April 2023 | Volume 33 | Number 1

Australasian BioTechnology

The journal of AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Attracting investment in Australian biotech: a US investor's perspective

Industry Excellence Awards winners making waves

Microbiome's role in drug development

Bias in AI: an approach to detection and evaluation

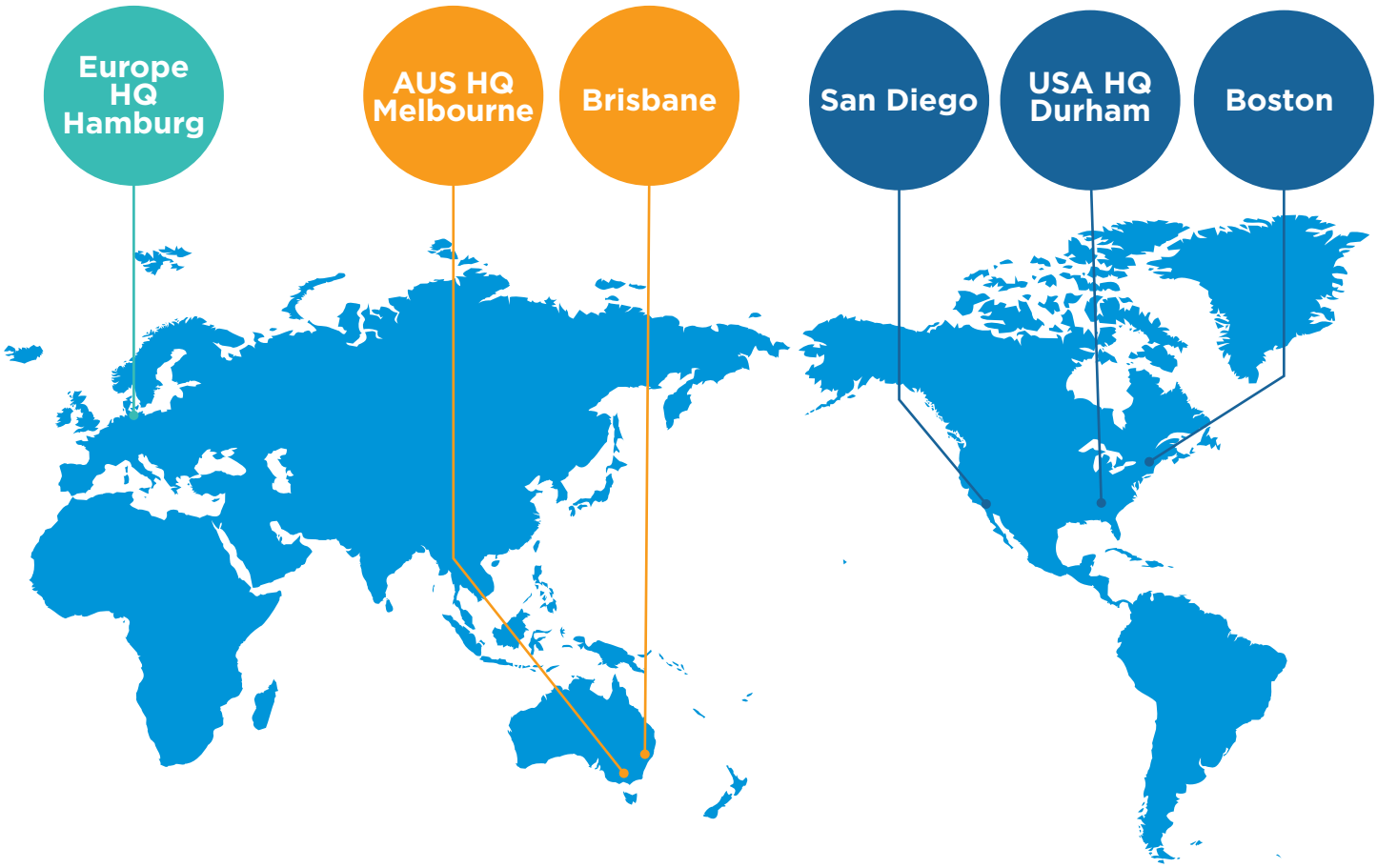
AND MORE...

PRINT POST APPROVED 10101022288

360biolabs® A BIOAGILYTIX COMPANY

Local knowledge, global network

We offer the full spectrum of bio-analytical lab services for small and large molecules in all phases of drug development, with the added benefits that come from conducting your early phase clinical trials in Australia.



Maintain continuous scientific excellence post Phase 1 in Australia with our USA and European laboratories operating under harmonised SOPs. Reduce study risk, cost and time by transitioning your successful Phase 1 assays, developed and validated at 360biolabs, to our global locations operating to the same high standards.

Contact
Angela Luttick

bd@360biolabs.com
+61 (0) 400 641 333

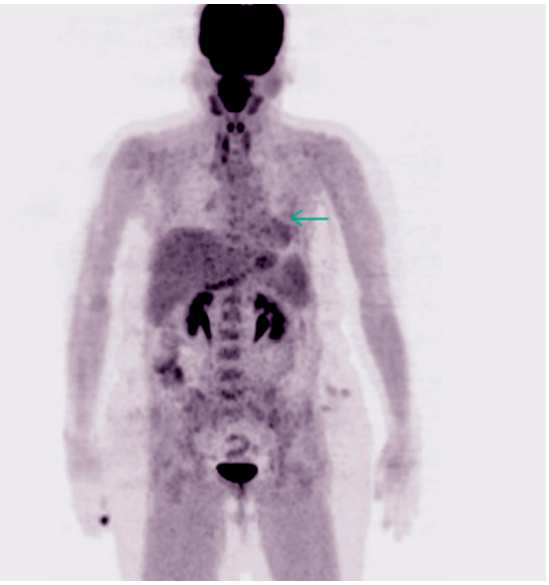
360biolabs Melbourne

85 Commercial Road,
Melbourne, Victoria,
3004, Australia

360biolabs Brisbane

37 Kent Street,
Woolloongabba, Queensland,
4102, Australia

360biolabs a BioAgilytix company



CONTENTS

Australasian BioTechnology **is the official journal of AusBiotech, Australia's Biotechnology Organisation.** ***Australasian BioTechnology*** **reports on research and business news within the biotechnology arena.**

AusBiotech: Level 33, 477 Collins Street, Melbourne VIC 3000
Tel: 0437 126 843 | Email: admin@ausbiotech.org | Web: www.ausbiotech.org

Published by: Executive Media ABN 30 007 224 204
PO Box 256, North Melbourne Vic 3051 | Tel: (03) 9274 4200
Email: media@executivemedia.com.au | Web: www.executivemedia.com.au

Editors: Eden Cox and Kate Hutcheson
Editor in Chief: Giulia Heppell
Designer: Sam Garland
All stock images from iStock.com

NONCLINICAL AND CLINICAL SUPPORT FOR PSYCHEDELIC COMPOUNDS IN AUSTRALIA

As Australia becomes the number one destination for psychedelic and psychoactive therapeutics in research and development, Agilex Biolabs' experience provides fast and efficient drug development.

AUSTRALIA MADE INTERNATIONAL headlines this year as the first country to officially recognise psychedelics as medicines.

This monumental step not only allows psychiatrists to prescribe drugs like MDMA and psilocybin to patients, but it also opens the door for biotech and pharma companies developing psychoactive therapeutics to gain efficiencies by placing research and development activities in Australia.

Conducting preclinical research and clinical trials for psychedelic compounds is, on average, four months faster in Australia compared to other countries. Every research facility involved in studies is required to have licences and permits in place to demonstrate and document the safe handling of materials, but the processes to obtain permits is relatively streamlined in Australia, and allows experienced and reputable laboratories to start research activities more quickly than those in other parts of the world.

One example of Australian efficiency is that in order to perform a contracted research study with a scheduled compound, the laboratory performing the study can start up research and development activities if they hold a valid permit to work with the drug (such as ketamine or tetrahydrocannabinols (THC)), rather than having to apply for a unique permit for each and every study, as is required in the United States and other countries. Laboratories do need to secure import permits for each shipment of restricted compound coming in from overseas, but there are also domestic sourcing options for drug manufacturing or commercial procurement within Australia.

As a leading United States Food and Drug Administration (FDA)-inspected bioanalytical laboratory in Australia, Agilex has more than 25 years of experience supporting clinical trials, and is at the forefront of bioanalytical support for psychedelic trials in Australia.

Drug sponsors with psychedelic compounds can depend on the experienced team at Agilex for nonclinical study packages, regulatory experience, and a strong track record of meeting international regulatory standards – including FDA and European Medicines Agency standards.

Agilex customers can contract packages that include a full Investigational New Drug-enabling preclinical study package, nonclinical bioanalysis, clinical pharmacokinetic sample analysis, biomarker analysis, and clinical kits – all together, with one provider. This alleviates stress from planning complex development programs, and instils confidence that many moving pieces are managed seamlessly to transition a new drug from preclinical development into clinical trials.

While clinical research support options are widely recognised as plentiful in Australia, the country's availability to support nonclinical drug development is not as well known.

The new custom-built toxicology facility in Brisbane

Agilex Biolabs offers the largest facility for GLP rodent studies in Australia. The new custom-built toxicology facility has more than 10,000 square feet of laboratory space, and the toxicology group has more than 15 years of experience in providing regulated in-life studies to drug sponsors headed towards clinical trials in Australia and elsewhere. In addition to the new Brisbane facility, Agilex's Adelaide campus houses multiple bioanalytical facilities for small molecules, peptides, biologics, cell and gene therapy, vaccines, and other modalities.

As new psychedelic compound–based medicines are developed, having an expert partner to develop specialised detection methods for patient and preclinical samples is of high importance.

Most psychedelic compounds belong in a drug category known as 'small molecules'. Small molecules are primarily detected using highly sensitive, specialised instruments called mass spectrometers. With a strong reputation in Australia for bioanalytical expertise, as well as access to the latest equipment, Agilex's quantitative mass spectrometry experts deliver rapid and reliable bioanalytical results for clients. The Agilex team is also often recommended for 'rescue studies', where the compound proved especially difficult to work with at other biolaboratories.

Both the bioanalytical and toxicology groups at Agilex have experience working with many existing scheduled compounds (e.g., ketamine and psilocybin), as well as new chemical entities based on psychedelically active molecules. As medicinal cannabis has drawn attention over recent years, Agilex has been involved in many clinical trials supporting the analysis of cannabidiol and THC, with assays developed and validated by its expert research and development scientists. A number of these trials have investigated novel delivery systems and combinations of drugs, which is also common to the psychedelics space.

Expert LC-MS/MS bioanalysts and world-class equipment for small-molecule bioanalysis

Another critical piece to consider when selecting a contract research organisation partner is whether they have, or can get, licences for the specific molecules of interest. Agilex has licences to work with an extensive list of scheduled drugs, including:

- CBD
- THC
- psilocybin
- psilocin
- ketamine
- morphine
- pentobarbital
- isoflurane
- heparins
- tetracaine
- benzylpenicillin
- buprenorphine
- MDMA.

As emerging biotech companies look to Australia as an option for their research and development activities, the capabilities and experience of Agilex and other specialised service providers can be an important factor in evaluating whether an Australian strategy will be the right fit. Ultimately, Australia's ecosystem of experienced research and development partners allows biotech companies to navigate their drug development pipeline with efficiency and confidence, which means sooner access for patients that need them.

To learn more about how Agilex can support you, visit www.agilexbiolabs.com or connect with the team for a confidential discussion at bd@agilexbiolabs.com.

CEO REPORT

BY LORRAINE CHIROIU, CEO, AUSBIOTECH

This year is off to a strong start as we steam ahead with work that aligns with the goals and vision set out in the 'Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry' (the Biotechnology Blueprint), which was launched last year.

DEVELOPED BY INDUSTRY for industry, the Biotechnology Blueprint presents a shared industry vision and a 'blueprint' for navigating the biotechnology ecosystem, as it aspires to build solid companies, create more jobs, commercialise more technologies, build sovereign capabilities, and deliver greater benefits and returns to Australia and Australians.

To capitalise on this, we held a one-day AusBiotech CEO Policy Forum that united 27 CEOs with the Hon. Ed Husic MP, Minister for Industry and Science, alongside commonwealth departments and a peak industry body to discuss the key topics of the Biotechnology Blueprint, as well as how, together, we can enhance our sector and support Australia's bioeconomy.

The Forum was a powerful opportunity to bring the life sciences sector's economic and social contributions to Australia to the forefront, and to facilitate increased communication and collaboration between industry and government.

Key policies and topics discussed included:

- the National Medicines Policy and Health Technology Assessment review
- the Medical Research Future Fund
- the National One Stop Shop and National Clinical Trials Front Door
- focus areas of the Therapeutic Goods Administration (TGA)
- the evolving landscape of intellectual property
- the University Research Commercialisation Action Plan.

Our policy and advocacy work has kept us extremely busy, as we have responded to a number of consultations on behalf of the sector, including those for the TGA funding, the National Reconstruction Fund, and a number of C-suite policy round tables and other events.

Record-breaking attendance at AusBiotech events

In line with sector-wide record-breaking stats, we are tremendously proud of the successes we have seen in our international, national and state-based events. Last year, we saw our largest numbers for AusBiotech 2022, AusBioInvest 2022, BIO 2022, AusMedtech 2022 and our NSW Women in Life Sciences Luncheon.

Lorraine Chiroiu

Held in Perth from 26–28 October, Australia's biggest week in biotech included AusBiotech 2022 – Australia's largest life sciences conference, which attracted more than 1000 registered attendees – and AusBioInvest, the sector's premier investment conference, with more than 300 registered attendees.

Running for over 37 years, AusBiotech 2022 featured an industry-led program of more than 160 thought leaders across over 40 sessions that succeeded in inspiring, informing, engaging and enhancing the biotech community.

AusBioInvest 2022, the largest investment and partnering conference in the Australian life sciences sector, featured a program rich with informative and insightful presentations from global venture capital and investment experts, in addition to the 29 Australian early- to late-stage biotechnology companies seeking funding partners that showcased their projects. Save the date for AusBiotech 2023 in Brisbane, from 1–3 November.

An addition to the AusBiotech Board

We were thrilled to welcome Erica Kneipp, Research Director for CSIRO's Human Health program, to the AusBiotech Board of Directors. Kneipp brings with her extensive government expertise and policy experience relevant to the Australian health sector.

Kneipp was a leading figure in the establishment of the $20-billion Medical Research Future Fund and its $500-million-plus Biomedical Translation Fund, which doubled Australia's investment in health and medical research. She also led the government's agenda on clinical trial reform, enhanced by a collaborative industry forum with state-agreed national partnerships, and worked to secure the Research and Development Tax Incentive clinical trial determination.

Kneipp was the driving force behind the Commonwealth Government's Health and Aged Care portfolio's first representation at the BIO International Convention, leading the 2018 ministerial delegation. To this day, she remains a strong advocate for Team Australia's approach to promoting our nation's great biotechnology innovation offerings.

In addition, Graham McLean has been appointed as a Board Observer. McLean brings with him rich and varied experience in health care, including 16 years in executive leadership roles at global medtech company Stryker, where he successfully accelerated technology-led growth in multiple businesses.

Based in Sydney, McLean currently serves as the Chair of the Board of Universal Biosensors (ASX:UBI), is a Non-executive Director at both CleanSpace (ASX:CSX) (a high-quality respirator manufacturer) and Suicide Prevention Australia, and holds advisory roles and investments in a number of smaller Australian biotech and medtech companies, including MedTech Actuator. He is also Chair of the AusBiotech NSW Committee, which provides support, advocacy and events for New South Wales members.

Cell and Gene Catalyst moves forward

The Cell and Gene Catalyst (the Catalyst) is progressing in leaps and bounds with the appointment of a new general manager to drive the initiative, the identification of key priority areas, and with expert working groups up and running.

The Catalyst aims to accelerate the development, manufacture and commercialisation of cell and gene therapies in Australia, positioning the country as a global leader in this field, and driving economic growth. Its vision is that Australian patients will have access to world-class advanced therapies sustained by a thriving Australian cell and gene industry. This national joint venture is a collaborative effort between AusBiotech and Medicines Australia, along with a steering group also comprising CSL Behring, Novartis, Pfizer, Therapeutic Innovation Australia and Cell Therapies.

A number of strategic priorities have been identified, with four key areas of focus now being worked on. These are: attracting, building and retaining world-class talent; fostering collaboration and knowledge sharing; creating a clear regulatory and market access pathway; and building Australian capability across the entire value chain.

The Catalyst has now established working groups to address these specific focus areas and develop solutions that will support the growth of the ecosystem.

Strong attendance at J.P. Morgan

AusBiotech's Australia Hub in San Francisco during the annual J.P. Morgan Healthcare Conference, in January 2023, was well attended, providing delegates with a central base from which to work in the heart of the action. In addition to providing industry colleagues with a base from which to conduct their business, the venue also hosted a networking event.

NSW Women in Life Sciences Luncheon: record numbers

Now in its seventh year, the annual NSW Women in Life Sciences Luncheon, co-hosted by AusBiotech and Medicines

Australia, attracted record numbers this year, with more than 550 attendees.

Keynote speakers included gender equality expert and thought leader Dr Kathryn J. Evans. Dr Evans has more than 25 years of international management experience working with world-leading life sciences companies such as Roche, Cochlear Limited and Sanofi, and is the author of the recently published *Advance Australia Fairly: How a Plan for Gender Equality Can Drive Australia's Economic Success*.

As one of Australia's leading experts in research on women in senior leadership, Dr Evans was awarded a Doctor of Business Administration for her work in this field and, in 2020, her research findings were published in the *Asia Pacific Journal of Human Resources*.

She was joined by CEO and President of Cochlear Limited Dig Howitt. Howitt has been committed to the Champions of Change Coalition's mission to help achieve gender equality and increase the representation of women in leadership since 2018, when he joined the coalition's STEM group.

Back to BIO

The highly popular Australian Pavilion will be back at BIO in Boston this year, showcasing the Australian biotech industry at the world's largest and most influential global life sciences conference. As the national voice of the Australian biotech community, AusBiotech has led the Australian delegation to BIO and hosted the Pavilion for more than 15 years. The Pavilion will showcase Australian capabilities and promote the strength of the national life sciences sector, helping attendees to foster global connections.

The annual mission to BIO is closely aligned with AusBiotech's strategic plan, which seeks to facilitate global engagement in strong, established markets. The BIO International Convention attracts more than 15,000 biotechnology and pharma leaders for one week of intensive networking to discover new opportunities and promising partnerships.

Register now for AusMedtech 2023

We're off to Adelaide this year for the medtech event of the year. AusMedtech 2023 will unite medtech executives, decision-makers and investors to learn, share, discuss and collaborate over the latest research, innovations, ideas, and trends from 24–25 May 2023 at the Adelaide Convention Centre in South Australia. It's an event that can't be missed!

The diverse, high-calibre program, with top-quality speakers, will cover the latest trends, technologies and research, and will include topics such as how to create effective relationships with investors, accelerators and incubators; big medtech and harnessing the pipeline; reimbursement; game-changing new technologies; manufacturing; and much more.

In addition to the jam-packed program, there will be lots of opportunities to network, connect and reconnect with key industry players.

Register now at www.ausmedtech.com.au.

Quality Automation, Locally Made

At **Bosch Australia Manufacturing Solutions (BAMS)**, we support medtech manufacturers with the commercialisation of their medical devices from our purpose-built Automation Centre in Clayton, Melbourne.

We support our customers, with a suite of quality services backed by global Bosch manufacturing know-how.

Robotics & Automation

Manufacturing Consulting Service

Equipment Servicing

Schedule a free tour of our Manufacturing Automation Centre today

boschmanufacturing.au
bams.sales@au.bosch.com
Bosch Australia Manufacturing Solutions (BAMS)

BOSCH | Bosch Australia Manufacturing Solutions

AUSBIOTECH BOARD

Geoffrey Kempler
Chair, AusBiotech Ltd
Chair, Alterity Therapeutics

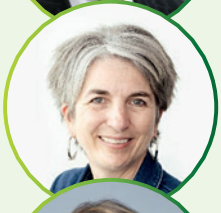
Lorraine Chiroiu
Chief Executive Officer and
Managing Director,
AusBiotech Ltd

Dr Megan Baldwin
Deputy Chair, AusBiotech Ltd
Managing Director and Chief Executive Officer, Opthea Ltd

Serg Duchini
Non-Executive Director, ESFAM Biotech

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

Dr Dean Moss
Chief Executive Officer, UniQuest Pty Ltd



Erica Kneipp
Research Director for the Human Health program, CSIRO

Linda Peterson
Chief Operating Officer and Company Secretary,
BioCurate Pty Ltd

Dr James Campbell
Chief Executive Officer, Patrys Ltd

Board Observer: Graham McLean
Chair, Universal Biosensors

AusBiotech staff list

Chief Executive Officer
Lorraine Chiroiu

Chief Operating Officer
Rosanne Hyland

Director, Membership & Engagement
Tanya Daw

Director, Communications & Policy
Karen Parr

Director, Investment
Lisa Renkin

Investment Events Manager
Kate Wicks

Event Manager
London Mills

Event Manager
Britney Toogood

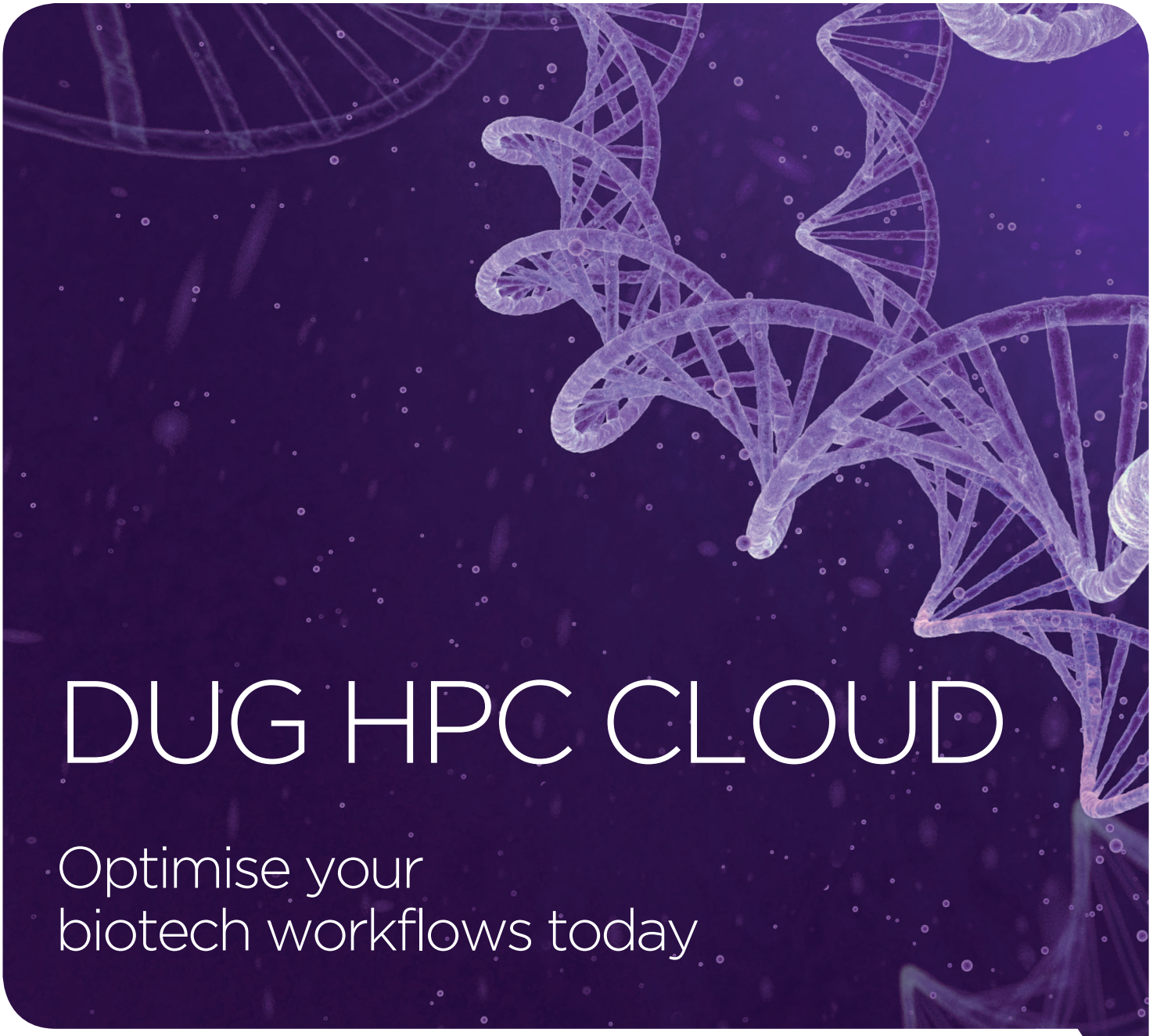
Event Manager
Kirsty Howell

Executive Assistant
Kate Donnellan

Finance Manager
Chaminda Galagedara

Marketing Communications Coordinator
Nicky Tillyer

Member Services Manager
Yvette O'Connor



DUG High Performance Computing Cloud. Green. Efficient. Tailored.

DUG offers powerful bare-metal compute and storage, expertly supported so your work scales with ease.

At the forefront of precision medicine, GenieUs Genomics are developing new treatments and diagnostic tests for neurodegenerative diseases. They were tackling long processing times as large datasets slowed down their workflows. **DUG HPC Cloud** enabled them to scale up and speed up. DUG's **HPC Experts** optimised GenieUs's workflows and software environment. With substantial performance improvements and reductions in memory consumption they were able to process significantly more genomic samples in a shorter time frame—with some parts of the workflow up to 60 times faster!

Email **info@dug.com** to optimise your biotech workflows today.

dug.com/hpcaas

AusMedtech 2023

Australia's Medtech Conference

Adelaide Convention Centre

BACK TO THE FUTURE
24-25 MAY

REGISTER NOW

Join our thriving network of over 400 industry leaders in Adelaide for AusMedtech 2023, Australia's premier medical technology conference for medtech executives, decision makers and investors.

Showcasing the extent of our capabilities, the strength of our talent, and the ingenuity of the industry that is continuing to lead and shape our medtech future, the two-day programme is packed with fantastic features:

- 70+ cutting-edge keynotes and experts
- 25+ interactive presentations and panel discussions
- AusPartnering: one-to-one private business matching
- Networking opportunities to reconnect face-to-face
- AusMedtech Conference Dinner
- Intimate workshops
- AusMedtech Exhibition Hall
- Early-Stage Innovation Forum featuring emerging technologies

Journey to the future of medtech with a programme packed with speakers and topics that will captivate and inspire. Learn from Australian success stories and presentations, with topics including investment, manufacturing, cybersecurity, clinical trials and so much more.

ausmedtech.com.au

HOST INDUSTRY BODY

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

HOST STATE PARTNERS

ADELAIDE CONVENTION CENTRE

SOUTH AUSTRALIA

Government of South Australia

Business Events Adelaide

WE 'CAME ALIVE' AT THE BIGGEST WEEK IN BIOTECH

Record numbers of delegates attended Australia's biggest week in biotech in 2022, held in Perth from 26–28 October, during which two conferences, AusBiotech 2022 and AusBioInvest 2022, lifted the profile of the Australian biotechnology industry.

AusBiotech 2022

THE TWO CONFERENCES shared new and groundbreaking knowledge, connected companies, and created access to greater funding sources for companies as they commericalise their world-class science into therapies, diagnostics, and medical devices.

AusBiotech 2022, Australia's largest life sciences conference, attracted more than 1000 registered attendees, while AusBioInvest 2022, the sector's premier investment conference, welcomed more than 300 delegates. The events featured a wide range of national and international experts and keynote speakers that contributed to programs that were rich in thought-provoking topics and discussions, and tackled the pressing issues in the life sciences sector.

AusBiotech 2022 and AusBioInvest 2022 were proudly supported by their Host State Partners, the Western Australian Government and Business Events Perth.

AusBiotech 2022

AusBiotech 2022, which has run for more than 37 years, featured an industry-led program of more than 120 thought leaders

across more than 40 sessions that succeeded in informing, engaging and enhancing the biotechnology community.

It also gave companies a valuable opportunity to meet and connect, both formally (through AusPartnering, AusBiotech's business matching program) and informally (during networking events). This created opportunities to access funding and partnerships to enable the development of world-class therapies, diagnostics and medical devices.

With the events returning to Western Australia for the first time in more than 15 years, the Western Australian community demonstrated their biotech passion, with the following people engaging throughout the week:

- the Hon. Roger Cook MLA, Deputy Premier of Western Australia
- the Hon. Stephen Dawson MLC, Minister for Innovation and the Digital Economy, Medical Research, Emergency Services, and Volunteering, Western Australia
- the Hon. Amber-Jade Sanderson MLA, Minister for Health and Mental Health, Western Australia
- Professor Peter Klinken AC, Western Australia's Chief Scientist.

Key highlights from the program included:

- Professor Fiona Wood AM (Director, Burns Service of Western Australia; and Director, Burn Injury Research Unit, The University of Western Australia) presented the inspirational story of spray-on skin cells that were used to treat burns victims of the 2002 Bali bombings, and marked the 20th anniversary of the tragedy.
- Professor Marvin Caruthers (Distinguished Professor, University of Colorado) shared his insights on the biotechnology industry's transformation through groundbreaking DNA synthesis chemistry.
- Elizabeth Koff AM (Managing Director, Telstra Health) revealed what's required before the full potential of our Australian health system can be realised.
- The illustrious AusBiotech and Johnson & Johnson Innovation Industry Excellence Award winners were revealed (see page 20).
- The AusBiotech Life Sciences Legacy Award recognised Dr Andrew Forrest AO and Nicola Forrest AO for their generous and active support of medical research and Australian life sciences innovation.

The Hon. Stephen Dawson MLC, Minister for Emergency Services, Innovation and the Digital Economy, Medical Research and Volunteering, Western Australia

Early-Stage Investment Forum

The Early-Stage Investment Forum encourages, recognises and rewards some of Australian life sciences' most promising early-stage technology and projects. It gives candidates the opportunity to receive early 'real life' feedback from a panel of experts and investors, which is essential for commercialising early-stage projects and technologies.

The Forum features quick pitch presentations to a panel of industry experts, who offer their time to support the next generation of leaders by giving presenters the opportunity to gather valuable feedback that will help them to commercialise their projects and technologies.

AusBiotech 2022's Forum welcomed 22 pitches from research institutes, universities, hospitals, and pre-series A companies in the area of human therapeutics and enabling technologies.

Congratulations to Dr Melissa Knight from Knight Life Consulting, representing QIMR Berghofer Medical Research Institute, for her pitch on Professor Rajiv Khanna and Dr Paulo Martins's off-the-shelf CMV EphA3 CAR T cell therapy; and to Jonathan Bernardini from the Walter and Eliza Hall Institute of Medical Research (WEHI) for his presentation on BioTACs, the next generation of cell-surface targeted protein degraders. See the article on page 27 to read more about the projects.

The 2022 Early-Stage Investment Forum was proudly supported by WEHI.

AusBioInvest 2022

AusBioInvest 2022, the largest investment and partnering conference in the Australian life sciences sector, featured a program rich with informative and insightful presentations from global venture capital and investment experts, in addition to the 29 Australian biotech companies seeking funding partners that showcased their projects.

Highlights included presentations from Australian expats Dr Arjun Goyal, Co-founder and Managing Director of US-based life sciences venture capital firm Vida Ventures; and Dr Nilay Thakar, Principal at global venture capital fund ARCH Venture Partners. They shared their perspectives on emerging funding models and strategies for capital raising, and provided their expertise on matching appropriate sources of capital to a

Continued on page 14

Revolutionising the Traditional Approach to Medicine

R529

R327

R435

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.

Sepsis

UTI

Burn Wounds

Diabetic Foot Ulcers

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

Universal **Mechanism of Action**

Recce Pharmaceuticals

recce.com.au

ASX: RCE, FSE: R9Q

Continued from page 12

company's point on the development pathway. In addition, Dr Daniel Getts, Co-founder and CEO of Myeloid Therapeutics (a US-based, clinical-stage mRNA-immunotherapy company), joined AusBioInvest 2022 to share his vast knowledge and experience in leveraging opportunities to accelerate innovation in Australia and the United States. Read more about their insights on page 30.

The Australian Securities Exchange's General Manager, Listings, James Posnett, joined AusBioInvest 2022 to provide an up-to-date market analysis, including opportunities and headwinds for Australian life sciences, which was particularly timely given the sector had seen 26 biotech listings in 24 months.

AusBioInvest 2022 also featured an invitation-only Investor–CEO Dinner, supported by Tenmile's Tattarang, enabling investors and CEOs to continue their conversations in a relaxed environment, and to build relationships that will contribute to the advancement of our sector.

Specialists in ultra-low temperature storage and cryogenic storage

Biological Storage Specialist

Cryosite has 20 years' experience in biorepository. We provide interim and long term secure storage for investigational products including drugs, biologics, human tissues, pharmacokinetic (PK) samples and material for GMP.

Cryosite provides storage across the temperature controlled spectrum: from controlled ambient storage (15–25°C), through cold room storage (2–8°C), including controlled cold room storage of vaccines, frozen storage –20°C to –80°C, to –150°C and below.

- BIOLOGICAL STORAGE
- CELL BANKS (MCB & WCB)
- CORD BLOOD
- CRYOGENIC STORAGE
- RESEARCH SAMPLES

CONTACT CRYOSITE:

+61 2 8865 2000
biologicals@cryosite.com
www.cryosite.com

cryosite
biological storage specialists

Licenses held include: TGA License Number MI-18072008-LI-002488-11 • Class 5.11 Biosecurity Containment – N2115 • NSW Health Department Licence (GWP)

INDUSTRY EXCELLENCE AWARDS WINNERS MAKING WAVES

The AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards recognise innovative companies and individuals in Australia's world-class biotechnology, medical technology and healthcare sectors. The winners were announced at AusBiotech 2022, with their outstanding contribution and achievement recognised.

AusBiotech and Johnson & Johnson Innovation Emerging Company of the Year 2022: Fusetec

When Fusetec set up shop in 2017, it had a burning ambition to respond to the need of all surgeons in training: something to practice on. Cadaver training has been the cornerstone of medical student and resident education for hundreds of years, but it has its limits. There aren't always enough of them, and it is tricky to order ones with the breadth and complexity of factors, and pre-existing conditions, that are routinely found on the operating table. What's more, cadavers come with risks; potentially harmful bacteria and the need for strict environmental conditions add further challenges to an already complex task.

Australian-grown Fusetec made international history when it sailed in with its anatomically accurate, soft-tissue, human bio-models to solve many of the issues that human cadavers pose.

By fully understanding the needs of surgeons and the patients it was treating, Fusetec designed and manufactured models with various complex anatomies and pathologies to upskill a surgeon on a specific procedure. Free of any harmful bacteria, and not requiring a wet lab environment, the models can be consistently reproduced to enhance surgical training standards globally. For the first time in history, manufacturing multiple and accurate models can translate to being able to access skills more

Left to right: Dr David Cade, Telix; Lorraine Chiroiu, AusBiotech; Professor Steve Wilton AO, Perron Institute for Neurological and Translational Science, and Murdoch University; Kathy Connell, Johnson & Johnson Innovation; Professor Sue Fletcher AO, Murdoch University and PYC Therapeutics; (on behalf of AusBiotech Life Sciences Legacy Award winners, Dr Andrew Forrest AO and Nicola Forrest AO) Dr Steve Burnell, Tenmile; Mark Roe, Fusetec; and Claire Beattie, Johnson & Johnson Innovation Partnering Office @Monash.

accurately in the classroom. This revolution has dramatically reduced the need for medical students, residents and surgeons to practice on living patients and/or cadavers.

The result is not only more accurate training, but also more accessible training. Another challenge that human cadavers pose is that they are not always in abundant supply, and the COVID-19 pandemic reduced their prevalence dramatically. The result was a gap in the market that Fusetec was able to fill.

With perpetual research and development intertwined into Fusetec's core DNA, Fusetec has commercialised products across several surgical disciplines, including orthopaedics, otolaryngology, neurology and gynaecology, with a pipeline of new products constantly under development.

Throughout 2022, Fusetec went global, exporting its bio-models to more than 20 countries and envisioning an increasing demand over the next decade. If technology continues to improve, there may even be a time when cadaver training is eliminated completely.

Fusetec also opened the world-first Advanced Surgical Training Clinic in Adelaide, using bio-models exclusively and creating a safe surgical training environment that is free from the risk of harmful bacteria. Throughout the year, Fusetec hosted surgical training courses for medical device companies including Johnson & Johnson, Stryker, Karl Storz, Medtronic, Hologic, Ipsen, Medartis, and more. Surgical training courses were attended by surgeons travelling from around the globe to rehearse the latest techniques or surgical approaches in everything from fixing fractures to removing tumours.

In 2023, Fusetec plans to scale up, creating 157 direct jobs in the fields of research, production and administration. In addition, it expects to create an additional 800 jobs indirectly in South Australia within the supply chain, medical tourism and higher education sectors.

Looking ahead, Fusetec foresees rolling out its surgical training clinic to medical institutions in all corners of the globe, thereby reducing risks in surgical training while also upskilling surgeons more readily and with a greater breadth of practice. The result is better trained surgeons and more lives saved. A win-win situation for all.

AusBiotech and Johnson & Johnson Innovation Company of the Year 2022: Telix

Australian-born and Melbourne-headquartered biopharmaceutical company Telix Pharmaceuticals Limited has gone global with its highly successful Illuccix®, generating A$156 million in fiscal year 2022 since it was launched in the United States in April 2022, and now with commercial operations in Europe and Japan.

With a total shareholder return of more than 800 per cent since its initial public offering in 2017, Telix also has a strong and significant pipeline of products being developed that address unmet medical needs, including more than 20 Telix-sponsored and -funded investigator-led clinical trials spanning Phases 1–3.

Success like this saw Telix win the AusBiotech and Johnson & Johnson Innovation Industry Excellence Award for Company of the Year 2022.

AusBiotech spoke to Kyahn Williamson, Senior Vice President Corporate Communication and Investor Relations, about the secrets to Telix's success in such a competitive market.

Congratulations on winning the 2022 Company of the Year! Telix is one of Australia's big success stories. What has been behind that?
A key driver of Telix's success has been the team's ability to identify assets that have shown promise in academic and preclinical or early-clinical-stage programs, sometimes as non-radiolabelled molecules. We have licensed these, or worked collaboratively to take them through trials on a pathway towards commercialisation, with the necessary investment in manpower and resources required for a marketing authorisation application.

We have also invested heavily in manufacturing and supply chain infrastructure, including our own manufacturing facility in Europe and working with best-in-class partners. This helps provide as much control as possible when dealing with radioactive products that are decaying from the moment they are produced and require just-in-time manufacturing, with meticulously planned logistics to reach a patient within a matter of days or hours, anywhere in the world.

Finally, everyone across the global Telix Group is united by a common purpose and shared values. Helping people with cancer and rare diseases live longer, with better-quality lives, motivates us in everything we do, every day.

You've gained regulatory approval in a number of international markets – a challenge for many Australian biotech companies. Do you have any advice to share?
Gaining regulatory approvals from the United States Food and Drug Administration, the Australian Therapeutic Goods Administration, and Health Canada is, quite rightly, a tough and extremely rigorous process, and the novel nature of radiopharmaceuticals adds to the complexity. A key to a successful regulatory strategy is developing, as early as possible, a focused target product profile, and mapping out the commercial plan and approval pathway in each country/region. Internal alignment on the product development plan, and on the patent journey, will support early discussions and agreement with regulators on expectations and label strategy.

As you've commercialised Illuccix, what have been the greatest challenges and how did you overcome them?
As second to market in the United States for PSMA-PET imaging of prostate cancer, we needed to really focus on points of difference and added value versus our competitor. The innovation in our product, Illuccix, is that it is a kit-based method for producing the radiotracer on site in any nuclear pharmacy or hospital setting using a benchtop generator. This replaces cyclotron manufacturing, which either requires investment in large capital equipment, or shipping finished doses from the nearest cyclotron source, sometimes thousands of kilometres away.

We built a category-leading distribution network together with our key partners and, from the launch, highlighted the flexibility and improved access afforded by Telix's generator-based product.

Your area of expertise is targeted radiation. What do you think the future is for such precision medicine and the potential it can offer?
Nuclear medicine remains a niche market, representing less than one per cent of the global pharmaceutical industry; but new opportunities lie ahead, especially in radiotherapeutics.

While Telix's lead product is an imaging agent, we are a therapeutics company and are exponents of the 'theranostics' approach, in which imaging and therapy are used together – to 'see and treat' – in order to tackle unmet need in cancer and rare diseases.

The market for therapeutic radiopharmaceuticals is predicted to grow at 17 per cent per annum to 2027 and, in recent years, there have been new approved agents that are starting to bring this category into the mainstream.

Take one area of our pipeline as an example: prostate cancer. Telix's focus on patients and innovation has created what we believe is the most clinically advanced antibody-based PSMA therapy program in development globally. This exciting development in an area of high unmet medical need has generated significant interest among clinicians and medical professionals since the antibody approach may deliver superior efficacy, with reduced potential for undesirable side effects, and a more efficient dosing regimen compared to a small molecule approach (the first small molecule approach approved in the United State during 2022).

What does it mean for Telix to have won this award?
It is an honour to have been recognised by AusBiotech, Johnson & Johnson Innovation and our industry peers on the judging panel. Last year was a pivotal year for Telix, in which we successfully launched our first commercial product, Illuccix, for prostate cancer imaging, and continued to advance a significant pipeline of products that address unmet medical needs. We are very proud to be a part of Australia's thriving, world-class life sciences sector and hope that Telix's story inspires other Australian biotechnology companies to achieve global success.

What's next for Telix?
In 2023, we have embarked on the next stage of our global growth strategy, with the aim of having multiple commercial products delivering on clinical milestones in our therapeutic programs, and continuing to advance the field of radiopharmaceuticals through our research and innovation program.

In the near term, we are focused on recruiting our pivotal Phase 3 prostate cancer therapy trial (ProstACT GLOBAL) and filing a biologics license application in the United States for our kidney cancer imaging agent, TLX250-CDx (which recently reported highly positive Phase 3 results), and a new drug application for our glioma imaging candidate (TLX101-CDx).

Later this year, we also expect to see our manufacturing capability expanded considerably as our radioisotope production facility in Europe is completed and commences operations.

Finally, having overseen a successful launch during 2022, we will continue to grow commercial revenues from Illuccix sales and expand into additional markets around the world.

PUTTING AUSTRALIA'S MEDICAL RESEARCH ON THE MAP

BY PROFESSOR STEVE WILTON AO AND PROFESSOR SUE FLETCHER AO

About our Industry Leadership Award winners
Professor Steve Wilton AO and Professor Sue Fletcher AO's collaboration and pioneering research has resulted in the development of three United States Food and Drug Administration–approved 'exon skipping' medicines that overcome specific genetic mutations that cause Duchenne muscular dystrophy. This saw them awarded the AusBiotech and Johnson & Johnson Innovation 2022 Industry Excellence Award for Industry Leadership.

Their contribution to Australia's biotech industry spans more than 25 years, and their work in antisense oligomer-induced exon skipping puts Australia's medical research into rare diseases and neuromuscular science on the map. All three medicines (Exondys 51, Vyondys 53 and Amondys 45) were developed at the Perron Institute for Neurological and Translational Science with The University of Western Australia, and have been licensed to the US company Sarepta Therapeutics (Cambridge, Massachusetts). In this article, they explain the science and thinking behind their achievements, and where it could lead them next.

Collectively, rare diseases affect approximately seven per cent of the global population, and have presented some of the greatest challenges in drug development. Advances in molecular technologies and an increasing understanding of ribonucleic acid (RNA) biology, however, are providing unique opportunities to address the underlying defects affecting one of the most underserved patient communities – those living with rare inherited disorders.

DUCHENNE MUSCULAR DYSTROPHY (DMD) is an X-linked progressive, life-limiting, muscle-wasting disorder affecting one in 5000 boys, caused by mutations in the dystrophin gene that disrupt the reading frame and prevent translation of a functional, full-length protein. DMD is most commonly caused by frame-shifting deletions of one or more exons that cause premature termination of translation of the dystrophin gene transcript.

Professor Steve Wilton AO

Nearly three decades ago, it was recognised that DMD might be alleviated by harnessing the cellular mechanisms responsible for processing messenger RNA (mRNA). Despite catastrophic mutations in the dystrophin gene, very low levels of alternatively spliced transcripts that could be translated into a functional protein were found in many DMD patients. Advances in nucleic acid chemistry enabled development of synthetic antisense oligonucleotides that can alter mRNA structure to specifically induce alternative 'splice forms' with the potential to alleviate human disease. Our therapeutic strategy for DMD was to redirect processing of the dystrophin mRNA to restore a functional form of the message by specifically removing (skipping) a section (exon) flanking the disease-causing gene lesion to generate an mRNA that can be 'read' by the cell machinery.

The dystrophin gene is massive and complex. The 79 exons that constitute the dystrophin protein-coding sequence are spliced from a 2,300,000-nucleotide pre-mRNA to produce a mature 14,000-nucleotide mRNA. It had been well established that,

Continued on page 22

lithia
life sciences

Australian owned full capability CRO
Local Directorship
Project Management
and Full Project Support

Taking a personalized approach to your project

Who are we?

Alithia Life Sciences is an Australian owned clinical research consultancy launched to support and assist pharmaceutical, biotechnology, device companies and institutional research groups undertaking their project in the Australian region and beyond.

What we do?

Project management and clinical strategy: local and international.

Sponsor executive management and Australian local director support provision.

Access to an extensive network of sites, Key Opinion Leaders (KOLs), vendors, laboratories and R&D tax experts.

Contact: A/Prof Tina Soulis

Founder and Director

tina.soulis@alithialifesciences.com

+61 (0) 429 300 705

SCAN ME

Continued from page 20

generally, dystrophin mutations that do not disrupt the reading frame cause the milder, sometimes asymptomatic disease Becker muscular dystrophy. Although this targeted exon-skipping approach is not a cure, there was hope that disease progression and severity could be reduced.

Eteplirsen, golodirsen and casimersen are three United States Food and Drug Administration–approved morpholino oligomer drugs, licensed through The University of Western Australia to Sarepta Therapeutics, which target dystrophin exons 51, 53 and 45 for skipping, respectively. Collectively, these compounds will restore the reading frame in the most common genomic deletion subgroups – approximately one in three DMD individuals. Treated patients have shown improvements in respiratory function and prolonged ambulation. One participant involved in the first clinical trial in the United States has now been receiving the drug for more than a decade. He turned 21 in January 2023, has graduated from college and remains ambulant. Natural history studies suggest that he should have lost the ability to walk at 11.1 years of age.

One participant involved in the first clinical trial in the United States has now been receiving the drug for more than a decade. He turned 21 in January 2023, has graduated from college and remains ambulant. Natural history studies suggest that he should have lost the ability to walk at 11.1 years of age

A major challenge in developing the exon skipping therapies is the inefficient delivery of the antisense oligonucleotide molecules used (morpholino oligomers) into muscle. Ongoing clinical trials of eteplirsen coupled to a cell-penetrating peptide are showing improved uptake into muscle. What's more, not only is the dosing regimen reduced to once a month rather than weekly, but much higher amounts of dystrophin are being induced.

RNA therapeutics can be considered the exemplar 'precision medicine'; however, mutation-specific therapeutics currently come at extraordinary cost, small patient cohorts present

Professor Sue Fletcher AO

Major advances in the synthetic nucleic acid field, coupled with innovative solutions to oligonucleotide delivery are seeing an almost exponential increase in the number of RNA therapeutics entering preclinical and clinical studies. Affordability of these promising therapies remains an impediment...

challenges in recruiting participants for clinical studies, and inefficient intracellular uptake of nucleic acids has hampered broader application of oligonucleotide therapeutics.

Nevertheless, the promise of disease-modifying therapies that address the underlying cause of diseases cannot be ignored. Major advances in the synthetic nucleic acid field, coupled with innovative solutions to oligonucleotide delivery are seeing an almost exponential increase in the number of RNA therapeutics entering preclinical and clinical studies. Affordability of these promising therapies remains an impediment and must be addressed with urgency. The immediate challenge is to determine how these life-changing drugs can be made available to those who need them, not only those with means. Our research into rare inherited diseases is ongoing.

Professor Steve Wilton AO is the Director of the Centre for Molecular Medicine and Innovative Therapeutics, and the Foundation Chair of Molecular Therapies at Murdoch University; as well as the Director of Perron Institute for Neurological and Translational Science in Perth, Western Australia. Wilton continues to work with Sarepta Therapeutics on neuromuscular diseases, and is also looking at myriad conditions involving metabolism, hearing, vision, skin, renal, neurological and neuromuscular disorders.

Professor Sue Fletcher AO is a Principal Research Fellow at the Centre for Molecular Medicine and Innovative Therapeutics at Murdoch University, where she is working on motor neuron disease. Fletcher is also Chief Scientific Officer at PYC Therapeutics in Perth, Western Australia, and is developing treatments for rare ocular and neurodevelopmental disease.

Professor Steve Wilton AO

2022 AUSBIOTECH LIFE SCIENCES LEGACY AWARD

Dr Andrew Forrest AO and Nicola Forrest AO were awarded the AusBiotech Life Sciences Legacy Award in recognition of their generous and active support of medical research and Australian life sciences innovation.

THE FORRESTS HAVE demonstrated a deep commitment to finding ethical and sustainable solutions to a range of global issues as diverse as childhood cancer, ending modern slavery, and ocean conservation.

Among Australia's most active philanthropists and investors, they have invested more than $2.6 billion since 2001 through the Minderoo Foundation, which they co-chair.

Their commitment to improving equitable health outcomes, and Australia's medical and biotechnology ecosystem through their philanthropic and investment activities is proving transformational for the Australian life sciences sector.

Minderoo's Collaborate Against Cancer initiative works with global partners to overcome the greatest barriers to cancer prevention, diagnosis and treatment. Through Minderoo, the Forrests are accelerating research and discovery of breakthrough therapies to make world-class cancer care accessible to everyone, no matter their address or background. In 2020, Minderoo mounted a pivotal response to the COVID-19 pandemic to buffer Australia's diagnostic testing capacity and personal protective equipment stockpiles in a time of critical need.

Beyond their philanthropy, the Forrest family's Tarrarang Group has supported Australian life sciences companies and recently launched Tenmile, a $250-million venture capital fund dedicated to supporting innovators and companies to create and nurture impactful health technology, and biotech solutions. Tenmile seeks to address unmet needs in health care, and scale an Australian health science and technology sector of global significance.

Dr Forrest said, 'We are passionate about finding ethical and sustainable solutions to a range of issues that impact people and the planet, and we trust that our commitment and passion, in both our philanthropy work and the commercial investments we make, is helping to make the world a better place.

'We back Australian research and businesses, as well as partner with people across the world to share information and accelerate the development of breakthrough therapies, life-changing products, and medical treatments. We are investing in the future of Australian healthcare innovation in a way that hasn't been done here before.'

Dr Steve Burnell, Executive Chair of Tenmile, accepted the award during AusBiotech 2022 on behalf of AusBiotech Life Sciences Legacy Award winners Dr Andrew Forrest AO and Nicola Forrest AO.

Steve Burnell, Tenmile

Pioneers in Field Clinical Engineering.

For over a decade, Clinical Research Engineers have been supplying expert field clinical engineer services. As the only CRO with a dedicated Field Clinical Engineer team in Australia and NZ, Crow Clinical is committed to supporting the advancement of biotech and medical technology and providing hassle free, timely and cost effective solutions for clinical trial sponsors.

Our Field Clinical Engineers (FCEs) are your ambassadors in any clinical environment, becoming an extension of your company and engaged in the full cycle of your medical device trial. Crow Clinical provides service in all aspects of clinical operations including site selection, project management, monitoring and pharmacovigilance.

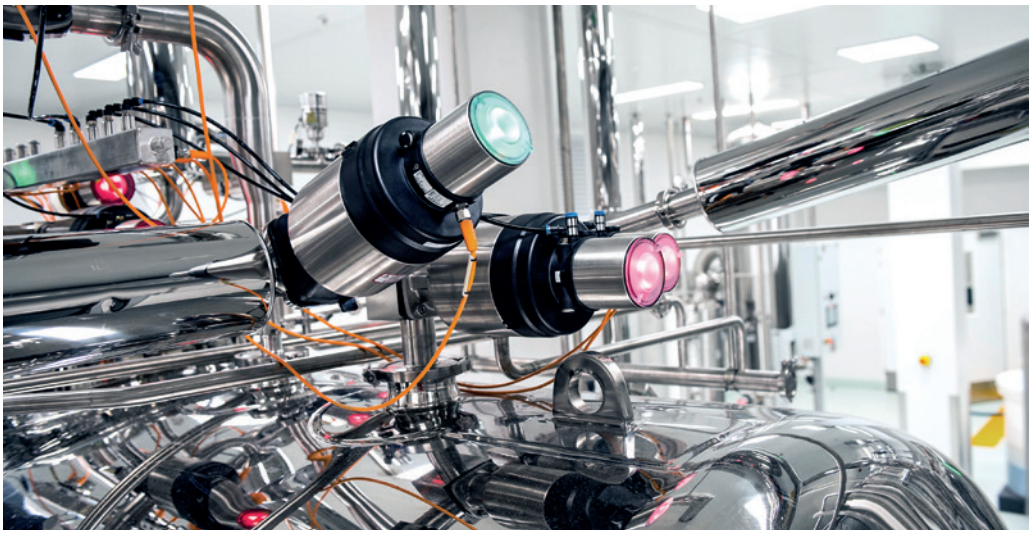
Discover the difference with Crow Clinical. Learn more about our affiliations, partners, and previous clients. Contact us today to tailor our services to your needs.

www.crowclinical.com | info@crowclinical.com

CROW CLINICAL

FROM CONCEPT TO COMMERCIALISATION

ASTRAZENECA SAVES TIME AND SPACE WITH BÜRKERT PROCESS CONTROLS



ASTRAZENECA HAS REVOLUTIONISED its production facilities to meet growing global demand for its products, increasing safety and efficiency for better batch process controls.

Creating a pharmaceutical manufacturing suite is a complex task that is governed by a host of standards and specifications. For the AstraZeneca manufacturing plant in North Ryde, Sydney, the decision to change its primary supplier of process control valves to Bürkert reduced installation and commissioning costs, while also improving process data availability.

The aim of this expansion is to fully automate and modernise the production process, as well as increase efficiency and safety, while also meeting the strictest pharmaceutical standards. The project involves three solution preparation suites, where the active ingredient is combined with water for injection (WFI) and other ingredients to create a batch of medication. Once the batch has been discharged from the storage containers, either clean-in-place or sterilisation-in-place processes are used to clean the production pipework and vessels, ready for the next batch.

Ryan Orbell, National Industry Manager for Bürkert Australia, explains: 'The project was already specified and quoted when we became aware of it; however, I knew Bürkert could offer improved functionality and save on installation time compared to the products that had been specified. I contacted the project team at AstraZeneca to explain how Bürkert could deliver a more effective solution.'

The project engineer with the capital engineering team says: 'Having completed the testing procedures, we believe we are in good hands with Bürkert, which has proven itself to be a true global engineering company with an understanding and a vision of how to truly add value to process automation applications.'

One of the initial criteria for the project was to reduce the number of welded joints and minimise the dead space in the system. Bürkert was able to design and manufacture a number of specialty distribution valve blocks that achieved this aim, while matching all other hygiene standards applied to the rest of the installation. This flexibility to design bespoke components impressed the engineering team at AstraZeneca.

'Bürkert has taken a very professional approach to this whole project,' continues the project engineer. 'Standard products have been available to meet almost every need, while the ability to also design and manufacture custom products in such a short time frame is very impressive. They will certainly feature in our upcoming projects.'

AstraZeneca has truly revolutionised its production facilities to meet growing global demand for its products. In partnering with Bürkert, AstraZeneca now has six suites either in full operation or in construction. As part of the project, AstraZeneca also completely automated processes for the WFI water purification production plant, clean steam, clean compressed air and nitrogen. The valued partnership has ensured that every step of the upgrade met stringent and demanding hygiene requirements, and achieved pharmaceutical manufacturing facility standards.

Up to 75%*
savings based on the reduction of product mixing

*individual results may vary

// Discover why pharma prefer to partner with us >

bürkert
FLUID CONTROL SYSTEMS

INSIGHTS INTO PROMISING EARLY-STAGE TECHNOLOGY

The calibre of candidates for the AusBiotech 2022 Early-Stage Investment Forum was so high that not one but *two* projects were selected as winners of the pitching event judged by an independent expert investment panel.

QIMR BERGHOFER MEDICAL Research Institute and the Walter and Eliza Hall Institute of Medical Research (WEHI) were selected from some of Australian life sciences' most promising early-stage technology and projects, offering them the chance to gather feedback that is essential for commercialising early-stage projects and technologies.

QIMR Berghofer

Dr Melissa Knight pitched QIMR Berghofer's off-the-shelf CMV EphA3 CAR T cell therapy developed by Professor Rajiv Khanna, Associate Professor Corey Smith and Dr Paulo Martins.

'I was thrilled to be one of the winners of the Early-Stage Investment Forum, as it helped to raise awareness of this innovative cell therapy developed by talented scientists with whom I have worked closely over the past three years to commercialise their work,' says Dr Knight. 'I received positive feedback following the pitch by the judges and audience members on the succinct and polished presentation, and on the exceptional science, which was highly encouraging. The successful pitch kickstarted the fundraising campaign required to take the cell therapy to the clinic.'

'QIMR Berghofer is now planning to spin-out the company Cyteph based on the underlying allogeneic CMV-specific T cells, whose unique properties can be harnessed for use as both a standalone cancer therapy and a CAR delivery platform, enabling the generation of multiple dual-targeting CAR T products.

'These virus-specific T cells have the potential to overcome current limitations in treating solid tumours with immunotherapies, with improved trafficking to the brain and cell persistence. Off-the-shelf T cell therapy products also drastically reduce time to treatment compared to autologous therapies, important for aggressive cancers. We are planning a Phase 1 trial of the off-the-shelf CMV T cell therapy in glioblastoma multiforme (GBM) to commence in [the second quarter of] this year, building on two promising Phase 1 clinical trials using autologous CMV T cells in this devastating brain cancer, for which current treatments are largely ineffective,' says Dr Knight.

'The CMV EphA3 CAR T cell therapy is the first asset in preclinical development using the allogeneic CMV-specific T cells as a CAR delivery platform.'

Cyteph is raising capital to fund a Phase 1 clinical trial in EphA3-positive solid tumours and to continue the clinical development of the allogeneic CMV-specific T cells in GBM patients into a Phase 2 clinical trial.

WEHI

WEHI's Jonathan Bernardini's presented BioTACs, the next generation of cell-surface targeted protein degraders (TPDs).

Left to right: Professor Rajiv Khanna, Dr Melissa Knight, Dr Paulo Martins and Associate Professor Corey Smith, QIMR

BioTACs are exciting new TPDs developed at WEHI in Melbourne by postdoctoral researchers Dr Jason Brouwer and Dr Jonathan Bernardini.

TPD therapies retrain the cell's own recycling machinery to target disease-causing proteins for destruction, and have tremendous potential to treat conditions such as cancer, viral infection, and inflammation. Unsurprisingly, there has been intense development of these breakthrough medicines in recent years, with exciting new companies such as Kymera, Nurix and Arvinas leading the way towards the clinic.

BioTACs represent the next generation of TPDs, comprised primarily of protein building blocks. This makes them easier to generate and test rapidly in the lab when compared to their small-molecule predecessors. BioTACs are remarkably efficient at degrading cell surface proteins and can be 'locked on' to specific tissues to minimise off-target effects.

While there is substantial potential for this platform technology, the team is focused on applying BioTACs to diseases of unmet need, where patients would benefit the most from new medicines.

Dr Brouwer and Dr Bernardini aim to spin-out a biotechnology company in 2023 to accelerate their ambition to see BioTACs enter the clinic. Following the AusBiotech Early-Stage Investment Forum presentation, Dr Brouwer and Dr Bernardini have been actively engaging with local and international venture groups and pharmaceutical companies to set the course for this exciting technology.

The team is backed by WEHI's leading clinician scientists, basic researchers and a business development office.

See Australia's latest emerging technologies being pitched at the AusMedtech 2023 Early-Stage Innovation Forum in Adelaide, 24–25 May 2023. Register at www.ausmedtech.com.au.

ATTRACTING INVESTMENT IN AUSTRALIAN BIOTECH: A US INVESTOR'S PERSPECTIVE

BY DANIEL GETTS, CO-FOUNDER AND CEO, MYELOID THERAPEUTICS INC

Australian expat Dr Daniel Getts, Co-Founder and CEO of Myeloid Therapeutics, a US-based clinical stage mRNA-immunotherapy company, joined AusBioInvest 2022 to share his vast knowledge and experience in leveraging opportunities to accelerate innovation in Australia and the United States.

Myeloid Therapeutics harnesses the power of myeloid cell biology to engineer new therapeutic alternatives for patients with cancer and autoimmune diseases. Integrating the fields of RNA biology, immunology, and medicine, the company's proprietary platform provides clinical solutions that match therapeutic modalities to disease conditions, including use of autologous cell therapies, in vivo cell programming using mRNA, RNA-based gene-editing using RetroT™ and multi-targeted biologics. Myeloid is advancing a broad portfolio of clinical and preclinical candidates designed to enable full immune system responses.

Dr Getts was also a primary inventor, and Founder and Chief Scientific Officer of Cour Pharmaceuticals Development Company, a nanotechnology platform company focused on autoimmunity and inflammation. Translating technology uncovered during his PhD, he founded and built the company from discovery through a successful Phase 2 program, culminating in a $420-million deal with Takeda. The company has subsequently completed numerous pharma deals and has multiple Phase 1 and 2 programs. Cour has been built on one round of seed financing with minimal dilution.

When I was asked to deliver a keynote address and chair an investor panel at AusBioInvest 2022, my initial feeling was trepidation. I do not hide well my general poor opinion of the capital markets in Australia; but discussions at the event were fruitful.

WHILE THERE IS strong global respect of Australian science and our early-stage clinical trial system, the overarching perception of the startup ecosystem reflects a nascent segment at best – non-existent at worst. Another looming question was whether the industry in Australia had taken advantage of the recent biotech boom, amplifying its global standing and surfeit of investor capital? The AusBiotech team rightfully focuses on shifting this perception by addressing these issues head-on.

But the discussions held at the event were fruitful. AusBiotech and the Western Australian Government team pulled together an impressive roster to represent the biotech spectrum, including

well-respected local venture capitalist Sarah Meibusch, Dr Tara Speranza, Hashan De Silva, Dr Nilay Thakar, and John Holyoake. Discussion highlighted the contrasting investment models that are being deployed by large US-based venture capitals, typified by ideation and venture creation.

Dr Thakar, representing ARCH Venture Partners, described the venture creation/ideation model of partnering with academics at the early stage, and his comments tell us there is investment enthusiasm and global capital to deploy for compelling opportunities with true transformative potential. This contrasts with the approach in Australia, which remains more traditional and risk averse, with investment being deployed to proven teams and de-risked technologies.

Unsurprisingly, a lot of the discussions focused on how to establish sustained access to capital. A larger pool of capital resides in the United States; however, many more companies vie for access to that same pool. Creating and positioning a differentiated technology is the first step, but gaining access to these pools is equally challenging. Unfortunately, not only is the success rate low, but larger, more sophisticated investors may also love your idea so much that they simply modify it and build their own newco, de novo. A key fact remains – relationships drive, or at least initiate, most investment decisions, presenting another obstacle for Australian biotechs looking to tap global capital reserves, as it requires either the management team or an existing inside investor to bring relationships to open these doors. For Australian companies, this creates a number of challenges to consider and navigate.

A further complicating factor is listing on the Australian Securities Exchange (ASX). In a very high percentage of these cases, an ASX-listing will negatively impact and even prevent US venture capital investors from looking deeply at the listed company. This topic proved a contentious issue. To my surprise, some of the people present highlighted the importance of the ASX as a source of early-stage funding for Australian biotechs,


Daniel Getts, Co-Founder and CEO, Myeloid Therapeutics Inc

rightfully pointing out that there may be no industry without it. At face value, their statements are not incorrect. But the perspective from outside Australia is that the local markets provide insufficient capital to complete the scaling effort and attain global attention to lift these assets to a transformational scale. The ASX listing can become an impediment to scaling companies, and unintentionally caps the potential of listed companies. The message remains that there's a need to develop new avenues to change this 'funding hangover' situation.

But, it's not all grim. On the contrary, there's an opportunity to leverage the inherent Australian ingenuity and pioneering attitude to take the sector to the next level.

Action plan for success

Think 'team Australia'

Understand scale. Within the United States in 2021, the biotech sector provided 2.1 million jobs and $2.9 trillion in economic impact. This is almost double the entire Australian gross domestic product. The size of the local community can be viewed as a blessing or a curse. The concentrated nature of our industry in Australia means it is easier to collaborate, easier to implement changes to promote the broader success of our industry, easier to communicate and easier to get together. Collaboration is inherent in our academic system, and it should be leveraged to push our small, emerging companies closer to the top. I foresee wonderful success for biotech in Australia, after we work together to leverage our size and collaborate effectively, as a team.

Look to universities for new technologies

Identify trends, unmet needs and niches that are less competitive. For example, CAR T companies are insufficiently differentiated and the segment is saturated, so it is a low priority. In contrast, I keep in regular contact with the universities in New South Wales and the Australian Capital Territory to understand the depth and potential of the RNA science, and to scout for innovation that can stimulate the transformative leap. Australian universities remain fertile ground for novel technology that will serve as substrate for new companies in the coming months and years.

Don't be a lemming

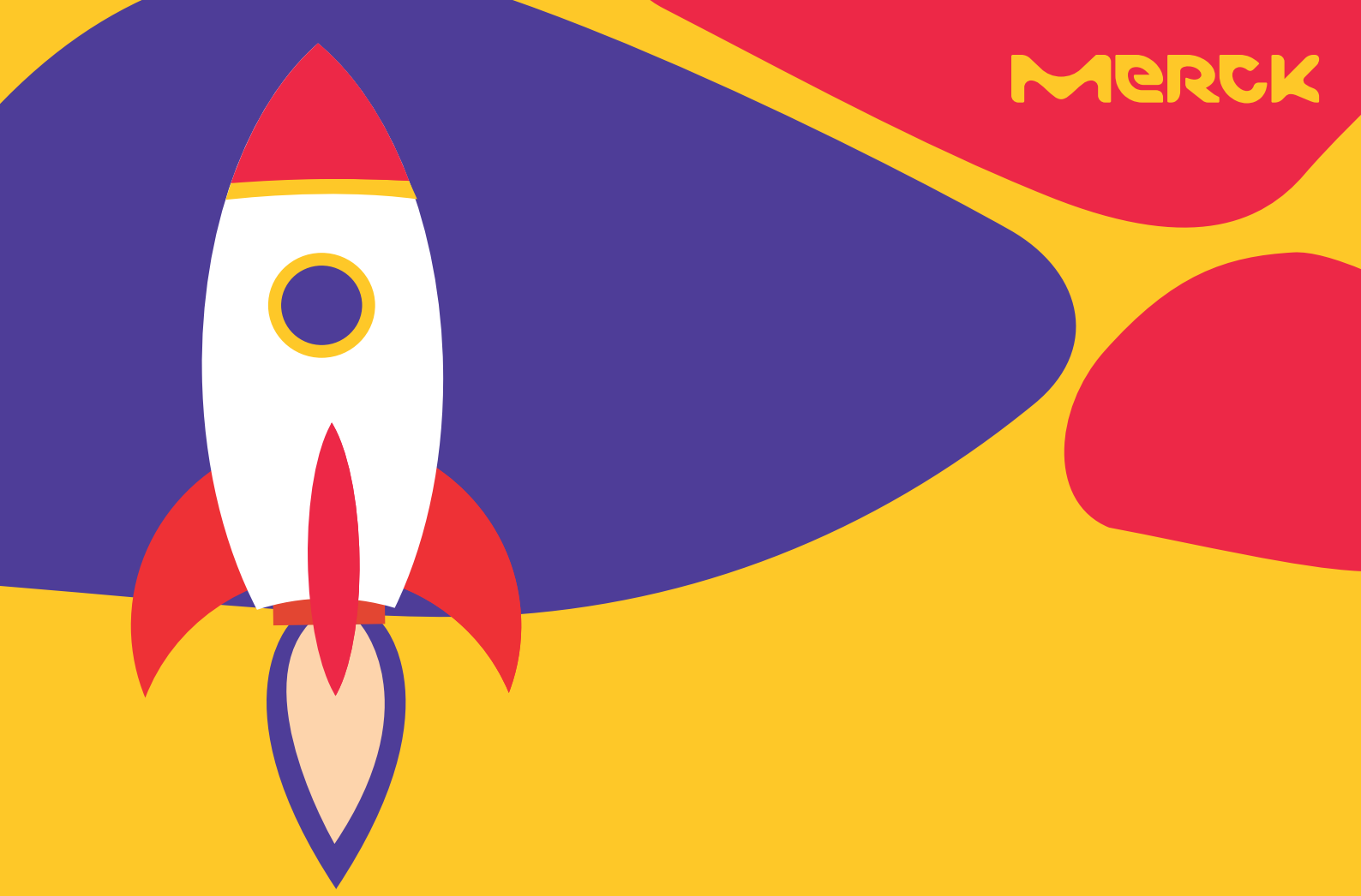
Adopt a forward-thinking mindset. Study and manage risks. Be done with tall poppy syndrome and be done with US bashing. We are a small player on the global biotech stage, and we need the strength of global capital and therapeutic markets. As the global political landscape shifts, our traditionally durable collaborators, including within the United Kingdom, European Union and the United States, will remain important to us. Local entrepreneurs should continue to work closely and stimulate more global contacts to promote overall success. Exposing our great science and capabilities to these countries earlier will further support long-term international investment into the space.

Spend more time with scientists

Show them how to start their businesses. Shape your next funds and team to be positioned to invest more within US biotech companies, alongside top-tier investment funds. Investments that build cross-continent and -border relationships will stimulate further investments, and important credibility. This advantage will ultimately serve the local entrepreneurs well by attracting international investment into the Australian space.

Australia has a lot of raw intellectual assets that can be positioned well to attract investment capital. I still call Australia home and I still believe in the limitless potential of the Australian entrepreneur. We have yet to show the world what we are capable of. There are great possibilities on the horizon. To bring some American bravado to the discussion: Let's do this!

Save the date for Australia's largest life sciences investment conference, AusBioInvest, which will be held on 30 October 2023 in Melbourne. Register at www.ausbioinvest.com.au.



New Lab? Let's Get You Started.

Get your lab off the ground faster with support at every step.

Our Starter Program for new Biotech labs simplifies the task of procuring all the supplies and equipment you need to transform experimental plans into results.

Let us partner with you to get your lab up and running sooner.

- Comprehensive catalog of over 300,000 products, covering solutions for analytical, biological and chemistry applications
- Discount program to support your budget
- Access to Merck Innovation projects including grant programs, awards, and collaboration centres
- Technical expertise and personalised support guiding you through the process

To find out how we can support you on your startup journey, scan the QR code or go to our Starter Program page and fill out the form.

SigmaAldrich.com/starterprogram

Contact Us:

Australia: 1800 335 571

New Zealand: 0800 463 725

Customer Service: CustomerSupport.ANZ@merckgroup.com

Technical Service: TechSupport.ANZ@merckgroup.com

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Ver. 1.0 45375 02/2023

WHY INVEST IN AUSTRALIAN BIOTECH? AN INVESTOR'S VIEW

BY NILAY THAKAR, PRINCIPAL, ARCH VENTURE PARTNERS

There's nothing like a 30-hour flight to remind you how geographically isolated Australia can be – to the investor world in the United States, at least. It would be easy to see that distance as a barrier to attracting capital, no matter how great modern technology can be. And for many US-based venture capitalists, it probably is. But it just means that the Australian industry has to shout a little louder, because it certainly has a lot to offer.

Nilay Thakar, Principal, ARCH Venture Partners

HAVING CREATED, LAUNCHED and worked at life sciences startups, I know all too well the challenges when it comes to raising capital and getting great ideas off the ground, and subsequently driving them to the clinic. These challenges are certainly magnified for life sciences startups within Australia, since most US-based investors may find it difficult to access the local scientific innovations. As my recent experience at AusBioInvest 2022 showed me, there are several reasons why US investors should explore Australian scientific innovation.

At ARCH Venture Partners, we are always looking for the next best thing. We have a capital fund that invests in cutting-edge therapeutics, and in life sciences tools and instrumentation technologies. We're currently operating out of our 12th fund, which closed in mid 2022 for around US$3 billion. We prefer to be the first institutional capital in a company, and build and/or invest in early-stage technologies out of academia typically at Seed Series A.

Indeed, two-thirds of the companies in our portfolio are ones that we have built internally. Some of our portfolio companies that we built and/or invested in at the earliest stage include Illumina, Alnylam, Agios, Beam Therapeutics, Resilience, Vir Biotechnology, bluebird bio, Karuna, GRAIL, Juno Therapeutics, Twist Bioscience, Prime Medicine, and many more. We search for scientific breakthroughs that help alleviate some of our most stubbornly unmet clinical needs; recruit exceptional talent that transforms these early scientific breakthroughs into products; and form a supportive syndicate of deep-pocketed, long-term investors around them that understand the nuances of investing in life sciences.

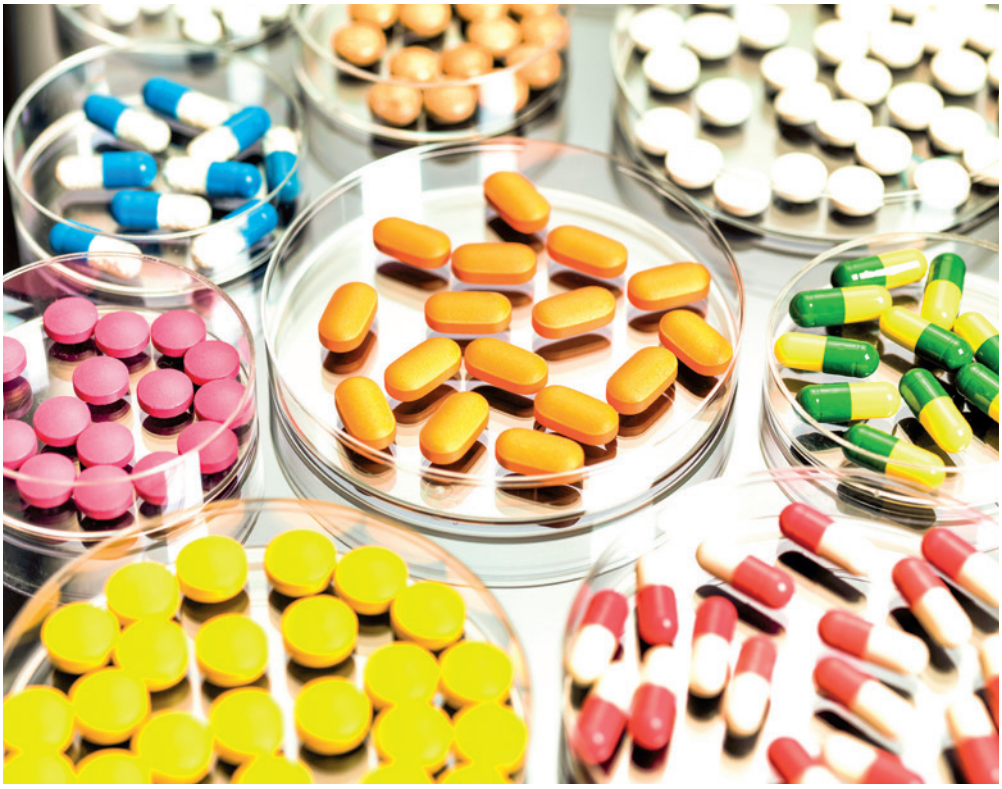
Coming to events like AusBioInvest helped to put me in touch with a sea of talent and expertise that I never knew about. I was able to hear about the latest scientific discoveries on the path to commercialisation, and met with several technology transfer offices at eminent Australian universities and research institutions. This gave me insight into other novel scientific work that is being developed within their institutions, which could be valuable to build a company around, or perhaps in-license as an asset within one of our portfolio companies.

Events like this are invaluable for Australian companies and, due to their geography, they should also be prepared to put in more work trying to network with investors in the United States, China, Japan, and Singapore on a regular basis. This could be at conferences such as AusBioInvest and AusBiotech, but also at other events overseas such as the J.P. Morgan Healthcare Conference, BIO International Convention, Redefining Early Stage Investments conference and other field-specific conferences. Australia-wide delegations, such as those organised by AusBiotech at conferences such as BIO and J.P. Morgan, are particularly powerful as they demonstrate more readily to investors the value of investing in Australia as a whole.

I was pleased to see the strong efforts that the state governments were making to promote investments into their scientific innovations. Australia may be geographically isolated, but colleagues at AusBiotech, Austrade, and state governments work very hard to ensure that the top science happening in Australia gets recognised by investors and pharma groups globally. The scientific, clinical and economic impact of their hard work, I believe, will materialise over the next five to 10 years. I certainly hope to return to AusBioInvest and AusBiotech in 2023 to keep working with the local ecosystem to find breakthrough science, and to drive it to the clinic by leveraging the capital and talent that ARCH Venture Partners brings to the table.

Save the date for Australia's largest life sciences investment conference, AusBioInvest, which will be held on 30 October 2023 in Melbourne. Register at www.ausbioinvest.com.au.

BUILDING A BETTER DOSE-FINDING STRATEGY WITH IQVIA BIOTECH



FOR DECADES, ONCOLOGY drug development has relied on the maximum tolerated dose (MTD) dose-finding method. With the United States Food and Drug Administration's (FDA's) Project Optimus initiative, the landscape of Phase I oncology trials is changing, and there is a greater focus on dose optimisation and patient-reported outcome.

A patient-centric approach to dose optimisation

Dose optimisation is a patient-centric approach that aims to identify a drug's most effective dosage and schedule, while also considering its toxicity to patients. By analysing a wider data pool of nonclinical and patient data, such as genetic make-up, biomarkers and pharmacokinetics, dose optimisation can provide a safer, personalised approach to dosing, leading to better treatment outcomes and fewer adverse events.

How does dose optimisation differ from the MTD method?

The MTD method is traditionally used to determine the highest drug dose a patient can tolerate without accounting for a range of factors affecting each patient's unique biological interaction with the drugs. Its theory is that higher doses lead to better efficacy, but this is not always true and can also lead to higher toxicity.

Dose optimisation, on the other hand, is a more targeted approach to dosing, especially relevant for novel therapies, such as targeted agents, antibody drug conjugates and immunotherapies. It also considers multivariate factors like pharmacokinetics, pharmacodynamics and biomarkers, advocating patients' comfort in treatment and efficacy.

Dose optimisation in early-phase oncology

The new dose optimisation paradigm involves a more sophisticated analysis of dose and schedule, before moving into later-phase trials. This approach will require innovative trial designs and analytical methods, such as modelling and simulation, to gather valuable insights during the early-phase oncology drug development.

An exciting shift in oncology drug development

In summary, the shift towards dose optimisation represents a significant change in oncology drug development. Sophisticated analyses of dose and schedule before moving into later-phase trials ultimately drives safer and better-tolerated treatments for patients, more efficient drug development, and a higher likelihood of success in later stages of clinical trials and regulatory interactions. Therefore, early-phase oncology studies should now include dose optimisation strategies to adhere to the new FDA guidelines.

IQVIA Biotech supports drug developers in dose optimisation

IQVIA Biotech provides adaptable clinical solutions to support drug developers in the new era of dose optimisation, and ensures effective treatment delivery to patients. Its clinical development team brings expertise from two decades of planning and executing clinical trials exclusively for biotech companies. Drawing on IQVIA's unparalleled data and advanced analytics, IQVIA Biotech creates intelligent connections to deliver powerful insights to help customers accelerate clinical development of innovative medical treatments.

For more information, visit iqviabiotech.com.

IQVIA BIOTECH

Integrated Clinical & Commercial Solutions for Biotech

We are the clinical and commercial partner you can count on for flexible solutions tailored specifically for the biotech and biopharma industry.

Our comprehensive suite of services supports you at every stage of the drug development process

- Asset Valuation & Due Diligence
- Drug Development Strategy & Analytics
- Clinical Development
- Launch Strategy & Planning
- Commercialization & Lifecycle Management

For more information, visit iqviabiotech.com

NEEDLE-FREE VACCINE TECH VAXXAS ON RAISING CAPITAL IN THE 2020s

After completing an A$34-million capital raise in late 2022, David Hoey, CEO of Brisbane-based biotechnology company Vaxxas, says that building a solid investment base of clinical data, industry partnerships and technology that poses a tangible solution to a global problem is more important than ever when it comes to completing a successful funding round.

FOUNDED IN 2011 on research from of The University of Queensland, Vaxxas is focused on enhancing the performance of existing and next-generation vaccines through its proprietary vaccine platform, the high-density microarray patch (HD-MAP).

Backed by clinical data, the technology has great potential to improve the speed, scale, and access of vaccine development and manufacturing in response to epidemic and pandemic threats, as well as to play a role in supporting routine vaccinations traditionally delivered via needles and syringes. Vaxxas expects that the patch will initially be used for vaccines for infectious diseases and cancer.

The latest funding is Vaxxas's first major equity round in eight years, and was successfully completed in a challenging investment landscape for biotech. Existing investors OneVentures and UniQuest Pty Ltd led the round, supported by other existing and new investors.

The company plans to use the new funds to advance multiple vaccine programs in the clinic, including its innovative needle-free COVID-19 vaccine patch.[1] Funds will also go towards installing the company's first manufacturing lines at its state-of-the-art biomedical manufacturing facility in Brisbane, which will support Vaxxas's first products through late-stage clinical studies and early commercial production.

Technology a drawcard for investors

Vaxxas's HD-MAP is a small patch with thousands of short microprojections on which vaccines can be 'printed'. Applied briefly to the skin, the patch delivers a vaccine to the high number of immune cells directly beneath the skin's surface. The microprojections trigger natural immune-cellular alarms, causing vaccine components to be trafficked rapidly to lymph nodes, prompting a strong immune response.

1 www.businesswire.com/news/home/20221108005505/en/Vaxxas-Announces-Initiation-of-Phase-I-Clinical-Study-of-First-Needle-Free-COVID-19-Vaccine-HexaPro-Delivered-Using-High-Density-Microarray-Patch-HD-MAP

Continued on page 40

At Syneos Health®, we are a leading fully integrated biopharmaceutical solutions organization built to accelerate customer success. We translate unique clinical, medical affairs and commercial insights into outcomes to address modern market realities. Our focus on customer success enables our experts to collaborate effectively to help accelerate the delivery of life changing therapies to patients worldwide.

Watch the *Conversations on Integration* stories to see how we demonstrate the advantages of implementing this collaborative approach for our customers' businesses.
Go to integration.syneoshealth.com

Syneos Health

Continued from page 38

The technology has clinically demonstrated that delivering vaccines to the dense populations of immune cells in the skin may result in a faster and higher immune response with lower doses, and potentially better protection from disease.

Clinical data also shows Vaxxas's vaccine patch may provide thermostability for certain vaccines, eliminating the need for cold chain storage and distribution. The ready-to-use HD-MAP could be applied by lower-skilled workers, or potentially be self-administered, which can reduce costs, and create access to markets traditionally not reached by needle and syringe vaccines, including low- and middle-income countries.

In combination, these factors offer great potential for the Vaxxas HD-MAP to be an alternative to needles and syringes as the preferred platform for many types of vaccines, something Hoey says is a real drawcard for investors.

'The Vaxxas HD-MAP platform has the potential to fundamentally transform vaccination globally by extending the reach and improving performance of existing and new vaccines. Unless you get a vaccine into people, they're not protected. We have rethought the vaccine equation to make it more seamless and better for the individual,' Hoey explains.

'Our main competitor is needle and syringe – technology that hasn't evolved in decades and that is almost universally disliked.'

Dipping into existing and new pools

Despite successfully raising A$34 million at the end of 2022, Vaxxas says 2021 and 2022 were among the most difficult years for fundraising as a pre-revenue biotech.

Hoey says that the company feels extremely fortunate to have secured such strong backing, and believes the support Vaxxas has historically received from experienced life sciences investors, industry, and government reflects the significant potential of the company's considerable product pipeline.

In 2020 and 2021, the company concluded several important commercial transactions, which fostered confidence among investors. These transactions included a collaboration agreement with global pharmaceutical company Merck, which involved an A$18-million investment, including a combination of equity funding and option fees; A$30 million awarded by the U.S. Government for clinical development of a pandemic influenza vaccine; and reaching an agreement with the Queensland Government to establish a state-of-the-art manufacturing facility at Northshore in Brisbane.

In 2022, Vaxxas completed an important clinical trial for the Bill & Melinda Gates Foundation using a measles-rubella vaccine, and secured more than A$14 million in funding from the Australian Government towards manufacturing infrastructure for the Northshore facility.

'This series of events created a momentum and solid framework from which to build an investment case,' Hoey says.

More to come

Vaxxas has now raised A$100 million in equity and has had considerable non-equity financial support, including more than A$100 million under development contracts with US and Australian governments and industry.

Financial supporters include the US Biomedical Advanced Research and Development Authority, industry collaborators such as Merck, and global health organisations, such as the Bill & Melinda Gates Foundation, the World Health Organization and the Coalition for Epidemic Preparedness Innovations.

With this support, the company is well positioned to advance current product opportunities towards commercial launch; but Hoey says there may be more yet to come as the technology is developed for commercial scale.

'As we continue to hit new value-creating milestones, we'll review opportunities to strengthen our capital base for further expansion,' he says.

Vaxxas vaccine patch in a GP setting

Learn why more clients that choose Crux, stay with Crux.

Over the past six months, Crux Biolabs has become one of the fastest-growing companies in the space. Talk to us to see **why more people are choosing Crux - and staying with us** - as their biolab of preference.

Outstanding customer service in Australia

Learn more about all that is new and why more companies are choosing Crux by getting in touch with our team:

enquiries@cruxbiolabs.com

cruxbiolabs.com

Building 21, 885 Mountain Highway – Bayswater VIC 3153 – Australia

Meet our lead scientists and our expert capabilities

Chemistry
Philip Wright

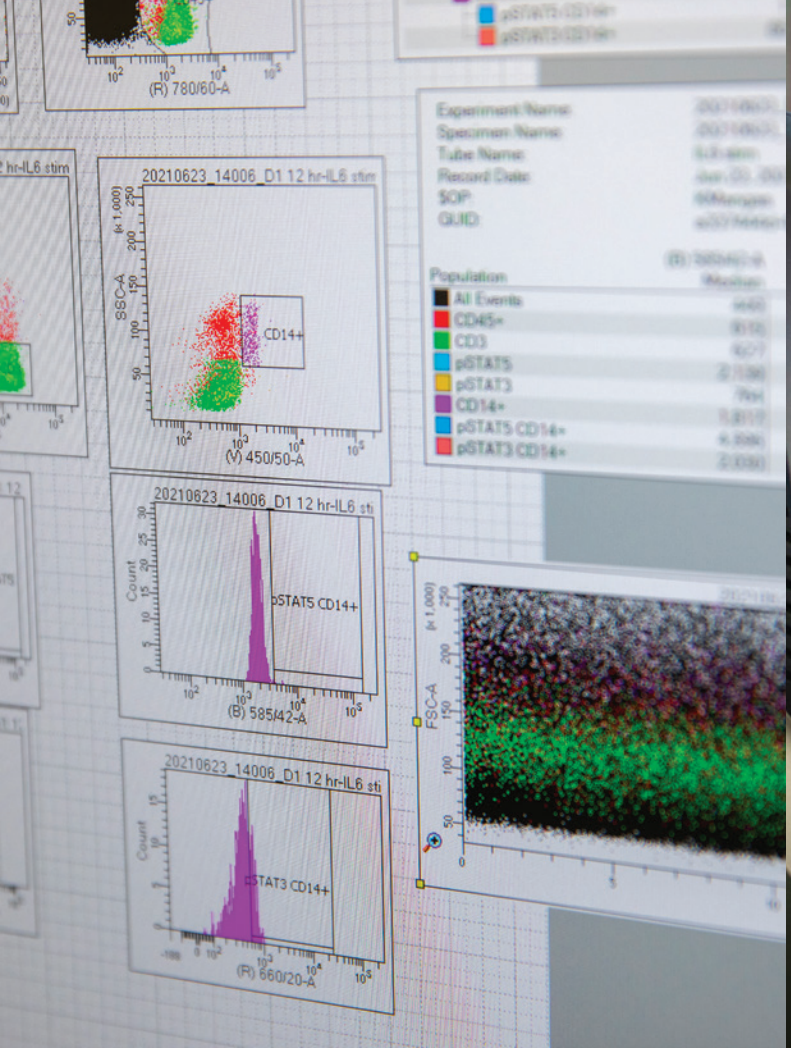
Immunoassays
Anita Yusim

Cellular Biology
Jonathan Ferrand

We specialise in:

- Small & Large Molecule PK
- PD Biomarkers
- EliSpot/Flurospot
- MesoScale Discovery (MSD)
- Anti-Drug Antibodies (ADA)
- Nucleic Acid Extraction (RNA, DNA, ctDNA)
- Flow Cytometry (21-colour)
- PBMC Processing (SepMate, CPT, traditional)
- Cell Culture & Functional Assays (PBMCs, Primary Cells, CAR-T)
- Multiplex Array (Luminex) (Cytokine/ Inflammation Panels, Cancer Biomarkers, Growth Factors, Metabolic Biomarkers)

And more - reach out via our website or email above to talk to our scientists and team.



360biolabs® A BIOAGILYTIX COMPANY

AUSTRALIA'S LEADING AND MOST COMPREHENSIVE SPECIALTY LABORATORY

In 2022, the FDA approved 37 novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs), or as new therapeutic biological products under Biologics License Applications (BLAs). Twenty of the 37 novel drugs approved (54%) were first-in-class, having a mechanism of action that was different from those of existing therapies. Ten of these approvals were biologics.

Biotherapeutics are an important class of drugs used in a range of therapeutic areas including oncology, neurology and rare diseases. The number of next-generation biotherapeutics in the R&D pipeline has risen, to 800 from 600 at the end of 2019. The greatest increase in activity has been seen in CAR-T and NK cell therapies, and gene editing and RNA therapeutics which is a testament to their immense potential for improving human health.

There is great diversity in the mechanisms of action (MoAs) for the pharmacological activity of these biotherapeutics; these can include stimulating a pathway, blocking a deregulated protein's activity and delivering a toxin to disease cells. All biotherapeutics have the potential to trigger an immune response, generating anti-drug antibodies (ADAs) that bind to different epitopes on the therapeutic protein. Of these ADAs, a subset can inhibit or completely neutralize a therapeutic molecule by binding to regions critical for its pharmacological activity. Known as neutralizing antibodies or NAbs, this subset of ADAs have been shown to impact the biological effect of a drug in vivo, and consequently impair clinical efficacy. The clinical effects caused by ADAs, especially NAbs, can range in severity, from benign to mild (loss of efficacy towards a drug for which an alternate therapy may be available) to life-threatening (fatal hypersensitivity response, neutralization of life-saving biotherapeutic, or a non-redundant endogenous counterpart of the therapeutic protein).

It is a regulatory expectation to monitor and characterize the ADAs specific to a biotherapeutic in order to evaluate the drug's efficacy and safety. The FDA and EMA provide recommendations to facilitate the development and validation of assays that assess a therapeutic's immunogenicity potential during clinical trials. The widely adopted multi-tiered strategy for evaluation of immunogenicity recommended by the FDA and EMA consists of a sensitive Screening Assay (tier 1) for the detection of all potential antibody-positive study samples, followed by a confirmatory Assay (tier 2) where screen-positive samples are tested for specificity to the therapeutic. Confirmed positive samples are then tested in a Titer Assay to determine the magnitude of positivity and in a Neutralizing Antibody (Nab) assay to evaluate their neutralising capacity. Further characterisation may include assays to detect particular isotypes.

Assays should be designed to be sensitive, specific, precise and robust. Assay formats can include indirect, bridging, and competitive immunoassays, including enzyme-linked immunosorbent assay (ELISA), electrochemiluminescence assay (ECL), radioimmunoassay (RIA), radioimmunoprecipitation assay (RIPA) and surface resonance assay (SPR).

Oncology is a therapeutic area well known to 360biolabs. In November 2019, 360biolabs supported a Phase 1 study involving melanoma and HCC patients. Thirty-six patients were recruited in Australia for dose escalation, with the study also expanding to the USA, Hong Kong and Netherlands for dose expansion. The study successfully closed in December 2022 after provision of PK, ADA, immunophenotyping via flow cytometry (10 colour flow panel) and inflammatory biomarker assessment (MSD 5-plex). Assays were transferred to our USA laboratories under harmonised SOPs for seamless continued support into dose expansion.

Biotherapeutics in the gene therapy, cell therapy and vaccine space have led to an increased need to perform not only ADA assessment but also cellular immunity testing in a regulated environment to ensure the safety and efficacy of these treatments. Cellular immunity assays are more complex than traditional immunoassays since they include cell culture, often resulting in assays that are less reproducible. Cellular immunity assays must be sensitive enough to reliably detect potentially low levels of T-cell populations and the lack of appropriate reference standards and positive control samples contribute to the challenges associated with these assays.

The current most common method for the measurement of cellular immunity has been Enzyme Linked Immunospot (ELISpot) assays; however, there is a lack of regulatory guidance available for developing and validating these types of assays. The Global CRO Council in Bioanalysis (GCC) was created in 2010 as an independent global consortium bringing together contract research organization (CRO) leaders to discuss various topics and challenges in scientific and regulatory issues related to bioanalysis. BioAgilytix, 360biolabs parent company, is a member of the GCC and prides itself on scientific excellence in cellular immunity testing assays. White papers on specific topics of widespread interest in bioanalysis, including ELISpot, have been published to provide unified GCC recommendations to assist the global bioanalytical community.

As a world-leading authority in the field of immunogenicity testing, large and small molecule PK, biomarkers, flow cytometry, cell-based assays and virology, BioAgilytix understands the complexities of bioanalysis. This case study outlined above demonstrate the diverse service offering at 360biolabs 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.

Contact
Angela Luttick

bd@360biolabs.com
+61 (0) 400 641 333
www.360biolabs.com

360biolabs
Melbourne

85 Commercial Road,
Melbourne, VIC,
3004, Australia

360biolabs
Brisbane

37 Kent Street,
Woolloongabba, QLD
4102, Australia

360biolabs a BioAgilytix company

RELIEF FROM NEEDLES THROUGH MEDLAB CLINICAL'S NANOCELLES

BY JEREMY D. HENSON, TOMAS ANDERSEN, IRENE MORONI AND SEAN HALL, MEDLAB CLINICAL LTD

More than 6.5 million Australians suffer from trypanophobia (fear of needles), but relief may be on the way thanks to innovations currently being developed by ASX-listed biotech Medlab Clinical Ltd.

IT ALL BEGAN when Medlab's Director of Science, Dave Rutolo, took food-grade ingredients and turned them into nano-sized micelles, and discovered that they were exceptionally good at crossing barriers. Materials gain new properties when formed at nanoscale, which is one of the reasons why nanotechnology is such an interesting domain. The superpower that Medlab's nano-sized micelles gain is the ability to carry medicinal cargo across barriers that their individual ingredients cannot traverse.

For example, none of these ingredients can penetrate a styrofoam cup; however, when formed into a nano-sized micelle, they find their way through the mesh of styrofoam fibres that form the wall of the styrofoam cup.

In the same way that Medlab's nano-sized micelles (NanoCelles®) can carry betacarotene across the styrofoam cup wall, they can carry medicines deep into the skin or mucous membranes. This capability can provide relief from needles in two ways: removing the pain caused by needles and replacing needles with a nasal spray.

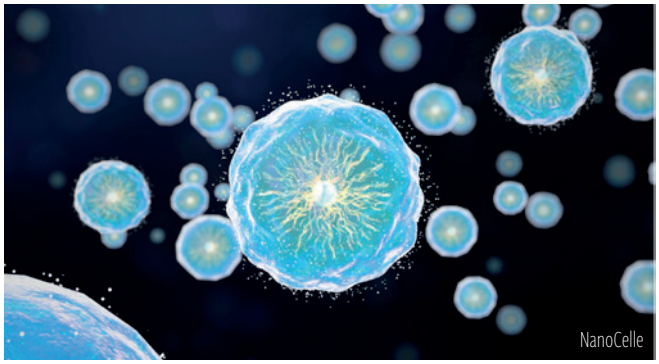
Medlab's scientists have developed a NanoCelle-lignocaine spray, which has completed proof of concept and is now on the pathway to commercialisation. There are plenty of lignocaine sprays and creams already available; however, they take 30–40 minutes to numb the skin. This delay is problematic in many situations, such as in hospitals where doctors move quickly between different areas and preparing the site of venous access 40 minutes before the procedure substantially reduces productivity. Medlab's NanoCelle-lignocaine spray works in less than two minutes and penetrates deeper under the skin to provide more extensive local analgesia. It could be conveniently used just before blood tests, insertion of venous or arterial cannulas, and immunisations to prevent pain, without impacting productivity.

Medlab's scientists are also working on NanoCelle versions of medicines that currently require administration by needles. This would allow them to be delivered by a nasal spray, thus removing the need for injection. This program is a collaboration with Professor Daniela Traini's team from Macquarie University and Woolcock Institute of Medical Research, and Professor Pall Thordarson's team from The University New South Wales RNA Institute. It was funded by a NSW Government grant.

What's more, there's good news for diabetics, as this collaboration is developing a NanoCelle-insulin nasal spray. The team has encapsulated insulin with NanoCelle technology and demonstrated that NanoCelle-insulin is suitable for nasal delivery. With that success under its belt, the team has now turned its attention to NanoCelle-RNA so that the needle can be removed from vaccinations and replaced with nasal spray immunisations.

Success with NanoCelle-insulin and NanoCelle-RNA may also unlock a whole new range of powerful peptide- and nucleic-acid-based medicines that have been ignored until now because there was no practical method of administration.

Medlab Clinical Ltd (ASX:MDC) is pioneering the use of NanoCelle, a proprietary, patented delivery technology using water soluble nanoparticles®, allowing for enhanced medical properties, including increased efficacy, safety, patient compliance and stability. Medlab's investigative drug pipeline comprises several small and large molecules, from repurposing generic medicines to enhancing the delivery of immunotherapies. Patented lead drug candidate NanaBis™ is being developed for cancer bone pain as a viable alternative to opioid use. Data to date strongly suggests that NanaBis may be equally effective in non-cancer neuropathic pain. Medlab operates in Australia (head office), the United States and the United Kingdom.


NanoCelle

AusMedtech 2023

Australia's Medtech Conference

Adelaide Convention Centre

BACK TO THE FUTURE
24-25 MAY

REGISTER NOW

Join our thriving network of over 400 industry leaders in Adelaide for AusMedtech 2023, Australia's premier medical technology conference for medtech executives, decision makers and investors.

Showcasing the extent of our capabilities, the strength of our talent, and the ingenuity of the industry that is continuing to lead and shape our medtech future, the two-day programme is packed with fantastic features:

- 70+ cutting-edge keynotes and experts
- 25+ interactive presentations and panel discussions
- AusPartnering: one-to-one private business matching
- Networking opportunities to reconnect face-to-face
- AusMedtech Conference Dinner
- Intimate workshops
- AusMedtech Exhibition Hall
- Early-Stage Innovation Forum featuring emerging technologies

Journey to the future of medtech with a programme packed with speakers and topics that will captivate and inspire. Learn from Australian success stories and presentations, with topics including investment, manufacturing, cybersecurity, clinical trials and so much more.

ausmedtech.com.au

HOST INDUSTRY BODY

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

HOST STATE PARTNERS

ADELAIDE CONVENTION CENTRE

SOUTH AUSTRALIA

Government of South Australia

Business Events Adelaide

LEADERSHIP AND MANAGEMENT SKILLS ARE KEY FACTORS IN THE SUCCESS OF SCIENTIFIC AND TECHNICAL TEAMS

'LEADING AND MANAGING the People Side of Technology and Manufacturing Teams in Bioscience: Leadership and Management Skills for Laboratory and Scientific Managers' is a training program for high-potential lab scientists, research leaders and technical managers to learn leadership skills, network with their peers, and prepare for more senior roles – conducted by Adjunct Professor Larry Marlow from Marlow Hampshire.

Marlow Hampshire has been privileged to be chosen by over 45 Australasian universities to assist with leadership capability development. The company has trained over 800 researchers, scientists and technicians from the biotech, university and life sciences sectors in areas of strategic thinking, people management and innovation. Many past participants of the program have been internally promoted or have gone on to senior roles at other organisations.

The evolution of this program arose from the realisation that many technical and scientific managers were not being trained in the necessary core skills needed to manage a research or other lab, and to effectively lead scientific, analytical or manufacturing project teams. Many up-and-coming leaders indicated that they wanted more training to prepare for the challenges that they faced in their labs.

Marlow Hampshire's research identified a set of skills and capabilities that, if developed, would assist individuals with a strong technical or scientific background to transition from a focus on their own work and in their own silo, to a different mindset and skill set.

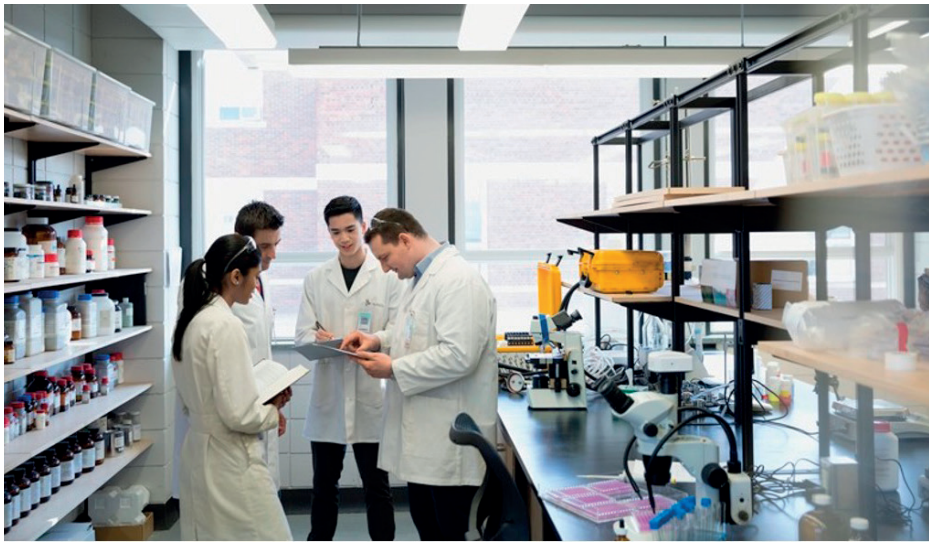
Over the past decade, this program has come to be regarded as the gold standard in Australasia for training technical and scientific leaders.

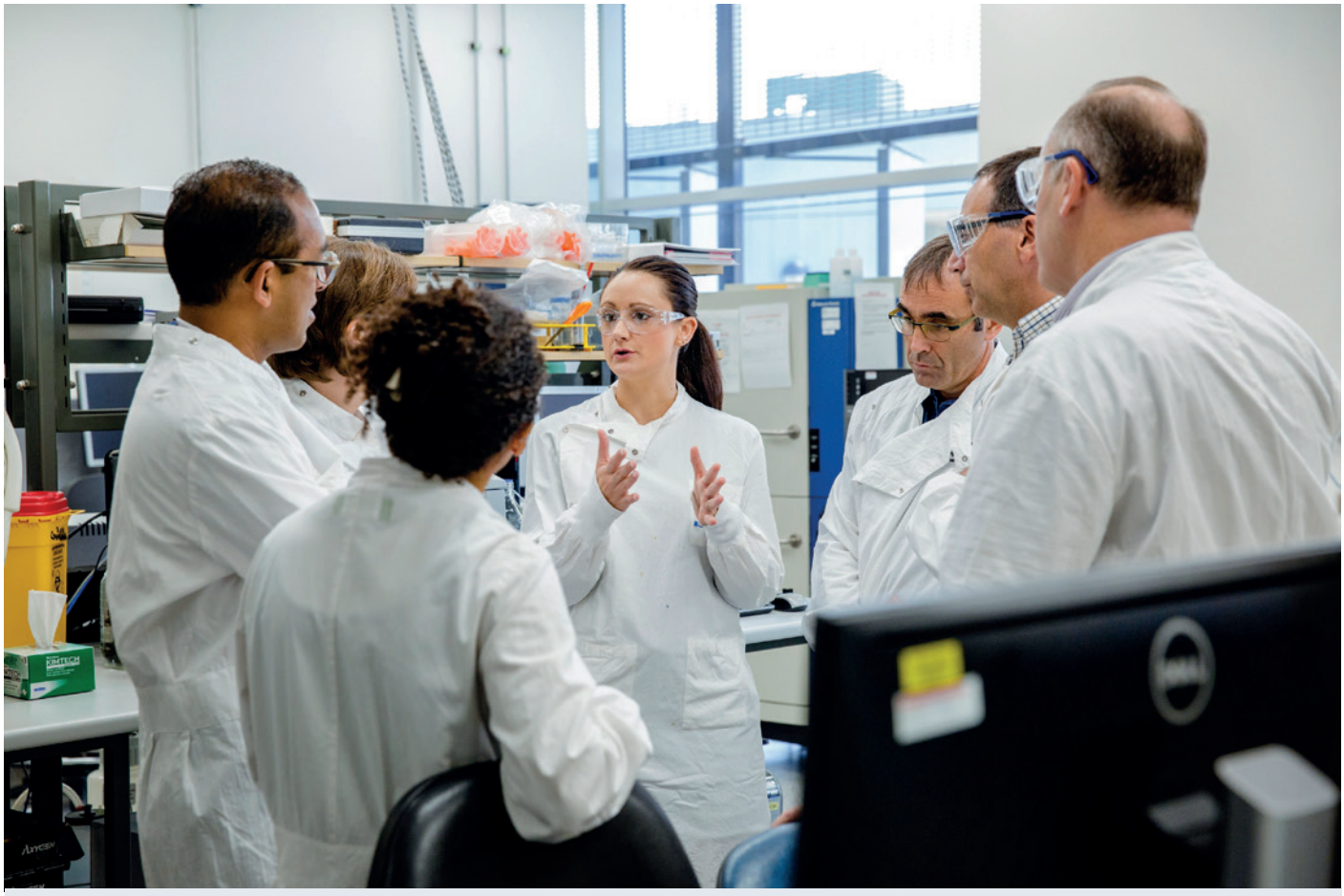
The program takes place over two days and introduces core leadership and management frameworks, concepts, and highly practical tools tailored to the biotech, life sciences, and academic research environments. It is highly interactive and includes an interdisciplinary simulation, as well as an opportunity to practice new skills in a supportive environment.

The program can also be run in-house, as well as customised to reflect a basic research (or academic) environment, or an applied (pharma, biotech, life sciences, private sector) environment.

Participants will learn how to think strategically, interview and hire the best team members, inspire and motivate others, enhance influence skills, give feedback, manage underperformance, navigate difficult conversations, run productive meetings, manage their time, communicate to different audiences, take people through change, build resilience and work-life balance, and so on.

The program can also be coupled with executive coaching sessions by request.





Join LEADING & MANAGING *THE PEOPLE SIDE* OF TECHNOLOGY & MANUFACTURING TEAMS IN BIOSCIENCE: Leadership and Management Skills for Laboratory & Scientific Managers

2023 PROGRAM SCHEDULE

MELBOURNE CBD Program 1: 16 June & 27 July | Program 2: 26 October & 30 November

SYDNEY CBD Program 1: 17 August & 15 September

BRISBANE CBD Program 1: 2 May & 24 May

COST $1,370 +GST

Enquiries, brochure & registration: Helen Cho 0422 449 394 mh@marlowhampshire.com.au

FEEDBACK FROM PAST PARTICIPANTS

"An engaging & thought provoking program"

"Recommend it highly. The best people management program I have attended"

"Every scientific leader needs a program like this"

"The program covered many aspects relevant to my industry. Larry Marlow has a broad experience, a fabulous collection of articles and examples and delivered the content in a very engaging way"

"Great leadership program, extremely beneficial with a good combination of reading material, slides and role play/discussions"

MARLOW HAMPSHIRE

MOLECULAR IMAGING: CHANGING THE WAY WE LOOK AT CANCER

BY BOB PROULX, CEO, IMAGION BIOSYSTEMS

There have been significant improvements in medical imaging technologies over the past 50 years, largely in the areas of improving sensitivity and image resolution while increasing speed and reducing costs. Now, there is a need for 'molecular imaging' that can help us go beyond 'suspicion' to diagnosis.

THERE ARE MANY Australia-based medtech companies working in the medical imaging space. X-rays (including mammography) and computed tomography (CT) have become less expensive and have reduced the amount of radiation needed, while ultrasound has expanded into many areas as a low-cost modality. Magnetic resonance imaging (MRI) remains the best method for most soft tissue imaging applications, due to its better resolution, with new developments in areas of both high magnetic fields (increased resolution) and low field (lower cost and faster). Machine learning (ML) and artificial intelligence (AI) are being applied to many areas of medical imaging to improve the interpretability of the images; for example, by improving mammography use for dense breast tissue.

Bob Proulx

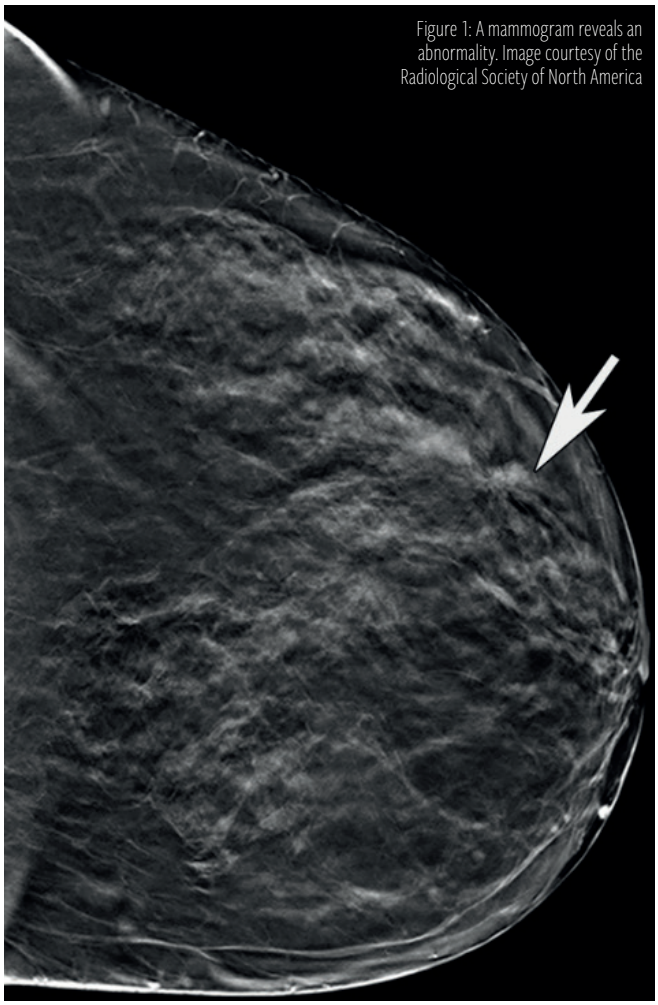


Figure 1: A mammogram reveals an abnormality. Image courtesy of the Radiological Society of North America

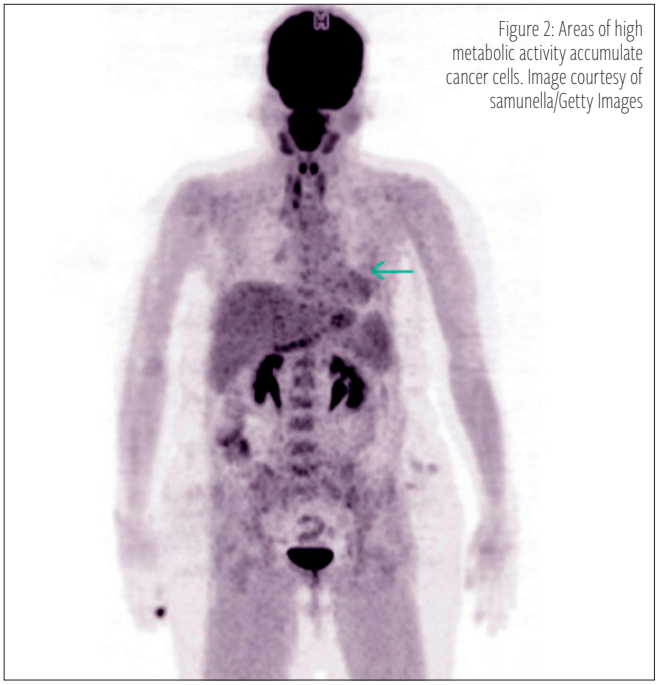


Figure 2: Areas of high metabolic activity accumulate cancer cells. Image courtesy of samunella/Getty Images

Most imaging technologies, however, are still largely limited to identifying a 'region of interest' because conventional imaging techniques are restricted to the identification of anatomical and morphological assessments. Morphological and anatomical visualisation is fine for identifying broken bones, the presence of a fetus, or an aortic blockage, but cancer is a cellular phenomenon and conventional imaging technology cannot identify or differentiate specific types of cells.

Herein lies the mismatch with conventional imaging – current technologies only allow us to find 'abnormalities' or 'suspicious lesions' (i.e., areas of tissue that don't look normal or are different to the surrounding 'normal' tissue). When it comes to diagnosing specific diseases, like cancers, these methods stop at finding a 'suspicious lesion'.

This can best be illustrated by a mammogram, which is a commonly used imaging method to screen for breast cancer. For a trained radiologist, the bright spot highlighted by the arrow in Figure 1 is identifiable as an abnormality. But what is it? Is it a fibrotic mass or cancer?

Over the past few decades, imaging technologies have made significant improvements in image resolution and quality. And, more recently, AI and ML are making advances in image analysis. As a result, we are seeing better sensitivity and an improvement in the ability of trained professionals to interpret disease and health conditions, even for small lesions like the one shown here.

But despite these advances, a biopsy is required to confirm what the abnormality is. While obtaining a biopsy for breast cancer is no picnic for the patient, imagine the complications with suspicious lesions in the brain, the prostate, or internal organs like the ovaries or the pancreas?

Many lives are shattered or lost because we cannot diagnose cancer until it is big enough to be identified as suspicious and then able to be biopsied. There is a need for 'molecular imaging', wherein the imaging modality incorporates the identification or detection of a molecular or cellular signature to go beyond 'suspicion' to diagnosis.

Positron emission tomography (PET imaging) became one of the first methods to add cellular context to anatomical imaging when radiotracers were first paired with a glucose molecule (FDG-PET). This ushered in the era of 'functional imaging' because the radiotracer is taken up in tissues with high metabolic activity. Since cancers are often fast growing, a whole-body scan can reveal where the FDG-PET tracer accumulates. A trained nuclear medicine physician can then identify those regions where the tracer is present due to possible cancer cells from the other areas where high metabolic activity causes accumulation, such as the brain, or areas of inflammation, etc. (as seen in Figure 2).

More recent advances in PET imaging are now pairing radiotracers with more specific biomarkers to achieve molecular imaging. For example, the prostate-specific membrane antigen (PSMA) has been approved for use with the radioisotope gallium (88Ga) for detecting metastatic prostate cancer.

Australia has been a leader in this area, with PSMA-PET being routinely used for patient care and with multiple companies working in this space. A whole-body scan by PET imaging can be

done relatively quickly, compared to a whole-body scan by MRI. Combined with its sensitivity, this makes PET imaging good for identifying if there are distant metastases anywhere in the body. But PET systems are not as prevalent as MRI, especially outside of urban areas of developed countries. Outside of Australia, it remains expensive.

Advances are being made to reduce the radiation dose, but there remain challenges with developing cancer-specific tracers because the half-life of the radioactive tracer needs to be closely matched to the circulating half-life of the targeting molecule. Nevertheless, this is a welcome advance moving in the right direction from functional imaging to true molecular imaging – where a targeting molecule ensures the specificity of the detected lesion.

For the medical imaging industry, improvements in imaging hardware and software, or analytical algorithms, will not be enough. Over the coming decade, we expect to see an increase in efforts to develop 'molecular imaging' agents for many of the imaging modalities, not just PET. For example, multiple companies have obtained regulatory approval for molecularly targeted agents for interoperative use to better identify surgical margins when resecting tumours.

At Imagion Biosystems, we are focused on developing molecular imaging agents using bio-safe magnetic nanoparticle technology. Rather than using radiotracers, the tiny nanoparticles in our MagSense® imaging agents are detectable by conventional MRI and eliminate exposure to radiation for the patient. Our Phase 1 study in Australia is the first of its kind to use magnetic nanoparticles to tag cancer cells and be detected by their magnetic signature. We believe the future is bright and that molecular imaging will change the way we look at cancer.

PROMOTING HEALTH SECURITY RESILIENCE

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

As a division of DMTC Limited, HSSA builds on DMTC's credibility in the defence and national security sectors and is backed by DMTC's internationally-accredited systems for quality and collaboration, and flexible engagement and contracting mechanisms.

HSSA invests in and delivers activities across the program themes pictured to the right. One theme, Medical Countermeasures (MedCM), has been critical in expanding national capabilities and capacity to research and develop vaccines, point-of-care diagnostics and therapeutics against CBR threats.

CAPABILITY THROUGH COLLABORATION

HSSA's success is driven by its ongoing collaboration and partnership with industrial and research organisations, as well as Defence and Government customers. Periodically, the Division seeks expressions of interest for collaborative proposals from prospective industry and research partners, hosts webinars and conferences, and engages with government and other key stakeholders in Australia and abroad.

HSSA welcomes enquiries from organisations interested in advancing sovereign science and technology capability aligned with Australia's national health security priorities.

- CBR Sensing Systems
- Medical Devices
- CBR Modelling & Simulation
- Medical Countermeasures
- Personal Protective Equipment
- Strategic Advisory
- Hazard Management

Learn more about HSSA

Health Security Systems Australia

Wurundjeri Country
Level 1, 620 High Street
Kew, VIC 3101, Australia

dmtc.com.au/hssa/
hssa.enquiries@dmtc.com.au

a Division of DMTC Ltd

MasterControl™

6 Must-Haves for an eQMS

Choose the right quality management system

Read the Industry Brief →

MasterControl

Stay Ahead of Pharma Trends in 2023

Get the tips you need to thrive in pharma manufacturing.

READ THE TREND BRIEF

WHY MICROBIOME DATA IS BECOMING ESSENTIAL IN DRUG DEVELOPMENT

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

Studying the microbiome's interactions with drug products can yield new insights into safety, efficacy and more.

SURPRISING NEW INFORMATION emerged about Metformin, the world's most prescribed blood glucose lowering agent for type 2 diabetes, nearly 20 years after it was approved for widespread use. The medication had a long history, originating as a herbal medicine and going through several cycles of research, rejection, and rediscovery between its first published preclinical study in 1918, and its introduction to the US market in 1995.

During its two decades on the market, Metformin's mode of action was not completely understood. The turning point came after a 2014 animal study showed that the drug seemed to achieve its therapeutic effects, in part, by altering the gut microbiome: the community of microorganisms, including bacteria, archaea, eukaryotes and viruses, that dwell in the host digestive system and are particularly prolific in the colon.

Researchers began to suspect that the gut microbiome, not the host, was, in fact, the drug's primary target. Then in 2015, a definitive study in humans showed a Metformin signature in the human gut microbiome and confirmed that gut microbes were strong drivers of its therapeutic effects. Further work showed that Metformin increased levels of an important metabolite, the bile acid glycoursodeoxycholic acid, by modulating the microbiota to suppress bacteria necessary for the deconjugation of bile acids. Thus, data on the gut microbiome yielded a novel perspective on an older drug, kicking off a new era of research on Metformin and how it can best be used.

The use of higher-resolution microbiome analysis, enabled by next-generation sequencing, has allowed researchers to discover important information about both established medications and new therapeutic agents. As scientific work continues to show the crucial role of the gut microbiome in host immune and metabolic function, microbiome data is becoming an essential addition to clinical trials.

Interactions between the host microbiome and medications have proven to be the rule, not the exception. With microbiome research gathering critical momentum, data and insights on the gut microbiome drives a number of opportunities in the drug development process, helping to build a better understanding of drug safety and efficacy, and potential avenues for a differentiated product on the market.

Indeed, product differentiation is becoming a core business strategy for many pharmaceutical companies, as the market sees fewer 'blockbuster drugs' and more specialty medications that provide smaller individual and targeted revenue streams. Importantly, gaining perspectives on microbiome interactions early in the drug development process can save time in development, ultimately lowering costs.

Drug–microbiome interactions

The unprecedented number of microbiome-related scientific publications show beyond a doubt that the gut microbiome has effects across multiple host systems through different signalling mechanisms, and is interconnected with the host immune system and metabolism.

Various types of evidence show the powerful effects of drugs on the human gut microbiome

In-vitro screening studies show that the majority of medications have the potential to alter the human gut microbiome; this is supported by large-cohort population studies showing that medications are consistently found to explain the largest amount of variation in subjects' gut microbiome composition compared to any other measured factor, including diet. The follow-up work to date has shown that drug-induced effects on the microbiome can have either specific or systemic impacts on the host. In turn, the host gut microbiome shapes the effect of a given drug. Examples in the literature show how the gut microbiome configuration of a patient can influence the effects of a medication, including physiological response, mode of action and toxicity.

Given this research on drug–microbiome interactions, the gut microbiome is shown to be a 'filter' between host and medication, so every drug can be envisioned on a spectrum – from being unaffected by this filter, to being completely dependent on this filter for its effects. This means the

microbiome cannot be ignored in studies of health interventions – whether dietary interventions or drug products. Data on the gut microbiome, in fact, constitutes an excellent opportunity for enhancing drug development, allowing drug developers to gather more information than ever on the drug's safety, efficacy and mode of action.

Benefits of including microbiome data

The insights that come from including quality microbiome data in your clinical trial offer potential advantages throughout the drug development process, irrespective of the investigational modality. These advantages include:

- *Efficacy:* Measuring the direct and indirect effects of a drug on the gut microbiome allows identification of which microbial taxa or functions are associated with efficacy or response. This may help drive more targeted efficacy by using the gut microbiome to stratify patient groups. The microbiome is also a rich potential source of biomarkers for different aspects of response to treatment. Further, since the gut microbiome is modifiable with appropriate interventions, it may be possible to turn drug non-responders into responders through a combination of therapy, diet and other means.

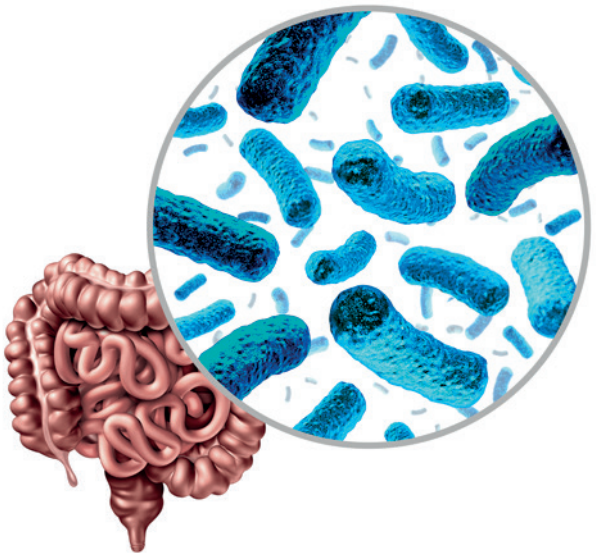
- *Safety:* The gut microbiome could be a means of identifying potential sources of off-target drug effects. Microbial clearance and persistence of a drug can be tracked. In some cases, adverse affects can be correlated with functional changes in the gut microbiome that could provide an opportunity to mitigate such effects.

- *Mechanisms of action:* As illustrated by the example of Metformin, gut microbiome data can create a better understanding of a drug's mechanisms of action, potentially strengthening and accelerating the regulatory pathway. Biomarkers of drug metabolism via the microbiome can potentially be identified.

The gut microbiome can therefore yield insights relevant to all phases of clinical and preclinical trials. Ultimately, such data can lead to safer and more effective products and, as the field advances, opportunities to differentiate it from similar therapeutics on the market.

Successfully incorporating microbiome data

The microbiome is vast and complex, so gaining useful data requires specialised tools for sample collection, measurement, analytics and interpretation. For maximum success, gut microbiome end points should be envisioned from the initial planning stages of the drug development process. Detailed microbiome data is also useful for helping capture potential biomarkers.



Quality, high-resolution data is particularly important early in the process to detect any signals that exist. This data is best obtained through high-resolution shotgun metagenomic sequencing, with specialised tools that can accurately detect and identify species and strains, as well as a comprehensive reference genome database to ensure that we are seeing the full microbiome, and not only the portion of it that is most commonly studied.

Metagenomic data can also interrogate important genes and pathways, which can help uncover the functional impacts of drug interventions. Together, these advanced tools ensure we are able to extract the most meaningful signals and biomarkers from trials, and produce the most powerful models for predictive modelling of response to treatment and patient stratification.

Many potential sources of variation exist in microbiome research. These occur due to cohort selection, sample collection, storage, lab processing and bioinformatic protocols. Confounding factors such as diet and medications must also be managed. This highlights the importance of using a service provider with deep expertise and optimised workflows for reliable results. By using the best tools for obtaining your data, and capturing a high-resolution snapshot of the microbiome in all its diversity, including both known and previously uncultured species, you ensure you can rely on – and invest in – your results.

The future of the microbiome in drug development

The new field of 'pharmacomicrobiomics' is gaining traction, with many more insights to be revealed in the years ahead. Incorporating microbiome data into clinical studies on drug products now is a way to prepare for a future in which gut microbiome data is expected or required by regulators and other stakeholders. More information about the gut microbiome can save money during the drug development process – and, moving forward, the gut microbiome may be the key to improving how patients benefit from drug products, increasing drug efficacy and safety for a healthier future.

Do you need **Life Science** or **Clinical Trial insurance?**

Newline is a leading provider of Life Science & Clinical Trial insurance solutions offering:

- Unparalleled expertise and service with local underwriting and claims handling
- Rapid response for compliant certificates and documents
- Global ability to issue local compliant policies in over 100 countries
- Full Policy limits for US exposures
- Bespoke Medicinal Cannabis wording and more!

*Contact your broker to **learn more.***

Will Clarke
T +61 3 9912 4021 | M +61 477 222 534
E wclarke@newlinegroup.com.au

newlinegroup.com.au

NEWLINE GROUP®

WHERE DO GOOD IDEAS COME FROM?

A YOUNG AUSTRALIAN doctor working in rural India 35 years ago was terrified to see the power of the tetanus toxin molecule when a fit and healthy teenager arrived at the small hospital's emergency department. With severe spasms ricocheting through his body, the boy was suffocating while his throat muscles contracted, completely occluding his airway. Tetanus toxin, secreted by an otherwise harmless bacteria, increases the nerve impulse discharge rate from normal (20 impulses per second at rest) to full bore (200 impulses per second). The result is a dramatic and horrifying presentation of full muscle contraction all over the body, a disease known since antiquity as tetanus. While this young man fully recovered, he was the first of more than 100 cases that the doctor encountered there.

But a thought emerged: what if a single tiny dose was injected into a weak muscle? Not an overwhelming dose, but just enough to move the nerve impulse discharge rate up a little in that muscle only? Back in Australia, the doctor – now a specialist – frequently saw cases of a different condition affecting the airway. Sleep apnoea is a condition where the nerve discharge rate to airway muscles falls to zero impulses per second in sleep. Could a tiny dose of the terrifying tetanus toxin prevent this fall? And could it possibly be safe?

Snoretox was founded to find out. The answers didn't come quickly. In 2002, a trial was run on a bulldog – injecting the floor of the mouth. Bulldogs have significant airway problems. Slowly, the dose was increased. On the seventh dose, the bulldog had a highly significant fall in the sleep apnoea score – from 20 down to six events per hour. The owner reported that the bulldog did not need to be carried home during its daily walk anymore, but bounded along instead. This was an exciting result, both clinically and... what do you call the measurable result? The concept worked!

But there was a major problem: vaccination. Humans are all vaccinated against this molecule – for very good reason. Bulldogs are not. How could this challenge be managed without exposing patients to the dangers of tetanus? In 2009, Snoretox won an ARC Grant and started work on cloning the tetanus toxin molecule. Subsequently, the structure of the molecule was altered to create a separate inactive 'decoy', which would attract all the antibodies for 24 hours, during which time the real unaltered tetanus molecule has time to safely enter the neuron. The result, finally obtained in 2018, is an injectable combination of the inactive and active tetanus molecules that is both safe and effective.

Another four bulldogs have had an excellent response. Six months after injection, the positive toning effect on their airways has not diminished, and they remain healthy and active. But this is much bigger than bulldogs, and airway muscles are not the only application. A trial has been run on mice with motor neurone disease (MND), with very good outcomes – increasing tone to affected limbs. Human trials are pending. Any weak muscle that needs toning is a candidate for treatment. Some examples include snoring and sleep apnoea; ectropion and cosmetic toning; anal and bladder incontinence; pelvic floor weakness; multiple sclerosis; MND and myopathies; muscle recovery post injury; and veterinarian uses like brachycephalic obstructive airway syndrome (BOAS) and pet incontinences.

Snoretox has received major awards, including:

- The United States Food and Drug Administration 'Breakthrough Status' for BOAS in bulldogs, 2020
- Medical Research Future Fund Frontier Fund Round 1, 2021
- MTEC U.S. Department of Defense Commercialization Grant, 2022.

This world-first invention is a completely unique drug without any evident competition to date, patented until 2042. It is cheap to manufacture. A worldwide need for the benefits of the first and only muscle toning drug is met with the elegant solution of modifying what nature has already given us. Many patients are expected to benefit, with a substantial and broad global market ahead.

Snoretox Ltd: Series A Raise

World's first and only muscle toning drug, for weak or injured muscles

Indications: OSA, MND, MS, ectropion, cosmetics, incontinences, pelvic floor weakness and veterinarian BOAS (bulldogs) and incontinences.

FDA Breakthrough Status for Bulldog BOAS Syndrome, MRFF Frontier Round 1 and USA MTEC DoD Commercialisation Grants.

Injected and localised into the target muscle, lasting up to 6 months.

2 min Video of efficacy, Pitch deck, Business Plan available on request

Snoretox Ltd

Web: www.snoretox.com
Inquiries: tony@snoretox.com

BIAS IN AI: AN APPROACH TO DETECTION AND EVALUATION

BY JACKIE KARCESKI, CHIEF TECHNOLOGY OFFICER, CAI

Interest in artificial intelligence (AI) is increasing as more individuals and businesses witness its benefits in various use cases[1]; however, because an AI system can only be as good as the quality of its input data, there are also some valid concerns surrounding the technology. AI bias can be minimised by testing data and algorithms, and developing systems with responsible AI principles in mind.[2] The intent of this article is to summarise a high-level approach to detecting and evaluating biases specific to software systems.

THE BEST APPLICATION of identifying and controlling bias is to begin as early in the product life cycle as possible, and to iterate the workflow periodically throughout the life cycle. This ensures the most current use, requirement, design and implementation information is considered in effectively addressing bias. The core steps are:

- analyse initial bias
- evaluate bias
- determine controls
- evaluate overall impact of bias.

1 https://research.aimultiple.com/ai-usecases/

2 https://research.aimultiple.com/responsible-ai/

Analyse initial bias

Identify the intended use

The first step in controlling bias in AI-based systems is to define the intended use against which the impact of bias can be measured.

For software systems, there are three main components of intended use, specifically:

1. purpose and intent of the software
2. software use requirements (e.g., use cases and user requirements)
3. software requirements.

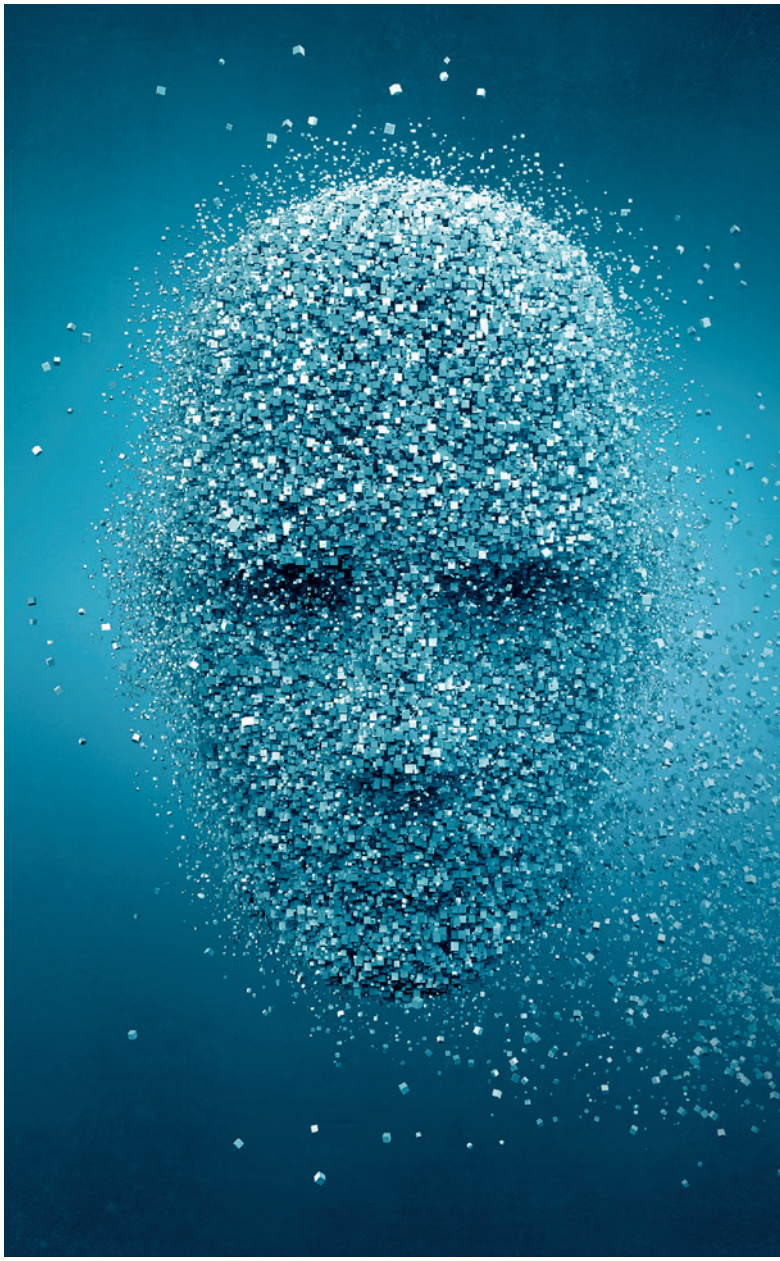
Identify applicable biases

Identifying foreseeable sources and types of bias associated with the intended use is critical. Where applicable, identify the sequence of events leading from the source of bias to the application of bias during use and foreseeable misuse of the system.

Estimate the impact of bias on intended use

Evaluate the impact of bias on the intended use in one of the following ways:

- Provide a subjective narrative for each combination that details the positive, negative or neutral impact of the application of bias.



- Establish a qualitative scale to categorise each combination, incorporating the following elements:
  - likelihood that there will be impact to the intended use if the combination occurs
  - degree (and categorical type) of impact if the combination occurs (Note: A more granular view of this attribute may be provided if there are variable degrees of impact, each with a separate likelihood for that impact given that the combination occurs. An example is shown in the 'evaluate bias' section below.)
  - indicator of positive, negative or neutral impact of the combination
  - likelihood that the combination will occur during real-world use (Note: The denominator in this calculation is an important element as it ensures an adequate scale for ultimately determining acceptability. For example, the number of installations of the system, the number of decisions made per system, per month and per year.)
  - likelihood that there will be impact if the combination occurs
  - degree (and categorical type) of impact if the combination occurs, including indicator of positive, negative or neutral impact.

Evaluate bias

Based on the impact estimation above, determine whether each combination is acceptable or unacceptable. Consider one of these methods for this determination:

- If a subjective narrative was used for impact estimation, provide a further narrative rationalising whether the combination is acceptable or unacceptable.
- If a qualitative or quantitative scale was used for impact estimation, use a series of decision matrices to make the acceptability determination.

Determine controls

For each combination considered unacceptable, determine (and document in the bias analysis) controls (e.g., changes to requirements, architecture, design and/or code/algorithms) necessary to bring the combination to an acceptable state. The goal of determining appropriate controls is to reduce the likelihood that the combination will occur, reduce the likelihood the combination will have a negative impact if it does occur, and/or reduce the level of impact of the combination.

- *Implement/verify controls:* Where controls have been identified, implement them using controlled design change and configuration management, as applicable. Verify implemented controls through both static and dynamic means (e.g., requirements reviews, technical reviews, code reviews, static code analysis, unit testing, integration testing, functional system testing).
- *Determine residual impact of bias on intended use:* Using the methods defined above to estimate and evaluate bias, determine the residual impact of bias on the intended use after bias control mechanisms have been implemented and verified.
- *Determine potential bias arising from controls*: Perform an estimation and evaluation of potential new or changed combinations that may arise from the implementation of bias controls. Where applicable, identify, implement and verify controls on these new or changed combinations.

- *Determine completeness of controls:* Review all bias control activities to ensure that the impacts from all combinations have been considered and that all bias control activities are complete.

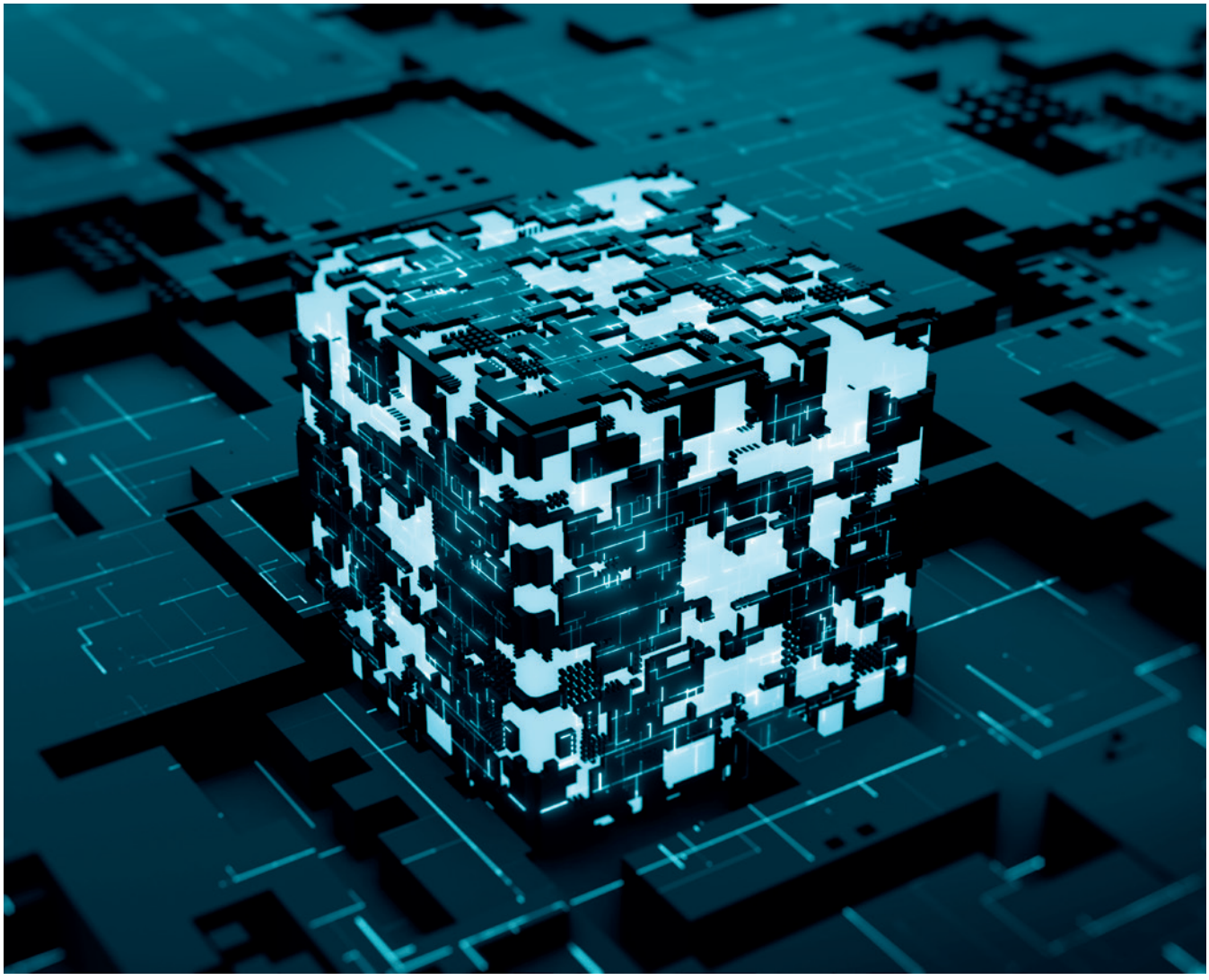
Evaluate overall bias

- *Determine overall acceptability of bias in the systems:* Taking into consideration the residual impacts of all combinations, determine if the overall residual impact of bias combinations is acceptable or unacceptable. If the overall impact is considered unacceptable, consider identifying and implementing further bias controls, making changes to intended use, or reconsidering whether to release the system in its current configuration.

- *Articulate benefit versus bias:* For combinations that remain unacceptable, gather and review data to determine if the benefits of the intended use (e.g., technical, clinical, economic) outweigh the residual impact for this specific combination. Consider also making an overall benefit versus bias determination at the system level. If the benefits do not outweigh the residual impact, consider further system design changes (including bias controls and/or changes to intended use), or reconsidering whether to release the system in its current configuration.

AI will continue to penetrate software development and deployment, as well as drug discovery in systems across all businesses. The growth of AI in Australia is driven by its potential to create jobs, improve lives and contribute to overall economic growth. Data-driven decisions will not be a 'nice to have' anymore. Continuously looking at data to inform and adjust decision-making will simply become more naturally intuitive to our minds and organisational culture.

Images in this article courtesy of Adobe Stock.



Australian Clinical Trials Alliance

Clinical Trials 2023: National Tribute & Awards Ceremony

ACTA's Trial of the Year Awards

Register your interest in nominating

The Australian Clinical Trials Alliance's (ACTA) **National Tribute and Awards Ceremony** was established in 2016 to honour and celebrate the outstanding Australian achievements that advance clinical practice and save or improve the lives of patients every year through collaborative, multicentre, investigator-driven clinical trials.

ACTA is hosting the ***2023 Trial of the Year Awards*** in Melbourne in true ceremony style during the *ACTA International Clinical Trials Symposium* on Tuesday, 28 November 2023.

The 8th Annual Awards will honour the remarkable Australians who advance our health system by designing, conducting, or participating in ground-breaking clinical trials. These awards acknowledge trialists, trial teams, consumers and industry partners' critical roles in delivering clinical trials across the country.

ACTA Award categories include:

- Trial of the Year
- STInG Excellence in Trial Statistics
- Consumer Involvement
- Industry Partnership
- Health Economist Alongside Trials (New in 2023!)

Nominations opening soon!

To nominate, please register your interest here: awards@clinicaltrialsalliance.org.au

About the *International Clinical Trials Symposium*:

The ***ACTA International Clinical Trials Symposium*** is the premier event on the clinical trials calendar, which brings together a broad range of local and international experts in the design and conduct of clinical trials, clinical data, healthcare funding, policy and regulation, healthcare service delivery, health information technology and patient advocacy.

Please join us on **27 – 29 November at the Park Hyatt, Melbourne**. The program is currently being finalised and will include both invited speakers as well as presentations chosen from submitted abstracts. ***Registrations opening soon.***

PCI'S ASEPTIC FILL SOLUTION

DRIVEN NOT ONLY by the pandemic, but also by the increasing demand for innovative therapies and the continued rise in chronic disease areas, such as oncology, the biologic market has grown expediently over the past few years. As a result, there has been a rapid growth of aseptic processing, which is expected to reach $24.36 billion by 2031, growing from $10.63 billion in 2020 – witnessing a compound annual growth rate of 7.9 per cent (2021–2031).[1]

Aseptic filling

Administered parenterally to patients, vaccines and other biologics require specific production processes to optimise both particulate and bioburden control while ensuring uncompromised sterility throughout the manufacturing process to maximise patient safety. Protecting drug products from contamination has led to the development of aseptic transfer and containment methods for clinical and commercial sterile injectable products.

Looking for advanced ways of improving efficiency, reducing costs and increasing sterility assurance, robotic processing is gaining huge popularity for the primary filling of ready-to-use (RTU) containers, such as vials, syringes and cartridges. Robotic aseptic fill-finish technology and the use of isolator-barrier systems is emerging as key to keeping pace with these requirements.

Robotic aseptic platforms at PCI Pharma Services

Complementing PCI's global sterile fill-finish and lyophilisation capabilities, PCI has invested significantly in state-of-the-art robotic technology at its facility in Melbourne.

Utilising the latest advancements of the Cytiva Microcell technology, PCI delivers flexible clinical scale aseptic fill-finish solutions meeting its clients' aseptic vial filling manufacturing needs – delivering products to patients safely and efficiently.

Advantages of robotic processing

Speed and accuracy

Expediting the filling process with automation while increasing accuracy, robotic platforms ensure accurate fill volumes with minimal product losses. This is a significant benefit to clients, who are often developing life-changing, high-value drug products that need to progress through the clinical pipeline with efficiency and speed.

Quality assurance and sterility

With a robot performing the processes in a recipe-driven, validated system and utilising single-use parts, pre-sterilised flow paths, and RTU containers, multiple sources of risk are eliminated. The eliminated risks include cross-contamination, human error, electromechanical filling and closure activity failures, environmental control failures, cleaning and set up errors, and product loss.

Using press-fit vial closures with integrated rubber stoppers not only reduces the risk of particle contamination, but also simplifies the manufacturing process with a one-step application process, versus the traditional two-step process of stoppering and aluminium crimp capping. All of this combined means that clients are able to move more rapidly through the clinical stages and provide safe, life-changing therapies to patients.

Flexibility and capacity

Robotic technologies are designed for maximum flexibility, while maintaining high aseptic processing rates. Minimal changeover time between batches provides greater available capacity, providing flexible solutions for clients who have urgent drug product supply needs.

Seamless sterile solutions

This innovative robotic aseptic fill-finish platform at PCI's Australian facility – combined with PCI's specialist biologic packaging, labelling and cold chain distribution solutions from a single site – provides a valuable end-to-end solution, simplifying the supply chain while delivering time and cost efficiencies for its client partners.

1 Aseptic Pharma Processing Market – Industry Analysis, Trends & Forecast 2031, BIS Research


pci
PHARMA SERVICES
Introducing speedsolutions™
Accelerating your product through development to commercialization and beyond
PH I
PH II
speedtostudy™
speedtopatient™
speedtoapproval™
speedtolaunch™
PH III
COMMERCIALIZATION
Harnessing decades of global drug product development and commercialization, you can rely on us for global, integrated CDMO services. speedsolutions™ combine expertise and services to simplify the supply chain, spanning the cycle from development to launch.
Development & Manufacturing | Clinical Trial Services | Commercial Packaging
Let's talk future™
talkfuture@pci.com | pci.com
Your bridge between life-changing therapies and patients

AUSBIOTECH CORPORATE MEMBERS

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.

360biolabs Pty Ltd
AbbVie Pty Ltd
AbCellera
Accelagen Pty Ltd
Actinogen Medical Limited
Acuity Capital
Aculeus Therapeutics Pty Ltd
AcuraBio Pty Ltd
AdAlta Limited
Adapt Ideations Pty Ltd
Additive Manufacturing Network
Agilex Biolabs Pty Ltd
Agriculture Victoria Services Pty Ltd
Alcolizer
Alithia Life Sciences Pty Ltd
Alliance for Regenerative Medicine (ARM)
Almac Group
Alterity Therapeutics
Amgen Australia Pty Ltd
Amplia Therapeutics Limited
Analytica Limited
Anatara Lifesciences
ANDHealth
Andi-Co Australia P/L
AnteoTech Ltd
Anteris Technologies Ltd
Antisense Therapeutics Ltd
Aravax Pty Ltd
Archer Materials Ltd
Argenica Therapeutics Ltd
Arovella Therapeutics Limited
Artificial Cell Technologies Australia Pty Ltd
AstraZeneca Pty Ltd
AusBiotech Ltd
Australia China Business Council (ACBC) Victoria
Australian National University (ANU), Business Engagement and Commercialisation
Australian Red Cross Lifeblood (ARCLB)
Australian Regenerative Medicine Institute
Australian Trade Commission (Austrade)
Australian Unity
Avatar Brokers Pty Limited
Avecho Biotechnology Ltd
Baker Heart and Diabetes Institute
Bellberry Limited
Bio101 Group Pty Ltd
Bio21 Molecular Science and Biotechnology Institute, University of Melbourne
BioCina Pty Ltd
BioCurate Pty Ltd
BioDiem Ltd
Biointelect Pty Ltd
Biointellix Pty Ltd
BiomeBank
BioMelbourne Network
Bionomics Limited
Biopharma Excellence
Bio-Rad Laboratories Pty Ltd
BioScience Managers Pty Ltd
Biotech Daily
BiotechGate
BioTech Primer Inc.
BIOTechNZ
Biotron Limited
Blueprint Life Science Group
Bosch Australia Pty Ltd
Botanix Pharmaceuticals Ltd
Brandon Capital
Bristol-Myers Squibb (Australia) Pty Ltd
Brooker Consulting Pty Ltd
BSI Group ANZ Pty Ltd
Burnet Institute
Business Events Sydney
Cancer Trials Australia
CareerLounge Pty Ltd
Carina Biotech
Carpe Vitae Pharmaceuticals Pty Ltd
Cell Therapies Pty Ltd
Cellabs Pty Ltd
Celosia Therapeutics Pty Ltd
Centenary Institute
Centralyze
Cerecin Australia Pty Ltd
Certa Therapeutics
Chimeric Therapeutics Ltd
Chubb Insurance Australia Limited
City of Perth
Clarity Pharmaceuticals
CMAX Clinical Research Pty Ltd
CMRI (Westmead Research Hub)
Cochlear Limited
Collaborative Drug Discovery, Inc
Commissioning Agents International (Australia) Pty Ltd
Cook Australia Pty Ltd
CROW Clinical
Crux Biolabs
Cryosite Ltd
CSIRO
CSL Limited
Cure 4 Cystic Fibrosis Foundation
Cyban Pty Ltd
Cynata Therapeutics Ltd
Datapharm Australia Pty Ltd
Davies Collison Cave
De Motu Cordis Pty Ltd
Deakin Research Commercial
Deloitte Touche Tohmatsu
Department Jobs, Precincts and Regions (VIC)
Department of Environment and Science (QLD)
Department of Jobs, Tourism, Science and Innovation (WA)
Department of State Development, Infrastructure, Local Government & Planning (QLD)
Diagnostic Technology Pty Ltd
Dimerix Limited
DMTC Ltd
E&P Financial Group
Ellume
Emerson Process Management Pty Ltd
Emyria Ltd
ENA Respiratory
Encap Solutions Pty Ltd
EpiAxis Therapeutics Pty Ltd
Epichem Pty Ltd
Ernst & Young
ESFAM Biotech
Eurofins | ams
Eversana
Evrima Technologies Pty Ltd
Exopharm Ltd
Facet Life Sciences, Inc.
FB Rice
FivepHusion
Flanders Investment & Trade Australia
FPA Patent Attorneys
Franke Hyland Pty Ltd
Garvan Institute for Medical Research
GenesisCare
Genetic Technologies Limited
GenScript Biotech Corporation
Gertrude Biomedical Pty Ltd
Ginkgo Bioworks
GPN Vaccines Ltd
Grant Thornton Australia Limited
GreenLight Clinical Pty Ltd
Gretals Australia Pty Ltd
Grey Wolf Therapeutics Pty Ltd
Griffith Hack
Griffith Institute for Drug Discovery
Griffith University, Griffith Enterprise
HaemaLogiX Pty Ltd
Hall & Wilcox
Health and Medical Industries
Heart Research Institute
Hemideina Pty Ltd
Herbert Smith Freehills
Horten Medical
Hydrix Pty Ltd
IDE Group
IDT Australia Ltd
Illumina Australia Pty Ltd
Imagion Biosystems Limited
Immuron Limited
Immutep Limited
Imugene Ltd
Incannex Pty Ltd
Ingham Institute for Applied Medical Research
Innovation & Commercialisation Services, The University of Adelaide
INOVIQ Limited
Institute for Glycomics
Institute for Molecular Bioscience (IMB), University of Queensland
Intellect Labs Pty Ltd
InterK Peptide Therapeutics Limited

Invest Northern Ireland
Investment NSW & NSW Health
Invion Limited
IP Group Australia
IQVIA
James & Wells Australia
James Cook University
Johnson & Johnson Australia
Johnson Matthey (Aust) Ltd
Karst Peak Capital Limited
Kazia Therapeutics Limited
KPMG
La Trobe University, Innovation & Commercialisation
Labcorp Drug Development
LBT Innovations Ltd
Life Sciences Queensland Ltd (LSQ)
Linear Clinical Research Ltd
Living Cell Technologies Ltd
Lucid Health Consulting Pty Ltd
Macarthur Human Capital
Macquarie University Faculty of Medicine & Health Sciences
Madderns Patent & Trade Mark Attorneys
Marken
McCloud Consulting Group
Meat & Livestock Australia Ltd
Medidata Solutions
Medlab Clinical Ltd
MedTech Actuator
Medtronic Australasia Pty Ltd
Melbourne Biotechnology
Melbourne Convention Bureau (MCB)
Melbourne School of Engineering, The University of Melbourne
Merck Pty Ltd
Mesoblast Limited
Microba Pty Ltd
Microbio Pty Ltd
Mobius Medical Pty Ltd
Molecule2Market Pty Limited
Monash Innovation
Morgans Financial Limited
Murdoch Children's Research Institute
MycRx Pty Ltd
Navbit Pty Ltd
Neo-Bionica
Neuren Pharmaceuticals Limited
Neuroscience Trials Australia
Newline Australia Insurance Pty Ltd
Next Science Technologies Pty Ltd
Nirtek Pty Ltd
Novartis Pharmaceuticals Australia Pty Ltd
Novotech
Noxopharm
NSW Stem Cell Network
Nucleus Network
Nutromics
OFX
Oli Biotech Pty Ltd
Oncology One Pty Ltd
OncoRes Medical Ltd
OncoSil Medical Ltd
OneVentures Pty Ltd
Opthea Limited
Optiscan Imaging Ltd
Opyl Ltd
Orthocell Ltd
Pakair Cargo
Paradigm BioPharmaceuticals Ltd
Patrys Ltd
Peter MacCallum Cancer Centre
Pfizer Australia
Pharmaceutical Solutions Limited
PharmaLex Pty Ltd
Pharmaxis Ltd
Phillips Ormonde Fitzpatrick
Piper Alderman
Planet Innovation Pty Ltd
PolyNovo Limited
Premier Research Australia Pty Ltd
Prescient Therapeutics Limited
Prime Accounting and Business Advisory Pty Ltd
Prism Surgical Designs Pty Ltd
ProPharma Group
Protagonist Pty Ltd
Proteomics International
Proto Axiom Pty Ltd
QBiotics Group Limited
QIMR Berghofer Medical Research Institute
Queensland University of Technology, Industry Engagement
Race Oncology Limited
Radium Capital
Recce Pharmaceuticals Ltd
Regeneus Ltd
Research Australia Limited
Research, Innovation & Commercialisation (RIC), The University of Melbourne
Resolutum Global Pty Ltd
Resonance Clinical Pty Ltd
Respirion Pharmaceuticals
RhinoMed
Roche Australia
RSM Australia Pty Ltd
Sanofi ANZ
Schott Australia
Scientia Clinical Research Ltd
Sementis Ltd
Silverstone Developments Pty Ltd
Sonic Clinical Trials Pty Ltd
Southern Star Research Pty Ltd
SpeeDx Pty Ltd
Spruson & Ferguson
St Vincent's Hospital Melbourne
Starpharma Holdings Limited
Syneos Health
Takeda Pharmaceuticals Australia Pty Ltd
TekCyte Ltd
Telethon Kids Institute
Telix Pharmaceuticals Pty Ltd
Tessara Therapeutics
TEVA Australia
The University of Newcastle, Knowledge Exchange and Enterprise (KEE)
The University of Queensland, Biotechnology Program
The University of Technology Sydney Biomed Initiative
The University of Western Australia, Office of Research Enterprise
The Walter & Eliza Hall Institute of Medical Research
Therapeutic Goods Administration (TGA)
Thermo Fisher Scientifc
Tissue Repair Ltd
Translational Research Institute Australia
TruScreen Pty Ltd
UniQuest Pty Ltd
Universal Biosensors
UNSW Knowledge Exchange
UNSW School of Biotechnology and Biomolecular Sciences
Vaxxas Pty Ltd
Vectus Biosystems Limited
Venture Valuation
Vestech Medical Pty Limited
Vetter Pharma International GmbH
VFV Pty Ltd
ViciBio Pty Ltd
Vitrafy Life Sciences Ltd
Vitura Health Limited
Wallonia Export & Investment Agency (Belgium)
WE Communications
West Pharmaceutical Services Singapore Pte Ltd
Worldwide Clinical Trials Australia
Wrays
Yuhan ANZ
Zelira Therapeutics Ltd
Zucero Therapeutics Ltd
Zuellig Pharma SSG Australia

AusBiotech

Business Solutions Programme

AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AVATAR

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.

CHUBB

Chubb is AusBiotech's endorsed property and casualty insurer for pharmaceutical, medical device and medical biotechnology life science companies. Chubb is one of the world's leading insurers of the life science industry. Members receive 5 per cent discount on the cost of property, general liability and clinical trials insurance products.

FROST & SULLIVAN

Frost & Sullivan's Knowledge Partnership with AusBiotech provides members with exclusive in-depth coverage of the life sciences sector. Members receive a range of specialised market insight reports at flagship conferences and can access a free one-hour demonstration/navigation session on data services.

OFX

Save money with your foreign exchange transactions. OFX provides the latest market information and commentary.

BIOTECH GATE
GLOBAL DATABASE

Biotechgate is the global lead-sourcing database for the biotech, pharma and medtech industries. Biotechgate is pleased to extend AusBiotech members a special 15 per cent discount on a subscription to the database.

biotechPrimer

BioTech Primer is pleased to extend AusBiotech members a special 10 per cent discount on course registration fees for BioTech Primer 'online' courses.

ausbiotech.org/member-services

NEW AUSBIOTECH MEMBERS

ACUITY CAPITAL

Acuity Capital is the leading provider of at-the-market (ATM) funding solutions to ASX-listed companies. It was the first to develop and introduce ATMs into Australia, and since its founding in 2012, it has established over 65 ATMs, including a number in the life sciences sector; made over $800 million of standby capital available; and provided over $130 million in equity capital to ASX-listed companies.

Phone: 1300 180 979 | Email: info@acuitycapital.com.au | Web: acuitycapital.com.au

BSI

BSI's mission is to ensure patient safety while supporting timely market access to global medical device technology. The company strives to set the global standard in thorough, responsive, robust conformity assessments, evaluations, and certifications that are recognised and trusted worldwide. BSI is a leading notified body; it reviews medical devices to ensure that they conform to the requirements of the European Union Directives and Regulations, and provides conformity assessments under the new United Kingdom Conformity Assessment scheme.

Phone: 1300 730 134 | Email: info.aus@bsigroup.com | Web: www.bsigroup.com/en-AU/Medical-Devices/

CARPE VITAE

Driven by a core team of world-leading scientists, Carpe Vitae is using its expertise in DNA damage repair and aging research to develop groundbreaking products and solutions to help people live healthier, for longer. The company's portfolio of first-in-class technologies includes a small-molecule drug that restores DNA repair; a novel biomarker to improve patient selection for PARP inhibitor therapy; and a platform technology to design drugs that target transcription factors to treat cancer.

Dr Rosalind Wilson | CEO | Phone: 0481 394 982 | Email: ros@carpevitae.com.au | Web: www.carpevitae.life

CELOSIA THERAPEUTICS

Celosia Therapeutics is a gene therapy company targeting neurodegenerative diseases for which there are limited therapeutic options. Celosia's lead candidates have, in multiple preclinical models of motor neurone disease, demonstrated significant improvement in motor function and life extension. With an initial seed investment from Macquarie University, Celosia will commence its preclinical activities, although further funding will be sought in 2023 to support all activities through to Phase 1 clinical trials.

Dr Brenton Hamdorf | CEO | Phone: 02 9850 2877 | Email: bhamdorf@celosiatx.com | Web: www.celosiatx.com

CROW CLINICAL

CROW Clinical is a full-service clinical research organisation (CRO) servicing Australia and New Zealand that provides all aspects of clinical operations, including pharmacovigilance, site selection, and monitoring. It is a CRO that offers a dedicated team of field clinical engineers or medtech engineers. The company's speciality is supporting high-tech medical device startups, pharma therapeutics and biotech companies. The team has extensive experience in case support in the operating room and catheterisation laboratory in a vast array of medical faculties.

Phone: 0423 766 321 | Email: info@crowclinical.com | Web: www.crowclinical.com

DUG

DUG is an ASX-listed technology company headquartered in Australia that specialises in analytical software development and reliable, green, high-performance computing (HPC). DUG is built on a strong foundation of applied science and a history of converting research into practical, real-world solutions. DUG delivers innovative software products and cost-effective, cloud-based HPC-as-a-service, backed by bespoke support for technology onboarding. DUG's expertise in algorithm development and code optimisation enables clients to leverage big data and solve complex problems.

Phone: 08 9287 4100 | Email: info@dug.com | Web: dug.com

EMYRIA

Emyria is a clinical-stage biotech informed by patient experience, tackling unmet needs in neuroscience and mental health. Its Ultra-Pure CBD Medicines program uses real-world evidence to create medications like EMD-RX5 (currently in Phase 3, targeting symptoms of psychological distress). The company also has prescription-strength formulations, such as EMD-RX7, in development. Its MDMA – New Drug Discovery program is investigating the therapeutic potential of MDMA-inspired analogues for treating symptoms of PTSD, Parkinson's and fibrotic disease.

Phone: 08 6559 2800 | Email: info@emyria.com | Web: emyria.com

GINKGO BIOWORKS

Ginkgo Bioworks is the world's leading platform for cell programming, providing flexible, end-to-end services solving challenges for biopharma companies, from discovery through to manufacturing and across diverse therapeutic modalities. Leveraging cutting-edge automation, large-scale DNA synthesis, high throughput analytics, and machine learning, Ginkgo's platform enables partners to explore vast biological design space to discover and optimise their targets and processes in mammalian and microbial cells, with applications in cell, gene, RNA, microbiome, and biologic modalities.

Natalie Curach | Senior Director | Email: ncurach@ginkgobioworks.com | Web: ginkgobioworks.com

PROPHARMA

For the past 20 years, ProPharma has improved the health and wellness of patients by providing advice and expertise that empowers biotech, med devices, and pharmaceutical organisations of all sizes to confidently advance scientific breakthroughs, and introduce new therapies. As the world's largest research consulting organisation, ProPharma partners with its clients through an advise-build-operate model across the complete product life cycle. With deep domain expertise in regulatory sciences, clinical research solutions, quality and compliance, pharmacovigilance, medical information, and research and development technology, ProPharma offers an end-to-end suite of fully customisable consulting solutions that de-risk and accelerate its partners' most high-profile drug and device programs.

Shannon McGrath | Phone: 0431 348 129 | Email: Shannon.mcgrath@propharmagroup.com | Web: www.propharmagroup.com/

INDEX

BY DAVID NAYAGAM, DIRECTOR – HEALTHCARE RESEARCH, EVANS & PARTNERS

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	9.15	0.03	0.07	0.03	-1.60	-1.81	-	-
4DX	4DMedical Limited	A software technology company in Australia. It commercialises XV Technology, a four-dimensional lung imaging platform.	7/8/2020	270.93	0.84	0.98	0.29	-13.05	-6.44	-	-
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	0.07	0.04	-5.34	-0.75	4.00	-
ACR	Acrux Limited	Transdermal drug delivery platform technology.	29/9/2004	14.67	0.05	0.09	0.05	-2.68	-2.01	2.00	-
ACW	Actinogen Medical Limited	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders including Alzheimer's disease.	16/10/2007	121.69	0.07	0.16	0.04	-0.61	-10.82	1.00	-
ADO	Anteotech Limited	Multi-component coatings for solid phase of immunoassays for biomarker development.	7/4/2000	71.75	0.04	0.16	0.04	-0.53	-6.79	-	-
ADR	Adherium Limited	Developer of digital technologies to monitor medication use in chronic respiratory conditions.	26/8/2015	14.99	0.00	0.01	0.00	-0.44	-0.68	-	-
AFP	AFT Pharmaceuticals Limited	Develops, licences and sells a range of medical products globally.	22/12/2015	335.57	3.12	3.77	2.90	15.07	20.70	13.00	-
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	22.07	0.06	0.20	0.04	-4.39	-1.37	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	27.00	0.44	0.70	0.35	-4.90	-8.98	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	16.86	0.09	0.25	0.08	-5.61	-1.52	1.00	-
AHX	Apiam Animal Health Limited	iVet technology for real-time animal health monitoring, including on-farm welfare assessments.	15/12/2015	95.40	0.52	0.87	0.50	3.78	13.76	-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	67.24	0.08	0.11	0.02	-1.33	-6.09	-	-
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	152.17	0.12	0.21	0.10	-0.04	-300.00	-	-

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)
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	7.31	0.07	0.18	0.06	-2.02	-3.47	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	9.87	0.03	0.05	0.02	-1.51	-1.72	2.00	-
ANN	Ansell Limited	Ansell Limited is involved in the development, manufacturing and sourcing, distribution and sale of gloves and protective personal equipment in the industrial and medical end markets.	20/11/1985	3,511.11	27.33	29.83	21.11	172.91	15.81	583.00	74.33
ANO	Advance Zinctek Limited	Advance ZincTek Limited, together with its subsidiaries, manufactures aluminum oxide powder, as well as zinc oxide dispersions and powder for use in the personal care sector in Australia, the United States, Canada, Europe, and internationally.	24/2/2005	140.40	2.25	2.70	1.99	3.90	57.69	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	62.92	0.09	0.15	0.07	-1.21	-7.11	2.00	-
ANR	Anatara Lifesciences Limited	Natural, plant-based therapeutics for gastrointestinal diseases.	16/10/2014	3.60	0.03	0.10	0.03	-3.09	-0.94	1.00	-
ARX	Aroa Biosurgery Limited	A regenerative medicine company, it develops and manufactures medical devices for wound and tissue repair in the United States and internationally.	24/7/2020	360.26	1.05	1.25	0.63	-0.34	-307.35	20.00	-
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	19.98	0.04	0.13	0.04	-1.58	-2.22	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	19.52	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	16.30	0.09	0.16	0.08	-2.91	-2.92	6.00	-
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	5.74	0.06	0.14	0.05	-3.26	-1.72	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	9.19	0.01	0.02	0.01	-0.13	-4.62	-	-
AVH	Avita Medical Incorporated	Skin regeneration technology for the treatment of wounds, scars and skin defects.	24/6/2020	317.89	4.50	4.90	1.28	-157.93	-2.85	512.00	-
AVR	Anteris Technologies Limited	Anteris Technologies Limited (formerly Amedus Limited). Tissue engineering and vaccine development for herpes and HPV.	24/3/2004	374.85	23.70	30.89	14.06	-332.00	-7.14	89.00	-
AXE	Archer Materials Limited	Archer Materials Limited (formerly Archer Exploration Limited) has 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	105.76	0.42	0.99	0.39	-5.86	-7.08	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	14.44	0.23	1.20	0.22	-22.19	-1.01	39.00	-
BCT	Bluechiip Limited	Bluechiip Limited develops and commercialises wireless tracking solutions for the healthcare and life sciences, security, defence, and manufacturing industries.	9/6/2011	15.56	0.03	0.05	0.02	-0.61	-4.26	-	-
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	9.80	0.07	0.12	0.05	-2.19	-3.33	-	-

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)
BGT	Bio-Gene Technology Limited	Insecticide product development. 'Qcide' and 'FLAVOCIDE' focused on insect control in agriculture and animal health.	29/11/2017	14.16	0.08	0.29	0.07	-2.00	-4.00	-	-
BIO	Biome Australia Limited	Biome Australia Limited develops, commercialises and markets various live biotherapeutics and complimentary medicines in Australia and internationally.	30/11/2021	12.83	0.07	0.12	0.06	-2.20	-3.27	2.00	-
BIT	Biotron Limited	Antiviral drug developer for HIV and hepatitis.	24/1/2001	25.25	0.03	0.11	0.03	-0.23	-12.17	1.00	-
BNO	Bionomics Limited	Small molecule developer in areas of cancer and central nervous system disorders.	21/12/1999	33.78	0.02	0.07	0.02	-1.51	-1.32	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	9.95	0.06	0.18	0.05	-5.50	-1.16	239.00	-
BOT	Botanix Pharmaceuticals Limited	Developer of therapeutics for skin diseases including acne, psoriasis and dermatitis.	24/1/1985	121.42	0.09	0.12	0.05	-1.13	-8.14	1.00	-
BXN	Bioxyne Limited	Gut and immune health probiotic products, including a patented probiotic range.	14/12/2000	16.64	0.03	0.03	0.01	-0.05	-50.00	1.00	-
CAJ	Capitol Health Limited	Provider of diagnostic imaging services to the Australian healthcare market.	9/6/2006	297.79	0.28	0.35	0.24	-1.18	-23.31	-3.00	1.00
CAN	Cann Group Limited	Research and development, as well as cultivation to facilitate the supply of medicinal cannabis.	4/5/2017	60.16	0.16	0.44	0.13	-10.47	-1.48	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	183.04	0.79	1.36	0.61	-27.79	-2.82	-7.00	-
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 their thoughts and neuroelectric signals.	7/12/2020	14.48	0.14	0.42	0.12	-6.75	-2.07	-	-
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 – providing digital and device-based solutions for large-scale population health disorders with significant market scale.	9/11/2005	40.17	0.30	0.60	0.24	-13.00	-2.31	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	0.04	0.02	-3.33	-0.63	3.00	-
CGS	Cogstate Limited	Diagnosis and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's).	13/2/2004	236.20	1.40	2.46	1.14	3.06	45.75	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	30.60	0.07	0.15	0.06	-3.90	-1.79	1.00	-
CLV	Clover Corporation Limited	Supplies science-based oil products to the medical food market for infants and children.	30/11/1999	201.23	1.22	1.47	0.95	5.26	23.19	38.00	1.75
CMP	Compumedics Limited	Designs and manufactures technologies for the diagnosis of sleep disorders, neurodiagnostics solutions and brain research technologies through the Compumedics Neuroscan brand.	21/12/2000	25.69	0.15	0.31	0.14	-3.50	-4.14	6.00	-
COH	Cochlear Limited	Manufacture and sale of cochlear implant system for impaired hearing.	4/12/1995	16,353.95	247.45	251.50	184.62	397.50	62.25	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	21.37	0.01	0.07	0.01	-2.24	-0.45	-	-
CSL	CSL Limited	Development, manufacture and marketing of pharmaceutical and diagnostic products.	8/6/1994	145,607.99	300.24	314.28	254.30	665.03	45.15	497.00	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	30.81	0.40	1.24	0.31	-13.83	-2.89	-	-
CT1	Constellation Technologies 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	5.88	0.00	0.01	0.00	-	-	-	-

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)
CTE	Cryosite Limited	Collection, processing and long-term storage of blood stem cells.	9/5/2002	35.63	0.73	0.87	0.55	2.58	28.29	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	135.84	0.72	1.05	0.36	-8.20	-8.78	32.00	-
CUV	CLINUVEL Pharmaceuticals Limited	Developer for treatment of UV-related skin disorders. Lead product SCENESSE completed Phase III clinical trials for prevention of phototoxicity in adult patients with erythropoietic protoporphyria.	13/2/2001	1,011.92	19.90	28.72	13.16	53.40	37.27	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	206.13	2.19	2.28	0.95	-7.17	-30.54	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	31.36	0.19	0.45	0.20	-6.62	-2.79	12.00	-
DVL	DorsaVi Limited	Motion analysis device technologies for clinical, elite sports, and occupational health and safety.	11/12/2013	7.58	0.01	0.02	0.01	-0.41	-3.17	-	-
DXB	Dimerix Limited	Development of therapeutic treatments identified using drug discovery platform, Receptor-Heteromer Investigation Technology.	4/2/1993	33.69	0.10	0.19	0.10	-4.15	-2.41	2.00	-
EBO	EBOS Group Limited	Distributor of healthcare products.	6/12/2013	7,912.79	41.50	45.77	31.10	122.70	33.82	379.00	81.88
EBR	EBR Systems Incorporated	EBR Systems Incorporated develops implantable systems for wireless tissue stimulation. The company offers WiSE cardiac resynchronisation therapy system, which uses a proprietary wireless technology to deliver pacing stimulation directly to the inside of the left ventricle of the heart.	24/11/2021	180.24	0.68	0.71	0.33	-17.71	-3.84	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	22.13	0.02	0.03	0.01	0.06	31.67	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 includes EMD-003, a cannabinoid medicine for treating patients with mental health; and EMD-004, a cannabinoid medicine targeting irritable bowel syndrome.	12/2/2020	48.13	0.16	0.34	0.16	-2.76	-5.80	-	-
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	132.85	1.53	2.36	1.18	-6.24	-24.44	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	59.37	0.18	0.45	0.17	-7.63	-2.33	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; the development and delivery of medicinal cannabis; and provides turnkey cultivation solutions.	4/5/2017	5.41	0.02	0.04	0.02	-6.56	-0.27	4.00	-
EX1	Exopharm Limited	Exopharm Limited focuses on developing and commercialising human therapeutics using extracellular vesicles as medicines in Australia.	18/12/2018	1.57	0.01	0.23	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	47.56	0.27	0.36	0.18	-7.58	-3.56	4.00	-
FPH	Fisher & Paykel Healthcare Corporation Limited	A New Zealand-based company engaged in 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	14,281.60	24.49	25.57	16.11	38.58	63.48	-	36.74
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	20.83	0.20	0.48	0.19	-1.85	-10.81	3.00	-

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)
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	11.60	0.20	0.44	0.12	-5.90	-3.39	-1.00	-
GSS	Genetic Signatures Limited	Molecular diagnostics company focused on the development and commercialisation of its proprietary platform technology, 3Base.	31/3/2015	121.90	0.85	1.36	0.63	-5.67	-14.90	31.00	-
GTG	Genetic Technologies Limited	Molecular diagnostics specialising in women's health. Lead product BREVAGen plus is a risk assessment test for non-hereditary breast cancer.	30/7/1987	40.40	0.00	0.01	0.00	-0.10	-3.50	-	-
HCT	Holista CollTech Limited	Development and commercialisation of food ingredients and ovine collagen.	26/2/2004	4.46	0.02	0.04	0.01	-0.52	-3.08	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	11.96	0.05	0.07	0.05	-4.36	-1.15	11.00	-
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	6.68	0.03	0.08	0.02	-1.42	-2.11	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	24.27	0.11	0.22	0.09	-3.39	-3.10	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	1.84	0.01	0.42	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	10.17	0.04	0.11	0.03	-2.67	-1.35	-	-
IBX	Imagion Biosystems Limited	Detection and localisation of cancer and other diseases using nanoparticle technology. Proprietary MagSense bio-imaging detection technology.	22/6/2017	20.58	0.02	0.06	0.01	-0.87	-1.95	-	-
IDT	IDT Australia Limited	Manufacturer of pharmaceuticals and clinical trial management services.	24/9/1993	18.50	0.08	0.18	0.06	-3.41	-2.38	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	190.44	0.13	0.53	0.10	-1.39	-8.99	-	-
IIQ	INOVIQLimited	INOVIQ Ltd (formerly 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	44.17	0.49	0.88	0.39	-10.24	-4.74	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	5.69	0.07	0.22	0.07	-4.16	-1.78	4.00	-
IMC	Immuron Limited	Oral immunotherapy products that target the human gut immune system and gut microbiome.	30/4/1999	17.08	0.07	0.13	0.07	-1.35	-5.48	9.00	-
IMM	Immutep Limited	Developer of novel immunotherapy agents treatments for cancer and autoimmune disease. Lead product candidate is eftilagimod alpha for breast cancer and melanoma.	23/6/1988	215.43	0.25	0.44	0.23	-4.21	-5.94	8.00	-
IMU	Imugene Limited	Developer of HER-2+ gastric and breast cancer immunotherapies.	2/12/1993	899.23	0.14	0.32	0.12	-0.68	-20.59	3.00	-
IPD	ImpediMed Limited	Diagnostic devices for lymphoedema, muscle wasting and metabolic disorders utilising bioimpedance technology.	24/10/2007	178.71	0.11	0.14	0.05	-1.62	-6.79	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	6,253.96	3.22	4.17	3.12	52.20	6.17	155.00	27.00

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)
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	7.59	0.05	0.12	0.03	-1.10	-4.09	1.00	-
IVX	Invion Limited	Developer of treatments for inflammatory diseases.	15/2/2010	44.94	0.01	0.02	0.01	-0.03	-23.33	-	-
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	33.07	0.44	0.75	0.43	-8.01	-5.49	33.00	-
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	2.81	0.01	0.01	0.00	-2.90	-0.28	-3.00	-
KZA	Kazia Therapeutics Limited	Development of anti-cancer drugs.	1/9/1994	42.19	0.20	1.11	0.07	-18.08	-1.08	-4.00	-
LBT	LBT Innovations Limited	Automated systems for the preparation, screening, interpretation and streaking of microbiological specimens.	31/7/2006	13.28	0.04	0.10	0.03	-1.80	-2.11	-	-
LCT	Living Cell Technologies Limited	Developer of live cell therapy products for treatment of neurological and metabolic disorders	1/9/2004	12.47	0.01	0.02	0.00	-0.21	-4.29	-	-
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	6.02	0.02	0.36	0.02	-40.82	-0.05	-1.00	-
LER	Leaf Resources Limited	Leaf Resources Limited manufactures and supplies pine chemicals in Australia. It provides natural wood rosin and turpentine, alongside cellulose and cellulosic fuels.	5/1/1999	43.30	0.02	0.04	0.01	-0.39	-5.13	-	-
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	53.62	0.18	0.48	0.17	12.00	1.46	37.00	-
M7T	Mach7 Technologies Limited	Imaging IT solutions, 3D printing and holographic projection provider.	30/11/2005	152.20	0.62	0.80	0.45	-1.62	-38.27	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	99.04	0.32	0.45	0.14	-1.98	-15.91	13.00	-
MDC	Medlab Clinical Limited	Research and development of novel biotherapeutics to improve health outcomes in chronic diseases such as chronic kidney disease and obesity.	14/7/2015	15.07	6.60	19.50	6.45	-7,100.00	-0.09	342.00	-
MEB	Medibio Limited	Diagnostic tests for depression and other mental health disorders.	29/1/2001	4.15	0.00	0.00	0.00	-0.59	-0.17	-	-
MEM	Memphasys Limited	Cell and protein separation systems.	14/5/2007	17.27	0.02	0.06	0.01	-0.28	-6.43	-	-
MSB	Mesoblast Limited	Commercialisation of adult stem cell technology.	16/12/2004	737.12	1.00	1.33	0.61	-18.63	-5.34	-13.00	-
MVF	Monash IVF Group Limited	Assisted reproductive technologies, genetic testing and ultrasound services.	26/6/2014	430.55	1.11	1.27	0.87	4.30	25.81	1.00	4.40
MVP	Medical Developments International Limited	Medical and veterinary equipment including pain management, resuscitation and asthma management products.	15/12/2003	94.94	1.07	3.64	1.01	-3.83	-27.94	53.00	-
MX1	Micro-X Limited	Develops and manufactures a range of mobile X-ray imaging systems for medical applications.	22/12/2015	49.37	0.10	0.25	0.09	-2.58	-3.72	4.00	-
MXC	MGC Pharmaceuticals Limited	Innovator in phytocannabinoid-based medicines within the biopharmaceutical industry.	21/12/2006	30.46	0.01	0.03	0.01	-0.74	-1.08	-	-
MYX	Mayne Pharma Group Limited	Pharmaceutical commercialisation and manufacturing. Development of oral drug delivery systems.	29/6/2007	342.85	4.01	7.47	2.68	82.63	4.85	70.00	-
NAN	Nanosonics Limited	Ultrasound probe disinfection – Trophon device.	17/5/2007	1,578.06	5.17	5.45	2.87	3.39	152.51	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	7.15	0.05	0.12	0.04	-0.89	-5.39	1.00	-

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)
NEU	Neuren Pharmaceuticals Limited	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders.	3/2/2005	1,702.31	14.20	13.84	3.33	0.15	9,466.67	33.00	-
NGS	Nutritional Growth Solutions Limited	Develops, produces and sells pediatric protein supplements in the United States and internationally.	30/10/2020	3.26	0.02	0.17	0.02	-4.43	-0.43	-	-
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	26.88	0.09	0.29	0.09	-42.88	-0.21	-64.00	-
NOX	Noxopharm Limited	Development of drugs to make radiotherapy more effective. NOX66 is the company's pipeline product.	9/8/2016	21.33	0.06	0.33	0.06	-5.28	-1.17	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	11.33	0.08	0.29	0.07	-5.41	-1.48	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	48.07	0.05	0.13	0.05	-0.70	-7.29	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	2,199.14	5.73	6.93	4.75	28.00	20.46	253.00	10.00
NXS	Next Science Limited	Next Science Limited is a medical technology with a research and development centre in Florida, United States.	18/4/2019	156.80	0.74	1.08	0.53	-8.90	-8.31	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	17.16	0.11	0.20	0.10	-2.46	-4.47	6.00	-
OCC	Orthocell Limited	Soft tissue cellular therapies for restoration of tendon and cartilage injuries.	12/8/2014	82.83	0.44	0.51	0.30	-4.40	-10.00	3.00	-
OIL	OptiScan Imaging Limited	Microscopic imaging technologies for medical markets.	8/8/1997	65.75	0.10	0.16	0.08	-0.75	-13.33	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	40.01	0.08	0.28	0.06	-3.15	-2.57	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	2.40	0.03	0.08	0.03	-2.29	-1.31	-3.00	-
OPT	Opthea Limited	Developer of novel therapy OPT-302 for treatment of eye diseases.	18/4/1991	315.33	0.65	1.40	0.65	-47.89	-1.36	27.00	-
OSL	OncoSil Medical Limited	Brachytherapy device that implants a dose of beta radiation into a pancreatic tumour.	15/8/2005	10.94	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	0.02	0.04	0.02	-5.24	-0.38	2.00	-
PAA	PharmAust Limited	Developer of targeted cancer therapeutics for humans and animals. Specialises in repurposing marketed drugs.	5/10/2001	33.28	0.10	0.12	0.06	-0.16	-60.00	1.00	-
PAB	Patrys Limited	Developing novel antibody therapies for a range of oncology indications.	13/7/2007	30.86	0.02	0.04	0.01	-0.30	-5.00	-	-
PAR	Paradigm Biopharmaceuticals Limited	Biopharmaceutical company focused on repurposing the drug pentosan polysulphate sodium for the treatment of inflammation.	19/8/2015	283.74	0.99	2.15	0.85	-16.36	-6.02	25.00	-
PBP	Probiotec Limited	Manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, medicines and consumer health products.	14/11/2006	191.92	2.40	2.45	2.02	18.18	13.20	-5.00	6.50
PCK	PainChek Limited	Smartphone app to provide pain assessment for those who are unable to communicate.	1/5/2012	33.75	0.03	0.04	0.02	-0.58	-4.83	-	-
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	307.94	0.38	0.85	0.37	-2.42	-15.70	11.00	-

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	184.62	0.28	0.44	0.22	0.73	37.67	-	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	115.92	0.92	1.18	0.61	-5.19	-17.73	6.00	-
PME	Pro Medicus Limited	Provider of radiology information systems and diagnostic imaging.	10/10/2000	6,630.40	62.45	68.93	36.54	48.83	127.89	84.00	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	1,183.75	1.71	2.71	0.85	-1.00	-170.50	9.00	-
PTX	Prescient Therapeutics Limited	Developer of anti-cancer drugs. Lead drug candidate PTX-200.	19/12/1986	74.73	0.10	0.26	0.08	-0.80	-11.88	3.00	-
PXS	Pharmaxis Limited	Drug discovery to treat inflammatory and fibrotic diseases using amine oxidase inhibitor chemistry platform.	10/11/2003	40.30	0.06	0.11	0.04	0.84	7.02	2.00	-
PYC	PYC Therapeutics Limited	Development of intracellular biological therapeutics using its Functional Penetrating Phylomers.	30/3/2005	194.43	0.06	0.10	0.06	-0.75	-8.00	1.00	-
RAC	Race Oncology Limited	Development of chemotherapy drug Bisantrene for cancer, particularly Acute Myeloid Leukemia.	13/7/2016	310.52	1.88	2.87	1.45	-6.74	-27.89	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, Victoria, Australia.	25/11/2021	41.82	0.18	0.27	0.10	-5.28	-3.31	2.00	-
RCE	Recce Pharmaceuticals Limited	Development of synthetic antiobiotics to address the threat of antiobiotic resistance.	15/1/2016	126.56	0.71	0.93	0.54	-7.82	-9.02	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	3.68	0.01	0.07	0.01	-1.29	-0.85	-	-
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	22.12	0.05	0.13	0.04	-0.25	-20.00	2.00	-
RHY	Rhythm Biosciences Limited	Development of an affordable blood test for the early detection of colorectal cancer, ColoSTAT.	7/12/2017	111.30	0.56	1.63	0.43	-3.84	-14.58	4.00	-
RMD	ResMed Incorporated	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing.	25/11/1999	14,097.78	33.36	36.10	27.37	83.00	40.19	-	17.84
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	24.86	0.09	0.23	0.09	-2.37	-3.67	-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	0.61	0.01	0.08	0.01	-3.72	-0.19	-	-
RSH	Respiri Limited	Devices for detecting and monitoring respiratory disorders.	14/7/2000	44.69	0.05	0.08	0.03	-0.82	-6.46	-	-
SCU	Stemcell United Limited	Growth, reproduction and extraction of plants stem cells for medical and healthcare products.	13/6/2000	6.42	0.01	0.01	0.00	-0.48	-1.04	-	-
SDI	SDI Limited	Research and development, manufacturing and marketing of specialist dental materials.	7/11/1985	98.06	0.83	0.95	0.73	6.15	13.41	49.00	3.25
SDV	Scidev Limited	Offers coagulants, 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; friction reducers and dynamic shears.	2/5/2002	66.43	0.32	0.46	0.16	1.03	31.07	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	7.15	0.06	0.21	0.05	-5.37	-1.14	2.00	-
SHL	Sonic Healthcare Limited	Laboratory medicine/pathology, radiology/diagnostic imaging and primary care medical services.	30/4/1987	16,822.03	35.83	37.46	28.07	214.00	16.74	-1.00	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	80.28	0.95	2.05	0.95	-6.66	-14.26	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	198.49	0.49	0.88	0.43	-3.95	-12.41	10.00	-
TD1	TALi Digital Limited	Cognitive training program for children with attention difficulties.	23/9/2004	6.59	0.00	0.01	0.00	-0.39	-0.51	-	-
TLX	Telix Pharmaceuticals Limited	Development and commercialisation of molecularly targeted radiation in the management of prostate, renal and glioblastoma (brain) cancer.	15/11/2017	2,504.46	8.89	8.20	3.55	-33.50	-26.54	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	258.54	1.65	3.71	1.62	3.24	50.77	9.00	-
TRP	Tissue Repair Limited	Tissue Repair Limited, a clinical-stage biopharmaceutical company, developing advanced wound-healing products for chronic wounds and the aftercare of cosmetic procedures in Australia.	18/11/2021	9.59	0.21	0.38	0.20	-6.44	-3.26	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	9.58	0.03	0.07	0.02	-2.00	-1.25	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	2.53	0.02	0.18	0.01	-3.10	-0.55	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	57.34	0.27	0.80	0.21	-14.00	-1.89	12.00	-
UCM	Uscom Limited	Non-invasive medical devices in the field of cardiac, vascular and pulmonary monitoring	10/12/2003	7.95	0.04	0.10	0.04	-1.20	-3.33	2.00	-
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	31.38	0.60	1.38	0.42	-9.03	-6.59	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	195.65	0.75	0.90	0.40	-4.61	-16.27	1.00	-
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	192.00	0.34	1.05	0.18	1.79	18.72	4.00	1.00
VLS	Vita Life Sciences Limited	A pharmaceutical and healthcare company, mainly engaged in formulating, packaging, sales and distribution of over-the-counter medicines, health supplements, vitamins and investments.	23/8/2007	76.37	1.42	2.20	1.35	13.37	10.62	61.00	6.00
WNX	Wellnex Life Limited	Wellnex Life Ltd (formerly Wattle Health Australia Limited). Health and wellness products with scientific and nutritional benefit.	15/3/2017	27.31	0.07	0.11	0.05	-3.05	-2.16	-	-
WOA	Wild 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	22.62	0.21	0.77	0.15	-9.19	-2.29	12.00	-
XRF	XRF Scientific Limited	Manufacturer and marketer of instrumentation for scientific industries, including commercial laboratories	31/10/2006	174.05	1.29	1.28	0.51	5.20	24.81	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	11.35	1.05	5.00	0.90	-108.07	-0.97	8.00	-

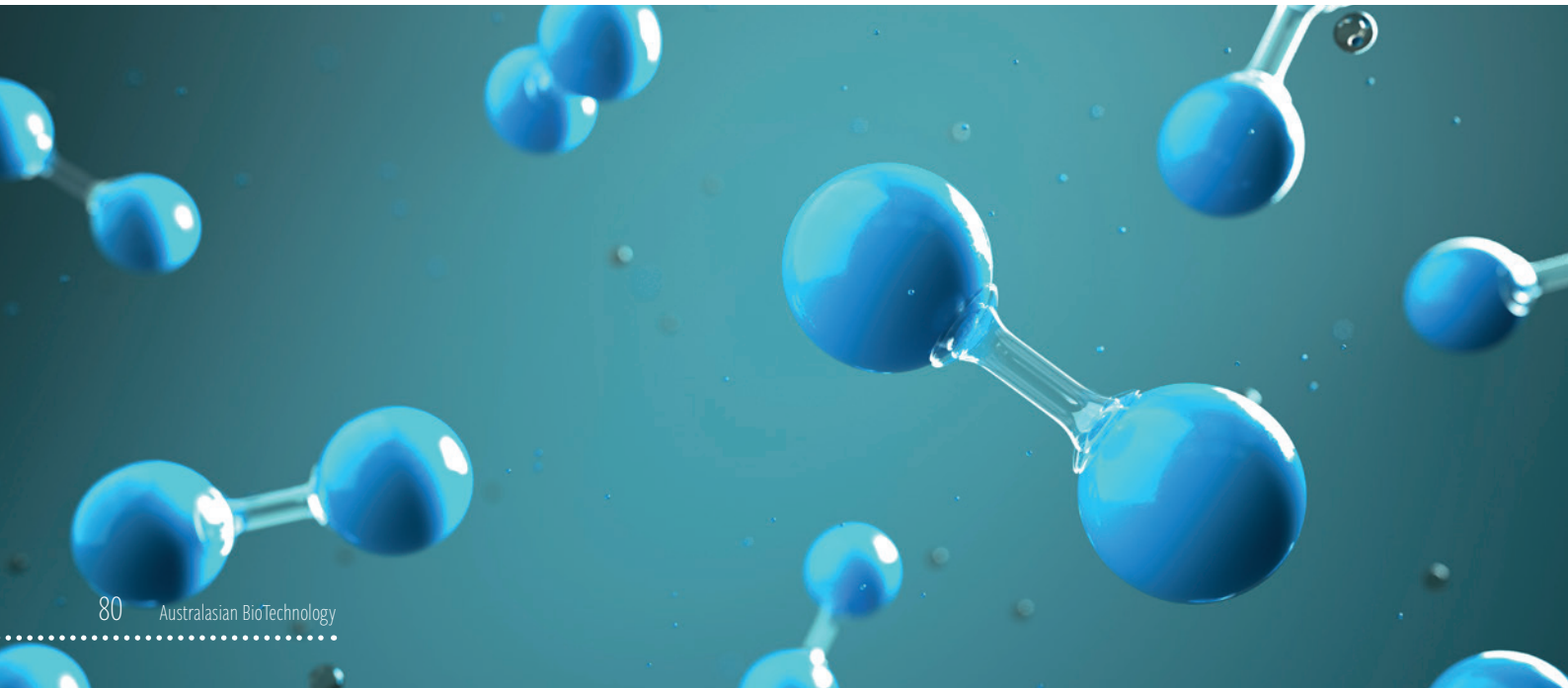
This quarter's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Quarter Return %
ALA	Arovella Therapeutic	$0.08	237.50
AVH	Avita Medical	$4.50	85.95
4DX	4Dmedical Limited	$0.84	78.72
KZA	Kazia Therapeutics	$0.20	62.50
BOT	Botanix Pharma Limited	$0.09	61.40
NEU	Neuren Pharmaceuticals	$14.20	58.84
IPD	Impedimed Limited	$0.11	57.14
XRF	XRF Scientific	$1.29	56.36
CYC	Cyclopharm Limited	$2.19	46.33
RAD	Radiopharm	$0.18	29.63
TLX	Telix Pharmaceutical	$8.89	25.74
BDX	Bcaldiagnostics	$0.07	21.67
EBR	EBR Systems	$0.68	19.30
COH	Cochlear Limited	$247.45	17.36
GTG	Genetic Technologies	$0.00	16.67
SHL	Sonic Healthcare	$35.83	15.56
MEM	Memphasys Limited	$0.02	12.50
PBP	Probiotec Limited	$2.40	11.98
RCE	Recce Pharmaceutical	$0.71	9.30
NAN	Nanosonics Limited	$5.17	9.07
DVL	Dorsavi Limited	$0.01	8.33
MVF	Monash IVF Group Limited	$1.11	8.33
CAT	Catapult Group International Limited	$0.79	6.80
PAA	Pharmaust Limited	$0.10	6.67
OCC	Orthocell Limited	$0.44	6.02
RSH	Respiri Limited	$0.05	6.00
BIO	Biome Australia Limited	$0.07	5.88
FPH	Fisher & Paykel Healthcare Corporation Limited	$24.49	4.57

This year's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Year Return %
NEU	Neuren Pharmaceuticals	$14.20	258.59
AVH	Avita Medical	$4.50	107.37
ALA	Arovella Therapeutic	$0.08	102.50
XRF	XRF Scientific	$1.29	97.74
TLX	Telix Pharmaceuticals	$8.89	90.36
PNV	Polynovo Limited	$1.71	53.60
CTE	Cryosite Limited	$0.73	51.02
BXN	Bioxyne Limited	$0.03	47.06
CYC	Cyclopharm Limited	$2.19	46.67
ARX	Aroa Biosurgery	$1.05	36.60
NAN	Nanosonics Limited	$5.17	33.59
AVR	Anteris Technologies	$23.70	32.25
PME	Pro Medicus Limited	$62.45	28.93
CU6	Clarity Pharma	$0.72	25.76
EBR	EBR Systems	$0.68	19.30
FPH	Fisher & Paykel Healthcare Corporation Limited	$24.49	18.48
4DX	4Dmedical Limited	$0.84	15.86
CSL	CSL Limited	$300.24	14.60
LCT	Living Cell Technologies	$0.01	13.90
CUV	Clinuvel Pharmaceut.	$19.90	13.68
ANO	Advance Zinctek Limited	$2.25	13.24
VIT	Vitura Health Limited	$0.34	13.11
ANN	Ansell Limited	$27.33	11.49
BOT	Botanix Pharma Limited	$0.09	10.84
COH	Cochlear Limited	$247.45	10.76
EBO	Ebos Group Limited	$41.50	9.32
RMD	ResMed Incorporated	$33.36	6.10
EYE	Nova EYE Medical Limited	$0.27	5.88

Data current at 18 April 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.



RESEARCH VALET®

ST VINCENT'S HOSPITAL MELBOURNE

Your Lead Site Solution - 临床研究主导场地服务 - 앞서 가는 현장 솔루션

- Single point of access for all regulatory advice for Australia
- Speedy start-up time for Australian clinical trials (Phases I-IV) - including drugs, devices, GMO/cell therapies and AI/Machine Learning studies
- Ethics outcomes within 30 days of committee meeting (Phase II-IV)
- Start-up to full study management options
- Ethics approval from single HREC for all Australian states (except Northern Territory)
- St Vincent's Hospital Melbourne not required to be a participating site
- Post approval management services that facilitate all post-approval project submission and ongoing ethics management

ST VINCENT'S HREC MEETING EVERY 2 WEEKS!

Talk to our team to learn more about the Research Valet® Service

Dr Megan Robertson
Director of Research
T: +61 0412 051 215

Dr Tam Nguyen
Deputy Director of Research
T: +61 3 9231 6980

Dr Trixie Shinkel
Valet® Manager
T: +61 3 9231 6977

valet@svha.org.au | www.researchvalet.com.au

Do you need **Life Science** or **Clinical Trial insurance?**

Newline is a leading provider of Life Science & Clinical Trial insurance solutions offering:

- Unparalleled expertise and service with local underwriting and claims handling
- Rapid response for compliant certificates and documents
- Global ability to issue local compliant policies in over 100 countries
- Full Policy limits for US exposures
- Bespoke Medicinal Cannabis wording and more!

*Contact your broker to **learn more.***

Will Clarke
T +61 3 9912 4021 | M +61 477 222 534
E wclarke@newlinegroup.com.au

newlinegroup.com.au

NEWLINE GROUP®