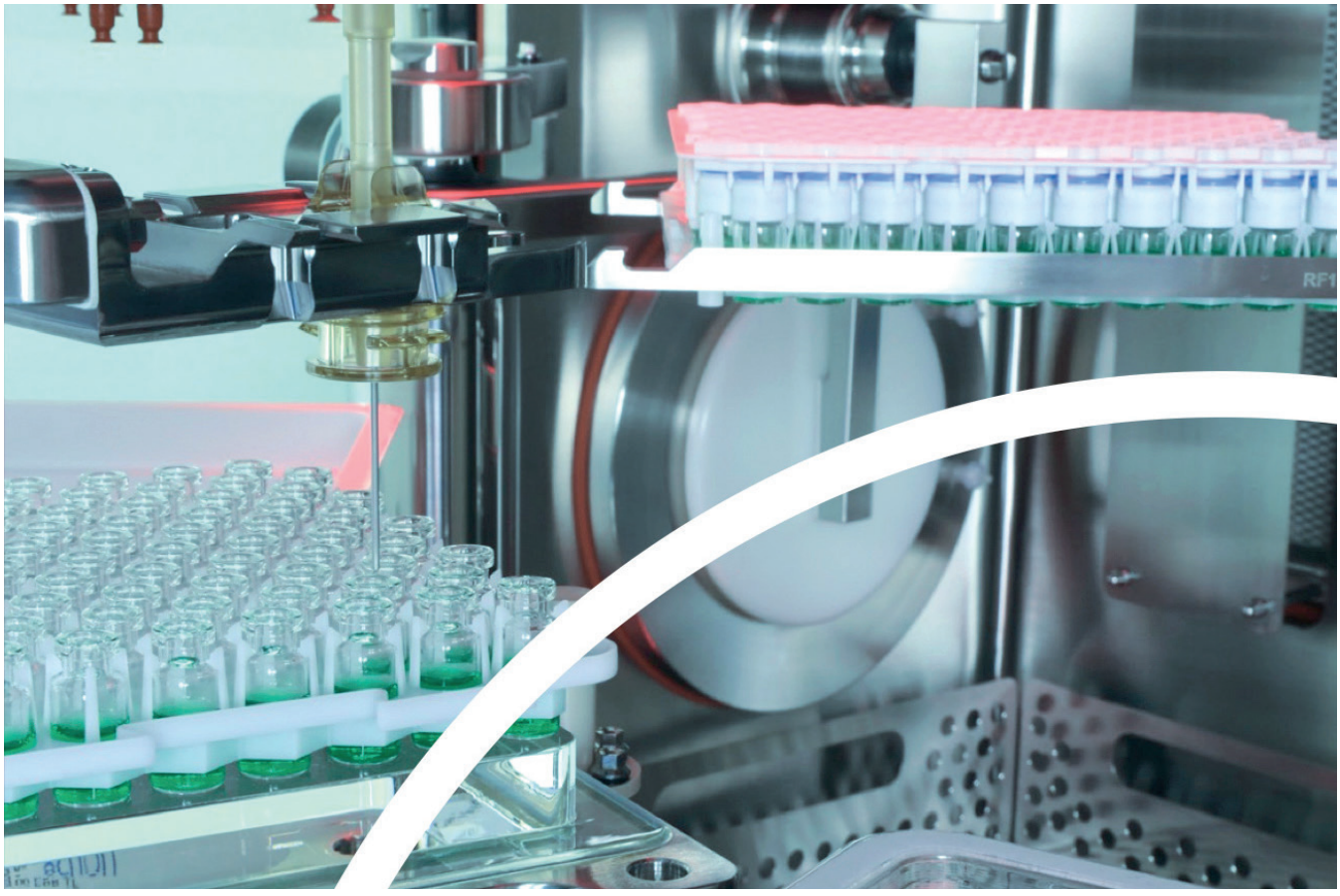
- *Flexibility in manufacturing capacity:* A CDMO with scalable technologies is able to adapt its manufacturing capacity to accommodate changing needs throughout the clinical life cycle, ensuring an adequate supply of investigational products, while avoiding underutilisation or excessive costs.

- *Scale up without transfer:* If a clinical trial progresses successfully and moves to later phases, the demand for the investigational product can increase significantly. Partnering with a CDMO able to support all phases of the clinical life cycle and global requirements mitigates the need to transfer the manufacturing and/or packaging process to an alternative supplier, delivering both time and cost efficiencies.

- *Reducing time to market:* The ability of a CDMO to quickly scale up production can significantly reduce the time to commercialisation. Rapid production scalability can help meet clinical trial time lines and accelerate the overall drug development process through to commercial launch.

- *Mitigating supply chain risks:* Unforeseen events, such as supply chain disruptions or increased demand, can impact the availability of critical trial supplies. A CDMO able to scale to meet demand can provide a buffer against such risks by swiftly adapting production levels in response to changes in demand or supply chain challenges.

- *Meeting global demand:* If a clinical trial generates positive results and leads to regulatory approval, the demand for



the drug may surge globally. A CDMO with a scalable, global service offering can help ensure a smooth transition from clinical- to commercial-scale manufacturing and packaging, meeting the increased demand while maintaining product quality and consistency with local regional supply.

The scalability of a CDMO's service offering is critical for supporting clinical trials effectively. It not only enables adaptive responses to changes in trial requirements, but it also helps manage risks, reduces time to market, and contributes to overall cost efficiency. This ultimately facilitates the successful progression of clinical trials – from early phases to regulatory approval.

PCI Pharma Services – your clinical trial destination

PCI is a leading global CDMO that is truly spanning the cycle; connecting development and commercialisation; de-risking the supply chain; providing clients with integrated end-to-end drug development; and manufacturing and packaging capabilities that increase a product's speed to market, and opportunities for commercial success.

PCI provides a global service with a localised focus, delivering more than 200 clinical protocols per year in more than 100 countries – utilising best-in-class technologies combined with experienced and dedicated teams. Its global network of innovative centres of excellence across the Asia-Pacific, Europe, North America, and Canada provide a seamless service, supporting the global supply of investigational medicines with pharmaceutical development, clinical drug product manufacturing, packaging, labelling, storage, distribution, and full-returns service.

Scalable solutions

PCI's clinical- to commercial-scale capabilities use geometrically similar equipment trains, providing true life cycle management for all dosage forms. This includes sterile liquids, lyophilised liquids, high-potent oral solids, and non-potent solid and semi-solid drug products.

Supporting early phase clinical trials, PCI's drug product manufacturing facilities utilise flexible API-saving technologies, such as Xcelodose® microdosing encapsulation platforms and robotic aseptic Cytiva Microcell isolators for filling vials.

Harnessing its experience and expertise to deliver a seamless global scalable solution, combining formulation and analytical development with expert clinical trial supplies, PCI can optimise formulations and manufacturing processes to scale up in support of late-phase clinical trials. PCI can also transfer to larger-scale manufacturing technologies across its global network to provide regional clinical supplies.

For example, for preclinical/first-in-human studies in the Asia-Pacific, PCI's client partners can leverage the benefits of its Cytiva Microcell fully automated gloveless isolator technology at the Melbourne facility for aseptic vial filling. As trials progress and sponsors seek to include wider populations and globalise trials in preparation for launch, PCI's larger-scale Cytiva SA25 platform in San Diego can aseptically fill larger volumes with the added flexibility of filling vials, syringes, and cartridges for auto-injectors.

Precise, programmable robotic functions cover all aspects of the Microcell and SA25 fill process, including isolator leakage tests, vaporised hydrogen peroxide sterilisation of the container closures, filling into the contamination control strategy of choice, capping and batch delivery. The advanced robotic platforms are also compatible with ready-to-use containers and closures, removing the container and closure preparation stage, and aiding the speed of delivery of a sterility-assured drug product.

These innovative robotic aseptic fill-finish platforms enhance PCI's renowned sterile and lyophilisation capabilities across its global network. PCI not only expedites the filling process with automation, but is also able to pivot between filling different sterile medications into multiple dosage formats – bringing even broader sterile fill-finish solutions to PCI clients across the entire drug product life cycle, and bringing therapies to market with enhanced quality and sterility assurance.

Streamlining clinical supply chains

Complementing PCI's scalable drug manufacturing solutions, its global packaging centres of excellence offer a comprehensive range of flexible labelling and packaging capabilities across multiple delivery systems. These include bottles, blisters, vials, ampoules, syringes, pre-filled syringes, auto-injectors, cartridges and medical devices. This truly integrated, global proposition of end-to-end tailored solutions can help mitigate risk and reduce complexity in the drug product supply chain.

Meeting the dynamic needs of the clinical trial landscape, PCI provides a collaborative, creative and tailored approach to deliver upon its mission of being the bridge between life-changing therapies and patients. By combining its expertise in drug product manufacturing and packaging with the latest advanced scalable technologies across its global network, PCI provides a valuable integrated solution – simplifying the supply chain while delivering time and cost efficiencies throughout the development to commercialisation life cycle.

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LEADING THE WAY IN MENTAL HEALTH RESEARCH 360BIOLABS EXPANDED CAPABILITIES TO MEET RISING DEMAND

Australia is fast becoming the global leader in approving and trialing new and repurposed drugs for psychiatric conditions. The country's drug regulatory body, the Therapeutic Goods Administration (TGA), recently approved the use of psilocybin and methyl enedioxy methamphetamine (MDMA) to treat mental illnesses including depression and post-traumatic stress disorder. This follows the legalisation of medicinal cannabis in 2016 for indications such as anxiety, depression and pain, and the expanding investigation into the use of ketamine for mental health, sedation and pain management. As interest in the therapeutic potential of these drugs intensifies, the Australian clinical trials sector needs to be ready to grow alongside this emerging and evolving market.

The use of these drugs may be considered controversial; however, early evidence suggests they can provide long-term, sustainable benefit to patients. As such, an increasing number of clinical trials are being initiated to answer questions and gather more evidence. There are currently over 40 clinical trials listed in the Australian New Zealand Clinical Trials Registry involving these substances, demonstrating the medical community's enthusiasm for determining the most efficacious and safest form, dosage and mode of delivery of these drugs in a range of therapeutic areas. These drug classes often require highly specialised and specific assays, including:

- Pharmacokinetic analysis: Assays that measures the absorption, distribution, metabolism, and excretion of drugs compounds in the body. These provide valuable information on how the product is processed by the body and its bioavailability. Some drugs have short half-lives and are rapidly metabolised, making sample collection and analysis time-sensitive. Developing sensitive and specific analytical methods to detect and quantify these substances and their metabolites can be challenging.
- Safety Assessments: Several different assays may need to be conducted to evaluate the safety profile of drug products. These may include liver function tests, kidney function tests and blood cell count. This may include High-performance liquid chromatography (HPLC) or gas chromatography (GC) coupled with mass spectrometry (MS) to facilitate sensitive and selective detection of the drug and its metabolites.
- Biomarker Analysis: Biomarkers associated with treatment response or a drug's mechanism of action may be studied. These assays may involve the measurement of neurochemicals, hormones, inflammatory markers or other relevant biological indicators. This can include Enzyme-Linked Immunosorbent Assay (ELISA).
- Genetic and Epigenetic Analysis: Psychedelics, in particular, can have interactions with the genetic and epigenetic factors that influence an individual's response to treatment. Genetic analysis techniques, such as genotyping or whole-genome sequencing, can help identify genetic variations associated with treatment outcomes. Epigenetic analysis, such as DNA methylation profiling, can provide insights into the long-term effects of psychedelics on gene expression regulation.

These tests work in tandem with clinical efficacy evaluations, such as the Hamilton Depression Rating Scale (HDRS) or Montgomery-Åsberg Depression Rating Scale (MADRS), psychiatric assessments and neuroimaging studies to ascertain safety and efficacy. This multifaceted approach speaks to the complexity of these clinical trials and the need for specialised expertise.

360biolabs is expanding its sample analysis capabilities to support these clinical trials and to meet rising demand. Our industry-experienced chemistry and biology teams excel at developing, validating and conducting sensitive quantitative determinations as well as metabolite identification and other complex analytical requests. We have the latest cutting-edge technology and equipment to conduct assays at our sites, ensuring that high quality data is produced timely. Our quality systems drive our preclinical and clinical activities from custom research to full assay validation, compliant with ICH, FDA and EMA.

Talk to 360biolabs about how we can help you conduct clinical trials in psychedelics and other drugs for mental health conditions in Australia, and in our North America and European laboratories. Utilising a bioanalytical laboratory with locations across the globe ensures that our clients can remain with the same high quality laboratory as they progress their programs successfully from Phase 1 to Phase 2 and beyond.

To hear about how 360biolabs, a BioAgilytix company, can support your clinical programs contact Angela Luttick, EVP Commercial.

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AusMedtech 2023
Exhibitor's Hall

BACK TO THE FUTURE: AUSMEDTECH 2023

Reflecting on the past to inform the future was the major theme for AusMedtech, Australia's premier medical technology event, held in Adelaide this May.

AUSMEDTECH HOSTED 430 delegates from across the medical technology sector, which was the largest delegation to date, and represented 12 different countries, including China, India and the United States.

Themed 'Back to the Future', the two-day conference – created by industry, for industry – included more than 100 local and international speakers, with inspirational keynotes from industry leaders, and panel sessions on the latest medtech advancements and trends.

Held at the Adelaide Convention Centre from 24–25 May, the 16th annual AusMedtech national conference was officially opened by the Hon. Chris Picton, Minister for Health and Wellbeing for South Australia, and Major Sumner AM (Uncle Moogy), a renowned performer and cultural ambassador of Ngarrindjeri traditional culture.

The opening keynote was delivered by Bronwyn Le Grice, CEO of ANDHealth, and discussed if and how we can build long-term capabilities, and maintain impact in innovation and commercialisation, in the absence of long-term public investment programs.

Tracey Duffy, First Assistant Secretary, Medical Devices & Product Quality Division of the Therapeutic Goods Administration, discussed the challenges of regulating new and emerging technologies, and what this means for Australian patients.

Chief Scientist for South Australia Professor Caroline McMillen, and the Hon. Stephen Dawson MLC, Minister for Innovation and the Digital Economy, and Minister for Medical Research, Western Australia, discussed the visionary public policy that has supported the sector's growth and their respective roles in policy development, with Lorraine Chiroiu, CEO of AusBiotech, chairing the fireside chat.

Professor Anton van den Hengel, from The University of Adelaide and Amazon, shed light on artificial intelligence–based platforms and large language models (LLMs), and the serious implications they can have in medicine and health care. In a keynote chaired by Lusia Guthrie, Chair of Neo-Bionica, Professor van den Hengel discussed how the medtech industry can respond to the challenges and opportunities LLMs present.

Rounding out AusMedtech2023, Peter Bradley, Managing Director of Qatalyst BioConsulting, debated whether we could and should build the 'Six Million Dollar' person, a '70s sci-fi fixture, in a plenary session with Australian medtech leaders.

Other topics explored included creating effective working relationships with investors, sensors and wearables, lessons from onshoring and establishing manufacturing in Australia, and the role of technology in the future of positive aging.

Early-Stage Innovation Forum

Complementing the informative keynotes and panels, AusMedtech featured the 2023 Early-Stage Innovation Forum (ESIF), a rapid-fire

The Hon. Susan Close, Deputy Premier and Minister for Climate, Environment and Water, Minister for Industry, Innovation and Science, and Minister for Defence and Space Industries, South Australia

Major Sumner AM (Uncle Moogy) provides a Welcome to Country at AusMedtech 2023

Left to right: Professor Caroline McMillen, Chief Scientist for South Australia; The Hon. Stephen Dawson MLC, Minister for Emergency Services, Innovation and the Digital Economy, Science and Medical Research, Western Australia; and Lorraine Chiroiu, AusBiotech CEO

pitch event featuring presentations from Australia's local research institutes, universities, hospitals and pre-series A companies in the areas of medical devices and diagnostics, digital health, and enabling technologies.

Thirteen presenters from across Australia pitched their innovations to presenters and received feedback critical to their commercialisation journey from an expert panel, including Ashley Wittorf (Johnson & Johnson Medtech), Rachel Hooke (FB Rice), Michelle Gallaher (Opyl), Amanda Gillon (BioScience Managers), and Kumaran Mani (Astrazeneca).

Congratulations to QIMR Berghofer Associate Professor Michelle Hill, who was the winner of the Best Translational Research at the AusMedtech ESIF competition for her presentation on a novel ovarian blood cancer diagnostic. Associate Professor Hill represented QIMR Berghofer Precision & Systems Biomedicine Laboratory to present a novel glycosylation-focused proteomics platform to examine blood protein glycosylation changes that are known to occur during cancer development.

Hear more about Associate Professor Hill's winning project and how the ESIF competition has influenced the technology's commercialisation plan on page 74.

The conference dinner was the social highlight of AusMedtech, and was opened by the Hon. Susan Close, Deputy Premier for South Australia, and Minister for Industry, Innovation and Science, Minister for Defence and Space Industries, and Minister for Climate, Environment and Water.

Chris Bond OAM PLY, Australian wheelchair rugby player and Paralympic gold medallist, and Ross Pinder, Performance Insights and Innovation Lead, Paralympics Australia, provided an inspiring conference dinner keynote on why paralympic sport is a rich environment for innovation in technologies. This has been our most successful conference dinner keynote to date, with an audience of hundreds so captivated by their powerful conversation that you could have heard a pin drop. Witnessing the impact that medtech can have provides a clear line of sight on our sector's purpose. The standing ovation said it all!

AusMedtech 2023 was supported by host state partners Business Events Adelaide, the Government of South Australia, and Adelaide Convention Centre; event sponsors, exhibitors and the AusMedtech program committee.

Thank you to the program committee, led by Peter Bradley of Qatalyst BioConsulting, for its dedicated work, ongoing commitment and ideas in support of Australia's premier medical technology conference, AusMedtech 2023.

Save the date now for AusMedtech 2024: 22–23 May. For more information, visit ausmedtech.com.au.

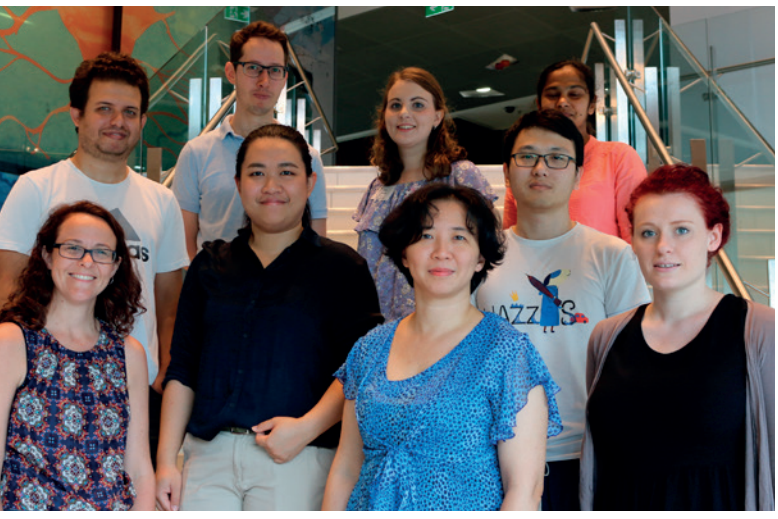
AN UNEXPECTED JOURNEY: THE QUEST FOR NEW OVARIAN CANCER TESTS

BY ASSOCIATE PROFESSOR MICHELLE HILL, FOUNDER, PROSEEK BIO; AFFILIATE, QIMR BERGHOFER MEDICAL RESEARCH INSTITUTE; HONORARY ASSOCIATE PROFESSOR, THE UNIVERSITY OF QUEENSLAND

Early detection of cancer saves lives, but many cancers don't have specific, fit-for-purpose diagnostic tests. Thus, diagnostic test innovation was one of my quests upon establishing my academic research laboratory some 13 years ago.

WHILE METICULOUS SCIENCE and teamwork enabled the discovery of robust blood biomarkers for oesophageal and ovarian cancers, developing those into commercial clinical tests required entrepreneurship. Adding these skills on my unexpected journey, I was privileged to win a MTPConnect Researcher Exchange and Development in Industry (REDI) Fellowship, and the 2023 AusMedtech Early-Stage Innovation Forum.

My idea to pursue genetics research in my bachelor of science honours year was thwarted by the institute receptionist, who said a different professor would have more time to devote to being an adviser on my project. This unexpected advice set me on a path of proteomics research, which was a nascent field in the late 1990s.



Precision & Systems Biomedicine Lab research team (2017)

Associate Professor Michelle Hill

Training for the journey: proteomics exploration of cell biology

Proteomics is the large-scale study of proteins, the workhorse molecules of the cell. Traditionally, new proteins are characterised after laborious biochemical purification, after which antibodies are developed to facilitate detection and measurement of individual proteins. The possibility to profile hundreds or thousands of proteins in a single experiment was transformational.

My honours and PhD years at The University of Queensland were spent in cell biology research using proteomics. After postdoctoral roles in Switzerland and Ireland, and then back again at The University of Queensland, I wanted to establish my own translational cancer research program. Securing funding was not easy – a recurring theme in this journey. After unsuccessful attempts, I obtained two awards in 2009: a Prostate Cancer Foundation of Australia early investigator grant on cholesterol in prostate cancer progression, and a NHMRC Career Development Fellowship on oesophageal cancer. The latter set me on the quest to find oesophageal cancer biomarkers in blood.

A new tool in the quest for cancer biomarkers

A biomarker is an objective measure that indicates particular physiological states. Body temperature, blood pressure and

Continued on page 76

EDV TECHNOLOGY

ENGENEIC, A CLINICAL-STAGE biotechnology company based in Sydney and New York, has created a broad and versatile delivery technology that functions across cancer, infectious diseases and gene therapy.

The technology platform is built around a non-living nanocell, the EnGeneIC Dream Vector (EDV), which can be loaded with chemotherapeutic drugs, functional nucleic acids and adjuvants, and can be targeted to specific cell types to stimulate innate and adaptive immune responses.

A first-in-class therapeutic

For cancer, the EDV is a first-in-class immunotherapy and antibody-drug conjugate rolled into one therapeutic. Our interest is in low survival cancers (LSCs), where patients have no curative options and generally present or develop multi-drug resistance. Approved drugs are all subject to development of multi-drug resistance and eventual failure, but EDVs can be loaded with super-cytotoxic drugs like PNU-159682 – capable of overcoming multi-drug resistance. EDVs loaded with a glycolipid adjuvant are added to the cytotoxic EDVs to stimulate even more potent adaptive anti-tumour immune responses.

Exemplified in the recent Phase 1/2a Carolyn Trial, patients with advanced metastatic pancreatic ductal adenocarcinoma (PDAC) treated with the EDV combination had a significant increase in overall survival; rates were two times to eight times higher than historical controls, with minimal to no toxicity, nor loss of body weight.

Based on the Carolyn Trial results, an investigational new drug is now in place for an open label, randomised and controlled Phase 1/2a trial in the second-line treatment of advanced PDAC patients, to be carried out in US hospitals.

At the same time, and to fill the pipeline, EDVs will be deployed in Australia in the Bespoke EDV trial, a personalised treatment for LSCs, where the antibody attached to specifically target the EDV can be changed depending on the receptor expressed on the cancer cell.

Paving the way

For infectious viral diseases, the EDV has proven to be safe and efficacious in 80 healthy volunteers. Recruits were dosed with EDVs carrying the SARS-CoV-2 ancestral Spike protein and glycolipid adjuvant. The EDV-COVID vaccine resulted in the production of high-affinity antibodies that could neutralise all variants of concern and promote a memory response.

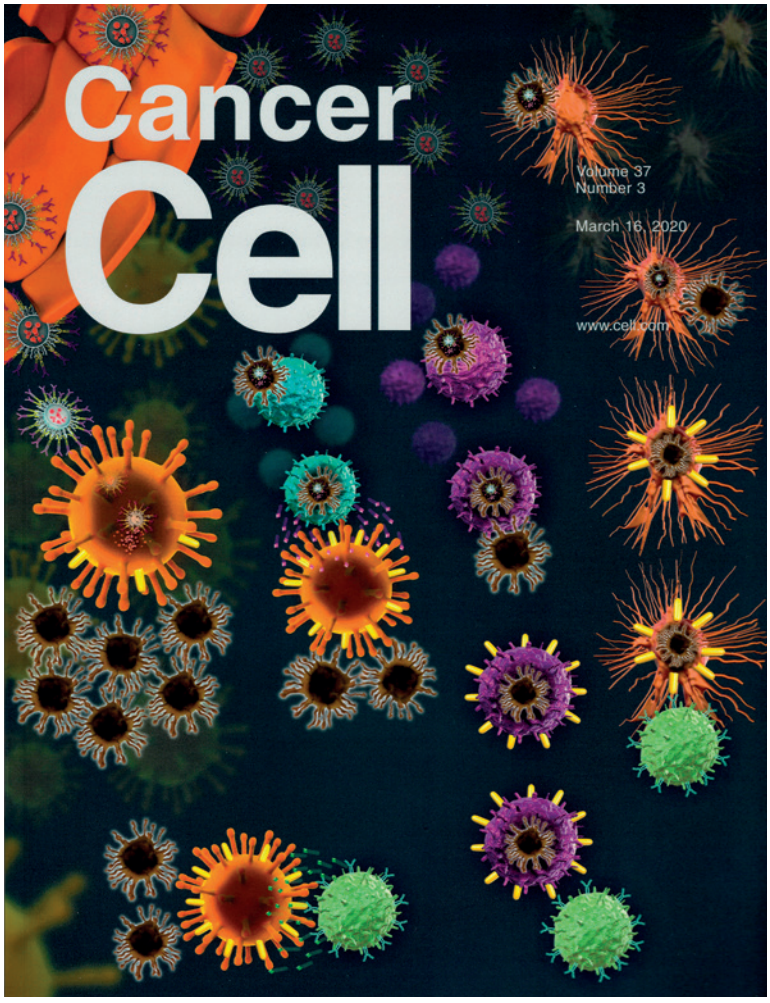
The EDV has advantages over other vaccine platforms since it has a long shelf life and does not require a cold chain. Since the viral antigen is driven off a plasmid carried by the EDV, up to five viral inserts can be included, paving the way for multi-virus vaccines.

While the EDV-COVID vaccine has many advantages, mild disease is still an issue when viruses gain entry via the respiratory tract. Antibodies produced by intramuscular dosing are less effective at viral neutralisation than antibody types like secretory IgA, produced in mucosal tissues. Importantly, the same EDV can be dosed both intramuscularly and intranasally (IN) and EnGeneIC has shown in pre-clinical models that dosing IN results in accumulation of EDVs in nasal-associated lymphoid tissue, resulting in a potent secretory IgA response.

EnGeneIC is the sole owner of all its intellectual property associated with the EDV technology and currently has more than 200 patents granted worldwide, with patent life out to 2040. EnGeneIC is currently in its final round of fundraising before a pharma deal or listing on NASDAQ.

The globally unique tumor cell killing and immune cell activation pathway elaborated by the EDVs has been published in a seminal paper and depicted in the cover art of *Cancer Cell*.

For more information, contact Dr Jennifer MacDiarmid via email at jmacdiarmid@engeneic.com.



Continued from page 74

blood cholesterol level are some familiar biomarkers used to assist in clinical assessment. While traditional cancer markers are single glycoproteins and lack specificity, new-generation diagnostics employ biomarker panels to increase accuracy.

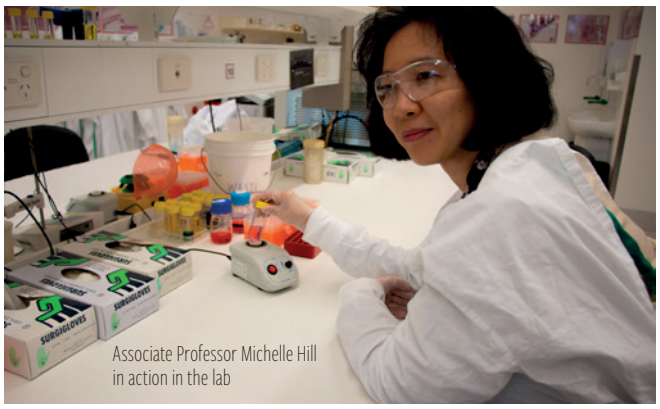
While the maturing proteomics technologies seemed ideal for protein biomarker discovery, early attempts at direct proteomic profiling of blood serum or plasma quickly revealed a major technical hurdle: the blood proteome is dominated by a few abundant proteins. This is the proverbial needle in the haystack problem, with the needle being the ideal cancer marker protein that is released only by the growing cancer.

Instead of following the popular abundant protein depletion approaches, I formulated a fresh strategy that looked for changes in protein glycosylation. Glycosylation is the process of adding sugar side-chains (glycans) to a newly produced glycoprotein (proteins with glycans). A vast body of research has demonstrated alterations in glycosylation of proteins during cancer development. Almost all of the current cancer markers, which are not specific enough as diagnostic tests, are glycoproteins (e.g., PSA for prostate cancer and CA125 for ovarian cancer). While the type of glycans are currently not monitored, some studies reported improved cancer biomarker specificity when a selected glycosylated form was measured. Moreover, different cancers appeared to be associated with different glycosylation.

To execute this strategy, and with the support of colleagues, I obtained funding to purchase a liquid handler and a mass spectrometer for the institute, thus enabling my team to develop a high-throughput translational glycoproteomics pipeline that measures different glycosylated forms of blood glycoproteins. Two talented PhD students worked on the development of the pipeline with rigorous quality control measures, and undertook meticulous linearity and reproducibility checks.[1] This technology was recently validated by another laboratory.[2] With modern clinical diagnostics laboratories already using liquid handlers and mass spectrometers, the methods can be deployed without novel reagent development (e.g., antibody).

1 Loo et al. (2010) J Proteome Res 9:5496; Choi et al. 2011 Electrophoresis 32:3564

2 Dutt et al. (2023) Methods Mol Biol 2628:395



Associate Professor Michelle Hill in action in the lab

Searching for cancer biomarkers

With the new super-tool in hand, my team set out on the quest to find biomarkers for several cancers, each requiring well-defined unmet clinical need and multiple serum sample sets from collaborators. The process for each quest involved candidate discovery, custom assay development and candidate validation in independent samples, looking for biomarkers distinguishing cancer from the relevant benign condition and healthy controls. With perseverance, we successfully validated biomarkers for oesophageal cancer, canine hemangiosarcoma[3] and, most recently, ovarian cancer[4]. Excitingly, using a unique longitudinal sample set from a large ovarian cancer screening study, we also had initial evidence for early detection biomarkers for ovarian cancer screening.[4]

From biomarkers to clinical test: journey into the 'valley of death' and back again

For the new biomarkers to be useful, they need to be developed into clinical diagnostic tests and evaluated for clinical utility. This is the well-known commercialisation 'valley of death'. Taking precious research findings through the valley to emerge with a startup company requires entrepreneurship skills and investor networks.

Sadly, Australia's entrepreneurship was ranked third worst of 64 countries in the world.[5] The MTPConnect REDI scheme addresses this entrepreneurship gap through industry exchange and mentoring. I was privileged to embed at Microba Life Sciences, an Australian microbiome startup success story.

To put my newly acquired knowledge to the test, I was excited to participate in the 2023 AusMedtech Early Stage Innovation Forum with a pitch on our new ovarian cancer biomarkers, and delighted to win Best Translational Project. The experience and the expert feedback have added rungs to the ladder out of the valley of death, and I am on the way to diagnostic test development with my startup company, ProSeek Bio. I am grateful for the companionship and support of the AusMedtech community in this unexpected but necessary entrepreneurial journey. Last, but not least, the new contacts from the AusMedtech community will be of great value in my unexpected entrepreneurial journey. Watch this space.

3 Shah et al. (2015) Mol Cell Proteomics 14:3023; Shah et al. 2018 Mol Cell Proteomics 17:2324; Oungsakul et al. 2021 Vet Sci 8:38

4 Dutt et al. (2023) Proteomics Clin App 2023:2200114

5 www.ceda.com.au/ResearchAndPolicies/Research/Economy/IMD-world-competitiveness-yearbook-2023

STRENGTHENING KEY COLLABORATIONS TO ADVANCE AUSTRALIAN BIOTECHNOLOGY

The perspective of a contract research organisation.

THE AUSTRALIAN BIOTECHNOLOGY industry has experienced a recent surge of growth, with nearly 800 new organisations added to the ecosystem between 2019 and 2022.[1] This significant increase and investment signals new opportunities for advancing healthcare breakthroughs. Biotech companies often seek the support of an experienced contract research organisation (CRO) to extend their team's expertise and help bridge the development gaps between discovery, the clinic, and global commercial markets.

The importance of partnership

Tom Pike, Chairman and Chief Executive Officer at Fortrea, recently shared his thoughts on Fortrea's important role as an independent CRO after its successful spin-off from Labcorp earlier this year.

'Fortrea was established to bring sharpened focus to our purpose, which is partnering with customers to bring life-changing therapies to patients faster,' says Pike.

Fortrea launched with a team of approximately 19,000 people, supporting customers in more than 90 countries across over 20 different therapeutic areas. With a robust customer base across pharmaceutical, biotechnology and medical device organisations, Fortrea's business is specifically designed to address customers' holistic needs across two reporting segments:

- Clinical Services provides Phase 1–4 clinical solutions, including clinical pharmacology and comprehensive clinical development capabilities, that are tailored to customer needs.
- Enabling Services provides technology-enabled solutions and post-approval patient access services.

'Now, as an independent company with increased operational agility and financial flexibility, we are the ideal size to deliver on this purpose,' explains Pike. 'Further, our proven leadership team and talented colleagues across the globe have the skills and experience to help us build a world-class culture of excellence. We look forward to continuing to deliver for patients, customers, employees and shareholders in the years ahead.'

Delivering tailored solutions at a global scale

'Our company is positioned to capitalise on growth opportunities in Phase 1–4 clinical trials and patient access, and to extend its leading positions in oncology, clinical pharmacology and partnership models,' adds Pike. 'With our global scale, access to clinical data-driven insights, site relationships and decades of experience, Fortrea is able to bring customers tailored solutions as a trusted partner.'

Learn more about how Fortrea is becoming a transformative force from pipeline to patient at www.fortrea.com.

1 AusBiotech Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry, www.ausbiotech.org/documents/item/703

AusMedtech 2024

Australia's Medtech Conference

Adelaide Convention Centre

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Join our thriving network of over 400 industry leaders in Adelaide for AusMedtech 2024, Australia's premier medical technology conference for medtech executives, decision makers and investors.

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AusBiotech thanks its Corporate Members for their ongoing commitment, participation and support of the biotech community. AusBiotech's substantial contribution to the ecosystem for more than 37 years is testament to the dedication of its 3000-plus members, volunteer committees, Board and business team.

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Artificial Cell Technologies Australia Pty Ltd
AstraZeneca Pty Ltd
Aucentra Therapeutics
AusBiotech Ltd
Australia China Business Council (ACBC) – Victoria
Australian National University (ANU), Business Engagement and Commercialisation
Australian Red Cross Lifeblood
Australian Regenerative Medicine Institute
Australian Trade Commission (Austrade)
Australian Unity
Avatar Brokers Pty Limited
Avecho Biotechnology Ltd
Baker Heart and Diabetes Institute
BCAL Diagnostics Pty Ltd
Bellberry Limited
Billard Leece Partnership
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Cerecin Australia Pty Ltd
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Department of Jobs, Tourism, Science and Innovation (WA)
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Innovation & Commercialisation Services, The University of Adelaide
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Intellect Labs Pty Ltd
InterK Peptide Therapeutics Limited
Invion Limited
IP Group Australia
IQVIA
James & Wells Australia
Johnson Matthey (Aust) Ltd
Karst Peak Capital Limited

Kazia Therapeutics Limited
KE Select Recruitment
La Trobe University, Innovation & Commercialisation
Labcorp Drug Development
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Piper Alderman
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Proto Axiom Pty Ltd
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The Queensland University of Technology – Industry Engagement
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Research Australia Limited
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Resolutum Global Pty Ltd
Resonance Clinical Pty Ltd
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Technovalia Pty Ltd
TekCyte Ltd
Teleaus Bioscience Health Pty Ltd (Genofax)
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Telix Pharmaceuticals Pty Ltd
Tenmile Ventures Pty Ltd
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The University of Queensland, Biotechnology Program
The Walter & Eliza Hall Institute of Medical Research
Therapeutic Goods Administration (TGA)
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Tissue Repair Ltd
Translational Research Institute Australia
TruScreen Pty Ltd
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UNSW Knowledge Exchange
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Vetter Pharma International GmbH
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AusBiotech has selected Avatar Brokers as its endorsed broker for life science companies. The key advantage Avatar offers is objective, in-depth research on industry-specific exposures. Avatar understands the unique requirements of your industry and takes the time to understand the specific issues and challenges facing your business. Nil commission, fee for service and fully transparent. AusBiotech members are offered a free confidential assessment of their insurance needs against industry best practice.

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Queensland is fast becoming a global research and innovation hub thanks to the Queensland Government's investment in state-of-the-art facilities, talent and partnerships. Our health precincts combine hospitals delivering high-quality care and researchers conducting world-leading research together with innovative companies developing new products.

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statedevelopment.qld.gov.au/biomedical

Queensland Government

NEW AUSBIOTECH MEMBERS

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Catalyst is a clinical research organisation that provides highly customisable solutions to the global biopharmaceutical industry through two established, branded solutions: Catalyst Oncology and Catalyst Flex. The company provides full-service oncology CRO offerings through Catalyst Oncology and multi-therapeutic client- or catalyst-managed functional services through Catalyst Flex. Catalyst's flexible service model is built from more than a decade of listening to customers, devising customer-centric solutions, and helping customers drive breakthrough clinical studies by leveraging expert teams and innovative technologies.

Phone: 0434 566 667 | Email: Kevin.Wightman@catalystcr.com | Web: www.CatalystCR.com

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Phone: 02 7902 0011 | Email: info@encapsolutions.com.au | Web: www.encapsolutions.com.au

EVERSANA®

EVERSANA® is the leading independent provider of commercialisation services to the life sciences industry globally. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for clients through 360-degree commercialisation support, and co-financing partnerships. The company serves more than 650 organisations, including innovative start-ups and established pharmaceutical companies, to advance their global commercialisation efforts.

Amish Chaturvedi | Senior Director Asia-Pacific | Phone: 0430 044 882 | Email: amish.chaturvedi@eversana.com | Web: www.eversana.com

FENIX INNOVATION GROUP

Fenix Innovation Group is an Australia-based innovation development company with a global reach commercialising first-in-class biotechnology and pharmaceutical products. Fenix provides a range of services, including research and development, preclinical and clinical project management, manufacturing, and strategic and regulatory guidance. Fenix has an unparalleled network of partnerships that can be brought together to assist, guide, develop and commercialise any project across the globe.

Phone: 0438 920 009 | Email: admin@fenixinnovationgroup.com

FORTREA

Fortrea is a leading global provider of clinical development and patient access solutions to the life sciences industry. Fortrea partners with emerging and large biopharmaceutical, medical device and diagnostic companies to drive healthcare innovation that accelerates life-changing therapies to patients in need. Fortrea provides Phase 1–4 clinical trial management, clinical pharmacology, differentiated technology enabled trial solutions and post-approval services. Fortrea's solutions leverage three decades of experience spanning more than 20 therapeutic areas. Its talented and diverse team of more than 19,000 people working in more than 90 countries is scaled to deliver focused and agile solutions to customers globally.

Daniel Berg | Business Development Director | Phone: 0408 885 942 | Email: daniel.berg@fortrea.com | Web: www.fortrea.com

GENETIC TECHNOLOGIES

Genetic Technologies (ASX: GTG; Nasdaq: GENE) is a global leader in Genetic Risk Assessment testing. Its geneType and EasyDNA brands offer integrated risk testing for a range of serious conditions, including cancer, metabolic diseases, pharmacogenomics, Non-Invasive Prenatal Testing (NIPT), carrier screen testing, oncogenetic diseases and pet care. GeneType disease prediction will facilitate the development of personalised preventative health plans to manage risk. Early detection leads to early intervention, and early intervention saves lives.

Mr Simon Morriss | Phone: 03 8412 7000 | Email: info@gtglabs.com

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Grey Wolf Therapeutics is a UK- and Australia-based drug discovery and development biotechnology company spearheading a new therapeutic approach in immuno-oncology. The company's first-of-its-kind immuno-oncology approach is centred on inhibiting the endoplasmic reticulum aminopeptidases (ERAP1 or ERAP2), resulting in an entirely novel T cell response against the tumour through the generation of novel cancer antigens and upregulation of certain other neoantigens. Their lead development candidate is GRWD5769.

Email: enquiries@gwt.bio

HEART RESEARCH INSTITUTE

The Heart Research Institute (HRI) is an internationally recognised medical research institute that performs groundbreaking cardiovascular research. HRI's mission is to prevent death and suffering from cardiovascular diseases, a complex array of diseases affecting the heart and blood vessels. Our leading researchers conduct scientific and clinical research into better understanding atherothrombotic and cardiac conditions through basic biomedical discovery, drug discovery and development, device improvement, clinical trials, and clinical initiatives.

Anna Grocholsky | Director, Commercialisation | Phone: 0447 933 414 | Email: anna.grocholsky@hri.org.au | Web: www.hri.org.au

HEALTH SECURITY SYSTEMS AUSTRALIA

Health Security Systems Australia (HSSA) leads and manages collaborations between industry, research, and government partners to enhance the protection of military and civilian personnel against chemical, biological, and radiological threats, emerging infectious diseases and pandemics. HSSA regularly scans the sector for capable partners with relevant expertise willing to participate in collaborative research and development projects. A division of DMTC Limited, HSSA is underpinned by DMTC's credibility as a trusted and strategic partner, and backed by its internationally benchmarked business and quality systems.

Harry Baxter | Head Government Relations | Phone: 0401 516 734 | Email: harry.baxter@dmtc.com.au | Web: https://dmtc.com.au/hssa/

INVION

Invion is leading the global development of the Photosoft™ technology for the treatment of a range of cancers, atherosclerosis and infectious diseases. It's working with partners like Peter Mac and Hudson Institute, and is preparing for clinical trials in 2023 on cancers. Preclinical results demonstrated Photosoft's potential to regress multiple cancer types, impede metastatic cancers and stimulate immune response. It also showed potential against bacteria, fungi, and viruses, including MRSA and COVID-19.

Phone: 03 9692 7222 | Email: investor@inviongroup.com | Web: https://inviongroup.com/

M:M BIO

M:M Bio co-creates, builds and scales biotech companies within its embedded ecosystem model. Currently based in Oxford, M:M Bio is growing its unique organisation globally, creating and enabling biotech centres of excellence, partnering with local experts, and accelerating innovation. Run by entrepreneurs, for entrepreneurs, M:M Bio is uniquely enabling the development of innovative new medicines and companies with leading minds across the world. The ecosystem integrates experienced drug discovery expertise with stage-appropriate, agile operational infrastructure.

Kirsty McCarthy | CEO | Email: enquiries@m2m.bio | Web: www.m2m.bio

MONASH TALENT

Monash Talent is committed to helping the life sciences sector build the workforce of the future by providing industry with easy access to student and graduate talent from Australia's largest university talent pool. Its centralised talent solutions reduce the complexity of navigating a university ecosystem, simplify hiring and help promote the employer brand. Monash Talent offers a multitude of early-career solutions, including temporary work, part-time and full-time placements, internships, workforce upskilling and more.

Marko Sanovic | Director of Industry Partnerships | Phone: 0484 248 304 | Email: marko.sanovic@monash.edu

OBATICA

Obatica's passion is bringing tailored, innovative solutions to drug development. Obatica provides drug development strategy, medical writing, medical monitoring and pharmacovigilance services. Its team of clinicians and scientists has extensive experience across all facets of drug development, from bench, to bedside, to industry. Complex oncology studies are Obatica's niche, with non-oncology experience rapidly growing. Obatica services academics, small to large biotechs and CROs, with more than 60 per cent of its clients returning with another project in the same year (with 30+ projects per year). Reach out for a free consult.

Phone: 02 9174 5224 | Email: info@obatica.com | Web: www.obatica.com |

ON Q RECRUITMENT

On Q Recruitment is a life sciences recruitment specialist providing executive search, contracting and permanent recruitment services in the STEM sectors. With 24 years of experience matching talent in the medical, technical, engineering, and scientific spaces, On Q operates across regulatory, quality, clinical research, market access, research and development, engineering and operations, health-tech, marketing, sales, business development and medical affairs.

Phone: 02 9431 2555 | Email: onq@onqrecruitment.com.au | Web: www.onqrecruitment.com.au

RESOLUTUM

Resolutum provides flexible, well-thought-out solutions to end-to-end biometrics that meet all regulatory requirements while being tailored to client needs, and being 100 per cent Australia based. Resolutum serves a global client base of pharmaceutical companies, other CROs, clinical groups, academic institutions and niche biotech companies by integrating as part of the team. Diverse therapeutic and global experience allows the company to understand and cater to the unique needs of each client and help them meet their trial goals.

Stella Burger | Director Client Engagement | Phone: 0456 308 137 | Email: stella.burger@rgcro.com | Web: www.rgcro.com

SCIENTIA CLINICAL RESEARCH

Scientia Clinical Research (SCR) is an FDA-audited, not-for-profit early-phase clinical trial company operating a 30-bed Phase I unit, co-located within the Prince of Wales Hospital. Scientia conducts approximately 40 clinical trials per year, the majority being first-in-human (FIH) single/multiple dose studies, food effect, drug interaction, and ethnopharmacology studies (Korean, Chinese, Japanese) and biosimilar, formulation and specialty studies. The company can manufacture finished products (investigational products) from active pharmaceutical ingredients and manage investigational product importation.

Phone: 02 9382 5800 | Email: BDenquiries@scientiaclinicalresearch.com.au | Web: www.scientiaclinicalresearch.com.au

SILVERSTONE

Silverstone is a private property development and investment company based in South-East Queensland. It is agile and future focused, specialising in state-of-the-art office, healthcare and life sciences facilities. To date, the company has completed more than $900 million worth of award-winning developments and holds a diverse portfolio of long-term, sustainable assets. The developer recently won approval for its new world-class, seven-storey life sciences project in Herston, the Brisbane Advanced Research Centre.

Anthony Fanning | Development Manager, Healthcare | Email: afanning@silverstonedevelopments.com.au | Web: www.silverstonedevelopments.com.au

THE UNIVERSITY OF QUEENSLAND INSTITUTE FOR MOLECULAR BIOSCIENCE

Institute for Molecular Bioscience is Australia's number one research institute.* Its vision is a world free of disease and it has spun out multibillion-dollar companies developing treatments for stroke, Parkinson's disease and cancer, and helped deliver the world's first bee-friendly plant-extract bioinsecticide. We partnered with parents and clinicians to diagnose rare genetic diseases in children, and with community groups to fight invasive pests – a premier track record of industry research partnerships with global community impact.

*Nature Index

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UNIVERSITY OF NEW SOUTH WALES SCHOOL OF BIOTECHNOLOGY AND BIOMOLECULAR SCIENCES

The School of Biotechnology and Biomolecular Science (BABS) at The University of New South Wales in Sydney is a leading place of education and research at one of Australia's premier universities. Expertise ranges across the fields of cell biology, genomics, microbiology, biochemistry, bioinformatics and biotechnology. BABS is home to the SynBio10X startup initiative and industry-accessible research infrastructure, such as the Ramaciotti Centre for Genomics, the Recombinant Products Facility and the Structural Biology Facility.

Phone: 02 9065 4060 | Email: babs@unsw.edu.au | Web: www.unsw.edu.au/science/our-schools/babs

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DAVID NAYAGAM, EXECUTIVE DIRECTOR – HEALTHCARE, RESEARCH; AND ALAN LIANG, ANALYST – RESEARCH, E&P

ASX	Issuer Name	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
1AD	AdAlta Limited	Drug discovery and development using its technology platform to generate a promising new class of protein therapeutics, known as i-bodies.	22/8/2016	10.16	0.02	0.06	0.02	-1.60	-1.44	1.00	-
1AI	Algorae Pharmaceuticals	Formerly Living Cell Technologies. Developer of live cell therapy products for treatment of neurological and metabolic disorders.	1/9/2004	22.89	0.01	0.02	0.01	-0.21	-6.67	-	-
4DX	4DMedical Limited	A software technology company in Australia. It commercialises XV Technology, a four-dimensional lung imaging platform.	7/8/2020	234.69	0.68	1.27	0.29	-13.05	-5.21	-	-
AC8	Auscann Group Holdings Limited	Cultivation, manufacture and distribution of medicinal cannabis products. Targeting medications for neuropathic and chronic pain.	3/5/1989	17.62	0.04	0.05	0.04	-5.34	-0.75	4.00	-
ACR	Acrux Limited	Transdermal drug delivery platform technology.	29/9/2004	14.12	0.05	0.09	0.04	-2.68	-1.83	2.00	-
ACW	Actinogen Medical Limited	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders, including Alzheimer's disease.	16/10/2007	49.04	0.03	0.15	0.03	-0.61	-4.43	1.00	-
ADO	Anteotech Limited	Multi-component coatings for solid phase of immunoassays for biomarker development.	7/4/2000	65.25	0.03	0.07	0.03	-0.53	-5.66	-	-
ADR	Adherium Limited	Developer of digital technologies to monitor medication use in chronic respiratory conditions.	26/8/2015	20.00	0.00	0.01	0.00	-0.44	-0.91	-	-
AFP	AFT Pharmaceuticals Limited	Develops, licences and sells a range of medical products globally.	22/12/2015	353.40	3.37	3.70	2.90	9.36	36.00	-	0.69
AGH	Althea Group Holdings Limited	An independent health technology service provider focused on the sales and distribution of medicinal cannabis products, along with the development of a manufacturing and cultivation facility.	21/9/2018	16.26	0.04	0.12	0.04	-4.39	-0.96	5.00	-
AGN	Argenica Therapeutics Limited	Argenica Therapeutics Limited researches and develops a neuroprotective therapeutic drug in Australia. The company's product is ARG-007, a neuroprotective peptide candidate for use in the protection of brain tissue against damage during a stroke and other acute central nervous system injuries.	11/6/2021	37.68	0.38	0.70	0.35	-4.90	-7.76	8.00	-
AHI	Advanced Human Imaging Limited (formerly MyFiziq Limited)	Advanced Human Imaging Limited operates as a mobile application and technology development company worldwide. It develops and patents a proprietary measurement/dimensioning technology that enables end users to check, track, and assess body dimensions privately using a smartphone.	17/8/2015	51.16	0.24	0.40	0.07	-5.61	-4.19	1.00	-
AHX	Apiam Animal Health Limited	iVet technology for real-time animal health monitoring, including on-farm welfare assessments.	15/12/2015	64.80	0.36	0.85	0.35	3.78	9.52	-21.00	0.40
ALA	Arovella Therapeutics Limited	Arovella Therapeutics Limited (formerly Suda Pharmaceuticals Limited). Oromucosal sprays for drug delivery treatment of off-patent drugs.	24/1/2002	43.19	0.05	0.11	0.02	-1.33	-3.61	-	-

ASX	Issuer Name	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
ALC	Alcidion Group Limited	Alcidion Group Limited, together with its subsidiaries, engages in the development and licensing of healthcare software products in Australia, New Zealand, and the United Kingdom.	24/6/2011	139.49	0.11	0.17	0.09	-0.04	-275.00	-	-
ALT	Analytica Limited	eHealth devices. PeriCoach system for stress urinary incontinence.	25/10/2000	4.61	0.00	0.00	0.00	-0.05	-2.00	-	-
AMT	Allegra Orthopaedics Limited	Prosthetic implant tools.	5/12/2007	6.27	0.06	0.14	0.05	-2.02	-2.97	1.00	-
AN1	Anagenics Limited	Anagenics Limited (ASX: AN1) has a range of clinically validated anti-aging and wellness products developed in house, or sourced from premium international brands.	9/12/2005	8.04	0.02	0.04	0.01	-1.51	-1.46	2.00	-
ANN	Ansell Limited	Ansell Limited is involved in the development, manufacturing, sourcing, distribution and sale of gloves, and protective personal equipment in the industrial and medical end markets.	20/11/1985	2,953.57	23.29	29.83	23.00	177.22	13.14	644.00	113.89
ANO	Advance Zinctek Limited	Advance ZincTek Limited, together with its subsidiaries, manufactures aluminium oxide powder, and zinc oxide dispersions and powder for use in the personal care sector in Australia, the United States, Canada, Europe, and internationally.	24/2/2005	93.34	1.50	2.68	1.35	3.90	38.33	45.00	6.00
ANP	Antisense Therapeutics Limited	Drug discovery and development. Antisense compounds for multiple sclerosis, Duchenne muscular dystrophy and acromegaly.	20/12/2001	42.65	0.05	0.15	0.05	-1.21	-4.21	2.00	-
ANR	Anatara Lifesciences Limited	Natural, plant-based therapeutics for gastrointestinal diseases.	16/10/2014	3.84	0.03	0.07	0.03	-3.09	-1.04	1.00	-
ARX	Aroa Biosurgery Limited	A regenerative medicine company that develops and manufactures medical devices for wound and tissue repair in the United States and internationally.	24/7/2020	303.65	0.89	1.25	0.74	-0.11	-804.55	22.00	-
AT1	Atomo Diagnostics Limited	Atomo Diagnostics Limited researches, designs, develops, manufactures, and sells medical devices for blood-based rapid testing for professional use and self-testing.	16/4/2020	19.18	0.03	0.10	0.02	-1.58	-1.90	3.00	-
ATH	Alterity Therapeutics Limited	Alterity Therapeutics Limited (formerly Prana Biotechnology Limited) is an Australian biotechnology company that focuses to commercialise research into Parkinsonian movement disorders, Alzheimer's disease, Huntington's disease and other neurodegenerative disorders.	28/3/2000	18.30	0.01	0.02	0.01	-0.59	-1.27	1.00	-
ATX	Amplia Therapeutics Limited	Amplia Therapeutics Limited (formerly Innate Immunotherapeutics Limited) is an Australian pharmaceutical company that is advancing a pipeline of focal adhesion kinase inhibitors for cancer and fibrosis.	23/12/2013	15.52	0.08	0.13	0.07	-3.22	-2.48	4.00	-
AUA	Audeara Limited	Audeara Limited, a hearing health technology company, develops and sells personalised listening products. It provides A–01 bluetooth headphones and BT–01 wireless transceivers.	18/5/2021	6.31	0.04	0.13	0.03	-3.26	-1.35	3.00	-
AVE	Avecho Biotechnology Limited	Avecho Biotechnology Limited (formerly Phosphagenics Limited) is a research-based biotechnology company that discovers and develops new ways to enhance the delivery, effectiveness, and/or tolerability of proven pharmaceutical, consumer and animal health products.	11/8/1993	15.14	0.01	0.02	0.00	-0.13	-5.38	-	-
AVH	Avita Medical Incorporated	Skin regeneration technology for the treatment of wounds, scars and skin defects.	24/6/2020	307.49	4.95	6.27	1.45	-184.13	-2.69	402.00	-
AVR	Anteris Technologies Limited	Anteris Technologies Limited (formerly Amedus Limited). Tissue engineering and vaccine development for herpes and HPV.	24/3/2004	297.89	19.10	26.99	18.05	-332.00	-5.75	89.00	-
AXE	Archer Materials Limited	Archer Materials Limited (formerly Archer Exploration Limited) has a focus on the development of the group's advanced materials, with a key focus on integrating graphite and graphene in key growth areas of reliable energy, human health, and quantum technology.	14/8/2007	128.70	0.51	0.98	0.36	-5.86	-8.62	11.00	-
AYA	Artrya Limited	Artrya Limited operates as a medical technology company that uses artificial intelligence–powered image-analysis software to enhance the detection and management of coronary artery disease.	26/11/2021	22.02	0.35	0.89	0.18	-22.19	-1.58	39.00	-
BCT	Bluechiip Limited	Bluechiip Limited develops and commercialises wireless tracking solutions for the healthcare, life sciences, security, defence and manufacturing industries.	9/6/2011	13.56	0.02	0.05	0.02	-0.61	-3.11	-	-

ASX	Issuer Name	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
BDX	BCAL Diagnostics Limited	BCAL Diagnostics Limited, a biotechnology company, engages in developing a non-invasive laboratory blood test for the detection of breast cancer.	21/7/2021	28.79	0.14	0.21	0.05	-2.19	-6.16	-	-
BGT	Bio-Gene Technology Limited	Insecticide product development. 'Qcide' and 'FLAVOCIDE' focused on insect control in agriculture and animal health.	29/11/2017	15.77	0.09	0.14	0.07	-1.85	-4.81	2.00	-
BIO	Biome Australia Limited	Biome Australia Limited develops, commercialises, and markets various live biotherapeutics and complementary medicines in Australia and internationally.	30/11/2021	20.31	0.13	0.15	0.06	-2.20	-5.68	2.00	-
BIT	Biotron Limited	Antiviral drug developer for HIV and hepatitis.	24/1/2001	26.16	0.03	0.07	0.02	-0.23	-12.61	1.00	-
BNO	Bionomics Limited	Small molecule developer in areas of cancer and central nervous system disorders.	21/12/1999	15.42	0.01	0.07	0.01	-1.51	-0.70	2.00	-
BOD	BOD Science Limited	A vertically integrated developer, manufacturer, distributor, and marketer of plant-based natural health supplements and beauty solutions.	27/10/2016	13.83	0.08	0.17	0.05	-5.50	-1.45	239.00	-
BOT	Botanix Pharmaceuticals Limited	Developer of therapeutics for skin diseases, including acne, psoriasis and dermatitis.	24/1/1985	255.82	0.18	0.20	0.05	-1.13	-15.93	1.00	-
BXN	Bioxyne Limited	Gut and immune health probiotic products, including a patented probiotic range.	14/12/2000	30.43	0.02	0.03	0.01	-0.05	-32.00	1.00	-
CAJ	Capitol Health Limited	Provider of diagnostic imaging services to the Australian healthcare market.	9/6/2006	249.93	0.24	0.34	0.23	-1.18	-19.92	-3.00	1.00
CAN	Cann Group Limited	Research, development and cultivation to facilitate the supply of medicinal cannabis.	4/5/2017	51.03	0.12	0.30	0.11	-10.47	-1.15	19.00	-
CAT	Catapult Group International Limited	A global sports analytics company that provides elite sporting organisations and athletes with detailed, real-time data and analytics to monitor and measure athletes.	19/12/2014	259.94	1.03	1.24	0.61	-19.96	-5.16	-11.00	-
CBL	Control Bionics Limited	Control Bionics Limited designs, manufactures, and sells wireless wearable electromyography-based augmentative and alternative communication technologies that allow users to operate and communicate through a computer using thoughts and neuroelectric signals.	7/12/2020	8.70	0.09	0.25	0.07	-6.75	-1.26	-	-
CDX	CardieX Limited	CardieX Limited (formerly AtCor Medical Holdings Limited) is an ASX-listed public company with operations in medical technology, wearable devices and telehealth. It provides digital and device-based solutions for large-scale population health disorders with significant market scale.	9/11/2005	23.71	0.17	0.44	0.15	-13.00	-1.27	3.00	-
CGB	Cann Global Limited	Cann Global Limited operates in medicinal cannabis and hemp food industries in Australia and internationally.	14/1/2008	5.44	0.02	0.03	0.02	-3.33	-0.63	3.00	-
CGS	Cogstate Limited	Diagnosis and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's diseases).	13/2/2004	263.24	1.52	2.46	1.14	3.06	49.67	16.00	-
CHM	Chimeric Therapeutics Limited	Chimeric Therapeutics Limited, a biotechnology company, develops and commercialises chimeric antigen receptor T cell therapy drugs for solid tumours in Australia.	18/1/2021	20.12	0.04	0.13	0.04	-3.90	-0.97	1.00	-
CLV	Clover Corporation Limited	Supplies science-based oil products to the medical food market for infants and children.	30/11/1999	175.35	1.05	1.47	0.97	5.26	19.96	38.00	1.75
CMP	Compumedics Limited	Designs and manufactures technologies for the diagnosis of sleep disorders; neurodiagnostics solutions and brain tesearch technologies through the Compumedics Neuroscan brand.	21/12/2000	30.12	0.17	0.31	0.14	-3.50	-4.86	6.00	-
COH	Cochlear Limited	Manufacture and sale of the cochlear implant system for impaired hearing.	4/12/1995	17,182.95	261.70	262.82	184.62	457.00	57.26	1,987.00	300.00
CPH	Creso Pharma Limited	Development and production of cannabis and hemp-derived therapeutic products and treatments for humans and pets.	20/10/2016	20.23	0.01	0.04	0.01	-2.24	-0.31	-	-
CSL	CSL Limited	Development, manufacture, and marketing of pharmaceutical and diagnostic products.	8/6/1994	130,514.65	270.57	314.28	255.87	686.27	39.43	431.00	337.98
CSX	Cleanspace Holdings Limited	CleanSpace Holdings Limited engages in the design, manufacture, and sale of respirators, and related products and services, for healthcare and industrial employers worldwide.	23/10/2020	21.58	0.28	0.85	0.16	-13.83	-2.02	-	-

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CT1	Constellation Tecbnologies Limited	Constellation Technologies Limited (formerly CCP Technologies Limited) engages in the Internet of Things product development and product management in Australia and internationally.	8/10/1987	2.94	0.00	0.01	0.00	-	-	-	-
CTE	Cryosite Limited	Collection, processing and long-term storage of blood stem cells.	9/5/2002	36.61	0.75	0.87	0.51	2.58	29.07	4.00	1.00
CU6	Clarity Pharmaceuticals Limited	Clarity Pharmaceuticals Limited, a clinical-stage radiopharmaceutical company, develops theranostic therapy and imaging products for the treatment of cancer in children and adults.	25/8/2021	186.78	1.02	1.05	0.59	-8.20	-12.44	32.00	-
CUV	CLINUVEL Pharmaceuticals Limited	Developer for treatment of UV-related skin disorders. Lead product SCENESSE completed Phase 3 clinical trials for prevention of phototoxicity in adult patients with erythropoietic protoporphyria.	13/2/2001	1,020.32	20.65	28.72	16.76	53.40	38.67	278.00	4.00
CYC	Cyclopharm Limited	Manufacturer and distributor of radiopharmaceuticals for imaging technology. Lead product is Technegas, a lung ventilation imaging drug.	18/1/2007	215.73	2.30	2.41	1.15	-7.17	-32.08	33.00	1.00
CYP	Cynata Therapeutics Limited	Stem cell and regenerative medicine platform technology, Cymerus, for production of mesenchymal stem cells.	20/12/2007	25.15	0.14	0.42	0.11	-6.62	-2.04	12.00	-
DVL	DorsaVi Limited	Motion analysis device technologies for clinical, elite sports, and occupational health and safety.	11/12/2013	6.68	0.01	0.02	0.01	-0.41	-2.93	-	-
DXB	Dimerix Limited	Development of therapeutic treatments identified using drug discovery platform, Receptor-Heteromer Investigation Technology.	4/2/1993	25.69	0.07	0.18	0.05	-4.15	-1.59	2.00	-
EBO	EBOS Group Limited	Distributor of healthcare products.	6/12/2013	6,181.44	32.26	45.77	31.10	122.70	26.29	379.00	81.88
EBR	EBR Systems Incorporated	EBR Systems Incorporated develops implantable systems for wireless tissue stimulation. The company offers a WiSE cardiac resynchronisation therapy system that uses a proprietary wireless technology to deliver pacing stimulation directly to the inside of the left ventricle of the heart.	24/11/2021	251.29	0.85	1.35	0.41	-17.71	-4.77	24.00	-
ECS	ECS Botanics Holdings Limited	ECS Botanics Holdings Limited engages in the cultivation, manufacture, and sale of medicinal cannabis products. It also retails hemp wellness and food products, and engages in the agriculture business.	13/3/1986	25.45	0.02	0.03	0.02	0.06	38.33	2.00	-
EMD	Emyria Limited	Emyria Limited, a clinical drug development and care delivery company, operates a network of specialist medical clinics. Its product pipeline include EMD-003, a cannabinoid medicine for mental health; and EMD-004, a cannabinoid medicine targeting irritable bowel syndrome.	12/2/2020	28.68	0.09	0.33	0.09	-2.76	-3.37	-	-
EMV	EMvision Medical Devices Limited	EMvision Medical Devices Limited, a medical device company, engages in the research, development, and commercialisation of imaging and diagnostic technology products. It develops a portable brain scanner for point of care, stroke diagnosis and monitoring.	13/12/2018	108.30	1.39	2.36	1.12	-6.24	-22.28	9.00	-
EOF	Ecofibre Limited	Ecofibre Limited is focused on selectively owning or controlling specific parts of the hemp value chain, in targeted geographies.	29/3/2019	66.35	0.19	0.45	0.15	-7.63	-2.49	7.00	-
EPN	Epsilon Healthcare Limited (formerly THC Global Group)	Epsilon Healthcare Limited operates as a healthcare and pharmaceuticals company primarily in Australia and Canada. It engages in the manufacture and distribution of hydroponics equipment, materials, and nutrients; and the development and delivery of medicinal cannabis, as well as providing turnkey cultivation solutions.	4/5/2017	6.31	0.02	0.04	0.02	-6.56	-0.32	4.00	-
EX1	Exopharm Limited	Exopharm Limited focuses on developing and commercialising human therapeutics using extracellular vesicles as medicines in Australia.	18/12/2018	4.39	0.01	0.14	0.01	-4.41	-0.23	3.00	-
EYE	Nova Eye Medical Limited	Designs, develops and distributes surgical devices for the treatment of glaucoma. The company offers various products like iTrack, iTrack Advance, Molteno3 and 2RT.	12/9/1994	47.63	0.25	0.36	0.18	-7.58	-3.30	4.00	-
FPH	Fisher & Paykel Healthcare Corporation Limited	A New Zealand-based company engaged in the design, development, manufacture, and marketing of products and systems for use in respiratory care, acute care, surgery, and the treatment of obstructive sleep apnoea.	21/11/2001	11,988.51	20.61	26.08	16.11	40.53	50.85	255.00	37.62
FRE	Firebrick Pharma Limited	Firebrick Pharma engages in the development and commercialisation of nasal spray treatment for the common cold under the Nasodine name in Australia.	28/1/2022	28.95	0.26	0.40	0.14	-1.85	-13.78	3.00	-

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GLH	Global Health Limited	Global Health Limited provides digital health solutions for the healthcare sector in Australia. It provides mental health software for psychologists and psychiatrists.	4/4/2000	8.71	0.15	0.44	0.11	-5.90	-2.54	-1.00	-
GSS	Genetic Signatures Limited	Molecular diagnostics company focused on development and commercialisation of its proprietary platform technology, 3Base.	31/3/2015	73.14	0.51	1.03	0.49	-5.67	-8.99	31.00	-
GTG	Genetic Technologies Limited	Molecular diagnostics specialising in womens health. Lead product BREVAGen plus is a risk assessment test for non-hereditary breast cancer.	30/7/1987	23.08	0.00	0.01	0.00	-0.10	-2.50	-	-
HCT	Holista CollTech Limited	Development and commercialisation of food ingredients and ovine collagen.	26/2/2004	3.07	0.01	0.04	0.01	-0.52	-2.12	1.00	-
HGV	Hygrovest Limited	Hygrovest Limited (formerly MMJ Group Holdings Limited). Aims to commercialise medical cannabis and high-value based cannabis therapeutics.	22/1/2015	9.46	0.05	0.07	0.04	-4.36	-1.03	10.00	-
HIQ	HitIQ Limited	HitIQ Limited develops and commercialises concussion management technology in Australia. The company offers Nexus A9 sensor to record individual head impacts.	16/6/2021	7.20	0.03	0.06	0.02	-1.42	-1.90	1.00	-
HMD	HeraMED Limited	HeraMED Limited, together with its subsidiaries, develops, manufactures, and sells fetal heartbeat monitors and other pregnancy monitoring solutions for home use in Australia, Europe, and Israel. The company provides HeraBEAT, a fetal heart rate monitor principally for use by an expectant mother to monitor their fetus's heartbeat.	12/12/2018	20.13	0.07	0.22	0.06	-3.39	-2.12	1.00	-
HXL	Hexima Limited	A biotechnology company that engages in the research and development of plant-derived proteins and peptides for applications as human therapeutics.	1/12/2020	3.84	0.02	0.03	0.01	-	-	-	-
HYD	Hydrix Limited	Hydrix Limited provides product design, engineering, and regulatory services in Australia and internationally. It offers a range of services, including software, electronics, and mechanical design; industrial design, user experience, and human factors engineering; and regulatory, clinical, and reimbursement consulting, as well as quality systems.	11/5/2001	8.39	0.03	0.09	0.02	-2.67	-1.24	-	-
IBX	Imagion Biosystems Limited	Detection and localisation of cancer and other diseases using nano particle technology. Proprietary MagSense bio-imaging detection technology.	22/6/2017	20.89	0.02	0.05	0.01	-0.87	-1.84	-	-
IDT	IDT Australia Limited	Manufacturer of pharmaceuticals and clinical trial management services.	24/9/1993	23.89	0.07	0.14	0.06	-3.41	-1.99	10.00	-
IHL	Incannex Healthcare Limited	Incannex Healthcare (formerly Impression Healthcare). A manufacturer and distributor of professionally made home-impression custom-fit dental products.	23/5/2007	158.70	0.10	0.35	0.08	-1.39	-7.19	-	-
IIQ	INOVIQ Limited	INOVIQ Limited (formely BARD1 Life Sciences Limited) is an Australian life sciences company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer.	18/4/1991	64.87	0.71	0.99	-	-10.24	-6.88	12.00	-
ILA	Island Pharmaceuticals Limited	Island Pharmaceuticals Limited, a drug research and repurposing company, focuses on the development of preventive or therapeutic drugs for viral infections. Its lead product candidate is ISLA-101, a drug for the prevention and treatment of dengue fever and other mosquito-borne diseases.	13/4/2021	6.91	0.09	0.22	0.07	-4.16	-2.04	4.00	-
IMC	Immuron Limited	Oral immunotherapy products that target the human gut immune system and gut microbiome.	30/4/1999	17.54	0.08	0.11	0.07	-1.35	-5.70	9.00	-
IMM	Immutep Limited	Developer of novel immunotherapy agent treatments for cancer and autoimmune diseases. Lead product candidate is eftilagimod alpha for breast cancer and melanoma.	23/6/1988	332.45	0.28	0.42	0.22	-4.21	-6.65	8.00	-
IMU	Imugene Limited	Developer of HER-2+ gastric and breast cancer immunotherapies.	2/12/1993	507.42	0.08	0.27	0.08	-0.68	-11.62	3.00	-
IPD	ImpediMed Limited	Diagnostic devices for lymphedema, muscle wasting and metabolic disorders that utilises bioimpedance technology.	24/10/2007	403.76	0.20	0.24	0.06	-1.62	-12.35	2.00	-
IPL	Incitec Pivot Limited	A manufacturer and distributor of industrial explosives, industrial chemicals, and fertilisers to the agriculture and mining industries.	28/7/2003	5,690.72	2.93	4.15	2.58	50.60	5.79	158.00	27.00

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IRX	InhaleRx Limted	InhaleRx (formerly Lifespot Health Limited). Medical diagnostic and monitoring technology using smartphones. BodyTel system for management of chronic diseases and My-Lifespot system for skin disease diagnosis.	11/1/2017	8.35	0.04	0.07	0.03	-1.10	-4.00	1.00	-
IVX	Invion Limited	Developer of treatments for inflammatory diseases.	15/2/2010	32.11	0.01	0.02	0.00	-0.03	-16.67	-	-
IXC	Invex Therapeutics Limited	A biopharmaceutical company, focused on the research and development of Exenatide as an efficacious treatment for neurological conditions.	5/7/2019	13.53	0.18	0.70	0.17	-10.31	-1.75	28.00	-
JTL	Jayex Healthcare Limited	A provider in the United Kingdom and Australia of integrated healthcare services delivery platforms, incorporating the company's four interconnected and proprietary technologies.	17/12/2015	2.53	0.01	0.01	0.01	-2.90	-0.31	-3.00	-
KZA	Kazia Therapeutics Limited	Development of anti-cancer drugs.	1/9/1994	36.63	0.16	0.27	0.07	-18.08	-0.86	-4.00	-
LBT	LBT Innovations Limited	Automated systems for the preparation, screening, interpretation and streaking of microbiological specimens.	31/7/2006	8.75	0.03	0.09	0.02	-1.80	-1.39	-	-
LDX	Lumos Diagnostics Holdings Limited	Lumos Diagnostics specialises in rapid, cost-effective and complete point-of-care diagnostic test solutions to help healthcare professionals more accurately diagnose and manage medical conditions.	5/7/2021	36.81	0.08	0.18	0.01	-40.82	-0.20	-1.00	-
LER	Leaf Resources Limited	Leaf Resources Limited manufactures and supplies pine chemicals in Australia. It provides natural wood rosin and turpentine, and cellulose and cellulosic fuels.	5/1/1999	30.93	0.02	0.04	0.01	-0.39	-3.85	-	-
LGP	Little Green Pharma Limited	Little Green Pharma Limited engages in the cultivation, production, and distribution of medicinal cannabis products in Australia and internationally. It offers cannabis flower products.	20/2/2020	52.43	0.18	0.35	0.16	-6.91	-2.53	28.00	-
M7T	Mach7 Technologies Limited	Imaging IT solutions, 3D printing and holographic projection provider.	30/11/2005	187.41	0.78	0.99	0.52	-1.62	-48.15	8.00	-
MAP	Microba Life Sciences Limited	Microba Life Sciences provides microbiome testing and analysis services for clinicians, consumers, and research customers in Australia, Europe, New Zealand, the United Arab Emirates, the United Kingdom, and the United States.	5/4/2022	109.56	0.37	0.45	0.14	-1.98	-18.69	13.00	-
MDC	Medlab Clinical Limited	Research and development of novel bio-therapeutics to improve health outcomes in chronic diseases, such as chronic kidney disease and obesity.	14/7/2015	15.07	6.60	14.94	6.55	-7,100.00	-0.09	342.00	-
MEB	Medibio Limited	Diagnostic tests for depression and other mental health disorders.	29/1/2001	12.20	0.00	0.00	0.00	-0.59	-0.34	-	-
MEM	Memphasys Limited	Cell and protein separation systems.	14/5/2007	14.39	0.02	0.04	0.01	-0.28	-6.07	-	-
MSB	Mesoblast Limited	Commercialisation of adult stem cell technology.	16/12/2004	293.11	0.36	1.43	0.34	-18.63	-1.93	-13.00	-
MVF	Monash IVF Group Limited	Assisted reproductive technologies, genetic testing and ultrasound services.	26/6/2014	463.67	1.19	1.28	0.87	4.30	27.67	1.00	4.40
MVP	Medical Developments International Limited	Medical and veterinary equipment, including pain management, resuscitation and asthma management products.	15/12/2003	82.85	0.96	1.96	0.71	-3.83	-25.07	53.00	-
MX1	Micro-X Limited	Develops and manufactures a range of mobile X-ray imaging systems for medical applications.	22/12/2015	56.81	0.11	0.19	0.09	-2.58	-4.26	4.00	-
MXC	MGC Pharmaceuticals Limited	Innovator in phytocannabinoid-based medicines within the biopharmaceutical industry.	21/12/2006	11.68	0.00	0.02	0.00	-0.74	-0.41	-	-
MYX	Mayne Pharma Group Limited	Pharmaceutical commercialisation and manufacturing. Development of oral drug delivery systems.	29/6/2007	404.10	4.75	6.51	2.68	82.63	5.75	70.00	-
NAN	Nanosonics Limited	Ultrasound probe disinfection: Trophon device.	17/5/2007	1,423.91	4.71	5.81	3.27	3.39	138.94	46.00	-
NC6	Nanollose Limited	Uses industrial organic and agricultural waste products to produce plant-free cellulose for use in the food and medical industries.	18/10/2017	8.19	0.06	0.09	0.04	-0.89	-6.18	1.00	-

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NEU	Neuren Pharmaceuticals Limited	Biopharmaceutical therapies for brain injuries, and neurodegenerative and neurodevelopmental disorders.	3/2/2005	1,537.77	12.15	15.17	5.31	0.15	8,100.00	33.00	-
NGS	Nutritional Growth Solutions Limited	Develops, produces and sells pediatric protein supplements in the United States and internationally.	30/10/2020	4.27	0.02	0.14	0.01	-4.43	-0.38	-	-
NOU	Noumi Limited	Sourcing, manufacturing, selling and distribution of plant-based beverages, and dairy and nutritional ingredient products to wholesale and consumer markets.	7/11/1985	33.25	0.12	0.26	0.06	-42.88	-0.28	-64.00	-
NOX	Noxopharm Limited	Development of drugs to make radiotherapy more effective. NOX66 is the company's pipline product.	9/8/2016	11.11	0.04	0.33	0.03	-5.28	-0.72	6.00	-
NSB	Neuroscientific Biopharmaceuticals Limited	NeuroScientific Biopharmaceuticals Limited develops diagnostic and therapeutic treatments for neurodegenerative diseases through preclinical studies of patented technologies.	27/7/2018	13.01	0.09	0.27	0.07	-5.41	-1.66	2.00	-
NTI	Neurotech International Limited	Development and commercialisation of technological solutions for the diagnosis and treatment of neurological conditions. Flagship device is Mente Autism.	4/11/2016	37.58	0.04	0.13	0.03	-0.70	-6.29	1.00	-
NUF	Nufarm Limited	Crop protection and specialist seed company. Manufacturing and marketing of products to help farmers protect crops against damage.	10/11/1988	1,910.26	5.02	6.41	4.85	41.00	12.24	295.00	11.00
NXS	Next Science Limited	Next Science Limited is a medical technology with a research and development centre in Florida, United States.	18/4/2019	123.50	0.58	0.99	0.48	-8.90	-6.46	4.00	-
NYR	Nyrada Incorporated	A preclinical-stage drug development company. The company specialises in the development of novel small-molecule drugs pertaining to the underlying pathological processes involved in cardiovascular, neurodegenerative and chronic inflammatory diseases.	16/1/2020	4.21	0.03	0.17	0.03	-2.46	-1.10	6.00	-
OCC	Orthocell Limited	Soft tissue cellular therapies for the restoration of tendon and cartilage injuries.	12/8/2014	77.93	0.40	0.51	0.32	-4.40	-8.98	3.00	-
OIL	Optiscan Imaging Limited	Real-time digital microscopic imaging for medical, translational and preclinical applications.	8/8/1997	64.30	0.08	0.15	0.07	-0.75	-10.27	1.00	-
ONE	Oneview Healthcare Public Limited Company	Software platform for patients in hospital and aged care facilities, including dietary services and care management.	17/3/2016	154.81	0.24	0.33	0.06	-3.15	-7.62	1.00	-
OPL	Opyl Limited	Opyl Limited (formerly ShareRoot Limited) provides biopharma and health organisations access to emerging artificial intelligence–assisted technologies and professional guidance to understand and improve healthcare design, development, and delivery.	7/3/1996	4.19	0.05	0.06	0.02	-2.29	-2.10	-3.00	-
OPT	Opthea Limited	Developer of novel therapy OPT-302 for treatment of eye diseases.	18/4/1991	287.30	0.62	1.26	0.52	-47.89	-1.28	27.00	-
OSL	OncoSil Medical Limited	Brachytherapy device that implants a dose of beta radiation into a pancreatic tumour.	15/8/2005	19.76	0.01	0.05	0.01	-1.17	-0.85	1.00	-
OVN	Oventus Medical Limited	Medical devices for sleep apnoea treatment incorporating Oventus Airway Technology.	19/7/2016	4.83	-	-	-	-5.24	-	2.00	-
PAA	PharmAust Limited	Developer of targeted cancer therapeutics for humans and animals. Specialises in repurposing marketed drugs.	5/10/2001	25.46	0.07	0.12	0.06	-0.16	-45.63	1.00	-
PAB	Patrys Limited	Developing novel antibody therapies for a range of oncology indications.	13/7/2007	19.55	0.01	0.04	0.01	-0.30	-3.17	-	-
PAR	Paradigm Biopharmaceuticals Limited	Biopharmaceutical company focused on repurposing pentosan polysulphate sodium for the treatment of inflammation.	19/8/2015	223.86	0.80	2.00	0.79	-16.36	-4.89	25.00	-
PBP	Probiotec Limited	Manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, medicines, and consumer health products.	14/11/2006	212.25	2.61	2.91	2.02	18.18	14.36	-5.00	6.50
PCK	PainChek Limited	Smartphone app to provide pain assessment for those who are unable to communicate .	1/5/2012	38.94	0.03	0.04	0.02	-0.58	-5.17	-	-
PEB	Pacific Edge Limited	Pacific Edge Limited, a cancer diagnostic company, researches, develops, and commercialises diagnostic and prognostic tools for the early detection and management of cancers in New Zealand, the United States, Australia, Singapore, and internationally.	27/9/2021	105.35	0.13	0.49	0.08	-3.09	-4.21	9.00	-

ASX	Issuer Name	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
PGC	Paragon Care Group Limited	Provider of medical equipment, devices and consumables to the healthcare market.	15/10/1999	145.06	0.22	0.44	0.21	0.73	30.14	-	1.20
PIQ	Proteomics International Laboratories Limited	Focused on proteomics. Developed a platform technology for discovering diagnostic tests based on the differences in the protein make-up of people.	16/4/2015	90.53	0.74	1.18	0.61	-5.19	-14.26	6.00	-
PME	Pro Medicus Limited	Provider of radiology information systems and diagnostic imaging.	10/10/2000	7,320.70	70.10	74.99	49.25	58.10	120.65	89.00	25.00
PNV	PolyNovo Limited	Developer of biodegradable polymers for use in medical devices. Lead product is NovoSorb technology in the treatment of burns, surgical wounds and negative pressure wound therapy.	26/11/1998	1,045.70	1.52	2.71	1.22	-1.00	-151.50	9.00	-
PTX	Prescient Therapeutics Limited	Developer of anti-cancer drugs. Lead drug candidate: PTX-200.	19/12/1986	48.32	0.06	0.23	0.06	-0.80	-7.50	3.00	-
PXS	Pharmaxis Limited	Drug discovery to treat inflammatory and fibrotic diseases using an amine oxidase inhibitor chemistry platform.	10/11/2003	28.10	0.04	0.09	0.04	0.84	4.64	2.00	-
PYC	PYC Therapeutics Limited	Development of intracellular biological therapeutics using its functional penetrating phylomers.	30/3/2005	223.97	0.06	0.10	0.05	-0.75	-8.00	1.00	-
RAC	Race Oncology Limited	Development of chemotherapy drug Bisantrene for cancer, particularly acute myeloid leukemia.	13/7/2016	151.65	0.93	2.87	0.82	-6.74	-13.80	17.00	-
RAD	Radiopharm Therapeutics Limited	Radiopharm Theranostics Limited develops radiopharmaceutical and nuclear medicine products for diagnostic and therapeutic uses. Radiopharm Theranostics Limited was incorporated in 2021 and is based in Carlton South, Australia.	25/11/2021	20.34	0.09	0.22	0.09	-5.28	-1.61	2.00	-
RCE	Recce Pharmaceuticals Limited	Development of synthetic antiobiotics to address the threat of antibiotic resistance.	15/1/2016	128.34	0.72	0.90	0.51	-7.82	-9.21	1.00	-
RGI	Roto-Gro International Limited	Automated farming system for producing high-quality plants indoors, including medicinal cannabis, pharmaceuticals and food products.	10/2/2017	4.33	0.22	-	-	-84.40	-0.26	11.00	-
RGS	Regeneus Limited	Cellular therapies focusing on osteoarthritis and other inflammatory conditions, cancer, and wound healing.	19/9/2013	2.76	0.01	0.05	0.01	-1.29	-0.70	-	-
RHT	Resonance Health Limited	Non-invasive medical imaging software services. MRI for liver fat, liver iron concentration and iron levels in bone marrow.	23/10/1987	33.18	0.07	0.09	0.04	-0.25	-28.80	2.00	-
RHY	Rhythm Biosciences Limited	Development of an affordable blood test for the early detection of colorectal cancer – ColoSTAT.	7/12/2017	85.05	0.39	1.42	0.34	-3.84	-10.03	4.00	-
RMD	ResMed Incorporated	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing.	25/11/1999	11,171.96	26.18	36.37	25.63	92.24	28.38	-	18.83
RNO	Rhinomed Limited	Nasal, respiratory and breathing technologies – Mute, a nasal device to assist with breathing through the nose; and Turbine, a nasal dilator.	21/9/2007	21.43	0.08	0.19	0.05	-2.37	-3.16	-1.00	-
ROO	Roots Sustainable Agricultural Technologies Limited	Developing and commercialising technologies to address problems faced by agriculture, including plant climate management and shortage of water for irrigation.	7/12/2017	0.55	0.00	0.06	0.00	-3.72	-0.11	-	-
RSH	Respiri Limited	Devices for detecting and monitoring respiratory disorders.	14/7/2000	31.16	0.03	0.08	0.03	-0.82	-3.90	-	-
SCU	Stemcell United Limited	Growth, reproduction and extraction of plant stem cells for medical and healthcare products.	13/6/2000	2.67	0.00	0.01	0.00	-0.48	-0.42	-	-
SDI	SDI Limited	Research and development, manufacturing, and marketing of specialist dental materials.	7/11/1985	101.63	0.86	0.95	0.77	6.15	13.90	49.00	3.25
SDV	Scidev Limited	Offers coagulants and flocculants in powder and liquid form under the MaxiFlox and MaxiDry name; engineering and process control; chemistry products; chemical batching, storage and dosage systems; engineering solutions; and friction reducers and dynamic shears.	2/5/2002	55.04	0.29	0.46	0.24	1.03	28.16	11.00	-
SHG	Singular Health Group Limited	Singular Health Group Limited, a medical technology company, develops and commercialises volumetric rendering platform for the 3D and virtual reality visualisation of anatomy using standard radiological imagery.	12/2/2021	6.78	0.05	0.17	0.03	-5.37	-0.93	2.00	-
SHL	Sonic Healthcare Limited	Laboratory medicine/pathology, radiology/diagnostic imaging and primary care medical services.	30/4/1987	15,359.62	32.57	36.97	28.07	145.80	22.34	28.00	102.00

ASX	Issuer Name	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
SOM	SomnoMed Limited	Specialises in products for sleep apnoea. Lead product: SomnoMed mandibular advancement splint.	27/8/2004	74.48	0.90	1.72	0.82	-6.66	-13.51	6.00	-
SPL	Starpharma Holdings Limited	Developer of dendrimer products. Lead product: VivaGel for bacterial vaginosis. Dendrimer-enhanced docataxel in clinical development for solid tumours.	28/9/2000	63.63	0.16	0.75	0.15	-3.95	-3.92	10.00	-
TD1	TALi Digital Limited	Cognitive training program for children with attention difficulties.	23/9/2004	3.30	0.00	0.01	0.00	-0.39	-0.26	-	-
TLX	Telix Pharmaceuticals Limited	Development and commercialisation of molecularly targeted radiation in the management of prostate, renal and glioblastoma cancer.	15/11/2017	3,150.07	9.88	12.79	4.37	-33.50	-29.49	3.00	-
TRJ	Trajan Group Holdings Limited	HitIQ Limited develops and commercialises concussion management technology in Australia. The company offers Nexus A9 sensor to record individual head impacts.	7/6/2021	267.67	1.76	2.28	1.35	3.24	54.32	9.00	-
TRP	Tissue Repair Limited	Tissue Repair Limited, a clinical-stage biopharmaceutical company, develops advanced wound healing products for chronic wounds and the aftercare of cosmetic procedures in Australia.	18/11/2021	13.10	0.28	0.38	0.20	-6.44	-4.35	37.00	-
TRU	TruScreen Group Limited	TruScreen Group Limited, together with its subsidiaries, develops, manufactures, and sells cancer-detection devices and systems in New Zealand, Mexico, China, Russia, Zimbabwe, Papua New Guinea, and internationally.	6/1/2021	10.00	0.02	0.05	0.02	-0.62	-3.87	1.00	-
TSN	The Sustainable Nutrition Group Limited	The Sustainable Nutrition Group produces, manufactures, and distributes a range of hemp products in Australia. The company offers its hemp products under the Mt Elephant, Australian Primary Hemp, Australian Superfoods, and Field Day brands to retail, wholesale, ecommerce, and white-label customers.	23/12/2003	1.41	0.01	0.12	0.01	-3.10	-0.32	2.00	-
UBI	Universal Biosensors Incorporated	Specialist medical in-vitro diagnostic tests for point-of-care; blood test C-reactive protein test.	13/12/2006	50.97	0.24	0.35	0.19	-10.18	-2.36	11.00	-
UCM	Uscom Limited	Non-invasive medical devices in the field of cardiac, vascular and pulmonary monitoring.	10/12/2003	9.91	0.05	0.08	0.04	-1.50	-3.47	-	-
VBS	Vectus Biosystems Limited	Drug discovery and development company. Lead product VB0004 has anti-hypertensive properties, and anti-fibrotic activity in the heart and kidneys.	23/2/2016	21.28	0.40	1.05	0.40	-9.03	-4.43	9.00	-
VHT	Volpara Health Technologies Limited	Research, development and manufacturing company that provides digital health solutions for personalised breast cancer screening.	27/4/2016	203.49	0.80	1.05	0.46	-3.74	-21.39	2.00	-
VIT	Vitura Health Limited	A medicinal cannabis company that plans to enter the medicinal cannabis market in Australia with both THC and CBD products.	7/11/2019	250.44	0.45	1.05	0.29	1.79	25.14	4.00	1.00
VLS	Vita Life Sciences Limited	A pharmaceutical and healthcare company, mainly engaged in formulating, packaging, and sales and distribution of over-the-counter medicines, health supplements, vitamins, and investments.	23/8/2007	79.85	1.48	2.10	1.35	13.37	11.07	61.00	6.00
WNX	Wellnex Life Limited	Wellnex Life Limited (formerly Wattle Health Australia Limited). Health and wellness products with scientific and nutritional benefit.	15/3/2017	22.70	0.05	0.10	0.05	-3.05	-1.72	-	-
WOA	Wid Open Agriculture Limited	Wide Open Agriculture Limited operates as a regenerative food and agriculture company in Australia. It offers regenerative beef, lamb, and poultry products, as well as pantry staples under the Dirty Clean Food brand; and regenerative carbon-neutral oat milk under the OatUP brand name through retail and online stores.	6/7/2018	46.57	0.33	0.63	0.15	-9.19	-3.54	12.00	-
XRF	XRF Scientific Limited	Manufacturer and marketer of instrumentation for scientific industries, including commercial laboratories.	31/10/2006	168.57	1.23	1.44	0.62	5.20	23.65	20.00	2.50
ZLD	Zelira Therapeutics Limited	Investing in research and clinical trials to study medical cannabis for a variety of ailments.	28/7/2003	14.18	1.25	3.35	0.90	-108.07	-1.16	8.00	-

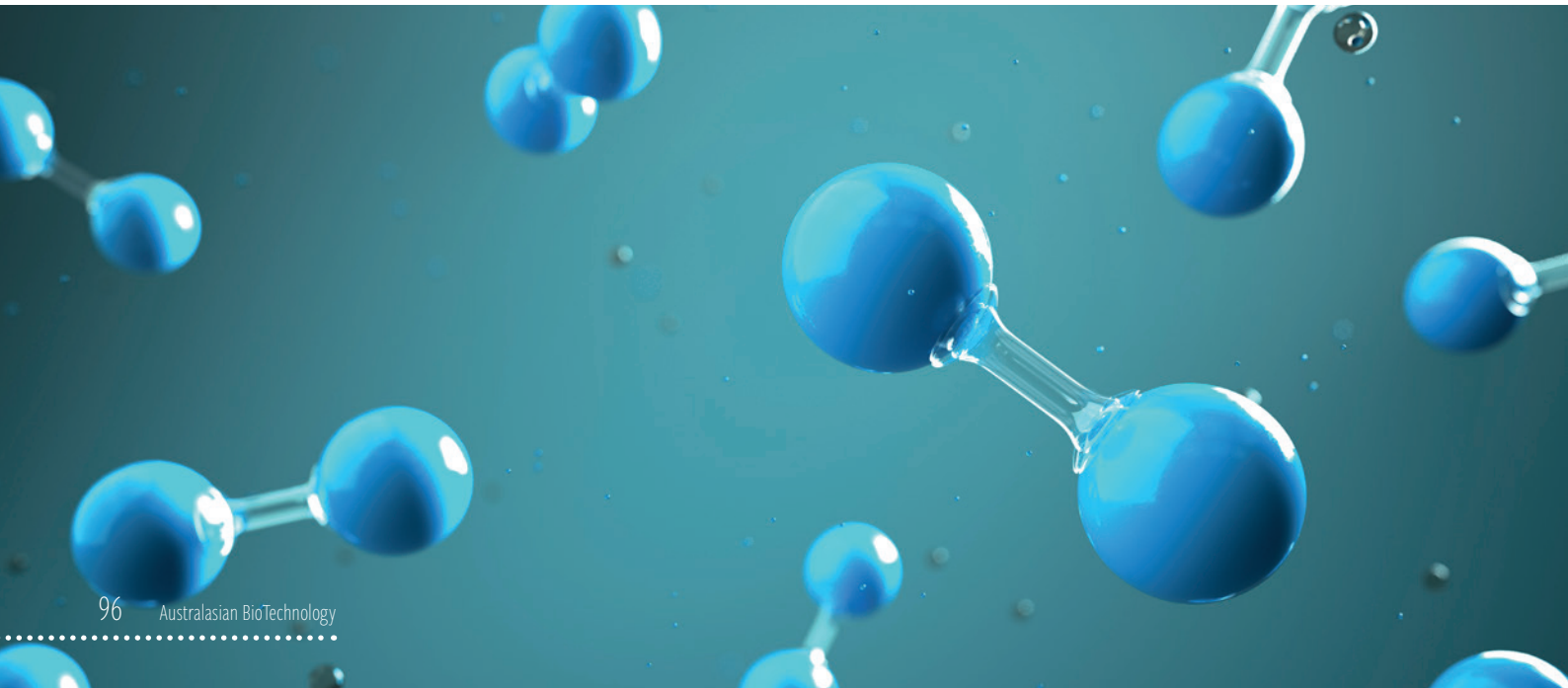
This quarter's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Quarter Return %
LDX	Lumos Diagnostics	$0.08	453.33
AHI	Advanced Health	$0.24	167.05
BOT	Botanix Pharma Limited	$0.18	114.29
HXL	Hexima	$0.02	109.09
OPL	Opyl Limited	$0.05	92.00
RHT	Resonance Health	$0.07	71.43
BIO	Biome Australia Limited	$0.13	71.23
NOU	Noumi Limited	$0.12	60.00
FRE	Firebrick Pharma	$0.26	59.38
AYA	Artrya Limited	$0.35	55.56
BDX	BCAL Diagnostics	$0.14	51.69
BOD	BOD Science Limited	$0.08	50.94
IPD	Impedimed Limited	$0.20	48.15
M7T	Mach7 Tech Limited	$0.78	47.17
CU6	Clarity Pharma	$1.02	46.76
AVH	Avita Medical	$4.95	44.74
IIQ	Inoviq Limited	$0.71	41.00
CAT	Catapult Group International Limited	$1.03	40.14
AVE	Avecho Biotech Limited	$0.01	40.00
ZLD	Zelira Therapeutics	$1.25	37.36
1AI	Algorae Pharmaceuticals	$0.01	33.33
VIT	Vitura Health Limited	$0.45	32.35
AXE	Archer Materials	$0.51	31.17
NGS	NGS Limited	$0.02	30.77
MYX	Mayne Pharma Limited	$4.75	29.08
MX1	Micro-X Limited	$0.11	27.91

This year's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Year Return %
IPD	Impedimed Limited	$0.20	170.27
AVH	Avita Medical	$4.95	156.48
NEU	Neuren Pharmaceuticals	$12.15	125.00
BOT	Botanix Pharma Limited	$0.18	114.29
XRF	XRF Scientific	$1.23	100.80
ALA	Arovella Therapeutic	$0.05	84.62
HXL	Hexima	$0.02	84.00
MAP	Microba Life Sciences	$0.37	72.09
BDX	BCAL Diagnostics	$0.14	68.75
AHI	Advanced Health	$0.24	67.86
ONE	Oneview Healthcare	$0.24	65.52
BIO	Biome Australia Limited	$0.13	62.34
CU6	Clarity Pharma	$1.02	60.63
TLX	Telix Pharmaceutical	$9.88	56.08
CYC	Cyclopharm Limited	$2.30	51.48
VIT	Vitura Health Limite	$0.45	48.39
1AI	Algorae Pharmaceuticals	$0.01	41.74
LDX	Lumos Diagnostics	$0.08	33.87
PME	Pro Medicus Limited	$70.10	29.87
EBR	EBR Systems	$0.85	25.19
BXN	Bioxyne Limited	$0.02	23.08
COH	Cochlear Limited	$261.70	20.94
PBP	Probiotec Limited	$2.61	19.42
MVF	Monash IVF Group Limited	$1.19	18.65
M7T	Mach7 Tech Limited	$0.78	18.18
VHT	Volpara Health Technologies	$0.80	17.65

Data current at 20 August 2023. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Evans and Partners Proprietary Limited and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.



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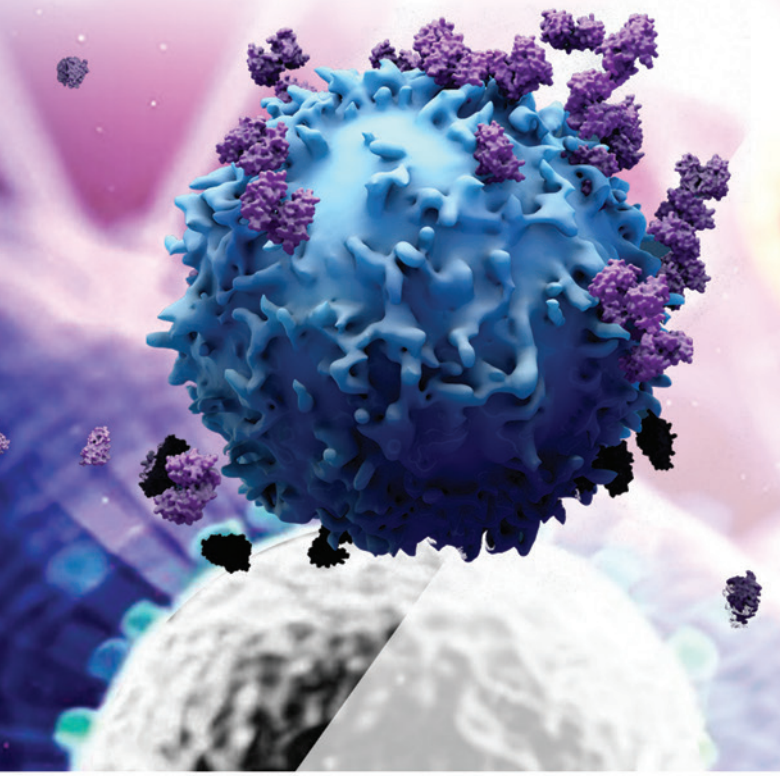

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