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Australasian BioTechnology

The journal of AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

What's next in Australian investment

The secret sauce of biotech investor relations

Australian innovation with global impact

The role of patents in drug development

AND MORE...

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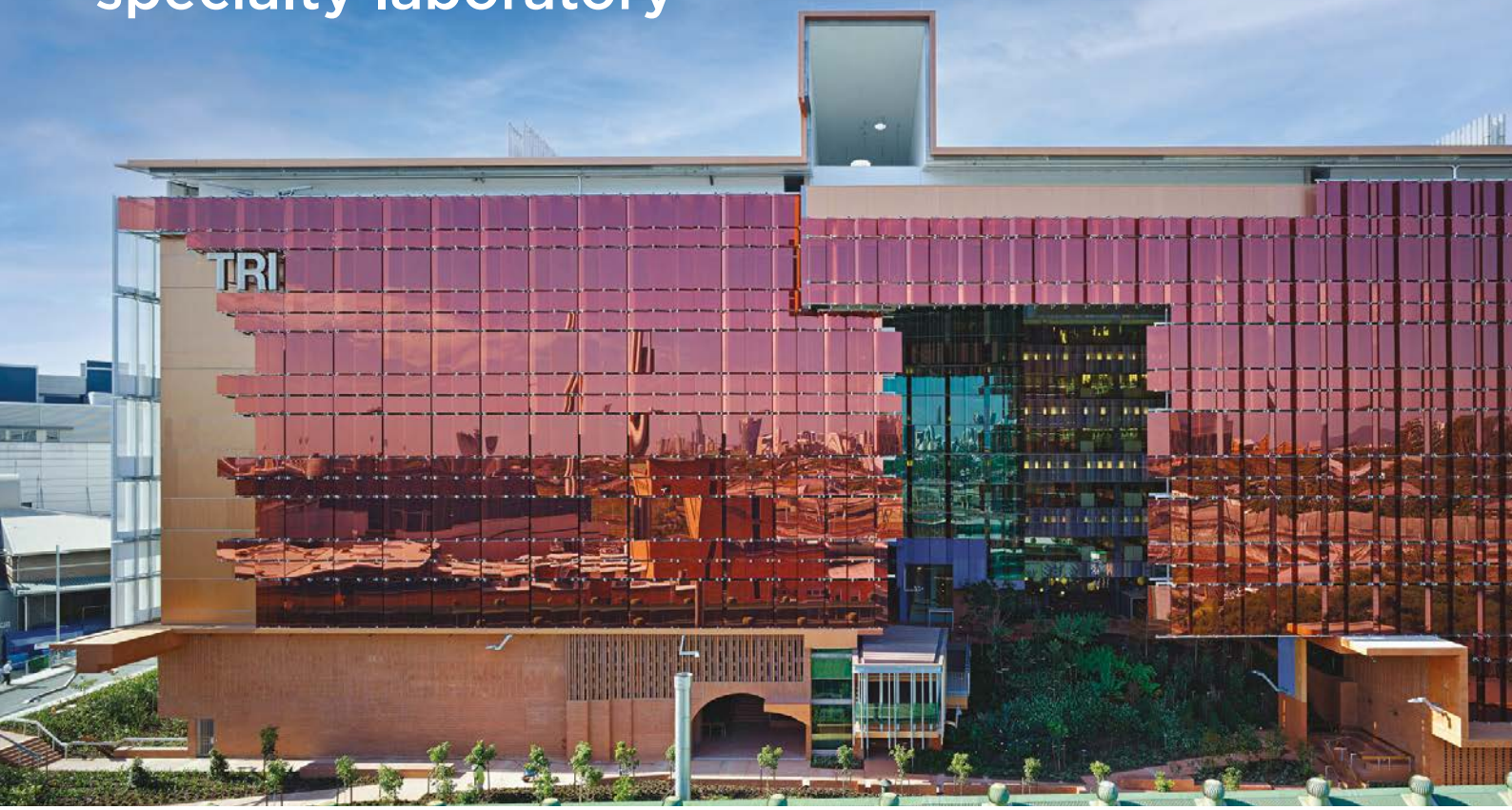
Australia's leading and most comprehensive specialty laboratory



Continuing to exceed our clients' needs, 360biolabs has opened a Brisbane laboratory to further support clinical trials in the north-east region of Australia.

As Australia's leading and most comprehensive specialty laboratory, 360biolabs often receives requests to process samples for downstream enzymatic or immunological assessments within hours of blood draw.

"Receiving samples within a very short time-frame from sites and Phase 1 units located in and around Brisbane ensures sample integrity is maintained at the highest level, which is our utmost priority" said Dr Melinda Pryor, EVP, Clinical Operations.

After an extensive search, the Translational Research Institute (TRI) in Woolloongabba was selected. TRI's vision is exceptional science and healthier lives. This focus on 'bench to bedside' is consistent with 360biolabs mission of enabling future medicines.

Want to know more about our Brisbane specialty lab and how we can support your clinical trial?

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

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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 3, 15 Queen Street, Melbourne VIC 3000
Tel: 0437 126 843 | Email: admin@ausbiotech.org | Web: www.ausbiotech.org

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FASTER PBMC ISOLATION LEADS TO MORE RELIABLE RESULTS

BY MADISON ESELY-KOHLMAN

The first satellite bioanalytical lab offers fastest option for peripheral blood mononuclear cell (PBMC) processing in Australian clinical trials.

ON 9 SEPTEMBER 2022, Australia welcomed its first ever bioanalytical laboratory inside a Phase 1 clinical unit.

Agilex Biolabs, the leading bioanalytical laboratory supporting Australian clinical trials, has established its first satellite processing unit staffed by highly specialised technicians on the fifth floor of the CMAX Clinical Research facility in Adelaide, South Australia. The Agilex satellite laboratory will perform time-sensitive sample processing techniques in the same building as clinical trial participants, opening the door for new drug sponsors to reduce risk in their studies by truncating the decline of sample integrity.

PBMCs include several hallmark cell types involved in immune response, such as T cells, B cells, and NK (natural killer) cells. The count of a certain blood cell type is often a critical piece in assessing the impact of a drug on the immune system. Similarly, cytokines released by immune cells can indicate the level of immune response or unwarranted inflammatory response, such as cytokine storm.

As soon as a blood sample is drawn from a person's body, that sample begins to deteriorate as blood cells are no longer resupplied with oxygen. When a clinical trial hinges on a reliable count of PBMCs or cytokines, whole blood from the patient must be processed as quickly as possible to stop deterioration and ensure that quantitative analysis of the sample is an accurate reflection of the cells in the human they came from. The sooner a whole blood sample is treated, the less deterioration of cells has occurred and, therefore, sample integrity is higher.

While clinical sites are well-equipped to draw samples from clinical trial participants, they are not normally outfitted with a specialised laboratory where sample preparation can take place. Instead, after a sample is taken from the vein of a patient, it must immediately be transported to a different location for processing. Through the Healius network and Linear Clinical Research in Perth, who have extensive experience with PBMC processing across their cancer and healthy volunteer trials, offsite PBMC processing is accessible to Phase 1 units throughout Australia.

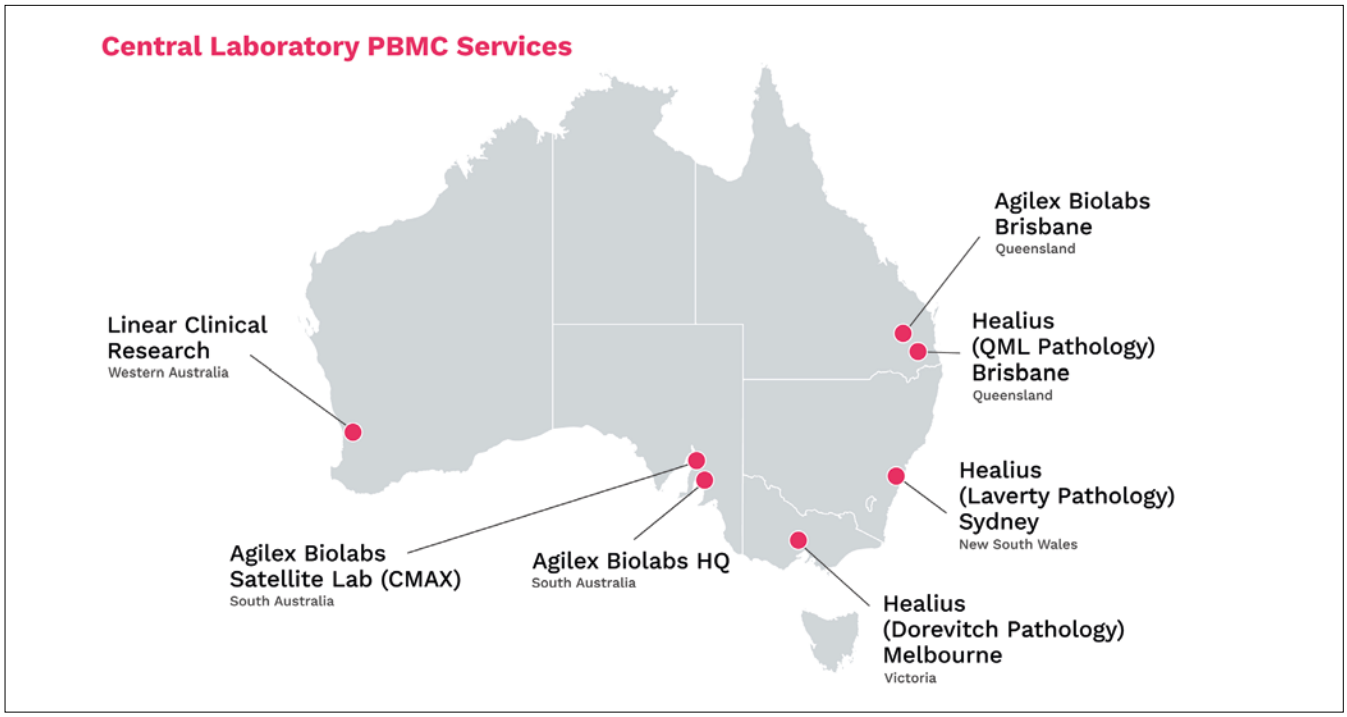
'Even when the processing lab is only a few kilometres from the clinical site, risk accumulates with every passing minute,' says Jane Kelly, CEO of CMAX. 'An extra stoplight here, a road closed there – the integrity of a sample is declining, so every trip is a race against time. In partnership with Agilex, we are eliminating that risk from CMAX clinical trials.'

At CMAX, a blood sample will soon go from patient to processing at a specialised laboratory unit in 15 minutes – the Agilex satellite laboratory is only metres away.

Technicians at the Agilex laboratory on the fifth floor can immediately stop the clock and begin processing samples. In addition to isolating PBMCs from whole blood, Agilex laboratory specialists are also trained in other time-sensitive sample preparation techniques, such as stimulation of whole blood for cytokine release assays or stimulation of isolated PBMCs for studies measuring NLRP3 inflammasomes.

Following onsite processing, samples are shipped quickly to the nearby Agilex Biolabs headquarters, also located in Adelaide. With its rapid-turnaround sample analysis team, Agilex provides reliable quantitative data within just a few days of sample collection at CMAX.

PBMC quantitation by flow cytometry is just one of many bioanalytical services Agilex performs for biopharma clients



worldwide. The sprawling campus includes multiple facilities for large and small molecule bioanalysis, supporting new and repurposed drug programs in many therapeutic areas, including immunology, immuno-oncology, infectious diseases, vaccines and many others.

In a steadfast commitment to quality and speed, the satellite laboratory is just one of several leaps in innovation Agilex is making to improve pipeline advancement for its customers.

'This is a huge win for clinical trials in Australia,' says Agilex's Chief Scientific Officer, Kurt Sales. 'Until now, time-critical whole blood stimulation or PBMC processing had to occur at offsite processing units in Adelaide. A clinical research facility with onsite processing capabilities presents an opportunity to achieve faster turnaround of sample processing and more reliable results.'

This collaboration between Agilex and CMAX improves reliability of bioanalytical data by conserving sample integrity with faster processing. Equipped with the services of Agilex and CMAX, drug sponsors can have confidence in their data and save time getting through clinical trials to deliver new, safe, and efficacious therapies to the patients with an unmet need.

About Agilex Biolabs

Agilex Biolabs is Australia's largest and most technologically advanced regulated bioanalytical and toxicology laboratory. For 25 years, Agilex has equipped biopharma companies around the globe with reliable and defendable, clinical bioanalysis, biomarker data and toxicology studies as they champion new therapeutics and modalities that improve human health. Agilex's global clientele includes drug sponsors shepherding small molecules, biologics, cell and gene therapies, and vaccines through preclinical and clinical development. Agilex is a proud member of the Healius network.

About Healius

One of Australia's leading healthcare companies, Healius is synonymous with quality, affordable and accessible health care for all Australians. It has an expansive network of pathology laboratories, diagnostic imaging centres and day hospitals. Healius provides quality healthcare services that are easily accessible and cost efficient, while supporting the coordination and continuity of quality patient care.

About CMAX Clinical Research

CMAX Clinical Research has been a leader in delivering early-phase clinical trials for more than 28 years, making it one of the most respected clinical trial businesses in Australia. Since 1993, CMAX has delivered more than 700 early-phase clinical trials, including more than 150 first-in-human studies. CMAX's modern facility is equipped with 78 inpatient beds, inclusive of a new low-stimuli suite and negative-air-pressure isolation rooms, and has ready access to state-of-the-art facilities, equipment, and world-class medical and pharmacology specialists.

CEO REPORT

BY LORRAINE CHIROIU, CEO, AUSBIOTECH

With record-breaking numbers at face-to-face AusBiotech-hosted or -led events, it's clear that the biotech buzz is palpable. Behind these significant numbers lie lively opportunities that mark biotech's global resilience and Australia's world-renowned capabilities. We look forward to advancing Australia's life sciences capabilities and proactively positioning our industry with a new federal government.

WITH THE SWEARING-IN of Australia's 47th federal Parliament – including an unprecedented increase to more than 16 independents and minor parties – the importance of ongoing long-term and nonpartisan support for biotechnology is evident.

This nonpartisan and solid support from governments, at the federal and state levels, over many years will be critical as industry seeks to successfully implement the 'Biotechnology Blueprint: A Decadal Strategy for the Australian Biotechnology Industry' (Blueprint). A shared vision and strong relationships are key in understanding each other's needs, and in obtaining agreement and meeting the Blueprint's recommendations in both the short and long term. This includes fulfilling Australia's ability to meet sovereignty, innovation, technology and manufacturing goals.

Our eyes are now set on October's federal budget, as we learn more about the Australian Labor Party's (ALP's) support of investment in 'medical science', innovation and advanced manufacturing, and in legislating the Australian Economic Accelerator as part of the University Research Commercialisation Action Plan. In the lead-up to the election, the ALP had also pledged a $15-billion National Reconstruction Fund to invest in our national sovereign capability, including a dedicated $1.5-billion Medical Manufacturing Fund.

The power of face-to-face connection is mighty, so we are eagerly returning to a face-to-face format for the biggest week in biotech, as well as for our state-based events. Enabling easier access to talent, expertise, education and partnerships, we are actively participating and showcasing Australia's capabilities within the highly competitive global biotech marketplace.

Facilitating industry growth

BIO International Convention 2022: the largest delegation in history

Australia's reputation as a leading hub for biotechnology was unmistakable during BIO 2022, held in San Diego, with the strongest delegation from Australia to date.

More than 400 Australians united around the Australian delegation, and showcased national capabilities, promoted the strength of the Australian life sciences, and fostered connections with our global biotech community.


Lorraine Chiroiu

Having led the delegation to BIO for more than a decade, AusBiotech was delighted to have the support of Australia's Ambassador to the United States, the Hon. Arthur Sinodinos AO; the New South Wales Minister for Health, the Hon. Brad Hazzard; and the Western Australia Minister for Medical Research, and Innovation and ICT, the Hon. Stephen Dawson; alongside strong state representation from Victoria, New South Wales, Western Australia, South Australia and MTPConnect.

We are also grateful for Austrade's ongoing support, including from Regina Crameri, Head of Health, Centre of Excellence; Benson Saulo, Consul General and Senior Trade and Investment Commissioner; and Emma Aitken, Investment Director, Health & Life Sciences. We also had the support of Global Victoria's Simon Phemister, Secretary, Department of Jobs, Precincts and Regions; Caroline Edwards, Commissioner to the Americas; and the New South Wales Government's Trade and Investment Commissioner Joseph Kaesshaefer.

Mark your diaries now: AusBiotech will host an Australian Hub during the J.P. Morgan 41st Annual Health Care Conference (9–12 January 2023, San Francisco, United States), and the Australian Pavilion at the BIO International Convention (5–8 June 2023, Boston, United States).

AusMedtech 2022: a record-breaking conference

Demonstrating the buoyancy and growth of the sector, AusBiotech recorded its largest ever face-to-face AusMedtech conference, as the Australian medical technology sector reunited and celebrated its achievements.

More than 460 delegates gathered for the two-day conference, which reflected the industry's international successes and aspirations with its 'Medtech and Manufacturing: Building Global Capability' theme. Read more about the event on page 78.

Remember to save the date for AusMedtech 2023, which will be held from 24–25 May in Adelaide, South Australia.

BIO KOREA 2022: reciprocal relationships strengthened

Supporting Austrade's BIO KOREA 2022 delegation, AusBiotech showcased Australia's investment opportunities and life sciences

capabilities as I delivered an opening keynote address during the Australia-Korea Innovation Seminar.

Keeping its finger on the global pulse, AusBiotech signed a new memorandum of understanding (MoU) with the Korea Biomedicine Industry Association at BIO KOREA 2022 to strengthen and generate collaboration opportunities between Australian and Korean biotech and pharmaceutical businesses.

AusBiotech also has MoUs with Korea's regenerative medicine industry association, the Council for Advanced Regenerative Medicine; Korea Health Industry Development Institute; Japan's peak regenerative medicine industry body, The Forum for Innovative Research Medicine; and Biocom California, the largest, most experienced leader and advocate for California's life sciences sector. These alliances strengthen Australia's sector positioning, and offer international opportunities for collaborations and partnerships, with a focus on key markets and technologies that are important to members.

Through these MoUs and its partnership with Austrade, AusBiotech looks forward to welcoming a large number of delegates to AusBiotech 2022, and will be encouraging partnering meetings with their potential investors and partners.

Australia's Cell and Gene Catalyst moves ahead

Ensuring that the Australian life sciences industry is structurally supported to capitalise on new technologies and growth opportunities, AusBiotech is thrilled to announce that Australia's Cell and Gene Catalyst (The Catalyst) is moving ahead. With the establishment of its inaugural steering group and the opening of its recruitment process, the Catalyst formally signals the important next step in advancing cell and gene accessibility in Australia.

Offering tremendous promise and hope – some call cell and gene therapies the most important discoveries of our future – this Catalyst seeks to create an end-to-end, world-class value chain that can discover, develop, manufacture, and distribute cell and gene therapies to Australian patients, while also creating jobs, commercialising research, and exporting Australian therapies to the world.

The steering group leading the Catalyst includes AusBiotech, Medicines Australia, CSL, Novartis, Pfizer, Therapeutic Innovation Australia, and Cell Therapies. The Catalyst will bring to life the 'Regenerative Medicine in Australia: A Strategic Roadmap for the Regenerative Medicine Sector' through leadership, advice and support. To drive and deliver on this national strategy, a general manager is being recruited for a two-year period.

Leveraging the AusBiotech-led Regenerative Medicines Consortium Project's exceptional foundation work throughout 2020–21, which cemented and benchmarked Australia's place on the global cell and gene map, the Catalyst will advance cell and gene policy, mobilise resources, build community engagement, establish shared measurement practices, and support aligned activities.

The Catalyst is also being supported by the Victorian Government's Australian Medtech Manufacturing Centre to help examine manufacturing barriers and explore new opportunities for growth to unlock the potential for cell and gene manufacturing in Australia. A new role will develop a 'blueprint' report to build on the work published in the 'Australia's Regenerative Medicine Manufacturing Capacity and Capability' report, to determine what is needed to manufacture more cell and gene products locally, and to develop specific recommendations, as well as a strategy document. This will coexist in harmony with the Catalyst's work.

Investing in health

With Australia experiencing explosive growth in company numbers, as revealed in 'AusBiotech's Australian Biotechnology Sector Snapshot 2022', the appetite for capital within our sector is accelerating. In recognition of access to capital as one of the most significant drivers of growth and sustainability for Australia's life sciences sector, AusBiotech has expanded its investment attraction portfolio.

Identified during the development of the Blueprint, the work will bolster the evidence base and industry-level analysis available by refreshing and creating new resources.

It is critical for ongoing success in accessing and deploying investor capital that Australian companies remain competitive, and that the business operating environment is conducive to biotechnology investment. This requires maintenance of the factors that attract investors, while staying ahead of investment trends likely to impact the sector. This is why AusBiotech's recent bolstering of its investment attraction program will commence with the development of an environmental, social and governance (ESG) framework to support reporting for the industry, as it is increasingly important to employees, members and industry stakeholders – including investors – and is strongly aligned with community expectations.

The investment program will also build on AusBiotech's successful investment series that has brought together investors and Australian companies seeking capital over the past decade, including AusBioInvest 2022, Australia's largest life sciences investment conference.

Back in person for the first time in three years, we're building meaningful personal connections between innovative businesses and investors, to help great ideas get the funding they need to thrive in an extremely competitive market.

A recent McKinsey & Company report, 'What are the biotech investment themes that will shape the industry?' (June 2022), noted that from 2019 to 2021, venture capital companies invested more than $52 billion in therapeutic-based biotech companies, globally. Two-thirds of that went to startups with platform technologies.

Australian and global investors are hungry for more breakthrough ideas that can be life-saving, or life-improving, and this pre-eminent annual event will showcase, advance and celebrate up to 30 diverse biotechnology companies that are developing technologies in Australia. Keynote speeches and panel discussions will reveal industry trends and market updates, while connections can be made and re-established through one-on-one partnering opportunities and networking opportunities, and during an invitation-only investor–CEO dinner.

Investors and delegates can learn more and register at www.ausbiotechinvestment.com.au. AusBioInvest 2022 is proudly supported by Business Events Perth and the Western Australian Government.

AusBiotech 2022: Come Alive

After two years of disruption and change, we're reconnecting and recharging the biotech community to ignite what's next.

Australia's largest life sciences conference is overflowing with opportunity, and will see our thriving Australian and global biotechnology network come alive. We're reconnecting the biotech community under the sunny Perth skies to reflect on what we've achieved, to network face to face, and to advance the sector.

With more than 1000 delegates expected to attend, conference registration includes:

- access to three days of an interactive and cutting-edge program
- international and national keynote speakers, and expert panel discussions
- the AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards 2022
- three days of in-person AusPartnering (AusBiotech's highly popular business-matching program)
- social networking events, including a welcome reception, conference gala dinner and closing ceremony to engage and make new contacts
- the Early-Stage Investment Forum
- an opportunity to connect with industry through the BioIndustry Exhibition
- satellite events.

Proudly supported by Business Events Perth and the Western Australian Government, consider this event a destination of choice. Experience innovation coming alive at the conference; discover world-class research and development, and the entrepreneurial talent behind it; and add on a long weekend to explore Western Australia's raw natural beauty, which makes the conference so effortlessly Australian.

AusBiotech 2022, Australia's annual flagship industry conference, is the backbone of our biggest week in biotech.

Registrations for AusBiotech 2022 remain open. For more information, visit www.ausbiotechnc.org.

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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?

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Contact: A/Prof Tina Soulis

Founder and Director

tina.soulis@alithialifesciences.com

+61 (0) 429 300 705

SCAN ME

COMBATING ANTIMICROBIAL RESISTANCE

An Australian biotech company is advancing a new class of synthetic anti-infectives designed to treat a broad range of bacterial infections without contributing to drug resistance.

ANTIMICROBIAL RESISTANCE (AMR) is the third leading cause of mortality worldwide, with an estimated 4.95 million deaths associated with bacterial AMR in 2019, including 1.27 million deaths attributable to bacterial AMR directly. The Review on Antimicrobial Resistance, chaired by Jim O'Neill in 2016, estimated that as many as 10 million people could die annually from AMR by 2050. As a result of factors including persistent antibiotic use and hospital-acquired infections, the rapid emergence of AMR threatens our ability to treat common infections.

Squashing superbugs

Australian biotech company Recce Pharmaceuticals (ASX:RCE, FSE:R9Q) is developing a new class of synthetic anti-infectives that hold the potential to resolve multi-drug-resistant infections safely and effectively. Recce's lead anti-infective candidate, RECCE® 327 (R327), is a synthetic polymer designed to target a variety of infections caused by even the most difficult-to-treat bacteria. Through its unique and multi-layered mechanism of action, R327 permeabilises the cell membrane and enters the cell; interrupts bacterial cellular energetics via ATP synthesis disrupting the cellular division and non-dividing cell functions; and, at high concentrations, causes cell lysis. R327 is rapidly and irreversibly bactericidal and does not display any loss of efficacy against both Gram-positive and Gram-negative bacteria, including their multi-drug-resistant superbug forms, even after repeated use.

Tackling difficult and deadly infections

There is a strong unmet medical need for a broad-spectrum anti-infective to treat life-threatening sepsis infections without inducing toxicity or contributing to the rise of AMR.

Recce is conducting a Phase 1 intravenous safety study evaluating the safety and pharmacokinetics of R327 in healthy subjects.

Key takeaways from ongoing Phase 1 intravenous safety study

- Latest dosing at 6000 milligrams is completed: 120-fold increase from Cohort 1 at 50 milligrams.
- No adverse events have been reported in Cohorts 1 to 7 (50 milligrams – 6000 milligrams) thus far, with R327 indicating to be safe and well tolerated at 'low and high' doses.
- Based on previous animal models, R327 is now broadly in efficacy range.
- Next phase preparations are well underway.

While Recce is committed to significantly changing the treatment paradigm for sepsis, the company's Phase 1/2 study assessing the efficacy of R327 as a spray-on anti-infective for the treatment of burn wound infections has demonstrated promising results thus far.

Key takeaways from Phase 1/2 topical burn wounds study

- Topical application of R327 demonstrated broad-spectrum activity.
- Patients included in the trial suffered major burn injuries.
- Multiple bacterial species were found in and surrounding the wound.
- Growth swabs showed organisms including pathogens from the ESKAPE group of bacteria.
- Post R327 treatment, healthy skin growth returned, with reduced swelling and infection, and indications of tissue penetration to underlying infection.

The path forward

With a historical lack of antibiotic drug development, the need for new anti-infectives has never been greater. The global antibiotic pipeline remains deficient, as most drugs advancing through the clinic are predominantly derivatives of well-established antibiotic classes from more than 30 years ago. Recce's anti-infectives represent the first of a new class of antibiotics that hold the potential to be used as a treatment of serious and life-threatening infections due to Gram-positive and Gram-negative bacteria, including their superbug forms.

A Revolutionary Approach to Anti-infectives

An Australian based globally-focussed, biotech company engaged in the development and commercialisation of a new class of synthetic anti-infectives designed to address the urgent global health problem of antibiotic-resistant superbugs and emerging viral pathogens.

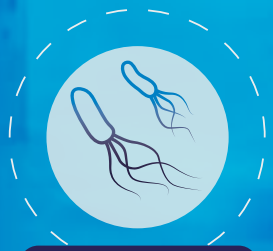
Built upon *good people and great science*, our compounds have a unique and multi-layered mechanisms of action that has been designed to be used against a broad range of bacteria and viruses without developing resistance – even after repeated use.

With no new class of antibiotics on the market in over 30 years, our synthetic anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

Sepsis

Topical burn wounds

Sinusitis



Pseudomonas aeruginosa

Staphylococcus aureus

Helicobacter pylori

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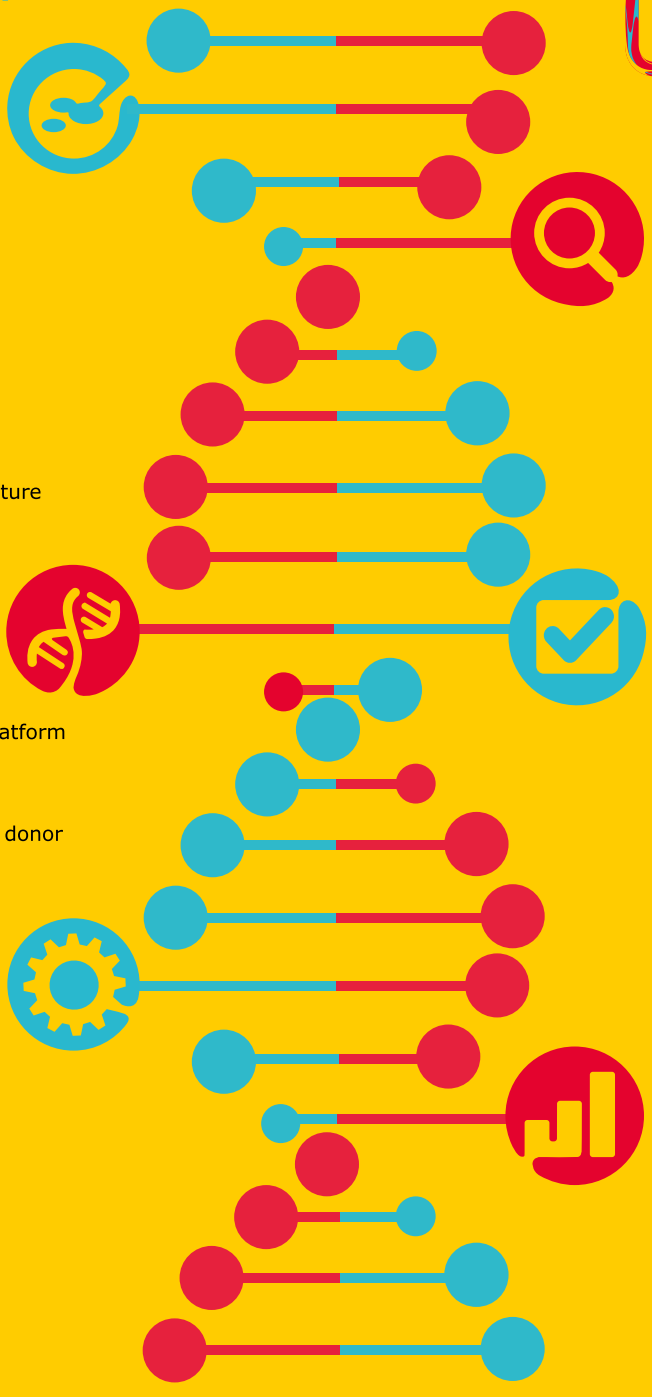
Enabling quality research at every stage of your workflow



Cell Culture:
Model Systems,
Growth & Maintenance

- Cell lines
- Sera
- Media
- Antibiotic selection guide
- Growth factors & cytokines
- Sterile filtration
- Labware
- 3D cell culture
- Cell lines and specialty cell culture

Select Target Genes & Design gRNA

- CRISPR design tool
- Easy-to-use online ordering platform
- Pre-cloned Sanger QuickPick™ KO guides
- CRISPR design specialists and donor design services

CRISPR Delivery

- Transformation
  - *E.coli* strain
  - TB broth
  - Antibiotics (e.g. Ampicillin)
- Lipid-based transfection
  - TransIT CRISPR® reagent
  - X-tremeGENE™ HP
- Lentiviral infection
  - Packaging mix
  - Polybrene® reagent
  - GenElute™ DNA/RNA prep kits
  - ExpressMag® system

CRISPR Strategy:
Gene Knockout, Knock-in, Activation or Inhibition

- Target a small number of genes
- Target a large number of genes
  - Pooled Screening (CRISPR KO, activation with SAM CRISPRa, inhibition with CRISPRi)
  - Arrayed Screening (e.g. Sanger lentiviral CRISPR library)
  - Single cell CRISPR screening

Order gRNA & Cas9

- Guide RNAs
  - *in vitro* transcribed gRNA
  - Plasmid - DNA/lentivirus
  - Synthetic - PUREdit™ and standard sgRNA, crRNA and tracrRNA
- Cas9
  - PUREdit™ and Cas9 proteins
  - Plasmid - DNA/lentivirus
  - mRNA
- Pooled/Arrayed screens
- Custom oligos (donors or single stranded gRNAs)

Analysis

- GenElute™-E single spin DNA/RNA purification kits
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  - PCR, qPCR, RT-PCR
  - KiCqStart® probe assays
  - Oligos & probes
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AUSTRALIAN INNOVATION WITH GLOBAL IMPACT

BY DR JACKIE FAIRLEY, CEO, STARPHARMA

The global pandemic has necessitated the rapid development of infection control measures, with major vaccines rolled out in 2021. Australian company Starpharma also contributed to the fight against COVID-19 with the development of its broad-spectrum antiviral nasal spray.

STARPHARMA IS A Melbourne-based biotechnology company focused on the development and commercialisation of pharmaceutical and healthcare products based on its dendrimer technology.

The company has already commercialised several medical products, now on market, based on its antiviral and antibacterial dendrimer called SPL7013, which was originally identified by Starpharma for its activity against sexually transmitted viral infections, including human immunodeficiency virus (HIV), human papillomavirus (HPV) and herpes simplex virus (HSV, genital herpes).

In numerous studies conducted by Starpharma and its international collaborators, as well as in published data in peer-reviewed scientific journals, SPL7013 has demonstrated impressive antiviral and antibacterial activity against a variety of pathogens, prompting the company to commercialise a number of products – the VivaGel® condom, VivaGel® BV and VIRALEZE™.

VivaGel BV is a novel, non-antibiotic gel containing SPL7013 for the treatment of bacterial vaginosis (BV) and the prevention of recurrent BV. This product is registered in more than 45 countries and is available for sale under different brand names in Europe, South-East Asia, South Africa, Australia and New Zealand.

Following the emergence of COVID-19 in early 2020, as companies and research organisations raced to develop a vaccine and treatments for the disease, Starpharma independently tested SPL7013 for activity against SARS-CoV-2 (the coronavirus that causes COVID-19). Consistent with activity against a broad spectrum of other viruses, SPL7013 demonstrated significant antiviral activity against the SARS-CoV-2 virus.

Dr Jackie Fairley

Even though we knew that SPL7013 had broad-spectrum activity, we were excited to see such impressive results demonstrating potent activity against the coronavirus SARS-CoV-2 and all of the variants subsequently tested.

Upon completion of initial testing, the company acted quickly to develop VIRALEZE – a convenient, cost-effective and easy-to-use nasal spray, which contains SPL7013. VIRALEZE provides a physical moisture barrier in the nasal cavity where viruses that cause colds and respiratory infections generally take hold. VIRALEZE irreversibly traps and blocks viruses, rendering them incapable of attaching to cells inside the nasal cavity.

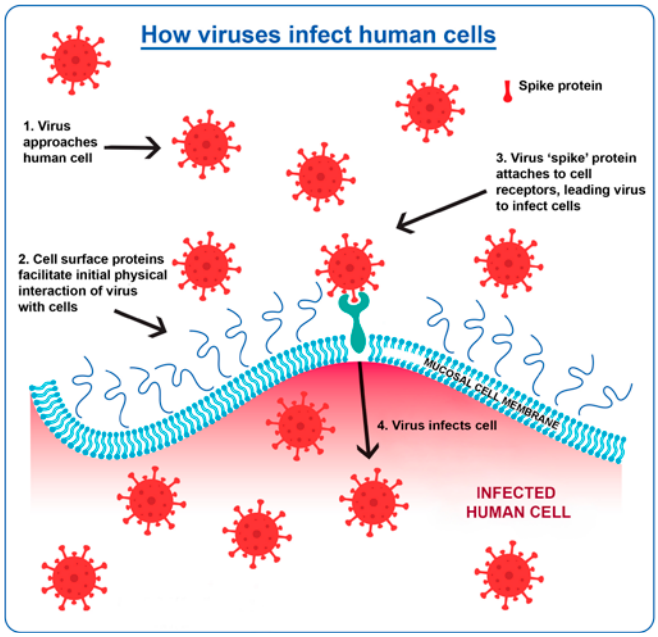
Throughout the course of the pandemic, Starpharma has worked closely with Scripps Research in the United States to undertake testing of SPL7013 against a range of important respiratory viruses. These included respiratory syncytial virus (RSV); other coronaviruses, such as severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS); influenza viruses; and multiple variants of SARS-CoV-2 as they emerged, including Delta and Omicron. SPL7013 has consistently demonstrated high levels of activity against all of these viruses in antiviral and virucidal studies.

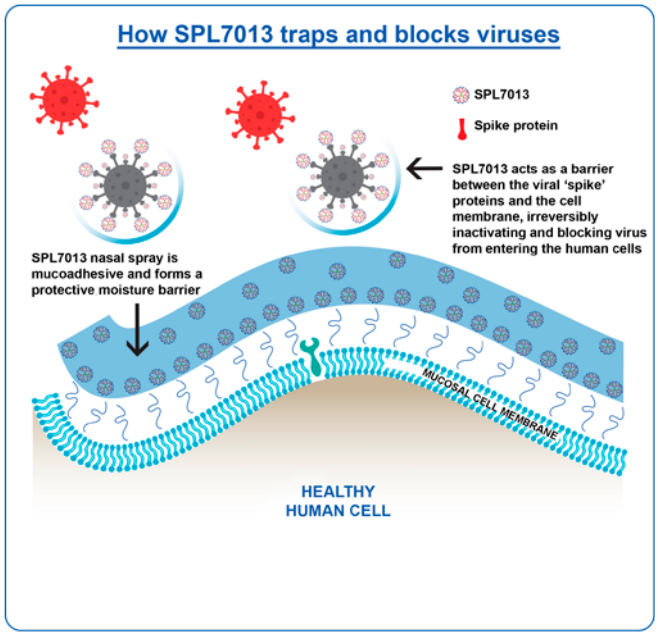
In September 2020, Starpharma was awarded $1 million in matched funding by the Australian Government's Medical Research Future Fund Biomedical Translation Bridge program, with support from UniQuest, to support commercialisation of the nasal spray.

Starpharma initially focused its registration and commercialisation activities in Europe, where, at the time, COVID-19 case numbers were soaring and there was an urgent need for additional interventions. The product was successfully registered in February 2021, just 10 months after the company first reported the antiviral activity of SPL7013 against SARS-CoV-2.

Following the product's registration, Starpharma launched VIRALEZE in Europe, and soon afterwards, the product was launched through LloydsPharmacy in the United Kingdom – one of the largest pharmacy groups in that region, with 1400 stores.

Today, the nasal spray is registered in more than 30 countries, including across Europe and the United Kingdom. The product is available in pharmacies, retail outlets and online in a number





of markets, and Starpharma continues to prioritise activities to expand the product's availability globally. A submission for the SPL7013 nasal spray is currently under review by the Therapeutic Goods Administration.

Starpharma also continues testing SPL7013 against important respiratory viruses in collaboration with Scripps Research. The company recently reported new results demonstrating the high level of protection afforded by the nasal spray against the highly infectious SARS-CoV-2 Omicron variant in a well-established humanised mouse challenge model of coronavirus infection.

These latest findings demonstrate that our antiviral agent SPL7013, in VIRALEZE, retains impressive antiviral effect, even against the most infectious variants of SARS-CoV-2. Importantly, the results also indicate that VIRALEZE has the potential to provide significant benefit when used both before and after exposure to virus, or only after exposure to virus. Further, given its broad-spectrum antiviral activity, SPL7013 may be of value not only for this pandemic, but also as part of a pandemic preparedness plan and in management of other respiratory viruses.

Alongside the development of these innovative products, Starpharma is also doing important work in oncology, and for drug delivery more broadly. Starpharma uses its DEP® drug-delivery technology to enhance the properties of existing and novel drugs, hence the name Dendrimer Enhanced Products (DEP).

From its headquarters in the former Carlton & United Breweries building in Abbotsford, Melbourne, Starpharma has developed four dendrimer-based oncology drugs, three of which are in Phase 2 clinical development for the treatment of a range of common cancers, with a fourth expected to enter the clinic later in 2022.

In a significant endorsement of the DEP technology, Starpharma has also established partnerships with a number of the world's largest biotechnology and pharmaceutical companies, including AstraZeneca and Merck & Co., Inc. The company is collaborating with these partners to explore the application of its DEP drug-delivery technology in multiple therapeutic areas, including oncology, antibody drug conjugates and anti-infectives.

Starpharma's most advanced partnered DEP program is with AstraZeneca for the development of a highly novel anti-cancer agent known as AZD0466, which is currently in two international clinical trials for the treatment of certain blood cancers.

Starpharma has a team of 50 highly skilled scientific and commercial people who are passionate about developing innovative products that have global impact. Starpharma's technology is at the cutting edge of science and can be applied to a wide range of pharmaceutical products, particularly in oncology, that have the potential to improve patients' lives and health outcomes around the world.

Hear Starpharma Holdings Limited deliver its company presentation at AusBioInvest 2022 in Perth, Western Australia, on 27 October. Join us in person for Australia's largest life sciences investment conference. For more information, visit www.ausbiotechinvestment.com.au.

SUCCESS FOR STRIATE+

Orthocell secures a lucrative boost for high-tech manufacturing in Australia

CONTENT PROVIDED BY ORTHOCELL

ORTHOCELL (ASX:OCC), ONE of Australia's fastest-growing regenerative medicine companies, has signed a global exclusive licence and manufacturing agreement worth A$23.1 million with a multinational dental implant company. The deal grants BioHorizons Implant Systems, Inc. an exclusive licence of intellectual property (IP) relating to Striate+™, a resorbable collagen membrane used for dental guided bone and tissue regeneration procedures.

Orthocell's innovative portfolio of breakthrough products includes biological medical devices and first-in-market cellular therapies. Its CelGro™ platform of collagen medical devices is designed to augment the surgical repair of bone and soft tissue in a variety of dental and orthopaedic/plastic reconstructive applications. Its autologous cell therapy pipeline, Orthocell's other major therapeutic platform, aims to regenerate damaged tendon and cartilage.

Striate+ was the first of Orthocell's collagen medical devices to achieve regulatory clearance for clinical use. Striate+ is a resorbable collagen membrane used for guided bone and tissue regeneration to augment bone regeneration around dental implants. It was invented, manufactured and clinically validated in Australia by Orthocell in conjunction with The University of Western Australia. In January 2022, Orthocell received Food and Drug Administration clearance to market and supply Striate+ in

Orthocell team project planning meeting. Image courtesy of Orthocell

the United States. Coupled with prior approvals in Europe and Australia, it has attracted serious attention from both corporate and clinical leaders globally.

In June, Orthocell signed a global exclusive licence and manufacturing agreement to the value of A$23.1 million with BioHorizons for its Striate+ collagen membrane. BioHorizons is part of the Henry Schein group, and is considered one of the largest dental implant companies in the world. As part of this agreement, BioHorizons has an exclusive licence of IP relating to Striate+. Orthocell will supply BioHorizons with Striate+ products and grant them exclusive distribution rights for these products globally. In all, it's an impressive achievement for Orthocell and Australia's biomanufacturing sector.

'The agreement with BioHorizons represents a significant milestone for Orthocell, and provides further external commercial and technical validation of the CelGro collagen scaffold platform, from which the Striate+ dental products were developed,' says Orthocell CEO and Managing Director Paul Anderson.

Orthocell's quality-controlled laboratory, located in the Murdoch Health and Knowledge Precinct in Perth, is a purpose-built facility licensed by the Therapeutic Goods Administration of Australia for the manufacture of human tissue and accredited for the manufacture of collagen medical devices. Orthocell is currently expanding its manufacturing facility to support the increased demand resulting from the BioHorizons deal, and to increase commercial production of nerve generation device Remplir™, the second product from the CelGro platform to achieve regulatory approval in Australia. Expansion of manufacturing capacity will create employment and career opportunities for entry-level graduates and skilled life sciences professionals locally, and will ultimately result in a net national benefit to the biotechnology sector.

'The Orthocell headquarters [were] purpose-built to manufacture, scale up and export Orthocell's high-quality healthcare products around the world. This is an outstanding example of Australian innovation – developed, manufactured and validated locally. It is a significant achievement to attract the biggest names in health care with a desire to access our quality innovation and specialist manufacturing services for global consumption,' says Anderson.

Orthocell is fortunate to have an advanced product portfolio, protected by patents in primary jurisdictions of the United States, Europe, Australia, China and Japan. Orthocell's vision is focused on delivering breakthrough products for the treatment of serious musculoskeletal disorders to restore mobility and function.

Having successfully closed on the dental deal, Orthocell is focusing on additional opportunities in nerve, tendon and ligament repair and reconstruction, all of which present compelling opportunities to further support Australian innovation, manufacturing and export capabilities.

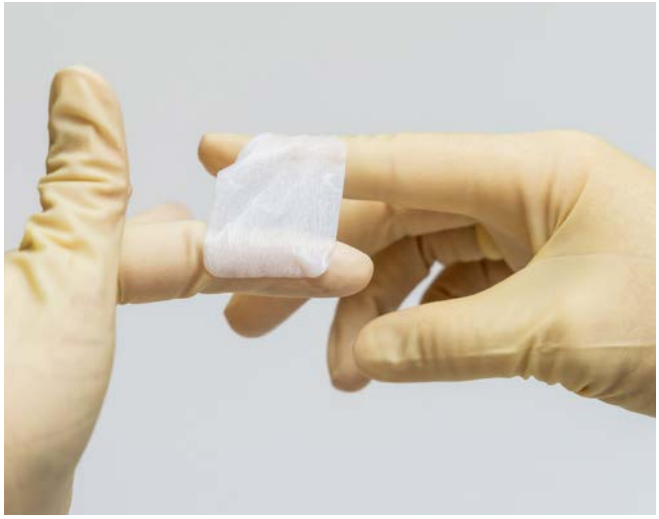
'Australia has seen an evolution in manufacturing, from heavy industrial to high-quality specialist-manufactured goods, like those being produced by Orthocell and others in the regenerative medicine field. We are well positioned to train and upskill the next generation of innovators and specialist manufacturing talent in Australia – just as our platform products move towards critical approvals,' says Anderson.

According to Anderson, who also sits on AusBiotech's WA State Branch Committee, this represents an enormous opportunity. For example, Orthocell's Remplir has an addressable global market in peripheral nerve repair, estimated to be worth more than US$7.5 billion per annum.

'There is already strong demand for products that enable surgeons to perform complex, often life-changing surgical repairs with better results,' says Anderson. 'We recently received Australian regulatory clearance for Remplir for use in the reconstruction of damaged or severed peripheral nerves, and we are moving methodically towards US clearance, too.'

Hear Orthocell Ltd deliver its company presentation at AusBioInvest 2022 in Perth, Western Australia on 27 October. Join us in-person for Australia's largest life sciences investment conference. For more information, visit www.ausbiotechinvestment.com.au.

Orthocell team. Image courtesy of Orthocell



Striate+ product. Image courtesy of Orthocell

FIVE STRATEGIES TO ACCELERATE THE LIFE SCIENCES PIPELINE

BY NATHAN PETTUS, EMERSON

LIFE SCIENCES RESEARCH and development is focusing on entirely new treatment types. Yet, at the same time, the delivery pipeline is changing to accommodate newer, faster ways to get those treatments into the world to save lives.

Modular manufacturing strategies are becoming much more common in the life sciences

Operating in this new world means rethinking some of the approaches production process manufacturers have relied on for decades. The global supply chain; availability of experienced personnel; and even the very methods companies use to deliver innovative, life-saving treatments are transforming the entire manufacturing pipeline.

Exploring some key pipeline acceleration strategies, based on the technologies that will win the future of manufacturing, can help teams develop transformative ways to meet the challenges their organisations face in the years ahead.

Strategy one: Test batch quality before completion

Everything hinges on quality. If a product doesn't meet the highest standards of both the manufacturer and industry regulators, it cannot be released.

Traditional manual testing takes time and is subject to human error. While a deep bench of experienced quality assurance personnel can cut that time and risk, the current process still leaves billions of dollars of work-in-progress inventory waiting for quality testing and release across the globe.

Today's innovators are using automation to dramatically reduce, or even eliminate, the time treatments spend on the shelf awaiting quality test results. These teams are using the newest automation technologies to bring quality analysis tools in line with the process, closing the loop on process control and delivering spectral analysis results for quality attributes (e.g., pH, glucose levels, dissolved oxygen). This inline analysis brings the information directly to the control system for instant identification and, when necessary, intervention.

Not only does inline analysis, such as the DeltaV™ Spectral PAT, help operations teams to instantly intervene to save batches (and potentially millions of dollars), but it also unlocks real-time exception review and release, enabling finished treatments to bypass work-in-progress holding – landing in the hands of patients in need much quicker.

Strategy two: Shift away from inflexible technology

The world is seeing a rapid shift in the way organisations run their facilities, moving from large bulk products to smaller batch sizes, especially in the areas of personalised cell and gene therapies. Traditional, monolithic manufacturing strategies make it difficult to accomplish these rapid pivots – product changeovers are typically quite slow, while equipment changes and replacements are costly and time-consuming.

Forward-thinking manufacturers are embracing new technologies, such as the Module Type Package (MTP), in protocols to create modular manufacturing lines. MTP is the closest thing to plug-and-play for industrial equipment, helping it to quickly and easily be swapped out to create a wide variety of production lines, all producing many different treatments on demand.

MTP uses a single package with standard configuration and documentation to eliminate the need for engineers to spend hours, days, or even weeks, integrating new equipment.

The most advanced automation systems, like DeltaV, offer seamless integration to further reduce the time and expense of configuration and validation. These systems are tested together to automatically normalise the MTP standard for successful integration. Some can even incorporate asset monitoring technologies to make it easier to integrate condition monitoring for improved reliability and performance.

Life sciences organisations that improve technology transfer are bringing new treatments to market more quickly

Digitalisation of processes and documentation has been critical to safe, rapid development of new treatments

Strategy three: Think holistically about technology transfer

Moving data from research to clinical trials, and then to full-scale manufacturing has traditionally been one of the industry's biggest challenges, one that adds years of time to the product pipeline. Improving this process is one of the biggest opportunities life sciences manufacturers can use to accelerate pipeline in automation, and there is a better way.

Today's innovative life sciences organisations are moving toward fit-for-purpose knowledge management software that digitalises a product's recipe through the entire pipeline. In turn, this information allows for automation of each stage of the tech transfer process in a way that has never before been possible. Knowledge management applications, like Process and Knowledge Management™, store information about every stage of treatment manufacture in a standardised way, so key personnel from every group can contribute, collaborate and validate using the same information.

Personnel from every functional unit in an organisation can quickly and easily access recipes, attach documents and utilise built-in workflows all from the same tool, from anywhere across the globe.

Strategy four: Improve awareness

As life sciences companies move into the era of modular manufacturing and personalised medicine – with the associated increases in recipe and equipment changes, added validations, and chain of custody tracking – planning and scheduling begin to take centrestage.

The complexities of modular manufacturing make it difficult to continue the traditional practice of maintaining schedules on a whiteboard. More commonly, teams are turning to real-time scheduling software that optimises efficient operation of facility resources to ensure as little downtime as possible. These scheduling packages can track personnel, feedstock, equipment maintenance schedules and more, to ensure that people and equipment make the most of every moment.

Accurate, adaptive real-time scheduling can also be coupled with real-time modelling software to consolidate, analyse and present accurate models of an entire process. The critical information discovered in the models helps produce an optimal scheduling overview, as well as a de-bottlenecking and capacity analyses for process optimisation.

Strategy five: Make your data digital from day one

There's no getting around it: the future of life sciences manufacturing is digital, not paper. Consider that digital production information is not only more easily transferred up the manufacturing chain to the enterprise to help the business make better strategic decisions, but it also untethers personnel from their desks, creating a highly mobile workforce that can collaborate and contribute from anywhere in the world.

Moreover, the flexibility of digital data is helping organisations develop multifunctional, highly adaptable plants that are always ready to meet the moment. Not only does this improve speed to market and help secure a competitive advantage, but it also prepares the organisations to be critical life sciences innovators, ready to meet the next big global health challenge.

Teams can implement all or some today

The technologies enabling these strategies are not science fiction – it is all available today. It is also critical in helping secure competitive advantage in an ever tighter and more complex global marketplace. By working with an expert partner, manufacturing teams can more easily identify, select and implement the best technologies for their processes, improving return on investment and total cost of ownership, while simultaneously securing competitive advantage in the changing life sciences landscape.

For more information, email Makarand.Mujumdar@emerson.com.

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TURNING TO SCIENCE TO BUILD NEW COMMERCIAL ENTERPRISES

BY DR LARRY MARSHALL, CHIEF EXECUTIVE, CSIRO

It's an uncomfortable truth in Australia that it took a pandemic for us to turn to science for solutions, after decades of comfortable economic growth on the back of the resources sector.

AS ECONOMIC CONDITIONS now begin to tighten, we run the risk of once again turning away from science and undoing all the progress we've made towards creating more solutions from science – progress that was accelerated by COVID-19 but built on a foundation of increasing commercialisation efforts in recent years.

CSIRO's Lab will strengthen Australia's ability to translate and commercialise research. Image © Nick Pitsas

When we turned to science at the outset of COVID-19, we found not only answers to understanding and fighting the pandemic, but also ways of working better together and ways of reinventing and creating new industries that grew new jobs as well. For example, Australia manufactured 50 million doses of one of the world's first vaccines by using science to solve a seemingly impossible challenge of sovereign supply.

In August, I was joined by federal Minister for Industry and Science the Hon. Ed Husic to officially open CSIRO's National Vaccine and Therapeutics Lab in Melbourne, which is a flasher version of what we created to scale up that first COVID-19 vaccine in our time of crisis. But like any good entrepreneur, we created it well before the crisis, because we had a clear market vision that drove us to solve a problem before it was upon us.

The new facility will supercharge our ability to produce vaccines and therapeutics right here in Australia. Biomedical manufacturing researchers will work alongside industry partners on vaccine candidates and drug discoveries to safely and precisely scale-up the products ready for clinical trials.

It will strengthen our ability to translate and commercialise research, contributing to bridging that valley of death that so often prevents our world-class research being turned into solutions from science that create new industries and jobs, both locally and globally.

The valley of death is where startups fail for lack of investment to see them through product development, scale up, distribution, and all the other hurdles they have to jump before they can learn to feed themselves. That valley is wider and deeper for startups from science.

In Australia, the knowledge that so many of our startups wither and die in that valley means that, rather than risking the valley of death, our best ideas go overseas to seek investment and support to grow. We then buy back their products once someone else has taken the risk for us and taken the value from us.

It's gotten to the point that, more often than not, it's the fear of the valley of death that stops us even trying to leap across it.

In recent years, we've been making steady progress on building bridges across that valley of death that give me great hope for Australia's future, as long as short-term economic cycles don't prove more powerful than the long-term benefit that science-driven innovation can deliver.

Two startups from science, in particular, have leapt across the valley to early commercial success: one is a graduate of CSIRO's ON program and the other is a portfolio company of CSIRO's Innovation Fund, managed by Main Sequence.

FutureFeed was in one of the earliest cohorts to go through ON, looking for ways to commercialise research that found adding a seaweed supplement to livestock feed can significantly reduce their methane emissions.

More than 3000 people have participated in ON programs, with more than 60 companies formed by participating teams. The program includes an intensive customer-focused accelerator to develop startups, preparing them for the leap across the valley of death.

After ON, FutureFeed did something we don't often see in Australia, it compelled local Australian companies to fund its seemingly impossible idea, including retail giant and supermarket chain Woolworths, commodities handler GrainCorp, agrifood group Harvest Road, and accelerator operator AGP Sustainable Real Assets–Sparklabs Cultiv8 joint venture.

Earlier this year, FutureFeed celebrated a major milestone with the sale of its first products to livestock feed suppliers, and now has licensees in Australia, New Zealand, the United State and Europe.

Plant-based protein company v2food was created with investment from the CSIRO Innovation Fund, as well as research and facilities from CSIRO and a pathway to market through Competitive Foods, owner of Hungry Jack's.

In the first two years, the company raised $182 million, and today v2food products are in Hungry Jack's stores, major supermarkets and in-flight meals, with plans underway to export to Asia.

By harnessing CSIRO's market vision and venture investment, we can de-risk investment opportunities for corporates in Australia, like Competitive Foods, to invest in deep-tech startups that would otherwise struggle to find a way across the valley of death.

FutureFeed and v2food are not flukes; there could be many more like them if we continue to bridge the valley of death.

CSIRO's National Vaccine and Therapeutics Lab will produce vaccine and drug treatments onshore.
Image © Nick Pitsas

CSIRO's new facility will supercharge Australia's ability to produce vaccines and therapeutic locally.
Image © Nick Pitsas

But if we let short-term economic conditions spook us, we'll lose our opportunity and it will take decades to make up the ground. By that time, we may well have realised the future predicted by our Australian National Outlook in 2019 – except we'll have taken the road to a slow decline instead of towards a bright outlook powered by innovation.

WE DO NEUROSCIENCE BEST

Neuroscience Trials Australia (NTA) is one of the few contract research organisations (CROs) globally that specialises in central nervous system (CNS) projects, including devices and synergistic therapeutic areas.

THE BARRIERS, ISSUES and challenges that exist in neuroscience clinical trials are often unique to neuroscience. With limited understanding of neurological disease biology due to brain inaccessibility and consequent lack of validated biomarkers and molecular targets, the cost and failure rates of clinical trials in this field are high. Globally, we are witnessing an exponential increase in activity in basic neuroscience research. Now more than ever, it is vital that clinical trials are optimised to increase the chances of success, to drive impact on health outcomes and, ultimately, to improve the lives of patients suffering from a CNS-related illness.

NTA has a thorough understanding of the nuances of neuroscience clinical trials, thanks to more than 20 years' experience in this niche. Since NTA's beginnings, it has partnered with The Florey Institute of Neuroscience and Mental Health (the largest research centre of its kind in the Southern Hemisphere), and has a unique and extensive network across research precincts and hospitals. NTA can provide clients with direct access to world-leading neuroscience disease specialists, key opinion leaders and highly regarded clinical trial sites, enabling strong recruitment outcomes.

NTA's staff members, with an average of 14-plus years' industry experience, continually work to address the evolving challenges that arise in the neuroscience area. The company's knowledge of neuroscience clinical trials, project management expertise, global management experience in all phases of clinical research, solid understanding of local and global regulatory requirements, and quality focus means consistent delivery of high-quality neuroscience clinical trials. NTA collaborates with pharmaceutical, biotechnology, device and cell therapy companies, granting bodies, collaborative groups, institutions, and investigator-initiated studies to advise on and implement the best clinical development pathway forward. NTA is a full-service CRO; it can take your project from start-to-end, deliver world-class results, and finish with a clinical study report. NTA can produce high-quality, globally accepted data for Therapeutic Goods Administration, Food and Drug Administration and European Medicines Agency review.

NTA looks forward to hearing from you and being able to assist you with your clinical development program.

For more information, visit neurosciencetrialsaustralia.com, or contact NTA by emailing NTA-BDev@florey.edu.au, or calling 0409 596 088. Follow NTA online at @NeuroTrialsAus and linkedin.com/company/neurosciencetrialsaustralia.

Your go to CRO for neuroscience

neuroscience trials australia

- Full-service CRO
- Direct access to Clinical Trial Networks
- 20+ years experience in neuroscience, synergistic indications and devices
- Average of 15 years industry experience amongst staff
- Partners with The Florey (largest brain research centre in southern hemisphere)
- Direct access to world leading specialists and high performing sites enabling strong recruitment
- Imaging, biomarkers and biobanking expertise
- Invests in neuroscience academic research

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neurosciencetrialsaustralia.com

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RAISING CAPITAL USING AT-THE-MARKET SOLUTIONS

BY STEPHEN EARL, CO-FOUNDER AND MANAGING DIRECTOR; AND
JEREMY GLAROS, DIRECTOR – ORIGINATION AND OPERATIONS, ACUITY CAPITAL

LISTED COMPANIES IN the United States use at-the-market (ATM) solutions for raising equity capital more than any other tool – and the life sciences sector is leading the charge.

An introduction to ATM solutions

The path to revenue for early-stage life sciences companies is typically long and challenging, resulting in a deep and ongoing need for capital. While meeting this need is not an exact science, a company that has access to the full suite of available capital management tools can increase the likelihood of achieving commercial success by minimising capital costs, maximising flexibility and positioning itself to take advantage of market opportunities.

ATM solutions can be a valuable source of additional capital for listed companies. Under an ATM, companies can raise capital by issuing shares at or near the prevailing market price, while retaining full control over the timing, minimum issue price and maximum number of shares to be issued. There is no obligation to use an ATM, and once established, an ATM can be activated in as little as 30 minutes.

In this way, ATMs offer an alternative source of equity capital that is often more efficient and more cost-effective than traditional capital-raising methods. ATMs have a fair, transparent pricing structure and, importantly, place no restrictions on accessing other forms of capital. As a result, ATMs are typically used as

part of a broad capital management toolkit to complement traditional capital-raising methods.

With an ATM in place, a company can:

- *Reduce the cost of capital*: ATMs broaden the capital-raising options that are available to a company. They reduce reliance on any one source of capital and help to lower the cost of capital across all sources.

- *Take advantage of market opportunities*: The ability to quickly activate an ATM allows a company to take advantage of favourable short-term market conditions, such as spikes in share price. This is often not possible using traditional capital-raising methods.

- *Maximise capital and reduce dilution*: By giving companies control over the timing, minimum issue price and maximum number of shares to be issued, ATMs help maximise the capital raised while minimising dilution.

History of ATM solutions in the United States

The United States is the world's largest capital market and arguably its most innovative. The capital-management tools that prevail in this landscape are ultimately those that most efficiently move capital from investors to companies. This helps explain why listed US companies of all sizes and across all sectors have embraced ATM solutions.

In 2021 alone, more than 700 ATMs were established in the United States, with a total ATM facility size of over US$140 billion (Figure 1). ATMs are offered by all major investment banks and brokers in the United States, from industry behemoths, such as JPMorgan and Goldman Sachs, down to boutique specialist ATM providers.

While ATMs are now well-established as an efficient capital-raising tool, it took time for the market to fully embrace them. Initial uptake in the 1990s was slow, as companies were unfamiliar with how ATMs worked. In addition, there was concern that the market would mistake ATMs for other alternative capital-raising tools, such as convertible notes or equity lines – instruments often viewed unfavourably in the market (and in many cases, with good reason).

The adoption of ATMs continued to increase through the early 2000s as more and more companies successfully used them to access additional capital at a lower cost. Mainstream adoption came with the onset of the GFC in 2008. The GFC caused extreme disruption to capital markets, making traditional capital-raising methods more expensive and, in some cases, impossible to access altogether. This significant tightening of markets forced many listed companies to explore

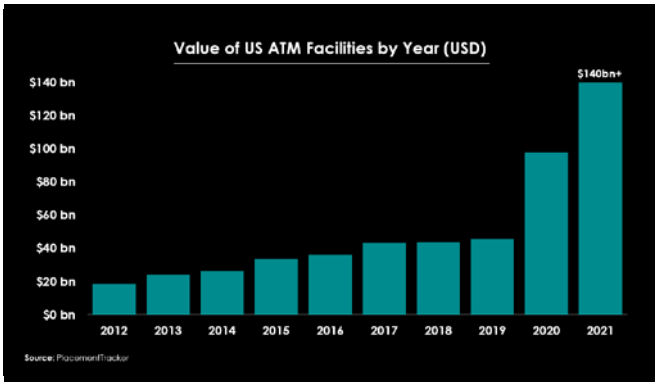

Figure 1. US ATM volumes by year. Source: PlacementTracker

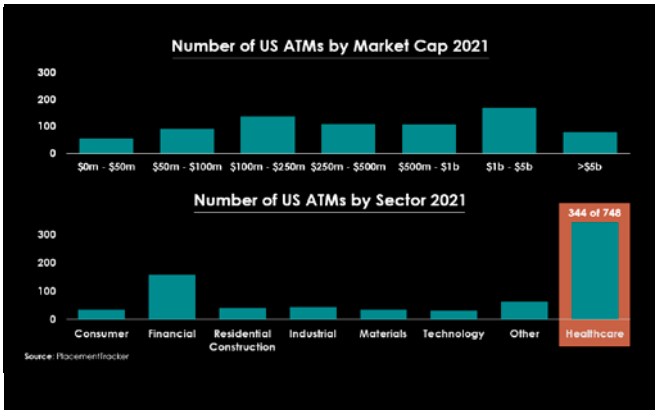

Figure 2. US ATM market cap and sector breakdown. Source: PlacementTracker

alternatives. The fact that ATMs are quick, simple and easy to establish, and can provide additional capital cheaply and efficiently, made them a compelling option.

ATM adoption and usage has accelerated rapidly from this point onwards. Today, a wide range of US-listed companies consider ATMs to be an integral part of their capital management toolkits. And it is not just large companies – such as Tesla, Bank of America, Ford and American Airlines – that have embraced them; ATMs also work particularly well for growth companies whose share prices can rise rapidly in response to reaching milestones or to broader macro-economic themes.

ATM solutions in action: the healthcare sector

ATMs are used by companies of all sizes and across all sectors in the United States, with the healthcare sector being the largest single user by number of ATMs. Healthcare companies established nearly half of all ATMs in the United States in 2021, or 344 out of the total of 748 (Figure 2). Users of ATMs in the United States include several dual-listed Australian companies, such as Alterity Therapeutics, Kazia Therapeutics and Opthea, each of which has put in place an ATM for its Nasdaq listing.

Continued on page 28

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Continued from page 26

Early-stage healthcare companies often share a similar set of characteristics that make ATMs a good fit for their capital management needs, including:

- volatile share prices that result in rapid, though often short-lived, share price spikes
- an ongoing need for capital to fund long and complex research and development
- unpredictable cash flows that limit other options for raising capital.

ATM solutions help healthcare companies to quickly respond to and take advantage of positive market conditions and sentiment, particularly when significant milestones are reached. This allows companies to take advantage of increased share prices to secure capital at favourable prices. These features help explain why so many US-listed healthcare companies use ATMs.

ATMs in Australia

The uptake of ATMs in Australia has increased significantly since Acuity Capital established its first ATM solution almost a decade ago. Since inception in 2012, Acuity Capital has:

- established more than 60 ATMs with Australian-listed companies
- made more than $650 million of stand-by equity capital available
- provided more than $130 million in equity capital.

While ATMs in Australia are not yet seen as mainstream, the growth of the Australian ATM market over recent years puts it on a path similar to that of the United States. ATMs are being embraced by a wide range of Australian companies, including in the life sciences sector, with ATM facility sizes and amounts raised continuing to break Australian records. Further, both ASX 200 and ASX 300 companies are now using ATMs as part of their capital management toolkits.

Greater awareness and understanding of ATMs is driving increased adoption, which, in turn, is building a growing body of evidence of the benefits of ATMs for Australian companies. This is illustrated by growth in ATM facilities of over 60 per cent per annum since Acuity Capital was established.

No other capital-raising method, traditional or alternative, consistently delivers capital as cheaply and efficiently as an ATM.

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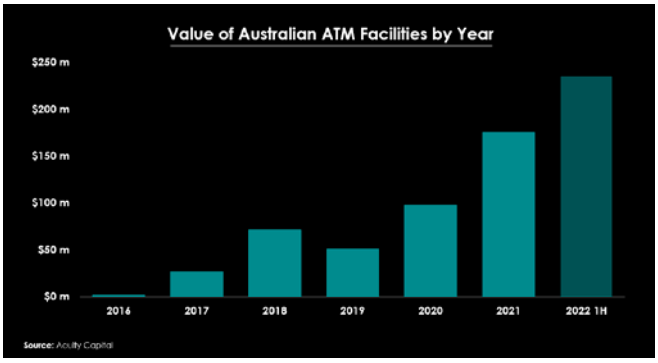

Figure 3. Australian ATM volumes by year. Source: Acuity Capital

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WHAT'S NEXT IN AUSTRALIAN INVESTMENT?

BY SCOTT POWER, SENIOR RESEARCH ANALYST, MORGANS FINANCIAL

SINCE UNDERPERFORMING IN the boarder market in the five months through to mid April, the Health Care Index (ASX:XHJ) – which is made up of the top 20 listed stocks by market capitalisation and includes companies from CSL (ASX:CSL), down to smaller names like Imugene (ASX:IMU) and Telix (ASX:TLX) – appears to have turned the corner, recording excess returns against the ASX 200 (1.1 per cent vs. -13.8 per cent, respectively).

Chalk it up to the sector's high-quality parameters, favourable fundamentals and low beta appeal in a world still awash with uncertainties (for example, slowing growth, supply chain issues, higher input costs, recession fears, central banks tightening, the Russo-Ukrainian War and COVID-19). Valuation also looks much more supportive, with many quality health companies trading below long-term averages and representing an excellent buying opportunity.

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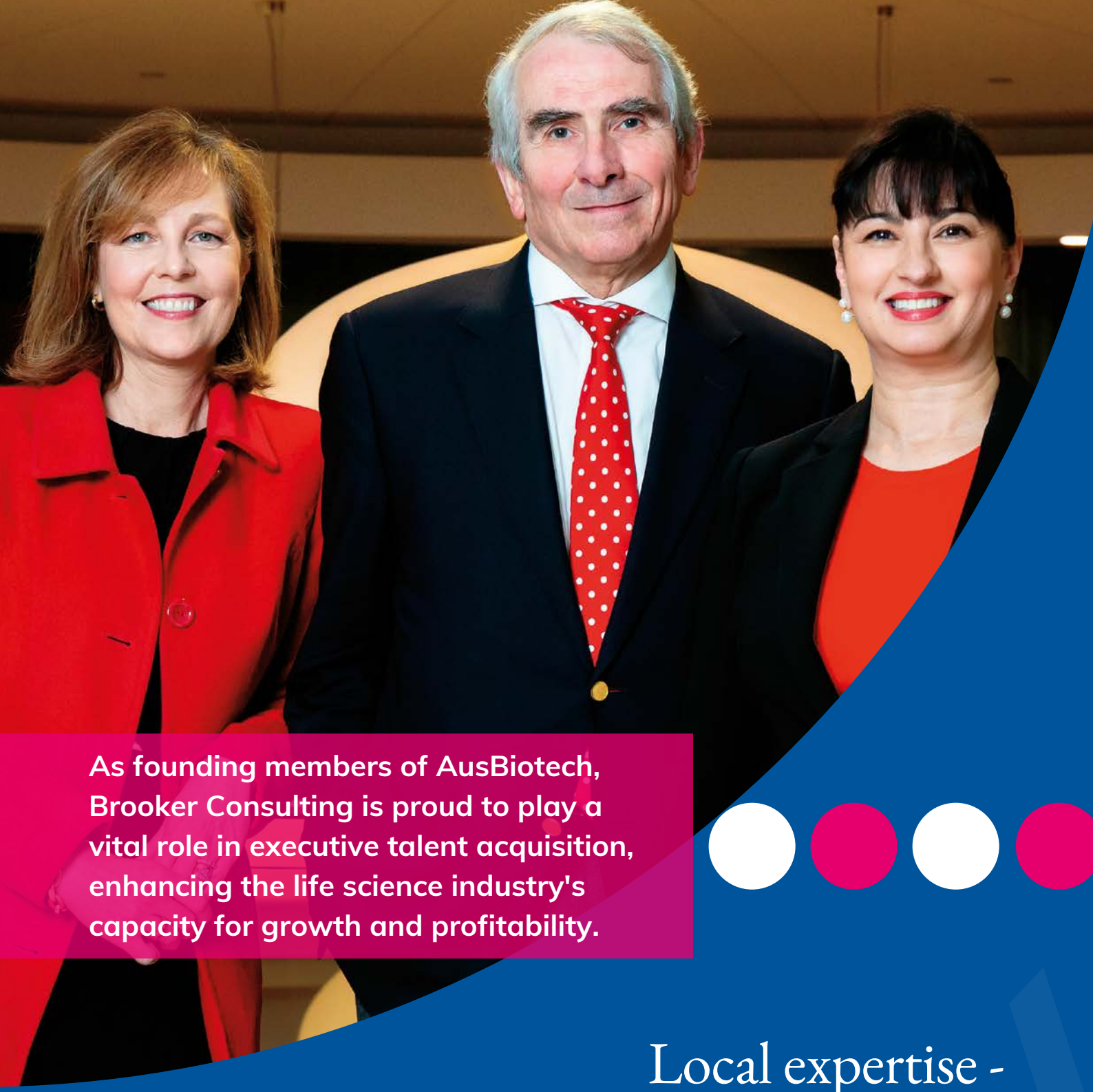

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Continued from page 30

Looking forward, we continue to view the sector as well-positioned to weather market turbulence, with strong industry growth across biotechnology, pharmaceutical, medical devices and services based on notable secular trends. Trends include:

- advanced precision (i.e., personalised) medicine
- hybrid care models combining virtual and in-person services
- the digitisation of healthcare specialties (i.e., improved workflow, scheduling, coordination, and data security)
- increased artificial intelligence (AI) adoption, with health systems moving to the cloud.

Overall, we maintain an overweight recommendation in the healthcare and life sciences sector for investors looking for a safe haven in a storm.

Putting some company names around these trends and considering the sell-off in the market, some attractive entry points have emerged. In the personalised medicine space, Volpara Health (ASX:VHT) stands out with its individual risk assessment and customised patient reporting and tracking systems. The systems provide the radiologist and the patient with important information for early detection, personalised screening and ongoing monitoring.

Figure 1 clearly demonstrates how Volpara's software fits into the operations of a breast screening clinic. ResMed (ASX:RMD) fits into the hybrid care model combining virtual and at-home services with its technology to treat and manage respiratory disorders. The further digitisation of health records and images, as well as increased adoption of AI, sits in the wheelhouse of both Pro Medicus (ASX:PME) and Mach7 Technologies (ASX:M7T), which have software for image management across different hospital departments (i.e., radiology and cardiology). Implementation of this software is improving workflow, scheduling and data security in hospital settings.

A number of the listed life sciences companies have seen significant erosion in share prices this year, despite having cash reserves and near-term value-adding milestones. The market is currently in a risk-off mode and looking through a number of key company achievements. Once sentiment turns more positive, the share price re-rate can occur quickly. We call out two companies that we think have been mispriced: EBR Systems (ASX:EBR), down approximately 50 per cent, and Impedimed (ASX:IPD), down approximately 70 per cent, since 1 January 2022. EBR is well cashed-up with top-line results for its leadless cardiac resynchronisation device, due in the first quarter of the 2023 calendar year; and IPD is waiting for a decision from the National Comprehensive Cancer Network as to whether its technology will be included in the cancer treatment guidelines. Positive outcomes for both of these companies will see a significant re-rating of their share prices.

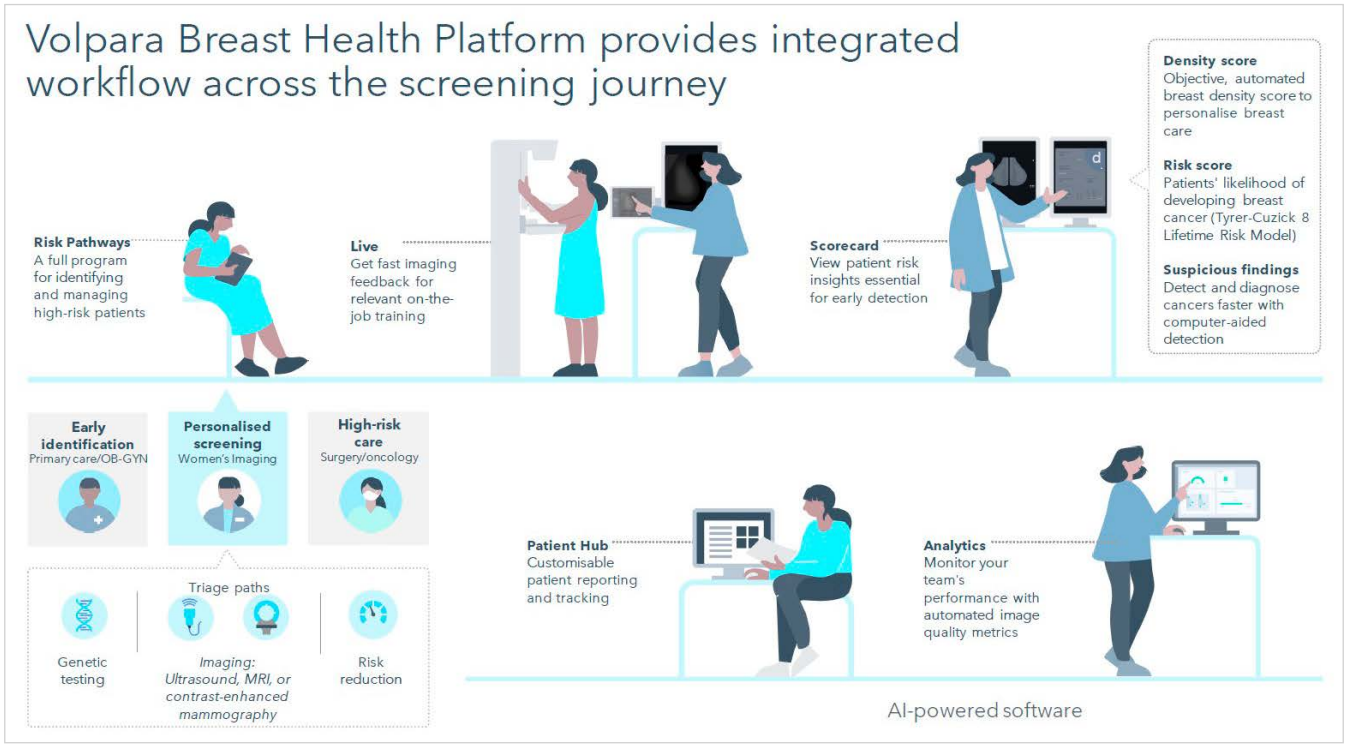


Figure 1. How Volpara's software fits into the operations of a breast screening clinic. Source: Volpara Health

REDESIGNING CONSENT TO RESEARCH

Simplifying participant information and consent forms

FOR CONSUMERS, DECIDING whether to participate in research should be supported by information that is clear, simple and easy to navigate. Despite this, current participant information and consent forms (PICFs) are often the opposite: long, complex and difficult for consumers to understand. The Clinical Trials: Impact & Quality (CT:IQ) InFORMed Project is developing templates and guidance to assist in the creation of more consumer-centric PICFs.

CT:IQ is a collaborative group of stakeholders with a mission to improve the impact and quality of clinical trials in Australia. CT:IQ comprises more than 50 member organisations and individuals who come together to pursue projects that will promote efficient, effective and participant-centred clinical trials. Initiated in 2021, the InFORMed Project team is made up of 35 stakeholders from across the research sector, including consumer representatives, sponsors, Human Research Ethics Committee members, governance offices and research sites. The project looks to fundamentally change informed consent to put consumers at the centre.

To provide an evidence base for reform, the team conducted surveys, gathering feedback from more than 700 respondents (consumers and other stakeholders) on issues with current PICFs and areas for improvement. The survey results provide widespread support for change, particularly towards simpler, less legalistic and more visually engaging forms. Literature and best practice reviews further support the need for simpler, consumer-focused PICFs, favouring a tiered or layered approach. That is, where key information for decision-making about study entry is contained in a concise, well-laid-out PICF, written in simple language, and supplemented by more detailed information for those who seek it out.

What's next?

The project is going into an exciting stage. After extensive work, the draft template will soon be entering into consumer consultation to assess whether the information is what potential participants want and need to make a decision about participation.

The team will conduct four demonstration projects based on real studies from different types of research, developing a PICF for each. They will run focus groups involving consumers with lived experience of the disease or condition being studied.

Incorporating this feedback will be pivotal to the development of the final template and associated resources and guidance to enable researchers to develop their own consumer-centric PICFs.

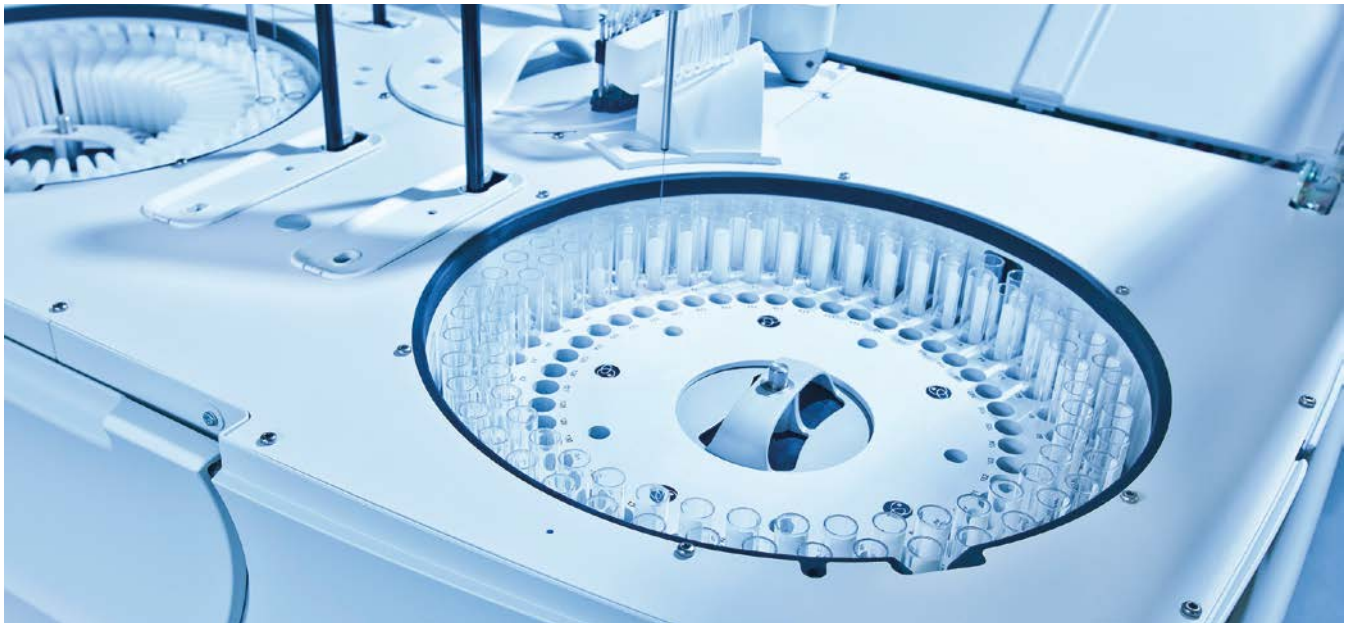
How can you get involved?

The project team aims to have a draft template ready to test by mid 2023. CT:IQ is keen to get a broad subsection of early adopters to see how it works in the real world. If you are interested, make sure you sign up to the CT:IQ email newsletter at https://ctiq.com.au/subscribe-to-our-enews/. To become more closely involved with InFORMed and other CT:IQ projects, consider becoming a steering committee member at https://ctiq.com.au/membership/.

For more information, contact CT:IQ on info@ctiq.com.au.

ACHIEVING MORE TOGETHER

Customised biomedical clinical analysis for blood samples in human medicines



IN CLINICAL DIAGNOSTICS, reliability and precision are essential. In the development of analytical devices for in-vitro diagnostics laboratories, Spanish company BioSystems S.A. aims to maximise cost efficiency and flexibility. To meet all requirements, BioSystems worked closely with Bürkert Systemhaus as a development partner. This gave rise to a unique customer solution for the dosing of various media, which also satisfies the highest precision requirements. BioSystems was also in search of innovation when it was customising its biomedical clinical analysis system.

Since 1981, BioSystems has been committed to offering effective, reliable analytical systems to laboratories around the world. Its facilities in Barcelona house a young and highly qualified team of researchers and microfluidic engineers that produces a wide variety of instruments and reagents of superior quality for customers. Working in the field of utmost accuracy, BioSystems strives to deliver equipment that is reliable and precise, but also cost efficienct and flexibile for its customers.

BioSystems' challenge was to innovate its dosing mechanism for liquids in a blood analysis system. The project was based on the requirements for BioSystems customers to have a very high dosing precision device fit into an extremely compact space, while maintaining precision and reliable measurement, regulation, and control of the flow rates – all while saving costs, without compromising on superior quality.

BioSystems and Bürkert had a trusted and long-term relationship, with each company's teams working together on a solution that met the required challenges of innovating the analysis system solution for existing and future BioSystems customers.

Meet the BA400 biochemical analysis device. Bürkert developed a modular dosing unit that incorporates various components: two or three valves, a pressure sensor and a filter on a transparent plastic injection unit. The fluid experts provided not only a solution to effectively control media flows, but also to avoid raw surfaces, empty spaces and sharp edges in order to prevent the formation of air bubbles. Alongside this, a transparent window also enables visual inspection. The dosing units can be conveniently scaled, and the jointly developed system is also so versatile that it can be used in any model of the BA400 analysis device, making it a genuine one-size-fits-all solution. The result of the close partnership was a system that impressed with its low water and material consumption as much as its reliability and precision.

'Despite the new challenges and difficulties normally occurring with innovative developments, the two partners succeeded together in working out a forward-looking solution,' says Francesco Grau, Mechanics Manager at Biosystems.

By combining core competencies, a tailored, single dosing unit was implemented into the new analysis instrument, meeting the complex and indispensable requirements of clinical diagnosis, while optimising internal cost structures and flexibility.

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CHANGING THE GAME IN CLINICAL TRIAL PATIENT RECRUITMENT

IN THE PAST, patient recruitment was not given the attention or dedication that it receives today. Pre-screen reporting was virtually non-existent, and standard advertising strategies included a flyer on a hospital noticeboard or university lift. In order to increase the number of participants in clinical trials, we need to find better ways to increase awareness, and to educate patients and their healthcare professionals about these studies.

More than 20 million Australians own a smartphone, and nearly 40 per cent of people look for online health information to take ownership of their health journey. In a 2021 survey conducted by CISCRP, 90 per cent of respondents who had not participated in a clinical trial before said it was important that their doctor be aware of clinical trials being conducted in their community. Additionally, four out of five patients would consider a clinical trial if it was recommended by their doctor.

Imagine for a moment that you are clinical study coordinator and you're working on a groundbreaking study investigating a potential new treatment for people with type 2 diabetes. The deadline for interim analysis is fast approaching, but enrolment is slow. What can you do? On the other hand, imagine you are a busy general practitioner (GP) who has hundreds of type 2 diabetic patients. You're interested in research as a care option, but don't have the means or information to provide clinical trials to your patients.

At Evrima, we're tackling these problems with our end-to-end recruitment solutions that connect researchers, GPs and patients to clinical trials. By developing digital phenotypes and integrating to GP clinical software, we're able to unlock the 99 per cent of potential participants that may be eligible for, but currently aren't participating in, clinical trials. We also offer the ability to centralise recruitment and pre-screening data using our proprietary software that encompasses workflows, referral management for sites, and access to robust reporting. Digital marketing and advertising packages are available to our clients to ensure their trial is reaching potential participants, who can register their interest and go through an online and phone-based qualification process with our patient experience and marketing teams, thereby creating an unparalleled offering.

Technology and embedding clinical trials in primary practice have a part to play in the promotion of clinical trials, ultimately leading to better trial enrolment rates. From our own research and experience, it is paramount to have multiple strategies to reach not only potential participants, but also their doctors.

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KEEP PATIENTS INFORMED
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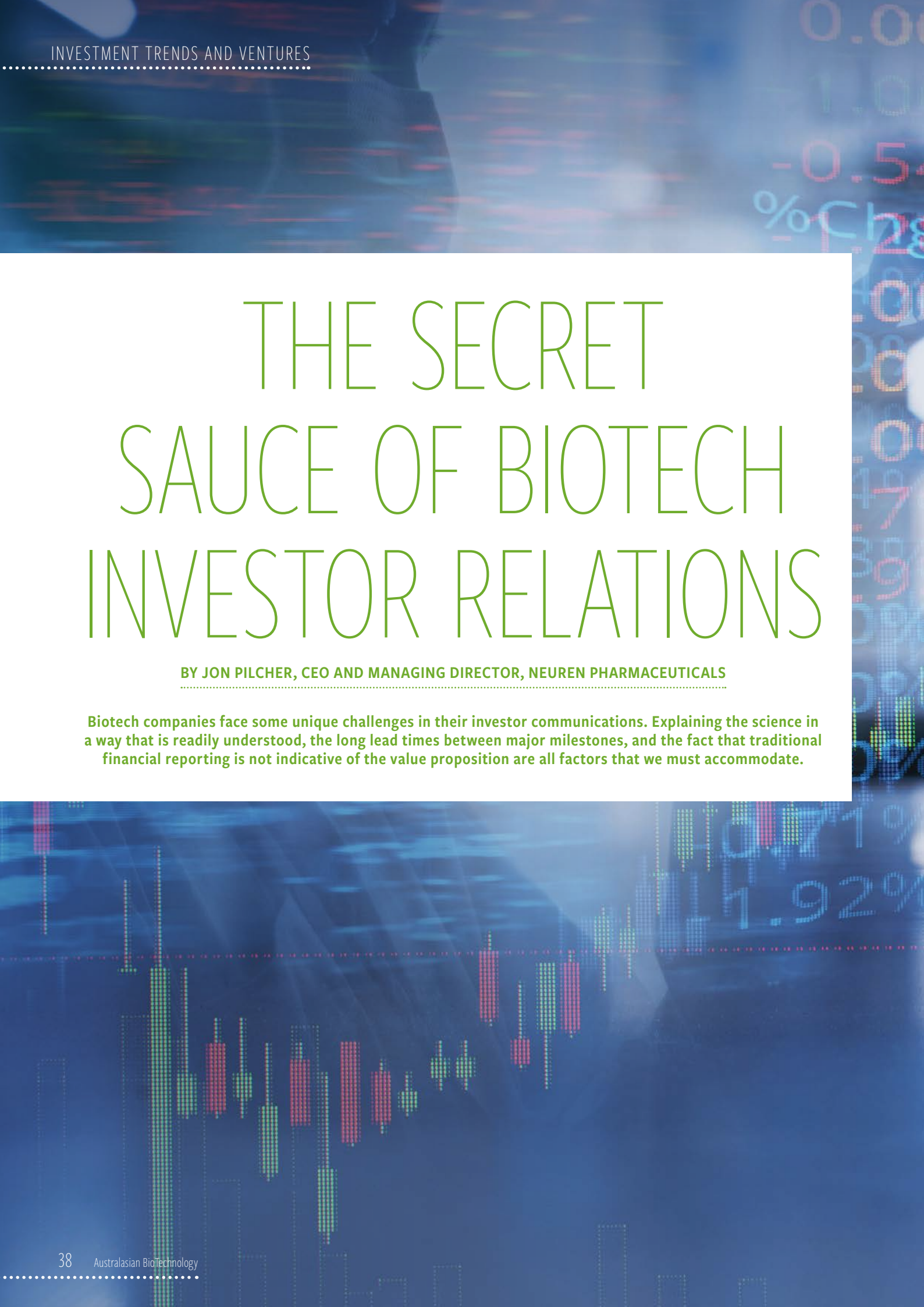

THE SECRET SAUCE OF BIOTECH INVESTOR RELATIONS

BY JON PILCHER, CEO AND MANAGING DIRECTOR, NEUREN PHARMACEUTICALS

Biotech companies face some unique challenges in their investor communications. Explaining the science in a way that is readily understood, the long lead times between major milestones, and the fact that traditional financial reporting is not indicative of the value proposition are all factors that we must accommodate.


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20.20
1.84
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31.25
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23.20
62.00
6.45
31.50
6.95
25.75

WHILE INVESTORS WANT to hear about commercial opportunities and the path to achieve them, we can't ignore the science, because the whole investment proposition is based on it, and if the science doesn't make any sense, then the investment proposition probably doesn't either. But as companies, we have to get it across in a way that people can understand and that doesn't consume the whole of their attention span. We also need to be ready to adapt the amount of detail that we provide for different audiences.

I don't believe that a listed biotech company has to do what everyone else on the ASX does, focusing on regular set piece presentations after financial quarters and halves. In biotech, value-adding events don't follow the financial calendar, and there will inevitably be long gaps between them. You have to find a way to remain visible all the time; that doesn't mean over-hyping the significance of minor news, but rather maintaining a constant narrative that demonstrates that you are making sound progress towards the important events.

Jon Pilcher

My philosophy is to talk to everyone and anyone, any time, because you never know who they're going talk to. Word of mouth is very powerful, and I often find that I get contacted by someone who has heard about Neuren from someone else. Brokers and analysts are an important part of that. You should be talking to them all the time, and to as many of them as you can. Securing formal broking research coverage can be a challenge, but if they speak positively to people about the company, that can be very valuable without formal coverage. Using third parties to open doors for you to speak with new people is helpful, and can be essential.

Continued on page 42

FAST-TRACKING EXPANSION THROUGH PARTNERSHIP

The Crux Biolabs team

Specialist Australian immunology service lab Crux Biolabs partners for growth with healthcare investment firm.

CRUX BIOLABS, a leading Australian immunology service lab for clinical and preclinical studies, has just announced a significant investment of growth capital by healthcare investor Genesis Capital. The investment will drive a new phase of growth for the company, allowing Crux Biolabs to quickly expand in line with the global demand for high-quality clinical testing.

Based in Melbourne and led by Chief Executive Officer Catherine Osborne and Chief Operating Officer Kate Porter, Crux Biolabs is known for its specialised immunology services, to help understand why cutting-edge cancer therapies work for some patients, but not others. Crux Biolabs works closely with pharmaceutical sponsors and contract research organisations globally in support of their growing clinical trial needs.

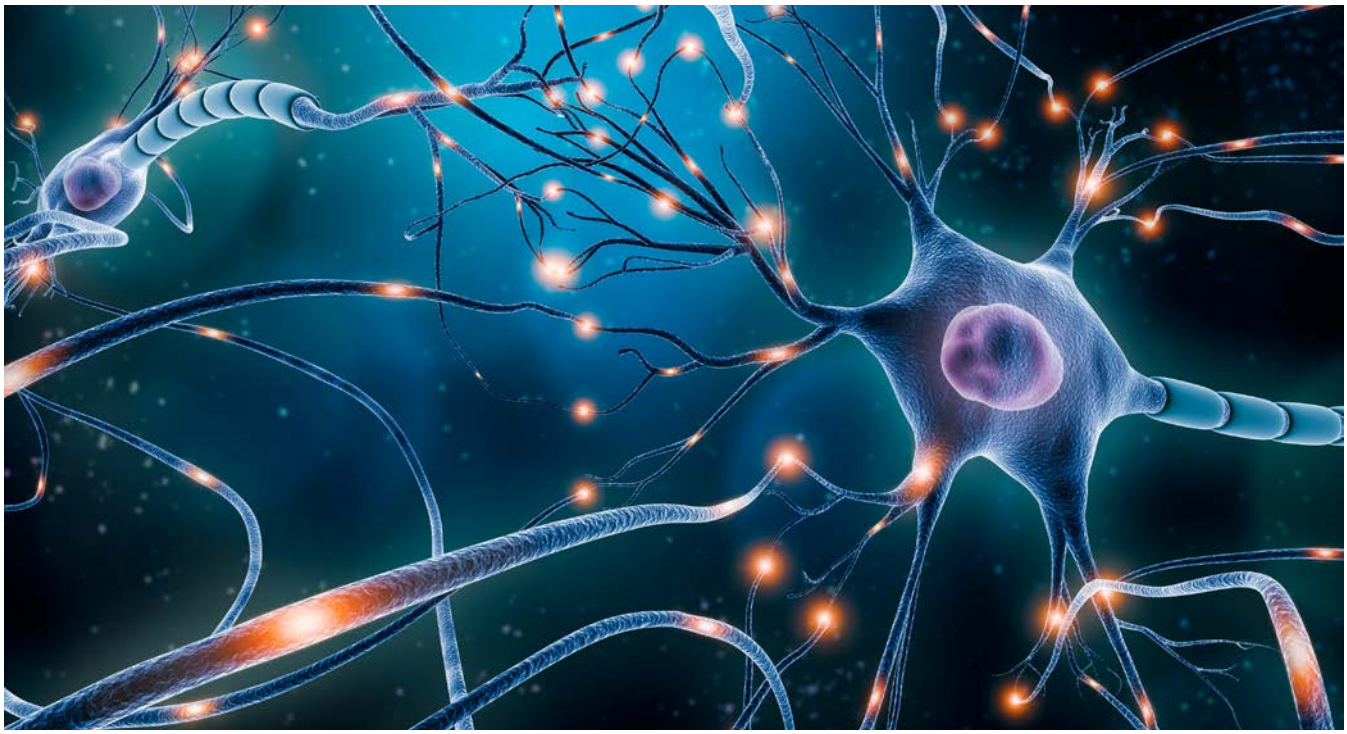
'In the past few years, we have seen a significant increase in demand for testing services from Crux Biolabs amid a growing demand for Australia-based clinical trials,' says Osborne. 'As a result of this surge, we have been looking for ways we can grow our capacity to be able to meet the increased needs of the global market.'

'Crux Biolabs has all of the elements needed for ongoing success, with momentum already to meet the rising demand,' says Genesis Capital Partner Dr Michael Caristo. 'We have been impressed with Catherine, Kate and the team, and their commitment to scientific excellence. We are delighted with the opportunity to partner with Crux Biolabs and assist it in its goal to continue to be a laboratory services partner of choice to sponsors and researchers looking to run clinical trials in Australia.'

The investment from Genesis Capital will fast-track expansion for Crux Biolabs, with a focus of capital into the business enabling an increasing in the breadth and volume of testing offered to the market. Crux Biolabs recently gained accreditation for its enzyme-linked immune absorbent spot (ELISpot) and DNA-extraction services, and plans to expand into MesoScale Discovery and analytical chemistry services once the lab expansion and renovation is complete at the start of 2023.

'The ability to be both thorough and agile is something we pride ourselves on at Crux Biolabs,' says Osborne. 'Working with Genesis Capital, we feel we will now be able to respond quicker than ever to the needs of clinical trials requiring high-end and accredited immunology.'

To learn more about the expansion plans for Crux Biolabs or how it can support you, visit www.cruxbiolabs.com or connect with the team for a confidential discussion at enquiries@cruxbiolabs.com.



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Neuren has used 'sponsored' research – that is, research that we pay for. If you are struggling to get coverage, this kind of research brings in someone else to tell your story, through their eyes and to different people. There is also an increasing number of video interviews and podcasts on various finance sites, and they can be a useful way to maintain that visibility.

At Neuren, we are developing therapies for some serious neurological disorders that emerge in early childhood and impact just about every aspect of life. Our lead drug compound, trofinetide, targets Rett syndrome – a devastating neurological disorder mainly affecting girls. Our second drug candidate, NNZ-2591, is targeting Phelan-McDermid, Angelman, Prader–Willi and Pitt-Hopkins syndromes, all highly debilitating disorders caused by genetic mutations. There are no approved treatments for any of Neuren's targets, and all of our programs have been granted 'orphan drug' designation from the Food and Drug Administration (FDA) – a designation that provides incentives to encourage development of therapies for rare and serious diseases.

The emotional aspect of what we do is powerful. Everyone at Neuren feels good about what we are trying to do – the prospect of helping these patients and their families is extremely motivating. We have many investors who have been long-term holders, including through some tough periods, and a lot of them feel that same motivation. There's often an emotional story behind a biotech company, and it can be a legitimate part of your narrative.

In July 2022, Neuren's US partner, Acadia Pharmaceuticals, submitted a New Drug Application to the FDA for trofinetide as a treatment for Rett syndrome. News of this very important milestone and the commencement of Phase 2 trials of NNZ-2591 were the start of a series of transforming catalysts over the next 18 months. During the past two years spent building the foundations for this period, we have tried to maintain a constant and clear story about the future that can be told at any time, including providing the road map to measure our progress.

In my view, the principle overlaying all these investor communication considerations is that gaining and maintaining the trust of investors is absolutely critical. That doesn't stop you being positive and enthusiastic about the prospects; there's nothing wrong with generating excitement about the future, but it must be honest, as well as supported by the fundamentals and the company's capability to deliver. People have to be able to look back and know that they can trust what you're saying. As soon as you lose that trust, you're in trouble.

James Shaw, Vice President, Clinical and Regulatory Operations at Neuren Pharmaceuticals (right) with Katelin (left), who has Rett syndrome

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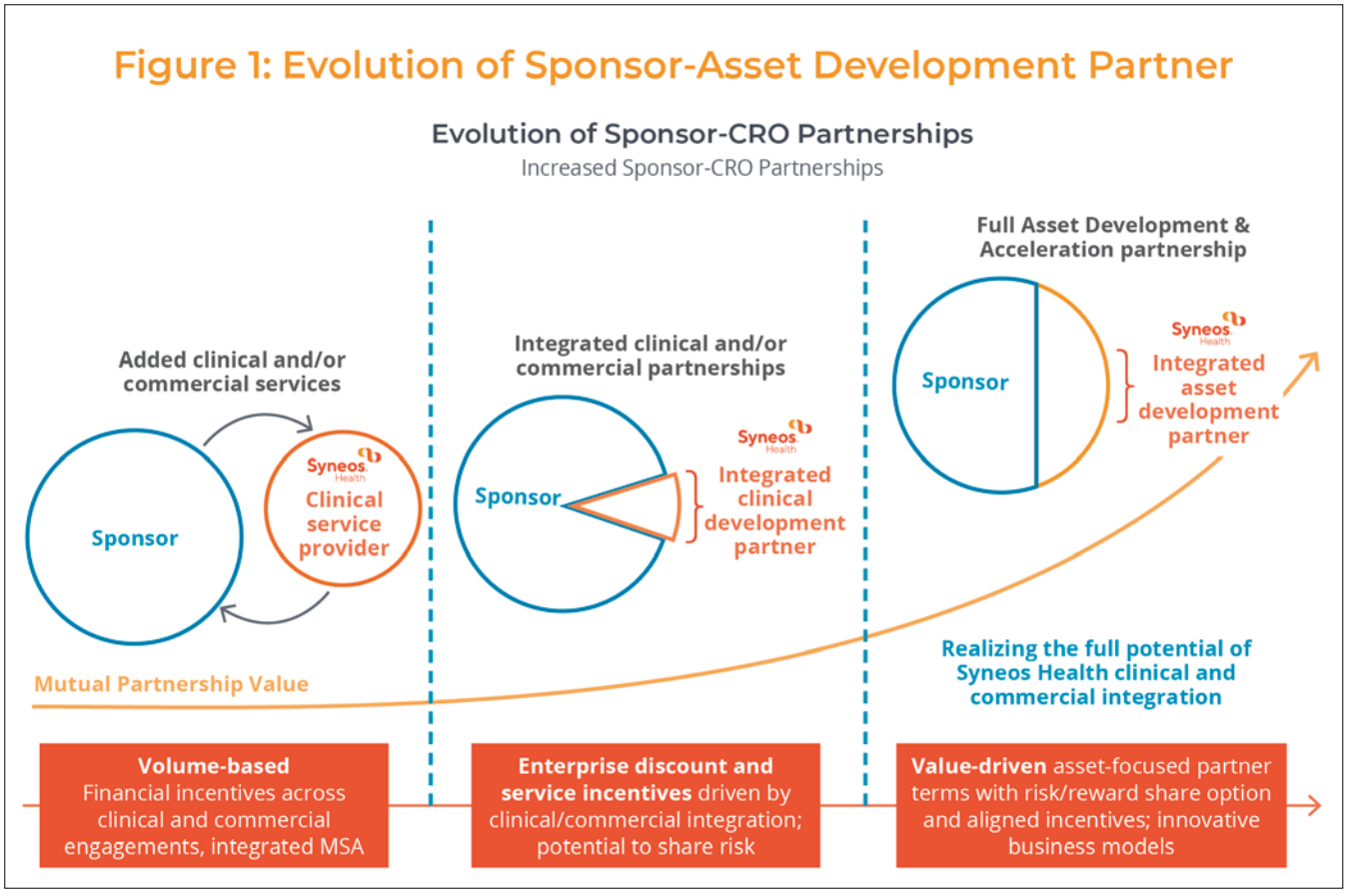
THE WIN-WIN OF END-TO-END OUTSOURCING FOR BIOPHARMA

BY DAVID BURNHAM, SENIOR VICE PRESIDENT, GLOBAL CLIENT SOLUTIONS; AND
PAUL GREENE, SENIOR VICE PRESIDENT, GLOBAL CLIENT SOLUTIONS, SYNEOS HEALTH

ON THE ROAD that a compound travels from the laboratory to the pharmacy, sponsors typically engage asset development partners or contract research organisations (CROs) in the final stages of product development – clinical trial conduct and product commercialisation. While the nature of the relationship between sponsors and these partners has been evolving, it has, nevertheless, stayed within the confines of those responsibilities and stopped short of full alignment on outcomes and finances.

Today, however, sponsors and asset development partners can form an end-to-end, integrated partnership with mutually beneficial objectives. This is possible when sponsors outsource all of their asset development work from the earliest stages (pre Investigational New Drug application) all the way through the product's commercialisation and maturity. Sponsors increasingly have the option to integrate development partners more deeply and uniquely at more points in the life cycle development process. In this model, a dedicated asset strategist leads an integrated, virtual product development team throughout the development program. Such a relationship allows for more creative financial structures, in which the asset development partner's incentives are aligned with the sponsor's own goals. This approach is ideally suited to small to medium-sized companies with several assets in early development, and a desire to keep a small, fixed-cost footprint.

As illustrated in Figure 1, the direction in which development outsourcing has been trending over the past decade has been away from transactional engagements, with unit-based pricing along a continuum toward more integrated and strategic relationships. The mutual value to the parties has increased with the progression.



In the simplest arrangement on the left end of the continuum, the CRO provides clinical services as an external partner, filling service gaps for customers. Pricing is based on volume with financial incentives offered to the CRO in a master service agreement. In the next phase of partnership maturity (in the middle of the continuum) the CRO is more integrated into the sponsor's business. In this relationship, the sponsor enjoys an enterprise discount and offers service incentives with the potential to share risk. Finally, the next stage of the evolution is a partnership that spans the full asset development cycle, and in which the CRO is fully integrated into the sponsor's business. Here, both parties act as end-to-end asset development partners. These partnership terms are value-driven and can include the option of business models built on sharing risks and rewards, with aligned incentives. This model allows the research organisation to function as a virtual product development partner for the sponsor.

Simultaneously, the business construct and incentive structure in outsourcing has been moving away from fixed-unit pricing at one end of the continuum, to contract modification reserve, volume incentives, and fixed pricing, as well as risk sharing at the far end of the continuum. This is where the asset development partners are either rewarded or penalised financially based on performance, or given the opportunity to earn back an initial discount.

A partnership that encompasses full asset development will be most advantageous under certain conditions. Firstly, the sponsor should have assets in early development and be seeking to progress those assets to key decision points, without adding substantial headcount to their fixed costs. Secondly, the development partner's asset team must be engaged early enough to be part of the diligence team. This ensures that the road map created for the asset is optimal, and also makes it possible for the CRO partner to have 'more skin in the game'. So much so, that the CRO partner outcome is aligned with that of the sponsor. Thirdly, the sponsor and CRO must be aligned not only on outcomes, but also on incentives. And lastly, the asset lead must, of course, be experienced in ushering multiple assets through all stages of development, and be capable of leading a multidisciplinary team.

Virtual project development gives the asset development partner the latitude to reimagine product development from end to end, with breakthrough analytics and design. The concept is a win-win, provided that the organisations are aligned on outcomes, with financial incentives for the asset development partner that reflect the risks taken and the investment made.

Sponsor Benefits of Virtual Product Development

- Removes risk from program delivery
- Reduces fixed costs
- Enables "more shots on goal" with the same amount of capital
- Enables sponsor to make go/no-go decisions sooner
- Accelerates time to market
- Provides access to large pharma expertise, data assets, and analytics
- Reimagines end-to-end product development, leading to breakthrough analytics and design

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EUROFINS CAMPUS OPENS IN WESTERN SYDNEY

In 2022 Eurofins opened it's 5,000 m^2 world-class, multidisciplinary, purpose designed testing campus in Western Sydney. The new campus consolidates the Bio-Pharmaceutical, Environment, Agroscience and Food Testing divisions on a single site within specialised, contained laboratories and workspaces.

The campus can accommodate up to 350 scientists and laboratory personnel with capacity for operations to double in size to support the strong growth Eurofins is experiencing in New South Wales and the market requirement for high quality, high throughput, rapid turnaround testing.

It is the latest addition to Eurofins' constantly expanding network of laboratory testing facilities in the Pacific region.

The new building is also designed to significantly reduce the environmental impact of Eurofins' operations and contribute to Eurofins' target of zero net carbon emissions by 2025

EUROFINS IS TESTING FOR LIFE

Eurofins is the global leader in food, environment, pharmaceutical and cosmetic product testing and in agroscience Contract Research Organisation services. Eurofins is one of the market leaders in certain testing and laboratory services for genomics, discovery pharmacology, forensics, advanced material sciences and in the support of clinical studies, as well as having an emerging global presence in Contract Development and Manufacturing Organisations. The Group also has a rapidly developing presence in highly specialised and molecular clinical diagnostic testing and in-vitro diagnostic products.

With over 50,000 staff across a decentralised and entrepreneurial network of more than 800 laboratories in over 50 countries, Eurofins offers a portfolio of over 200,000 analytical methods to evaluate the safety, identity, composition, authenticity, origin, traceability and purity of a wide range of products, as well as providing innovative clinical diagnostic testing services and in-vitro diagnostic products.

The Group's objective is to provide its customers with high-quality services, innovative solutions and accurate results on time. Eurofins is ideally positioned to support its clients' increasingly stringent quality and safety standards and the increasing demands of regulatory authorities as well as the requirements of healthcare practitioners around the world.

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COMPANY DESCRIPTION

Eurofins BioPharma Product Testing offers complete CMC Testing Services for the Bio/Pharmaceutical industry, including all starting materials, process intermediates, drug substances, drug product, packaging, and manufacturing support through our broad technical expertise in Biochemistry, Molecular & Cell Biology, Virology, Chemistry and Microbiology.

Our fundamental philosophy is to help clients efficiently allocate their research and manufacturing expenditures by strategically engaging them to meet their unique outsourcing needs.

We offer the ability to manage your testing programs more efficiently through your choice of three unique service models, including our award-winning Professional Scientific Services® (PSS), Full Time Equivalent (FTE) or traditional fee-for-service. You can choose the best, most cost-effective service solution for your project goals.

FACILITIES

Our local presence in Sydney, Melbourne and Auckland ensures personal service backed by a unique global breadth of harmonised capabilities that supports all functional areas of bio/pharmaceutical drug development.

LABACCESS - ONLINE INNOVATION

LabAccess.com, our innovative online data access tool, offers a timely and secure window to comprehensive laboratory information as projects progress. With LabAccess.com, you can view extensive, live project information such as submitted samples, analysts' notebooks, chromatograms, approved test results, Certificates of Analysis, raw data packages and invoices.

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- Cytotoxicity testing
- Preservative Efficacy Testing
- Container/Filter/Seal integrity testing
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EMPOWERING THE NEXT WAVE OF WESTERN AUSTRALIAN BIOTECH ENTREPRENEURS

BY DR JENNIFER HALTON (PHD) AND SAM MONKHOUSE, CERI

CERI, the Centre for Entrepreneurial Research and Innovation, is a not-for-profit startup incubator supporting the next generation of Western Australia's entrepreneurs.

CERI'S PROGRAMS HAVE been designed to educate and empower early-stage entrepreneurs, PhD students and visionaries within the Western Australian community. Since opening its doors in August 2016, CERI and its Founder, Charlie Bass, have led a passionate vision to catalyse innovation and entrepreneurship in Western Australia, with the goal of enabling the industries of the future. CERI provides startup office residency, mentorship and catalytic funding to high-potential startups. CERI's mission is to support Western Australia's entrepreneurial talent in high-impact technology commercialisation, empowering the leaders of the future. CERI's vision is to facilitate a sustainable economy for Western Australia by enabling the industries of the future. To date, CERI has trained more than 600 Western Australians with an entrepreneurial mindset, and the fundamentals of business formation and growth.

Historically, CERI has worked closely with entrepreneurs in the biotechnology sector. In 2017, CERI worked with MelDetect, which, at the time, was a company with a world-first blood test to diagnose early-stage melanoma. The company was announced as the winner of CERI's Concept to Creation program for 2017. Concept to Creation is a 14-week accelerator program, which takes founders through the essential steps of business formation. The company was represented by Postdoctoral Research Fellow Pauline Zaenker, from Edith Cowan University.

In 2018, CERI worked with Professor Joost Lesterhuis, Head of Sarcoma Translational Research at Telethon Kids Institute. Professor Lesterhuis founded ImmuMat, with the company also winning CERI's Concept to Creation program. The company produced a spray-on gel to fight secondary cancers, and there will be subsequent clinical trials of the gel on dogs with cancer. Professor Lesterhuis is a leader in cancer research, and has recently been awarded just shy of $1 million in grants, via the 2022 Innovation Seed Fund, to continue his research and commercialisation of cancer treatments. Professor Lesterhuis is currently exploring the activation of anti-cancer immunity, using small-molecule drugs as well as intraoperative immunotherapy, to prevent cancer recurrence after surgery.

Ones to watch: current biotech startups at CERI

Gene S

Gene S is a Western Australia–based startup biotechnology company founded by Dr Svetlana Baltic and Dr Suzanna Lindsey-Temple. Gene S, a CERI resident company, aims to provide accessible, affordable, rapid and reliable genetic solutions to facilitate personalised prescription therapies to improve the health and wellbeing of the population. The company has a novel, innovative and disruptive technology that provides personalised prescription medication using pharmacogenomics and a precise detection method. This personalised precision prescription medical device will assist doctors in prescribing the right medication at the right dose, the first time. The technology will allow doctors to assess a patient's genetic profile (their individual prescriptome) to specific medication pathways. This will ensure that patients receive the optimum treatment road map, and it will reduce the risk of medication side effects, as well as save governments billions of dollars every year in healthcare costs.

Lixa

Lixa (formerly Neolixir) is a private biotech startup and CERI resident company developing a scalable solution for problematic microbial contaminations across industries, including human health, animal health, aquaculture and marine antifouling. Lixa was the winner of CERI's 2021 Concept to Creation program. The Lixa technology, invented by Dr Angela Fonceca and her colleagues at The University of Western Australia, is a proprietary, small-molecule, antibiofilm technology that disrupts both longstanding as well as immature bacterial biofilms. Biofilms – the shield that bacteria create to protect their colonies – are thought to underlie approximately 80 per cent of all recurring bacterial infections. Antibiotics cannot penetrate these biofilms, leaving the colony in a state that encourages the development of antibiotic resistance. Within the human and animal antimicrobial market, biofilm disruption therapies are expected to break the ongoing cycle of antimicrobial resistance by dismantling the biofilm, thereby enabling existing or new antibiotics to clear otherwise persistent bacterial infections. Lixa's lead development candidate, Neo X 101, is expected to enter clinical development within the next 12 months. Lixa is inviting companies with antimicrobial technologies to explore co-development partnerships for next-generation, anti-infection combination therapies.

U-CAN

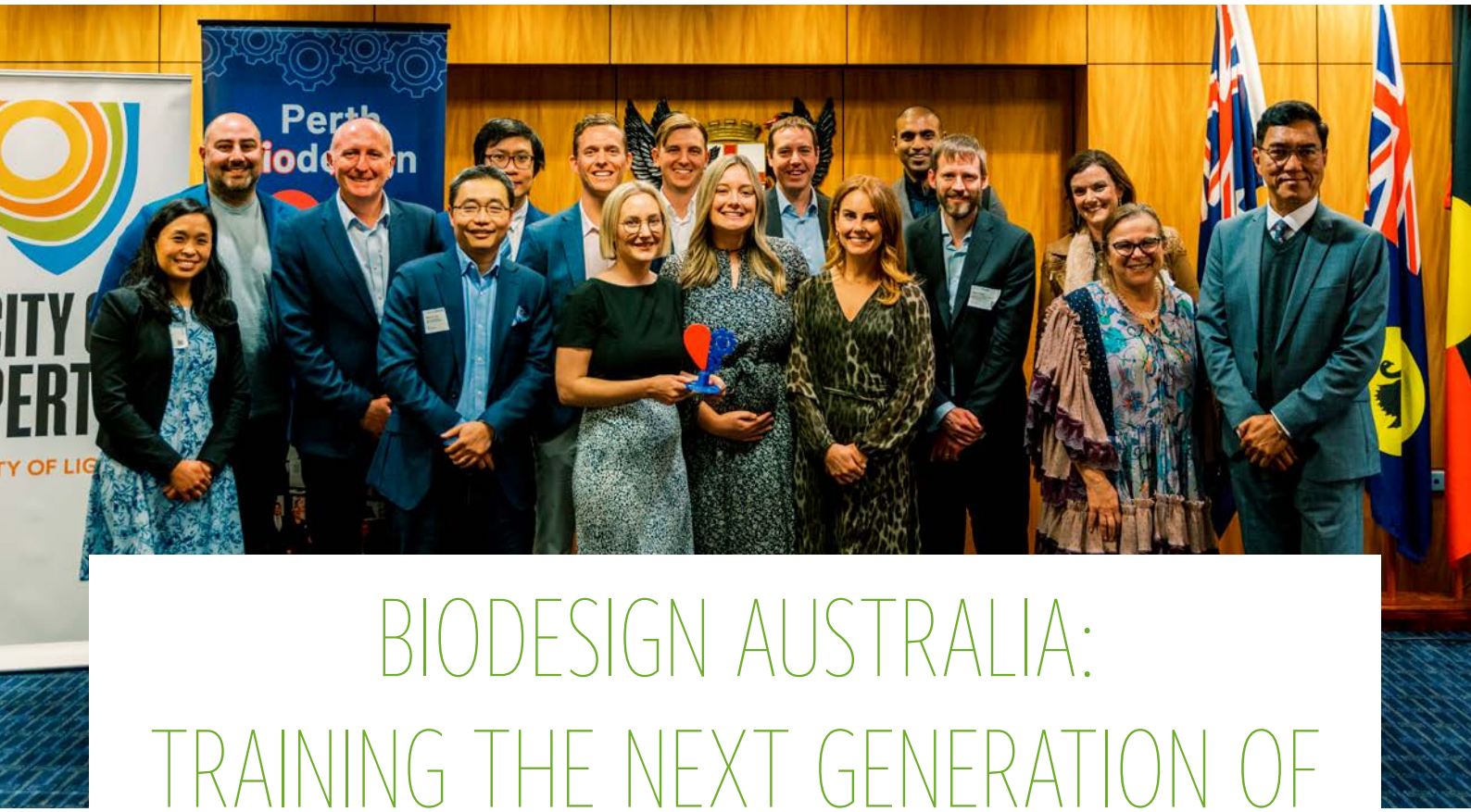
U-CAN Ostomy Systems is a biotechnology company, founded by Steve Sterling in 2019. The company has the potential to be a disrupter in stoma care, specialising in the design and development of unique proprietary solutions that can change the lives of people living with stomas across the globe, and improve the environmental sustainability of the ostomy pouch industry. U-CAN, a CERI resident company, has developed a proprietary, flushable and sustainable stoma pouch that is made from biological materials. The impact of the company could be monumental, with the current stoma pouch industry contributing 600 million single-use, plastic and waste-filled pouches to landfills across the world, each year. Potentially more impactful is the possibility of the solution normalising the lives of those living with stomas across the globe; the company has estimated that its proprietary solution will be able to reduce the time spent managing their stoma by 700 per cent when compared to current practices.

Left to right: Sam Monkhouse, Marketing Officer; Dr Jennifer Halton (PhD), CERI Chief Impact Officer; Charlie Bass, CERI Founder and Executive Chairman; Fiona Lye, Programs and Events Coordinator; and Kristen Houston, Program Lead. Photo by CERI

Dr Angela Fonceca, Lixa Co-founder and 2021 Concept to Creation winner, with her graduating Concept to Creation cohort. Photo by CERI

Enabling the industries of the future

CERI, among other accelerators and incubators in Western Australia, has an important role to play in the Australasian biotechnology sector. CERI is proud to remain a leading educational facility, support network and home to courageous entrepreneurs and biotech startups. Translating breakthrough research into successful companies through strategic commercialisation is an important pathway to diversifying Western Australia's economy. Western Australia has some of the leading researchers in the world, with a substantial number of companies created and research commercialised to date. Together with partner organisations in Perth and across Western Australia, CERI can move the dial towards a more sustainable, diversified economy by enabling the industries of the future, and can begin to minimise the over-reliance on the resources sector.



BIODESIGN AUSTRALIA: TRAINING THE NEXT GENERATION OF BIOMEDICAL ENTREPRENEURS

BY PROFESSOR KEVIN PFLEGER, DIRECTOR OF BIOMEDICAL AND HEALTH INNOVATION, THE UNIVERSITY OF WESTERN AUSTRALIA; AND CHAIR, BIODESIGN AUSTRALIA

IN A NUTSHELL, the Biodesign innovation process focuses on identifying and validating unmet health needs before inventing, developing and implementing a solution. It sounds simple, but so often in research, as in life, we quickly jump to an answer without fully understanding the question; or we even create solutions looking for problems. The Biodesign process puts rigour around the messiness of biomedical and health innovation. Its strength lies in transdisciplinary thinking, with clinicians, scientists, engineers and those with expertise in business coming together with a common goal, learning each other's language and respecting the role everyone has to play.

Biodesign is, of course, not unique to Australia. Indeed, the Biodesign program was officially launched in September 2001 at Stanford University in the United States, and Biodesign programs are also running very successfully in Texas, Japan, India, Singapore and Ireland, each with their different flavours. Furthermore, the Stanford Byers Center for Biodesign has a global faculty-training program that has trained a select group of innovators who have contributed to establishing the aforementioned international programs, as well as TMU Biodesign in Taiwan, Biodesign Rambam in Israel, and our own Perth Biodesign in Australia.

Most, if not all, of these programs will be represented in Perth in October at the Biomedical Engineering Innovation, Design and Entrepreneurship Alliance Asia-Pacific symposium, following AusBiotech 2022 – another great reason to come to Western Australia for AusBiotech's flagship conference!

Biodesign Australia is a network that enables Biodesign programs across the country to share resources, speakers and best practice. Based on the Biodesign innovation process, these programs are experiential in nature. With a focus on biomedical entrepreneurship, they are designed for the Australian biomedical environment and thrive on support from industry, healthcare providers, academic organisations and individual professionals with a breadth of expertise.

The network has nodes in Western Australia, South Australia, Victoria, New South Wales and Queensland, and affiliation with activity in Tasmania. Perth Biodesign (administered by The University of Western Australia) and Biodesign Innovation Melbourne (at the University of Melbourne) have both had several years of experience in running Biodesign courses using an ecosystem-wide and an internal academic model, respectively.

Left: Perth Biodesign for Digital Health Presentation Night at City of Perth Council House, June 2022

Bill McKeon, CEO and President, Texas Medical Center (left); and Professor Kevin Pfleger, Chair, Biodesign Australia

Perth Biodesign now has a suite of offerings, including two-day Biodesign Bootcamps; seven-week and three-month iPREP Biodesign industry placements; four-month Perth Biodesign for Digital Health courses; seven-month Perth Biodesign for Medtech courses; and the two-unit Biodesign capstone of the Master of Professional Engineering with a Biomedical Engineering specialisation at The University of Western Australia. It also assisted in the establishment of Biodesign Sydney and Adelaide Biodesign with the aid of funding from the federal government's MTPConnect Growth Centre Project Fund Program. Brisbane Biodesign, headquartered at Queensland University of Technology, rounds out the five Australian Biodesign programs, featuring its iFellowship with the School of International Biodesign in India and its Biodesign undergraduate unit.

Perth Biodesign is very much connected to its local ecosystem, with the support of universities, research institutes, the Western Australian Health Translation Network, WA Life Sciences Innovation Hub, WA Data Science Innovation Hub, the Australian Medical Association (Western Australia), patent attorneys, regulatory affairs specialists, and angel investors. Perth Biodesign also has the support of the health services that encompass all the major hospitals in Western Australia, including Fiona Stanley, Royal Perth, Armadale, Joondalup, Rockingham, and Sir Charles Gairdner hospitals. In addition, the courses rely on the great network of experts within the ecosystem to provide teaching and mentorship, as well as Western Australian Government funding, generous philanthropy and sector-wide sponsorship.

A notable example of success is Perth Biodesign for Medtech 2019 winner VeinTech, which went on to win the Medtronic Prize in the MedTech Actuator Origin competition in April 2021, and the WA Innovator of the Year 2021 'Great for the State' Platinum Award later that year. VeinTech has received a WA Manufacturing Voucher from the MTPConnect WA Life Sciences Innovation Hub, has recently been awarded a $500,000 Innovation Seed Grant from the Western Australia Government's Future Health Research and Innovation Fund, and has successfully raised its latest round of dilutive capital.

BioDesign Innovation Melbourne is a joint teaching program offered since 2016 at the University of Melbourne by the Faculty of Engineering and Information Technology, and Melbourne Business School for students in the Master of Engineering and Master of Business Administration degrees, respectively. Since the program's inception, it has been extremely successful in seeding startups, with 10 companies being formed from 18 teams between 2016 and 2019. Students in multidisciplinary teams learn to identify unmet medical needs, develop and prototype concepts, and generate business plans that support the creation of medical devices over the two semesters from March to November. The 10 companies formed out of the program have been successful in attracting Accelerating Commercialisation grants and millions of dollars in venture capital, and have participated in international competitions like the MassChallenge.

Adelaide Biodesign and Biodesign Sydney were able to run two cohorts and one cohort, respectively, before COVID-19 interrupted proceedings; however, with strong support from their local ecosystems, the intention is to restart those programs when circumstances allow.

Finally, Biodesign Australia has recently announced the signing of a memorandum of understanding (MoU) with the Texas Medical Center (TMC) – the largest medical centre in the world. TMC and Biodesign Australia will work collaboratively to facilitate opportunities between TMC Biodesign and programs within the Biodesign Australia network, and founders and entrepreneurs will be provided with access to talent, clinical trial activity, expanded funding opportunities, and market access.

TMC Biodesign, which launched in 2015, has raised more than $41 million in capital, with 11 companies founded and 25 corporate/academic relationships developed. This MoU also builds on the TMC | Australian BioBridge, which was launched in 2018.

For more information on Biodesign Australia, please visit www.biodesign.com.au.

THE ROLE OF PATENTS IN DRUG DEVELOPMENT

BY DR DAMIAN SLIZYS, DIRECTOR OF INTELLECTUAL PROPERTY, TELIX PHARMACEUTICALS

This article has been developed in collaboration with AusBiotech and its IP Advisory Group, and in response to the changes to the international TRIPS Agreement[1] waiver for IP rights, which has highlighted a fundamental misunderstanding of the role of intellectual property (IP).

THE WORLD TRADE Organization's waiver is in response to globally equitable health care and, under certain circumstances, will see member countries set aside patent rights for a vaccine in response to a public health emergency. At the time of writing, this waiver is now proposed to extend to medical technology and medicines.

Despite voluntary global agreements, and more collaboration and partnerships in biotech than ever before, a misguided understanding of equitable access remains, and the waiver will not overcome the real barriers: bottlenecks and shortages in the global supply chains, as well as strained healthcare systems in low- and middle-income countries, particularly.

Research and development is complicated, and few organisations around the world can do it at scale, at low cost, and in compliance with the strict standards and public expectations of manufacturing safety. Supply chain and distribution challenges, regrettably, prevented increased COVID-19 vaccine output and delivery.

1 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization

Waiving IP rights jeopardises the existing quality-control systems, and makes it far more difficult to distinguish genuine products from knock-offs that may target vulnerable communities. It also does not address workforce challenges.

While the support in some quarters was undoubtedly well-intentioned, it ignored the important role of IP as a means for incentivising groundbreaking research and facilitating investment into innovative biotechnology companies; IP was pilloried by some parties as a barrier to equitable distribution of vaccines and the technology transfer process to enable their manufacture.

Using an example from Telix, this article explains the role of patents and IP in drug development.

About Telix

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic products using Molecularly Targeted Radiation. Telix is headquartered in Melbourne, with more than 200 employees across offices in Belgium, Switzerland, Japan and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases. Telix was listed on the ASX (ASX:TLX) in 2017, and in less than five years it has transitioned from a small biopharmaceutical startup to an ASX 200 company.

Telix's lead product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been approved in the United States and Australia. Telix is also progressing marketing authorisation applications for Illuccix in Europe and Canada.

Telix collaborates extensively with universities and medical research institutions, both in Australia and internationally.

Patents 101

Patents, in essence, are a legal construct that defines an area of technology as being property in the sense that others can be excluded from using the technology for the term of the patent. They are also like property in that they can be traded (i.e., bought and sold) and licensed to others.

A cornerstone of the patent system is that it recognises and rewards the distinct contribution of the inventor(s) to society; for example, the patent document must publish the technology in a way that allows it to be used by others, and the patent cannot legally claim any aspect of the technology that was already known. Accordingly, practically all patent systems require a patent to be examined by a government body to confirm that it satisfies these criteria, and all patent systems allow the patent to be tested in court proceedings.

What is a robust patent system?

The difficulty with any IP right is that it is intangible. It cannot be physically handled, identified or handed over. In order for IP rights to be treated as property, their scope must be as clear as possible, and this scope should not be capable of being changed arbitrarily. In this way, when an IP right is sold or licensed, the buyer or licensee can be confident that what they have bought or licensed won't disappear or be compromised easily.

A robust patent system incorporates characteristics that mean decisions about patents are not arbitrary. The examination process should be reliable, rigorous and transparent so that the risk of the patent being found invalid by a court is minimised. Similarly, court enforcement proceedings should be reliable and transparent, and the ability to appeal a decision should be available. Australia is regarded as having a robust patent system because it has these characteristics. Many of our major trading partners – such as the United States, the United Kingdom, the European Union, Switzerland, Japan and, increasingly, China – are also seen as having these characteristics.

The international nature of the patent system

Each country has its own patent system, but there is a degree of mutual recognition by the operation of a number of treaties. The Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty allow for the recognition of the patents filed by inventors in other countries, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides for minimum standards of patent examination and patent coverage that are internationally coordinated.

These treaties mean that a patent filed in one country can effectively be extended to practically every other country in the world.

How do patents facilitate drug development?

Drug development is a long journey; it requires diverse skill sets and significant resources to take a drug from the initial drug discovery step through the clinical trials and other requirements for market authorisation, and then to distribute the drug to patients. To have all of these skill sets in a single

organisation is impractical. For example, many of the ideas for new pharmaceuticals come from the basic research carried out by universities and medical research institutes; however, it is unfeasible for universities to build the infrastructure to develop these new pharmaceuticals through to market authorisation and then to full life-cycle commercialisation.

The patent system means that a company, such as Telix, can acquire or in-license a new pharmaceutical using the patent system with confidence that the patent is defensible, and therefore that it's worth investing capital in its development. On the flip side, the initial developers of the new pharmaceutical are incentivised to make these developments because they can assign or license their patents instead of having to take the drug through to market in order to realise any benefits.

Ultimately, this means that a number of groups can participate in the drug development process, with each group being able to contribute what they specialise in. The patent system allows the baton of the technology to be passed from group to group, in order to bring life-saving and life-enhancing technologies to patients.

The other aspect of the system is that, as the market is international, patents to large markets, such as the United States, can be filed by inventors in any jurisdiction and acquired or licensed by organisations in any jurisdiction. By increasing the size of the market, there are more opportunities for each participant in the drug development process and overall for more drugs to be developed and made available for patients.

To quote Stephen Haber and Naomi Lamoreaux in *The Battle Over Patents: History and Politics of Innovation*[2]:

'For all their imperfections, US-style patent systems spread because they had multiple advantages. By creating property rights that could be traded in a market, they facilitated the development of a productive division of labour, either within the firm or through the market, that enabled inventors to specialise in technological discovery and leave the task of developing and commercialising their ideas to others. They also made it possible for firms to transfer technological knowledge to other firms, even to firms in other countries. Moreover, patents are available not just to inventors of breakthrough technologies, but also to those who improve existing technologies incrementally or find novel ways to use them in other applications.'

TLX101

Telix began its journey by in-licensing assets from a number of different universities and medical research institutions worldwide. One example is the L-type amino acid transporter 1 (LAT1) inhibitor designated TLX101. TLX101 is a radioactive peptide that targets glioma, a highly intractable form of brain cancer. This investigational asset was initially developed by an academic group at the University of Würzburg, and showed early promise in models of glioma.

The context of the in-licensing of TLX101 illustrates the principles discussed above. The academic group filed patent applications in a number of countries throughout the world, including Australia, for TLX101 in the treatment of glioma.

The academic research did not have a commercial focus, and the studies conducted were not sufficient to satisfy a standard preclinical package for regulatory approval of a pharmaceutical, let alone the entire gamut of requirements required for marketing authorisation. In order for this very promising pharmaceutical to become available to patients, a multi-year, multimillion-dollar program of development was required.

The academic group and the university did not have the time, manpower, resources or diverse skill sets to take this product down the development pathway, and without further intervention, the pharmaceutical product would have languished.

The ability of Telix to in-license the patent portfolio as a distinct piece of property has provided Telix with the confidence to invest capital into the substantial development program required to take TLX101 to approval – the preclinical programs; the clinical trials; the manufacturing campaigns; the establishment of relationships with key opinion leaders and strategic partners; the regulatory submissions; the reimbursement strategies; and setting up the commercial team and infrastructure required to sell TLX101, subject to approval, to healthcare systems around the world.

The ability of the academic group to out-license their patent portfolio means that they have benefited from their promising work without having to progress it further down the drug development pathway and incur significant additional cost.

The operation of the patent system in encapsulating the technology relating to TLX101 into a tradeable and investable asset means that a bright idea supported by successful exploratory experiments at a prestigious university has the opportunity to be transformed into a potentially life-saving pharmaceutical product.

Dr Damian Slizys is Director of Intellectual Property at Telix. He is responsible for managing Telix's intellectual property portfolio, and is a registered patent attorney with more than 20 years' experience.

2 www.hoover.org/research/battle-over-patents

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https://www.seerpharma.com/REDI

REAL-WORLD DATA'S ROLE IN DRUG REGISTRATION

BY DR MICHAEL WINLO, MANAGING DIRECTOR, EMYRIA LIMITED

In the world of drug development, there's a quiet revolution going on.

IN COUNTRIES ACROSS the world, more weight is being given to the role that real-world data (RWD) can play in helping evaluate new therapies for unmet medical needs. At Emyria, we're passionate about the possibilities and future of RWD, and it's been a core part of our business since inception.

We think that RWD can play a significant role in helping regulatory bodies, healthcare providers, major players and people around the world develop and use new health solutions for significant problems.

What is RWD?

In the world of clinical research, RWD and real-world evidence (RWE) are gaining popularity. As concepts, they represent an important and accelerating shift in attitudes for the ways in which new treatments are developed and evaluated. They support the move towards patient-centric and value-based care. But what does 'real world' mean? What can this data be used for, why should we care, and what comes next?

RWD captures the experiences of patients interacting with health care in their daily lives, as opposed to the kind of data that's created in tightly controlled or clinical trial settings.

RWD can come from a variety of systems and, by definition, represents the 'real world' diversity found among everyday patients and healthcare practices. Most of the time, we are talking about using data that is spun off as a by-product of modern health service delivery.

Compare this to controlled clinical trials, where a carefully selected group of patients and trial staff must follow strict protocols. This may mean that the trial is doing things that are not common, or not reflective of the way that medicine is typically practiced, which can affect how the final trial results may apply to the general population of interest under routine conditions.

'Real world' (non-trial participant) patients are complex, and real-world health services are not consistent, either. We expect our health system to only work with treatments that are safe and effective for the typical patient populations they are intended to treat – not just the carefully curated cohorts of most clinical trials.

While controlled clinical trials are still primarily how healthcare evidence is created, there is increasing recognition of the limited 'generalisability' of trial results, which is driving the interest in RWD – both how to capture it, and how to turn it into evidence.

The hope is that by using more RWD, we can improve the generalisability of research. This is why major international regulators are preparing guidance for industry on how to use RWE in market authorisation decisions; it's why sponsors, drug developers and contract research organisations are investing heavily in RWE programs; and it's why startups are sprouting up to support these efforts.

How is RWD collected?

At Emyria, when we talk about RWD we mean information gathered, with consent, from the diverse set of patients referred to our innovative clinics (Emerald Clinics) for access to new and unregistered medicines. Our clinicians work with patients to record their healthcare changes and experiences, and track their

health outcomes. Since we are working with new treatments where evidence is lacking, we are especially interested in a wide view of the individual's healthcare experience.

For every patient, our system collects more than 1000 different points of data.

By incorporating a broad set of validated assessments into our clinical reviews, we can help identify meaningful clinical changes for our patients sooner. This not only helps us personalise the care we provide, but it also helps us to see, across populations, what treatments are working, for what problems, and for which patient groups – while still being closely monitored by clinicians and researchers alike.

What are the advantages of RWD?

Establishing a strong RWD system requires significant investment but, at Emryia, we're now seeing the fruits of that labour. Emryia's RWD is not only helping us personalise care for our patients (informed by the lessons of prior patients), but our unique drug response insights are also allowing us to lead and launch our own drug development programs.

How can RWD accelerate the drug approval process?

The average drug development process takes more than 10 years. A major factor in that time frame is the arduous clinical trial process, which can often mean dozens of iterations of the various phases – especially Phase 2 – to optimise the dose-response relationship of a new treatment in a precise patient population.

In simple terms, RWD can help to point researchers in the correct direction earlier, setting or guiding the parameters of the clinical trial phases so less guesswork is required during the drug development process.

What role does RWD play in the medical registration process?

Major regulators around the world are now creating specific guidance for drug developers to better incorporate RWD into their drug development programs.

The number of Food and Drug Administration approvals where RWD played a significant role in the approval process now sits at 78 per cent, and is growing. The United Kingdom's National Institute for Health and Care Excellence introduced a framework to help use RWD to 'drive forward access to innovations for patients'.

Health services that are able to provide high-quality RWD can attract the interest of innovative drug developers or, in Emyria's case, start to lead their own drug development initiatives.

How is Emyria applying RWD?

RWD plays a significant role in our current repurposed drug development programs, where the findings of our proprietary RWD, covering thousands of patients, is informing the formulation and clinical trial process on our journey to global registration.

Our first proprietary cannabinoid-based capsule, EMD-RX5 – which seeks to treat the symptoms of psychological distress as an over-the-counter medication – has already been developed and passed Phase 1 clinical trials with flying colours.

With several other repurposed cannabinoid programs in various stages of development, our RWD insights will continue to be a huge factor in how those medicines progress to registration.

RWD also plays a role in our investment in remote monitoring technology and, most importantly, in helping the patients at our clinics get healthier.

We hope to demonstrate a new way of practicing medicine; one that is less transactional and more focused on creating knowledge with patients. Ours is a new model that more deeply invites the patient into the decision-making and treatment evaluation process more often, and pays closer attention to what's going on.

This requires investment in new technologies, as well as clinical workflows, but we believe that it will allow us to bring new treatments and care models to patients faster, thereby showing the value of making evidence creation a central purpose of care delivery.

Hear Emyria Limited deliver its company presentation at AusBioInvest 2022 in Perth, Western Australia, on 27 October. Join us in person for Australia's largest life sciences investment conference. For more information, visit www.ausbiotechinvestment.com.au.

INCANNEX INNOVATION

Pioneering development of cannabinoid and psychedelic pharmaceuticals

INCANNEX HEALTHCARE LIMITED is a clinical stage pharmaceutical company developing cannabinoid and psychedelic medicines for a range of indications, including, but not limited to, obstructive sleep apnoea (OSA), inflammatory diseases, traumatic brain injury, anxiety disorders, addiction disorders, spasticity, and pain in multiple sclerosis and skin conditions. Incannex is publicly traded company listed on both the ASX (ASX:IHL) and Nasdaq (IXHL). The company's board and senior management teams have experience that spans all aspects of drug development, including capital raising, scientific research, drug design, clinical trial design and logistics, and interaction with regulatory agencies.

Across all development programs, Incannex's strategy is to generate patent protected drug products with high-quality clinical evidence of safety and efficacy to support regulatory applications, with the goal of obtaining marketing approval from the United States Food and Drug Administration, as well as analogous agencies in other jurisdictions. To achieve research goals, Incannex works with world-class manufacturers, contract research organisations, clinical trial sites and academics. These relationships, combined with the company's internal expertise in capital markets and clinical research, allows Incannex to work at the cutting edge of all aspects of pharmaceutical research, and generate creative solutions to the many challenges of drug development.

Incannex's research is divided into the following three streams.

Cannabinoid combination products

Incannex's cannabinoid combination drug products combine cannabinoids with generic drug substances to create novel fixed-dose combination products. The rationale for these products is that the combination will have a greater therapeutic effect and/or reduced risk of side effects than either drug as a monotherapy. Incannex designed the drug combinations based on observational, preclinical and clinical evidence for the drugs in the indications of interest. Synergy between the cannabinoid and generic partner observed by Incannex in preclinical or proof-of-concept clinical studies provided the foundations for patent positions, which cover both compositions and methods of use for each combination product.

Novel cannabinoid formulations

In August 2022, Incannex acquired US-based cannabinoid development company, APIRx. APIRx had a suite of 22 programs developing novel, patent protected cannabinoid drug products across a range of therapeutic areas. The addition of APIRx patents means that Incannex now owns the world's largest portfolio of cannabinoid formulation patents.

Psychedelic medicines

Incannex's psychedelic drug development programs centre on the use of psychedelic drugs, such as psilocybin, to enhance the effect of psychotherapy. This works by opening the mind to the root causes of anxiety disorders and facilitates the formation of new neural connections that provide a lasting effect in patients. Incannex's psychedelic research is performed in collaboration with Dr Paul Liknaitzky, Head of Clinical Psychedelic Research at Monash University.

For additional information on Incannex's research programs, including results from Incannex's recent clinical trial assessing IHL-42X in patients with OSA, visit Incannex.com.au.

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Our new lab in Brisbane puts us in the right place at the right time - receiving requests to process samples for downstream enzymatic or immunological assessments within hours of blood draw.

Receiving samples within a very short time-frame from sites and Phase 1 units located in and around Brisbane ensures sample integrity is maintained at the highest level, which is our utmost priority.

After an extensive search in 2021, the Translational Research Institute (TRI) in Woolloongabba was selected to house 360biolabs' Brisbane laboratory. TRI's vision is **'Exceptional science, healthier lives'.** TRI has two Clinical Trial Units, the Clinical Research Facility co-located at the Princess Alexandra Hospital and TRI@Childrens located in the Centre for Children's Health Research opposite the Queensland Children's Hospital. These units provide state-of-the-art specialist facilities to deliver patients-centric, investigator-led or sponsored clinical trials across Phase 1-4 in the pharmaceutical and nutraceutical sectors. The clinical trials team at TRI have extensive experience in clinical trial management and coordination services across multiple phases of clinical research.

TRI's current clients and partners include leading top 10 pharmaceutical companies, biotechnology and clinical research organisations, hospitals, universities and research institutes. This focus on 'bench to bedside' is consistent with 360biolabs' mission of enabling future medicines.

In April 2022, 360biolabs was contracted by Novavax to conduct sample analysis for the Company's upcoming Phase 3 clinical trial.

A two-part Phase 3, Randomized, Observer Blinded Study to Evaluate the Safety and Immunogenicity of Omicron Subvariant and Bivalent SARS-CoV-2 rS Vaccines in Adults Previously Vaccinated with Other COVID-19 Vaccines.

Novavax is conducting a Phase 3 strain change trial in Australia to determine if its Omicron variant-specific vaccine induces superior antibody responses against the Omicron variant compared to its prototype vaccine in participants who have received either a primary (two doses) or booster (three doses) series of an mRNA vaccine. The trial will also seek to determine the antibody responses to a bivalent COVID-19 vaccine containing both the original vaccine and Omicron strain-specific administered in participants who have received a booster series of an mRNA vaccine.

Novavax is recruiting participants from 18 sites across the eastern seaboard of Australia. Whole blood samples for PBMC isolation and serum samples for immunological testing are shipped to 360biolabs for analysis. Multiple sites located in Queensland ship to 360biolabs' Brisbane laboratory for PBMC processing, while other sites ship to 360biolabs' Melbourne laboratory.

"360biolabs has been a responsive partner since our first COVID-19 Phase 1 trial in 2020, consistently delivering excellent quality results. We appreciate their agility and ability to receive samples at two locations in response to our needs for increased PBMC processing capacity in the Phase 3 variant clinical trial."

Chijioke Bennett, MD, MPH, MBA Senior Director,
Clinical Development, Novavax.

Want to know more about our Brisbane specialty lab and how we can support your clinical trial?

Contact our team.

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
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IMAGE: Elizabeth Quay, Perth | Jarrad Seng

RELENTLESS PERSISTENCE TO COMMERCIALISE

BY BRENDAN FAFIANI, CEO, CYBAN

Cyban Pty Ltd is an Australian medical technology company positioning itself to become the emerging leader in non-invasive critical organ pulse oximetry.

Cyban prototype

BRAIN INJURIES ARE the leading cause of death and disability worldwide. Every year, there are more than 27 million cases of traumatic brain injury (TBI) globally. TBI carries a 50 per cent mortality rate, and, of the survivors, 67 per cent suffer with long-term disability. In Australia, the overall annual cost of TBI is estimated to be $8.5 billion; in the United States, this rises to $76 billion. This is the second-highest economic cost of any health condition.

The impact is not limited to brain trauma; 20 per cent of high-risk patients undergoing carotid surgery and five per cent of high-risk patients undergoing cardiac surgery have a life-altering or fatal brain injury. A major cause is brain hypoxia, as brain cells die within minutes if deprived of sufficient oxygen.

When brain hypoxia is detected, treatments to maintain adequate brain oxygen levels and prevent secondary brain injury are often straightforward and effective. Evidence has confirmed that early detection and treatment of hypoxia improves patient outcomes. Clinical examination remains the fundamental monitoring procedure to identify neurological deteriorations, even in patients who are comatose or sedated.

In more severe cases, intracranial pressure (ICP) monitoring is the cornerstone of brain injury care. ICP monitoring requires a hole to be drilled into the skull to place a probe or catheter. Due to the risk of further injury and infection, and the high cost involved, only 50 per cent of patients with a severe TBI receive ICP monitoring.

Pulse oximetry has been used to measure blood oxygen levels since the 1970s; this is done by shining light into the body and measuring the relative absorption of infrared and red light that occurs with each pulse of arterial blood in the skin. Despite this, measuring the oxygen levels in the skin does not indicate brain oxygen levels.

Many attempts have been made to use red and infrared light to measure blood oxygen levels within the brain. The technical challenge is contamination of the light signal by blood flow in the skin.

Cyban's innovation in pulse oximetry solves the fundamental challenge of removing skin contamination from the reflected signal. The proprietary sensor design isolates photons reflected from the venous microvasculature overlaying the surface of the brain, providing access to a unique pulsatile waveform, to provide a reliable method for monitoring changes in brain blood flow, brain oxygen levels and intracranial pressure.

Non-invasive monitors can be employed faster, at significantly lower cost to invasive alternatives, and, due to the low risk, a greater number of patients can benefit from continuous monitoring.

By identifying a deterioration early, the intervention can often be more straightforward. This can range from repositioning the patient's head, changing the ventilator settings or giving more blood. It may trigger a decision to administer diuretics or anticonvulsants. In more severe cases, the patient may require an external ventricular drain to be placed. Or, the observations from the monitor may simply highlight the need for further imaging, to get a better understanding of the problem.

The technology allows clinicians to make more informed decisions more quickly, and also to monitor the effect of those decisions in real-time at the bedside. It can also provide an indication that no additional changes are needed, and that the patient's condition is stabilising.

The Cyban team strives to ensure that the largest number of patients will benefit from its proprietary pulse oximetry products and services, and create shareholder value. Success to date can be attributed to the following key factors.

The innovation and innovator

The Cyban oximeter was born out of 15 years of trial and error, which begun by using modified pulse oximeters to measure oxygen in the central veins. Dr Barry Dixon, Cyban's Founder and an intensive care physician, relentlessly persisted to find a better way to manage severe brain injury in order to improve patient outcomes, and his research and innovation is game-changing for how brain injuries will be managed in the future.

'As a clinician practicing in ICU, it is evident that a primary cause of poor outcomes for patients is the failure of our usual monitoring systems to detect complications early enough to allow interventions to prevent permanent injury or death,' Dr Dixon says. 'With this end in mind, I set out to develop a novel solution to this problem.'

Resources and time

Significant funding support – received from the Commonwealth Government through the BioMedTech Horizons initiative, the Targeted Translation Research Accelerator, the Accelerating Commercialisation service and the R&D Tax Incentive, together with the Victoria Government's Medtech Manufacturing Capability Program – has provided a springboard to enable Cyban to reduce the time and equity needed to achieve product-market fit.

Crucial to success to date has also been the close collaboration with St Vincent's Hospital in Melbourne. The ability to quickly prototype, iterate and evaluate the product within a clinical trial in an ICU setting has provided a competitive advantage.

Market opportunity

There is clear unmet need in the market, as well as a large relevant patient population. There is consensus in the clinical community on the pitfalls of existing methods, and a demonstrated willingness to pay for continuous brain monitoring at a higher level than the cost of Cyban's product.

Ability to commercialise value

In the first market, the United States, the device has a pathway to regulatory clearance via 510(k). There is also a pathway to payment via existing reimbursement codes, and clinical guidelines already recommend brain oxygen monitoring. As such, TBI remains a public health priority.

Market access potential

Cyban's existing published evidence portfolio includes a sheep study at the South Australian Health and Medical Research Institute, demonstrating the ability to detect acute intracranial haemorrhages, with the signal arising from brain, not skin.[1] A study in human volunteers at Duke University, in the United States, demonstrated a correlation between oxygen saturation measured with the oximeter, and in blood collected from the internal jugular vein.[2]

The results of a study at St Vincent's Hospital in Melbourne correlating the device with the 'gold standard' invasive ICP monitoring will be published shortly, and the results of a multi-centre study correlating with invasive $P_{bt}O_2$ probes will follow in 2023. Studies with key opinion leaders in centres of excellence in the United States are also being initiated. The plan, developed in conjunction with a highly experienced commercial and clinical advisory board, also includes generating evidence to support health economic claims.

The portfolio of published evidence, available prior to launch, forms part of a clinical communication strategy capturing the appropriate value messages that demonstrate the value of the Brain Pulse Oximeter to all relevant stakeholders to influence change of behaviour at the bedside and influence purchase decisions.

In addition to multiple near-term, value-driving milestones, Cyban's technology provides multiple opportunities for growth over time in new user segments, such as use by first responders and point-of-care stroke detection, and monitoring of other indications in large organs and animals. Cyban is on track to launch its first product to the market in 2024.

1 https://doi.org/10.2147/MDER.S235804

2 https://doi.org/10.2147/MDER.S250102

ADVANCING GROUNDBREAKING PARKINSON'S DISEASE RESEARCH

BY PROFESSOR BERNIE TUCH, EXECUTIVE CHAIRMAN, LIVING CELL TECHNOLOGIES

Australasian biotech company Living Cell Technologies (ASX:LCT) is advancing potentially groundbreaking research into Parkinson's disease, with the goal of developing a unique treatment to prevent progression of the disease.

PARKINSON'S DISEASE IS estimated to affect more than 10 million people globally, including 100,000 in Australia. The disease also inflicts a substantial cost on the community, estimated by Deloitte Access Economics at around $10 billion per year in Australia. Driven by an aging population in the developed world, the market for Parkinson's treatment is expected to reach US$11.5 billion by 2029, up from US$5.7 billion in 2022.

The only current treatments for the management of Parkinson's disease are drugs or medical implants to modulate symptoms and signs of the disease. Living Cell Technologies (LCT) is developing a treatment based on xenotransplantation technology, and is currently advancing a third clinical trial of its NTCELL product in Parkinson's disease.

NTCELL – from pig tissue to people

Porcine (pig) choroid plexus cells (brain tissue) produce a range of growth factors known to provide a neuroprotective effect (protecting nerve cells against damage, degeneration or impairment) on dopaminergic neurons in an experimental model of Parkinson's disease.

LCT has surgically removed choroid plexus cells from a breed of domesticated designated pathogen-free pigs, bred from stock originally discovered in the remote sub-Antarctic Auckland Islands in New Zealand.

These cells are encapsulated in alginate microcapsules that permit the inward passage of nutrients and the outward passage of essential growth factors normally secreted by choroid plexus cells. Importantly, these microcapsules also protect the cells from being attacked by the patient's immune system.

Clinical trial results

LCT has already conducted two clinical trials in New Zealand with NTCELL in Parkinson's disease. The second, a Phase 2B trial, examined NTCELL's effectiveness in treating people with moderate to late-stage Parkinson's.

The key measurement was the Unified Parkinson's Disease Rating Scale, a measurement of motor function when patients were tested in their 'off state', i.e., when not taking antiparkinsonian medications. In patients receiving 80 capsules of NTCELL (NTCELL80), a clinically relevant effect was observed (<-6.45 points from baseline) (Figure 1).

Based on these successful results, LCT is currently progressing a third clinical trial of NTCELL for people with early to mid-stage Parkinson's disease, likely to be the first xenotransplantation trial carried out in Australia.

In January 2022, LCT signed a services agreement with New Zealand biotech company NZeno to obtain tissue from pathogen-free pigs for the third clinical trial of NTCELL. NZeno maintains the only herd derived from pathogen-free pigs found on New Zealand's Auckland Islands. The choroid plexus tissue for the previous two clinical trials of NTCELL, in 2012 and 2015, was obtained from pigs in this herd.

In March, LCT further advanced the third clinical trial by signing a research agreement with the University of Technology Sydney (UTS) and the Australian Foundation for Diabetes Research.

The UTS agreement allows university facilities in Sydney to be used to optimise the production of NTCELL in Australia for the first time, prior to the third clinical trial.

LCT entered a new phase in its research in May, with the signing of an agreement with Sydney-based startup OptiCellAI to apply the benefits of artificial intelligence (AI) to the NTCELL project.

The use of AI, a relatively new technology based on machine learning, will ensure that the NTCELL product being manufactured for the company's third clinical trial of NTCELL in Parkinson's disease is of the highest possible quality. The introduction of automation into the process is expected to speed up the selection of the microcapsules to be implanted into each recipient.

'AI's ability to provide intelligent insights and predictive analysis to researchers has seen it become increasingly important in fostering preventative medicine and new drug discovery,' says OptiCellAI's Michael Urch.

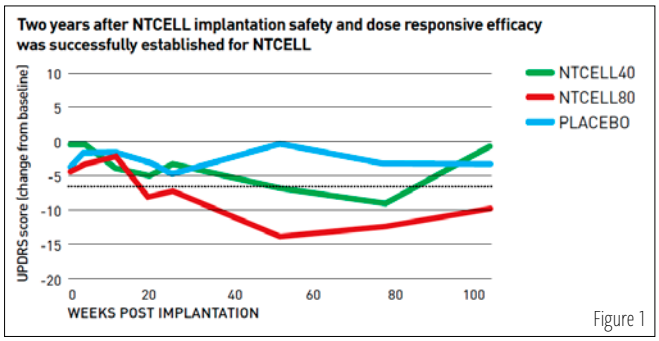

Figure 1

Next steps

With the approval of the Australian Government's Department of Agriculture, Fisheries and Forestry, porcine brain tissue will be shipped to Sydney from research partner NZeno's facility in Invercargill, New Zealand.

Once the Australian production of NTCELL has been optimised at UTS, the tissue will be sent to a Good Manufacturing Practice facility, where it will be manufactured under conditions suitable for it to be used clinically.

Approval for the use of the encapsulated pig tissue is required from a Human Research Ethics Committee, and the Therapeutic Goods Administration (TGA). Approval for two similar trials was previously obtained from Medsafe, New Zealand's equivalent of the TGA.

LCT anticipates that regulatory approval for the third clinical trial will be granted by late 2023, with the first implants in human trial participants in 2024.

Opportunity for Australia

The transplantation of living pig tissues and cells into humans has been in progress for almost three decades. Dr Carl-Gustav Groth, in Sweden, is credited with being the first to transplant pig pancreatic cells into diabetic humans as an attempted therapy for diabetes, which he did in 1993.

To prevent rejection of the pig cells, encapsulation techniques will be used, removing the need for recipients to take anti-rejection drugs. LCT has conducted several clinical trials with encapsulated pig insulin-producing cells in people with type 1 diabetes over the past two decades.

Despite this, while New Zealand has previously approved xenotransplantation trials by LCT, Australia is yet to approve the transplantation of living pig tissue, whether from unmodified or genetically modified pigs, into humans.

Pending approval, Australia now has the opportunity to become a world leader in the application of potentially groundbreaking xenotransplantation technology in its many forms for human health.

For LCT and Australia, success with NTCELL could prove another turning point in international recognition for the capabilities of our biotech industry and our world-leading researchers.

Hear Living Cell Technologies deliver its company presentation at AusBioInvest 2022 in Perth, Western Australia, on 27 October. Join us in person for Australia's largest life sciences investment conference. For information, visit www.ausbiotechinvestment.com.au.

Image courtesy of Living Cell Technologies

CULTURE KEY TO ATTRACTING AND RETAINING TOP TALENT

BIOTECHNOLOGY COMPANIES ARE in a war for talent. Surging industry growth driven by investment into the sector, along with the rapid maturation of technologies – such as gene therapy, mRNA and CRISPR – means there are now far more vacancies for highly specialised roles than there are people with the skills to fill them.

Companies are not only struggling to grow, but are also having increasing difficulty in keeping hold of their best employees, who are being lured away by competitors. This has left some employers in the sector dismayed by a seemingly never-ending cycle of recruitment.

Many biotechs have turned to high salaries, bonuses and perks, like flexible working, in a bid to secure new talent and prevent existing employees from departing.

Tom Parsons, Executive Vice President at Proclinical, a leading life sciences recruitment specialist, suggests a different approach. 'Since the pandemic forced people to work from home, and as many have continued to do so, we have seen a shift in attitude of workers and their relationships with employers, which has become far more transactional,' Parsons says.

'It has put both physical and emotional distance between people, and has killed a lot of the camaraderie and sense of team spirit that keeps teams pulling together. When workers feel a strong bond with their colleagues, leaving a business can feel like they are abandoning their teammates; however, more workers are now viewing their jobs as simply an exchange of services for money, and are focusing on their own needs and goals far more.'

Ending remote working altogether is unlikely to go down well. Instead, Parsons recommends employers incentivise people to come together by investing in their office environment and in-person team events, and by giving them a sense of purpose to rally around.

Tom Parsons

'When people fully understand the bigger picture of what they are working towards and feel what they are doing is meaningful, it unites teams and they give a greater degree of discretional effort,' explains Parsons.

As a biotech specialist recruitment agency, Proclinical throroughly understands what it is that each company offers that excites people, and helps its partners to articulate that to the market.

'Businesses who communicate their employer value proposition well fare much better at attracting and securing their preferred candidates than those who rely only on salary and perks. Work in this sector has an impact on the world that is like no other, and employees need to feel part of that,' says Parsons.

Proclinical is a global provider of tailored workforce solutions exclusively within the life sciences industry. For support with hiring biotech talent in Australia or globally, visit www.proclinical.com or call 03 8518 4459.

LEADING THE WAY WITH DIMERIX

There has been more change in kidney disease treatment in the past 24 months than the past 24 years.

DIMERIX (ASX:DXB) IS a Melbourne-based clinical-stage biopharmaceutical company with a portfolio of drug candidates for inflammatory diseases, including kidney and respiratory diseases. Dimerix's lead clinical asset, DMX-200, is a potential drug candidate that is in Phase 3 trials as a treatment for focal segmental glomerulosclerosis (FSGS), as well as in clinical studies in patients with COVID-19, pneumonia or diabetic kidney disease. In addition, DMX-700 is under development for chronic obstructive pulmonary disease (COPD). Both DMX-200 and DMX-700 drug candidates were identified using Dimerix's proprietary Receptor-Heteromer Investigation Technology (Receptor-HIT) assay, which can be leveraged to identify new opportunities, thereby strengthening the company's development pipeline and diversifying development risk.

DMX-200 single capsule. Image © Dimerix

Well-capitalised to deliver on its FSGS program

DMX-200 is currently in a Phase 3 trial for the treatment of FSGS, which is a rare kidney disease with no approved treatment anywhere in the world. The positive DMX-200 Phase 2 clinical data announced in 2020 demonstrated a strong safety and efficacy profile. DMX-200 was granted orphan drug designation for FSGS in the United States, Europe and the United Kingdom, in recognition that it addresses a very niche, under-serviced market with no effective treatment.

The promising Phase 2 data underpins the decision to progress into the Phase 3 clinical study, which is actively recruiting patients and spans approximately 75 clinical sites globally, including in the United States, where it is under an open Investigational New Drug Application with the Food and Drug Administration (FDA). The Phase 3 study is a randomised, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with FSGS who are receiving a stable dose of an angiotensin II receptor blocker. The primary end points for potential Accelerated Approval are the per cent change in protein in the urine (proteinuria), and the change in estimated glomerular filtration rate (eGFR) from baseline to week 35 following treatment with DMX-200, compared with a placebo. Accelerated Approval is marketing approval for serious conditions that fill an unmet medical need based on a surrogate or an intermediate clinical end point, much like Emergency Use Authorisations.

Historically, there was a lack of adequate public policy initiatives and incentives to promote the development of treatments for orphan kidney diseases like FSGS. This contributed to the high costs involved, and, often, poor management of these diseases. Since 2018, however, regulations have been rapidly revamped to adopt better treatment guidelines, such as acceptance of surrogate end points like eGFR and/or proteinuria decline in lieu of the former clinically meaningful end points, such as kidney

Image © Dimerix

DMX-200 capsules. Image © Dimerix

failure (also termed as 'hard end points'). These regulatory developments have caught the interest of many stakeholders, which is reflected in the number of licensing transactions that have been completed globally in this space since 2020. Dimerix is one of the only two companies with a potential drug candidate in a Phase 3 clinical stage for FSGS, and, more notably, DMX-200 likely complements other Phase 3 drug candidates under development. Interim data is anticipated from the study in the first half of 2023. Having completed a capital raise in mid 2021, Dimerix is well funded for its flagship FSGS program.

Aiming to prevent damaging immune response

Dimerix's lead drug candidate, DMX-200, is also being studied as part of two different investigator-led feasibility/Phase 3 studies in COVID-19 patients with respiratory complications. For one of these studies, Dimerix was awarded $1.1 million from MTPConnect's Biomedical Translation Bridge program provided by the Australian Government's Medical Research Future Fund, with support from UniQuest. Dimerix proactively supports both studies driven by the REMAP-CAP and CLARITY 2.0 teams in providing them information for the regulatory submissions, and in supplying DMX-200 to the study sites.

Reduction in lung injury of COPD model

The company's second drug candidate, DMX-700, is in a preclinical stage and is being developed as a treatment for COPD, a progressive and life-threatening lung disease. COPD is the third leading cause of death in the world, causing 3.23 million deaths globally in 2019. COPD affects one in eight Americans aged 45 and older, and one in 20 Australians aged 45 years and older, but millions more may have the disease without even knowing it. Although treatments exist to improve the symptoms of COPD, there is currently no way to slow progression of the condition or cure it.

In June 2022, Dimerix announced that DMX-700 had demonstrated a statistically significant 80 per cent reduction in induced lung injury in mice ($p<0.01$), when compared to the control group. This very promising data supports progression of DMX-700 into a clinical trial, planned for first half of 2023.

Well-positioned to commercialise DMX-200

Dimerix continues discussions with major international pharmaceutical companies globally for potential commercial partnerships for DMX-200, with the aim to provide the best outcome for both patients and shareholders. Dimerix has also developed manufacturing capability through an FDA-approved global contract manufacturing organisation, and has completed commercial-scale batch manufacturing for DMX-200 through this partner. With these arrangements in place, Dimerix is well positioned for DMX-200's commercialisation once it completes the Phase 3 trial and obtains regulatory approvals.

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Drawing on 60,000 years of knowledge in traditional medicine, from the world's oldest continuing culture, Western Australia truly is like no other.

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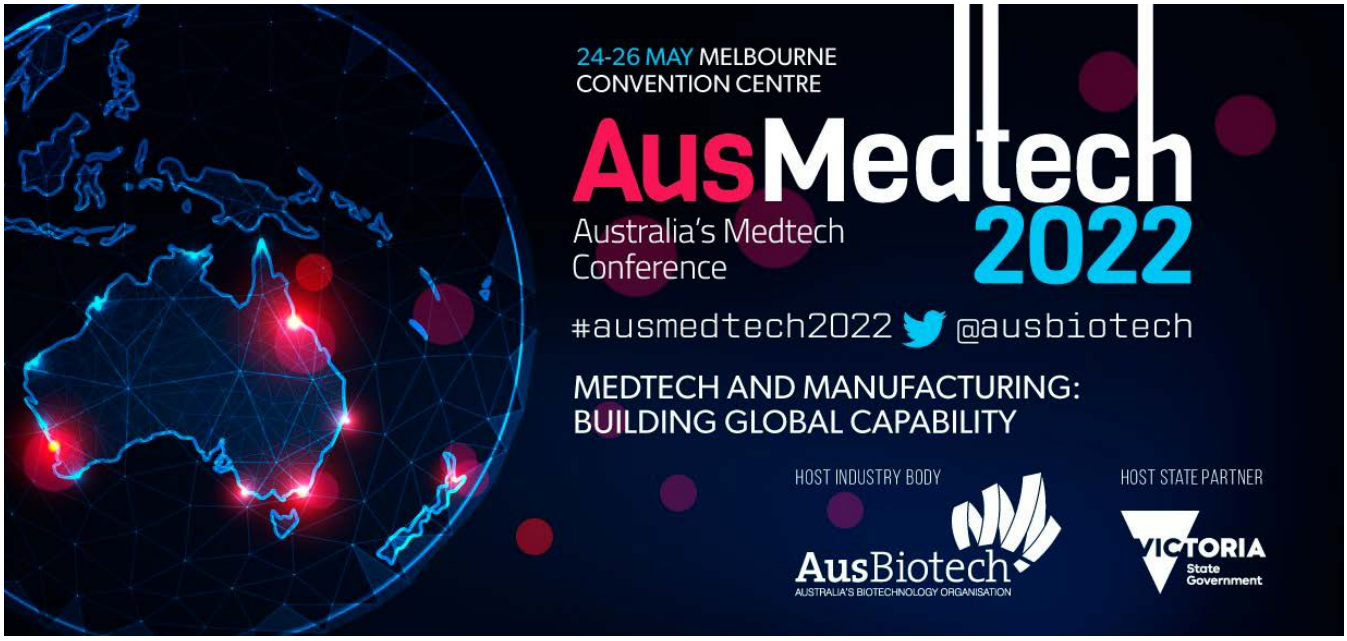

CELEBRATING THE MEDTECH SECTOR

AusMedtech 2022 marks highest attendance on record

DEMONSTRATING THE BUOYANCY and growth of the sector, AusBiotech recorded its largest ever face-to-face AusMedtech conference as the Australian medtech sector reunited and celebrated its achievements.

AusMedtech 2022's theme, Medtech and Manufacturing: Building Global Capability, reflected the industry's international successes and aspirations. The event, held at the Melbourne Convention and Exhibition Centre, drew more than 460 delegates and more than 120 speakers from the Australian and international medical devices and diagnostics sector.

AusMedtech 2022 showcased the extent of our capabilities, the strength of our talent and the ingenuity of the industry that is continuing to lead our life sciences future. The conference was a clear reminder of the strong and experienced industry that Australia holds – one that is demonstrating global leadership in addressing the challenges we face both during and beyond the current pandemic. This premier event is an influential platform for delegates to engage on key trends and issues, and it provides business partnering opportunities for decision-makers and investors.

The in-person, two-day conference offered delegates more than 25 cutting-edge conference sessions, and connected delegates through formal one-on-one AusPartnering business meetings and numerous informal networking opportunities. The exhibition hall showcased 27 exhibitors as they engaged in person for the first time in three years.

Keynote speakers included:

- Dr Vincent McCauley, Chief Medical Officer, Telstra Health, on 'The role of connectivity in transforming healthcare through COVID and beyond'.
- Tamir Meiri, Director of Venture Investments, and Kathy Connell, Senior Director of Early Innovation Partnering ANZ, both from Johnson & Johnson Innovation, on 'Medtech investment insights across Israel, USA and Australia: what's comparable and what's in contrast'.
- Professor Nicholas Opie, Chief Technology Officer, Synchron, on 'Unlocking the brain's roadmap for severely paralysed patients: accessing the brain's natural neurological highways through groundbreaking implantable technology'.
- Dr Amanda Caples, Lead Scientist for the Victorian Government's Department of Jobs, Precincts and Regions, on 'Investing in innovation, discovering the next breakthrough'.
- Adjunct Professor John Skerritt, Deputy Secretary, Health Products Regulation, Australian Department of Health, on 'Medical device regulation update'.
- Stuart Elliott, Co-CEO and Co-founder, Planet Innovation, on 'Manufacturing led innovation – insights into Australia's role in the global manufacturing ecosystem'.

Left to right: Kathy Connell, Senior Director, New Ventures ANZ, Johnson & Johnson Innovation; Ricardo Garcia-Rosas, Co-founder and CEO, Virtetic; Mojtaba (MJ) Golzan, Senior Research Fellow, the University of Technology Sydney; and Lorraine Chiroiu, CEO, AusBiotech

Dr Samih Nabulsi, Vice President and Managing Director, Cook Medical

Lorraine Chiroiu, CEO, AusBiotech, and David Latina, Deputy Secretary Jobs, Innovation and Business Engagement at the Department of Jobs, Precincts and Regions

Left to right: Lorraine Chiroiu, CEO, AusBiotech; Professor Philip Hugenholtz, Co-founder, Microba; and Professor Gene Tyson, Co-founder and Non-Executive Director, Microba, at the AusMedtech 2022 gala dinner

AusMedtech 2022 was proudly supported by the Victorian Government as the Host State Partner, and was officially opened by David Latina, Deputy Secretary of Jobs, Innovation and Business Engagement at the Department of Jobs, Precincts and Regions.

As a highlight of the event, the conference dinner offered stakeholders, including those who were unable to attend the wider AusMedtech 2022 conference, an additional chance to reconnect. Guests heard from the Hon. Jaala Pulford, Member of Parliament, Victorian Government, and Dr Samih Nabulsi, Managing Director, Cook Medical; while AusBiotech CEO Lorraine Chiroiu sat down with Microba Life Sciences' Co-founders, Professors Philip Hugenholtz and Gene Tyson, for a fireside chat as guests were inspired by the journey behind the most recent medtech initial public offering on the ASX. The dinner was supported by Cook Medical and the Victorian Government.

In support of startups and small and medium-sized enterprises, the AusMedtech 2022 program featured a new 'Lunch and Learn Reverse-Pitch' event, supported by Illumina for Startups. This session offered an innovative approach to pitching, with Australia's leading medtech accelerators and incubators presenting to entrepreneurs, and advising on how to connect with the right program at the right time.

AusBiotech's Early-Stage Investment Forum, supported by Davies Collison Cave, offered eight early-stage projects and technologies the opportunity to gather essential feedback for commercialising early-stage projects and technologies from a panel of experts. This included panel Chair Kathy Connell, Senior Director of External Innovation Partnering at Johnson & Johnson Innovation, as well as panellists Dr Emma Ball, Head of Illumina for Startups Australia; Dr Buzz Palmer, CEO, MedTech Actuator; Alistair Smith, Principal, Davies Collison Cave; and Dr Amandeep Hansra, Co-founder and Managing Partner, Caligo Health.

Ricardo García Rosas, Co-founder and CEO, Virtetic, was awarded first prize for Best Translational Research, which recognised the startup's game-based virtual reality therapeutics medical device for people living with limb loss. The company's mission is to help people transition to life with a prosthesis, and regain their function and independence faster. The expert panel also gave a special mention to Mojtaba (MJ) Golzan, from the University of Technology Sydney, for his medical device, A-EYE. The technology utilises a smartphone, and is a smart and non-invasive alternative to brain and spinal-cord injections. Its founder has secured a fast-tracked application into MedTech Actuator's Origin accelerator.

Save the date for AusMedtech 2023: held from 24–25 May in Adelaide, South Australia, and proudly supported by the Adelaide Convention Centre.

Virtetic product. Image courtesy of Virtetic

INTRODUCING VIRTETIC: GAME-BASED VIRTUAL REALITY THERAPEUTICS

BY RICARDO GARCÍA ROSAS, CO-FOUNDER AND CEO, VIRTETIC

I am honoured to have won the Early-Stage Investment Forum pitch competition at AusMedtech 2022, where I presented Virtetic, an early-stage startup developing game-based virtual reality therapeutics for people living with limb loss.

I PITCHED ALONGSIDE other fascinating entrepreneurs and researchers. Winning has been encouraging for me and my team to keep giving our best and bringing our virtual reality therapies to the market. Moreover, the feedback we received from the panel, and the interest from the wider community, has been empowering.

Virtetic has its origin in my PhD research at the Human Robotics Laboratory at the University of Melbourne. I developed a virtual reality software platform for testing the algorithms that I developed for prostheses on both able-bodied people and people living with limb loss. The platform allows anyone to virtually use a prosthesis, while allowing me to evaluate their movement and behaviour quantitatively.

Once we showed our virtual reality platform to our clinical advisers, they immediately highlighted its potential to be used clinically. This inspired me and my co-founders to join the research commercialisation workshops offered by Translating Research at Melbourne (TRAM). These workshops allowed me to clearly identify the problems that prosthesis users face soon after amputation, and the challenges that clinicians face with their clients in the early stages.

By interviewing people in the community, we learnt that people who lose a limb are subject to immediate loss of function and the risk of phantom limb pain post-amputation; however, it takes four to 12 months post-amputation for them to access a prosthesis, and even longer to be able to use it.

During this waiting period, people lose the ability to use the muscles in their residual limb, which is used to control a prosthesis. This loss of ability contributes to up to 40 per cent of people who have lost an arm abandoning their prosthesis once they receive it. Prosthesis abandonment can lead to long-term health issues, such as overuse syndrome, and it costs healthcare systems billions every year.

Phantom limb pain is most likely to first occur within a month post-amputation. Phantom limb pain significantly affects quality of life and, in some cases, if left untreated, it could prevail for life.

Virtetic's founding team (from bottom left) Jing, Carine, Raphael, Geremy and Ricardo. Photo by Justin Fong

Thus, it is necessary for people who have undergone an amputation to start meaningful rehabilitation and prosthesis-use training at the earliest stage possible, rather than waiting for months; however, current pre-prosthetic training and rehabilitation focuses on compensating for the missing limb. For example, current rehabilitation has people with limb loss learning to do daily activities one-handed or learning to use mobility aids.

At Virtetic, we are developing game-based virtual reality therapeutics (VRx) to support the rehabilitation and prosthesis-use training of people living with limb loss. Our solution combines the power of virtual reality technology, prosthetic-grade wearable sensors and data analytics to deliver our specialised game-based VRx programs to people living with limb loss. We also provide users and clinicians with actionable insights to support their progress towards their goals and clinical decisions.

Our approach is simple, engaging and evidence-based. We use virtual reality games that we specifically designed to help people build the skills they need to use a prosthesis. We also collect data from these games that is valuable for users, clinicians and insurers. The games start by building the basic skills that are used to operate a prosthesis, and gradually increase in difficulty and relevance to activities of daily living. We landed on this approach through several rounds of user and clinician feedback on multiple iterations of our clinical prototype.

The response to our approach has been positive on all fronts. Prosthesis users, clinicians and prosthesis manufacturers who have tried our minimum marketable product have all enjoyed it, and see its potential to change for the better how people learn to use a prosthesis.

We are currently working on bringing our first virtual reality therapy to the Australian market in 2023. We are also working with leading prosthetics manufacturer Ottobock to prepare for pilots and trials in the European market.

This is an exciting time for Virtetic, and we are grateful for the support we have received from the community. The recognition we received from the AusBiotech community through the Early-Stage Investment Forum motivates us further to bring the best virtual reality therapies possible to the prosthetics market.

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 over the past 36 years is testament to the dedication of its 3000-plus members, volunteer committees, Board and business team.

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Isabella Thompson | Marketing Manager Global Operations | Phone: 0432 247 320 | Email: enquiries@adaptideations.com | Web: www.adaptideations.com

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Dr Tina Soulis | Founder and Director | Phone: 0429 300 705 | Email: tina.soulis@alithialifesciences.com | Web: www.alithialifesciences.com

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Dr Christophe Demaison | Managing Director and CEO | Email: christophe@enarespiratory.com | Web: www.enarespiratory.com

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Phone: 0472 875 120 | Email: research@genesiscare.com | Web: www.genesiscare.com

GREENLIGHT CLINICAL

GreenLight Clinical is a boutique, full-service Australian CRO with its own world-class laboratory in Sydney, specialising in ophthalmology, oncology and rare diseases. The company transforms lives by accelerating the expansion of patients' treatment options, one trial at a time. GreenLight Clinical's research organisation includes an ISO9001:2015 accredited full-service CRO, with experience in a wide range of therapeutic areas; a NATA-accredited central laboratory, with an onsite PK/bioanalytical laboratory; and ophthalmology investigator sites. GreenLight Clinical has tailored solutions and consistent delivery.

Eliana Burke | Global Head of Customer Engagement and Marketing | Email: eliana.burke@greenlightclinical.com | Web: www.greenlightclinical.com

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Jacquie Palmer | Managing Director | Email: jacquiep@pharmasols.com | Web: www.pharmasols.com

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Anthony Zang | Finance and Operations Manager | Phone: 0410 557 275 | Email: anthony.zang@pharmsky.com.au | Web: www.pharmsky.com.au

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Phone: 03 9832 0893 | Mobile: 0432 013 316 | Email: shan.chan@premier-research.com | Web: www.premier-research.com

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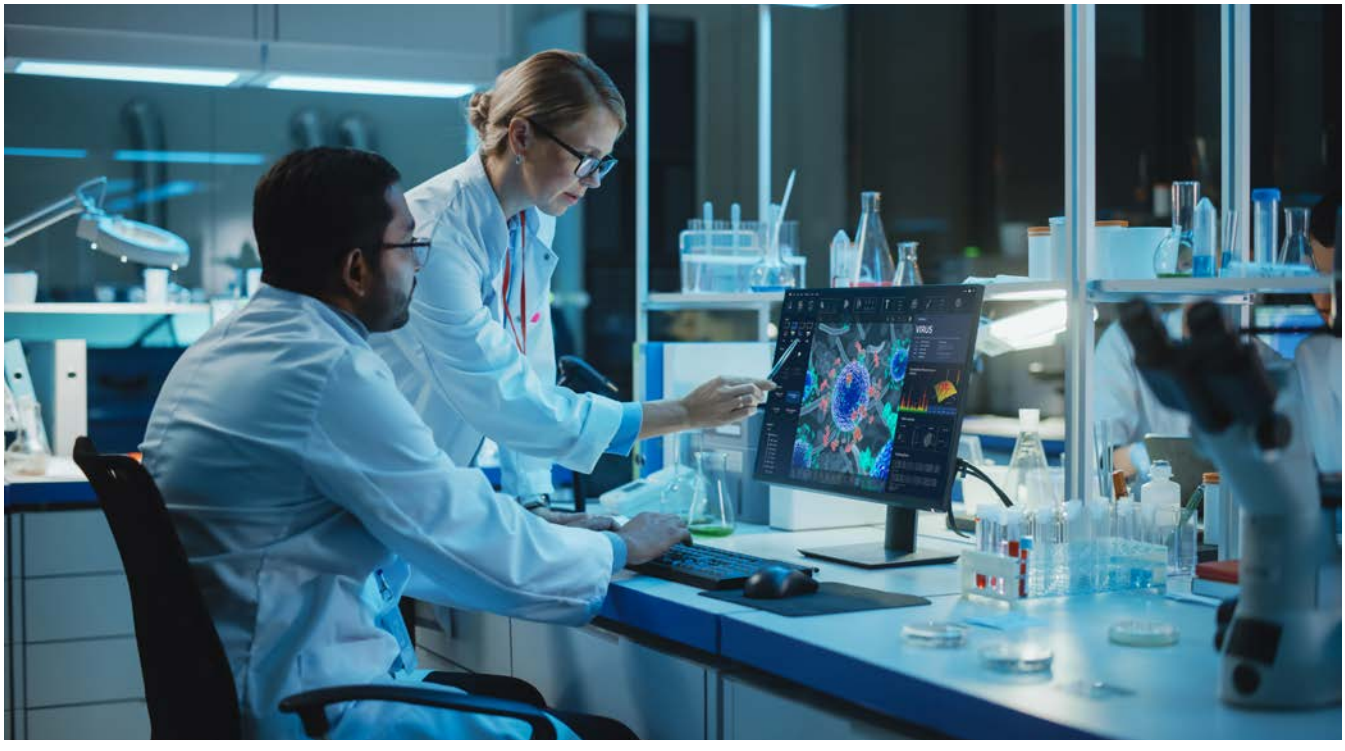
Roche is one of the world's largest biotechnology companies, headquartered in Basel, Switzerland. Roche is united by a purpose to 'do now what patients need next', through advancing medical innovations where there was previously unmet need. The company is pioneering personalised health care. Roche combines strengths in pharmaceuticals and diagnostics, and is growing capabilities in data-driven insights to deliver more tailored care to the individual, which helps to prevent, diagnose and treat patients more effectively and quickly.

Keong Chow | Innovation Hub Chapter Lead | Phone: 0402 802 205 | Email: keong.chow@roche.com | Web: www.roche.com

TISSUE REPAIR

Tissue Repair is a clinical-stage biopharmaceutical company working to develop advanced wound-healing products for chronic wounds and the aftercare of cosmetic procedures. Tissue Repair has developed technology to purify a naturally occurring β-glucan without compromising the inherent immunomodulatory properties. The hydrogel, known as TR Pro+, has a broad range of benefits to assist healing skin – more than any products currently available. Tissue Repair will launch its cosmeceutical product, TR Pro+, in the Australian market in 2023.

Darryl Reed | Chief Operations Officer | Phone: 0419 557 663 | Email: darryl.reed@trtherapeutics.com | Web: www.tissuerepair.com.au



INDEX

BY JAMES FLETCHER, INVESTMENT ADVISER, 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	16.97	0.05	0.11	0.04	-1.82	-2.97	2.00	-
4DX	4DMedical Limited	A software technology company in Australia. It commercialises XV technology, a four-dimensional lung imaging platform.	7/8/2020	187.00	0.64	1.66	0.32	-9.57	-6.64	-	-
AC8	Auscann Group Holdings Limited	Cultivation, manufacture and distribution of medicinal cannabis products. Targeting medications for neuropathic and chronic pain.	3/5/1989	20.71	0.05	0.11	0.04	-1.94	-2.42	5.00	-
ACR	Acrux Limited	Transdermal drug delivery platform technology.	29/9/2004	16.84	0.06	0.14	0.05	-3.22	-1.83	4.00	-
ACW	Actinogen Medical Limited	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders, including Alzheimer's.	16/10/2007	140.07	0.07	0.20	0.04	-0.47	-15.74	1.00	-
ADO	Anteo Diagnostics Limited	Multi-component coatings for solid phase of immunoassays for biomarker development.	7/4/2000	139.15	0.07	0.42	0.06	-0.44	-15.91	1.00	-
ADR	Adherium Limited	Developer of digital technologies to monitor medication use in chronic respiratory conditions.	26/8/2015	19.87	0.01	0.03	0.01	-0.64	-1.41	-1.00	-
AEI	Aeris Environmental Limited	Development and sale of products to eliminate biofilm growth in air conditioning systems and water treatment systems to enhance indoor air quality.	12/9/2000	12.95	0.53	0.17	0.04	-3.08	-1.69	4.00	-
AFP	AFT Pharmaceuticals Limited	Develops, licences and sells a range of medical products globally.	22/12/2015	334.52	3.19	4.80	2.91	17.66	18.06	-	-
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	35.34	0.11	0.31	0.06	-4.95	-2.22	9.00	-
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	30.22	0.47	1.02	0.22	-2.39	-19.67	7.00	-
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	24.40	0.15	1.43	0.11	-16.78	-0.86	7.00	-
AHX	Apiam Animal Health Limited	iVet technology for real-time animal health monitoring, including on-farm welfare assessments.	15/12/2015	139.56	0.80	0.98	0.63	3.36	23.81	-27.00	2.36
ALA	Arovella Therapeutics Limited	Arovella Therapeutics Limited (formerly Suda Pharmaceuticals Limited). Oromucosal sprays for drug delivery treatment of off-patent drugs.	24/1/2002	16.75	0.03	0.06	0.02	-1.71	-1.46	-	-
ALC	Alcidion Group Limited	Alcidion Group Limited, together with its subsidiaries, engages in the development and licencing of healthcare software products in Australia, New Zealand and the United Kingdom.	24/6/2011	196.55	0.16	0.41	0.10	-0.64	-24.22	-	-
ALT	Analytica Limited	eHealth devices. PeriCoach system for stress urinary incontinence.	25/10/2000	6.92	0.00	0.00	0.00	-0.06	-2.50	-	-

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)
AMT	Allegra Orthopaedics Limited	Prosthetic implant tools.	5/12/2007	17.76	0.17	0.27	0.12	-1.65	-10.30	3.00	-
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	7.29	0.03	0.07	0.02	-1.38	-2.39	4.00	-
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	3,251.03	25.51	40.97	21.11	231.54	11.02	504.00	93.11
ANO	Advance Zinctek Limited	Advance ZincTek Limited, together with its subsidiaries, manufactures aluminum oxide powder, as well as zinc oxide powder and dispersions for use in the personal care sector in Australia, the United States, Canada, Europe, and internationally.	24/2/2005	153.31	2.50	4.35	1.99	3.58	69.83	45.00	-
ANP	Antisense Therapeutics Limited	Drug discovery and development. Antisense compounds for MS, DMD and acromegaly.	20/12/2001	73.57	0.11	0.35	0.07	-1.59	-6.92	4.00	-
ANR	Anatara Lifesciences Limited	Natural, plant-based therapeutics for gastrointestinal diseases.	16/10/2014	4.85	0.07	0.17	0.05	-3.22	-2.11	4.00	-
APH	Australian Primary Hemp Limited	Australian Primary Hemp Limited (formerly Alchemia Limited) engages in hemp growing and production services, as well as handling in all areas of the hemp value chain.	23/12/2003	16.88	0.14	0.34	0.12	-6.72	-2.08	6.00	-
API	Australian Pharmaceutical Industries Limited	An Australian health and beauty services company. Australian Pharmaceutical Industries Limited provides wholesale product delivery services, retail services, marketing programs and business advisory services to customers.	16/6/1997	753.76	-	1.77	1.06	0.28	-	13.00	3.50
ARX	Aroa Bioscience 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	274.18	0.80	1.25	0.62	-2.28	-35.09	21.00	-
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	42.25	0.07	0.38	0.06	-1.05	-7.05	4.00	-
ATH	Alterity Therapeutics Limited	Alterity Therapeutics Limited (formerly Prana Biotechnology Limited) is an Australian biotechnology company which focuses to commercialise research into Parkinsonian movement disorders, Alzheimer's disease, Huntington's disease and other neurodegenerative disorders.	28/3/2000	38.51	0.02	0.03	0.01	-0.52	-3.08	2.00	-
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 (FAK) inhibitors for cancer and fibrosis.	23/12/2013	20.37	0.11	0.25	0.09	-2.50	-4.20	7.00	-
AUA	Audeara Proprietary Limited	Audeara Proprietary 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	8.90	0.12	0.15	0.07	-1.15	-10.43	4.00	-
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	25.73	0.01	0.02	0.01	-0.19	-7.37	-	-
AVH	Avita Medical Incorporated	Skin regeneration technology for the treatment of wounds, scars and skin defects.	24/6/2020	146.97	1.94	5.70	1.28	-182.45	-1.06	529.00	-
AVR	Anteris Technologies Limited	Anteris Technologies Ltd (formerly Amedus Limited). Tissue engineering and vaccine development for herpes and HPV.	24/3/2004	335.83	24.19	30.89	7.81	-309.00	-7.83	119.00	-
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	221.14	0.89	2.61	0.55	-1.42	-62.68	-	-
AYA	Artrya Limited	Artrya Limited operates as a medical technology company that uses artificial intelligence (AI) powered image analysis software to enhance the detection and management of coronary artery disease.	26/11/2021	48.86	0.78	1.75	0.32	-11.97	-6.52	57.00	-
BCT	Bluechiip Limited	Bluechiip Limited develops and commercialises wireless tracking solutions for the healthcare, life science, security, defence and manufacturing industries.	9/6/2011	22.75	0.04	0.07	0.02	-0.45	-8.44	1.00	-
BDA	Bod Australia Limited	A vertically integrated developer, manufacturer, distributor and marketer of plant-based natural health supplements and beauty solutions.	27/10/2016	10.16	0.10	0.33	0.07	-4.91	-1.96	6.00	-

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)
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	10.57	0.08	0.23	0.06	-0.64	-12.50	-	-
BGT	Bio-Gene Technology Limited	Insecticide product development. 'Qcide' and 'FLAVOCIDE' focused on insect control in agriculture and animal health.	29/11/2017	22.13	0.13	0.35	0.11	-1.79	-6.98	-	-
BIO	Biome Australia Limited	Biome Australia Limited develops, commercialises and markets various live biotherapeutics and complimentary medicines in Australia and internationally.	30/11/2021	12.33	0.08	0.14	0.07	-1.24	-6.21	4.00	-
BIT	Biotron Limited	Antiviral drug developer, HIV and hepatitis.	24/1/2001	41.41	0.06	0.12	0.05	-0.40	-14.50	-	-
BLT	Benitec Biopharma Limited	Development of a proprietary therapeutic technology platform to provide long-lasting silencing of disease-causing genes.	17/2/1997	8.35	-	0.15	0.02	-3.51	-	7.00	-
BNO	Bionomics Limited	Small molecule developer in areas of cancer and CNS disorders.	21/12/1999	70.37	0.05	0.21	0.04	-2.42	-2.17	3.00	-
BOT	Botanix Pharmaceuticals Limited	Developer of therapeutics for skin diseases, including acne, psoriasis and dermatitis.	24/1/1985	79.32	0.08	0.10	0.05	-1.08	-7.50	1.00	-
BXN	Bioxyne Limited	Gut and immune health probiotic products, including a patented probiotic range.	14/12/2000	8.32	0.01	0.04	0.01	0.01	130.00	-	-
CAJ	Capitol Health Limited	Provider of diagnostic imaging services to the Australian healthcare market.	9/6/2006	328.30	0.32	0.43	0.27	1.33	23.68	3.00	1.00
CAN	CANN Group Limited	Cultivation of cannabis for medicinal and research purposes, and manufacturing of medicinal cannabis products.	4/5/2017	97.84	0.28	0.44	0.23	-7.54	-3.71	29.00	-
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	253.10	1.08	2.08	0.71	-19.78	-5.46	4.00	-
CAU	Cronos Australia Limited	A medicinal cannabis company that plans to enter the medicinal cannabis market in Australia with both THC and CBD products.	7/11/2019	165.75	0.30	0.40	0.11	-0.74	-40.54	2.00	-
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	10.32	0.21	0.74	0.12	-6.86	-2.99	-	-
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	38.50	0.35	0.77	0.25	-9.20	-3.80	10.00	-
CGB	Cann Global Limited	Cann Global Limited operates in medicinal cannabis and hemp food industries in Australia and internationally.	14/1/2008	6.21	0.02	0.13	0.02	-1.75	-1.37	4.00	-
CGS	Cogstate Limited	Diagnosis and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's diseases).	13/2/2004	299.93	1.73	2.69	1.36	7.78	22.24	12.00	-
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	38.76	0.12	0.35	0.09	-2.91	-4.12	1.00	-
CLI	Croplogic Limited	Technology platform that improves crop yield.	12/9/2017	4.95	0.13	0.21	0.10	-20.28	-0.64	-	-
CLV	Clover Corporation Limited	Supplies science-based oil products to the medical food market for infants and children.	30/11/1999	181.42	1.09	1.80	0.95	3.31	32.93	36.00	1.00
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	44.29	0.25	0.45	0.15	0.06	416.67	9.00	-
COH	Cochlear Limited	Manufacture and sale of cochlear implant system for impaired hearing.	4/12/1995	14,089.10	214.20	257.76	178.55	394.70	54.27	2,040.00	295.00
CP1	CannPal Animal Therapeutics Limited	Pet pharmaceutical company developing cannabinoid-based medicines for cats, dogs and horses.	25/10/2017	15.83	-	0.25	0.07	-1.57	-	1.00	-
CPH	Creso Pharma Limited	Development and production of cannabis and hemp-derived therapeutic products and treatments for humans and pets.	20/10/2016	52.84	0.04	0.16	0.04	-2.71	-1.37	2.00	-
CSL	CSL Limited	Development, manufacture and marketing of pharmaceutical and diagnostic products.	8/6/1994	144,126.51	299.20	319.78	240.10	698.21	42.85	3,598.00	301.26

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)
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	65.47	0.85	1.75	0.66	-8.54	-9.95	-	-
CT1	Constellation Technologies Limited	Constellation Technologies Limited (formerly CCP Technologies Limited) engages in the Internet of Things (IoT) product development and product management in Australia and internationally.	8/10/1987	7.36	0.01	0.01	0.00	-0.21	-2.38	-	-
CTE	Cryosite Limited	Collection, processing and long-term storage of blood stem cells.	9/5/2002	33.92	0.70	0.87	0.33	2.38	29.20	3.00	-
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	114.99	0.64	1.71	0.36	-5.70	-11.14	40.00	-
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 (EPP).	13/2/2001	988.21	20.00	44.67	13.16	48.60	41.15	214.00	2.50
CYC	Cyclopharm Limited	Manufacturer and distributor of radiopharmaceuticals for imaging technology. Lead product is Technegas, a lung ventilation imaging drug.	18/1/2007	140.06	1.50	2.14	0.95	-5.63	-26.64	40.00	1.00
CYP	Cynata Therapeutics Limited	Stem cell and regenerative medicine platform technology, Cymerus, for production of mesenchymal stem cells.	20/12/2007	60.18	0.42	0.64	0.35	-2.60	-16.15	18.00	-
DVL	DorsaVi Limited	Motion analysis device technologies for clinical, elite sports and occupational health and safety.	11/12/2013	5.15	0.01	0.02	0.01	-0.81	-1.60	-	-
DXB	Dimerix Limited	Development of therapeutic treatments identified using drug discovery platform, Receptor-Heteromer Investigation Technology.	4/2/1993	49.74	0.16	0.36	0.12	-3.47	-4.47	6.00	-
EBO	EBOS Group Limited	Distributor of healthcare products.	6/12/2013	6,600.17	34.85	40.50	30.87	117.70	29.61	218.00	78.70
EBR	EBR Systems Incorporated	EBR Systems Incorporated develops implantable systems for wireless tissue stimulation. The company offers WiSE cardiac resynchronisation therapy system that uses a proprietary wireless technology to deliver pacing stimulation directly to the inside of the left ventricle of the heart.	24/11/2021	185.80	0.71	1.10	0.33	-	-	-	-
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	30.99	0.03	0.04	0.01	-0.40	-6.88	2.00	-
ELX	Ellex Medical Lasers Limited	Production of opthalmic instruments for treatment of impaired vision.	12/9/1994	36.39	0.25	0.47	0.18	-4.04	-6.19	11.00	-
EMD	Emyria Limited	Emyria Limited, a clinical drug development and care delivery company, operates a network of specialist medical clinics. Its product pipeline include EMD-003, a cannabinoid medicine for treating patients with mental health; and EMD-004, a cannabinoid medicine targeting irritable bowel syndrome.	12/2/2020	78.38	0.29	0.51	0.17	-2.66	-10.71	3.00	-
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	118.00	1.52	3.35	1.23	-10.12	-15.02	13.00	-
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	104.69	0.30	0.90	0.18	-2.46	-12.20	16.00	-
EPN	Epsilon Healthcare Limited (formerly THC Global Group)	Epsilon Healthcare Limited operates as a healthcare and pharmaceuticals company primarily in Australia and Canada. It engages in the manufacture and distribution of hydroponics equipment, materials, and nutrients; and development and delivery of medicinal cannabis, as well as provides turnkey cultivation solutions.	4/5/2017	9.13	0.04	0.19	0.02	-4.61	-0.82	7.00	-
ESE	Esense-Lab Limited	Israeli-based life sciences research and development company. Creates 'virtual plants' with commercial and medicinal applications. First plant targeted for re-engineering is cannabis.	14/2/2017	8.97	-	-	-	-1.56	-	-	-
EX1	Exopharm Limited	Exopharm Limited focuses on developing and commercialising human therapeutics using extracellular vesicles (EVs) as medicines in Australia.	18/12/2018	22.80	0.15	0.64	0.11	-6.24	-2.32	7.00	-
FFC	FarmaForce Limited	FarmaForce Limited is a contract sales organisation (CSO) offering innovative sales solutions to the Australian pharmaceutical industry.	27/10/2015	4.57	0.04	0.07	0.03	-0.76	-4.61	-3.00	-
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	11,053.25	19.14	33.01	17.14	60.69	31.54	243.00	38.12

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FRE	Firebrick Pharma Limited	Firebrick Pharma Limited, a pharmaceutical company, develops and commercialises nasal spray treatment for the common cold under the Nasodine name in Australia.	28/1/2022	36.20	0.34	0.75	0.23	-	-	-	-
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	19.83	0.35	0.50	0.20	-3.57	-9.80	6.00	-
GMV	G Medical Innovations Limited	Israeli-based company. Remote healthcare monitoring technology. Develops and markets clinical and consumer medical-grade health monitoring solutions.	10/5/2017	32.82	-	0.20	0.03	-4.31	-	-	-
GSS	Genetic Signatures Limited	Molecular diagnostics company focused on development and commercialisation of its proprietary platform technology, 3Base.	31/3/2015	147.69	1.03	1.86	0.94	1.37	75.18	38.00	-
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	36.94	0.00	0.01	0.00	-0.08	-5.00	-	-
HCT	Holista CollTech Limited	Development and commercialisation of food ingredients and ovine collagen.	26/2/2004	10.87	0.04	0.06	0.03	-0.46	-8.48	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	14.95	0.07	0.08	0.05	-3.10	-2.10	12.00	-
HHI	Health House Limited	Pharmaceutical distribution.	28/7/2011								
HIQ	HitIQ Limited	HitIQ Limited develops and commercialises concussion management technology in Australia. The company offers Nexus A9 sensor to record individual head impacts.	16/6/2021	7.36	0.07	0.22	0.03	-5.00	-1.30	4.00	-
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' heartbeat.	12/12/2018	30.72	0.15	0.34	0.09	-4.55	-3.19	-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	1.92	0.01	0.50	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	18.38	0.09	0.17	0.07	-4.40	-2.11	-1.00	-
IBX	Imagion Biosystems Limited	Detection and localisation of cancer and other diseases using nano particle technology. Proprietary MagSense bio-imaging detection technology.	22/6/2017	41.49	0.04	0.11	0.03	-0.60	-6.17	1.00	-
IDT	IDT Australia Limited	Manufacturer of pharmaceuticals and clinical trial management services.	24/9/1993	33.74	0.14	0.76	0.11	0.90	15.56	12.00	-
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	472.31	0.31	0.76	0.19	-0.98	-31.63	2.00	-
IIQ	INOVIQ Limited	INOVIQ Limited (formely BARD1 Life Sciences Limited) is an Australian life sciences company focused on developing and commercialising non-invasive diagnostic tests for early detection of cancer.	18/4/1991	57.97	0.63	1.71	0.39	-14.65	-4.30	19.00	-
ILA	Island Pharmaceuticals Limited	Island Pharmaceuticals Limited, a drug research and repurposing company, focuses on the development of preventative 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	7.35	0.19	0.38	0.12	-1.04	-17.79	7.00	-
IMC	Immuron Limited	Oral immunotherapy products that target the human gut immune system and gut microbiome.	30/4/1999	21.41	0.09	0.17	0.08	-1.99	-4.72	11.00	-
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	272.87	0.32	0.71	0.29	-3.14	-10.03	11.00	-
IMU	Imugene Limited	Developer of HER-2+ gastric and breast cancer immunotherapies.	2/12/1993	1,525.31	0.26	0.63	0.13	-0.54	-48.15	2.00	-
IPD	ImpediMed Limited	Diagnostic devices for lymph oedema, muscle wasting and metabolic disorders utilising bioimpedance technology.	24/10/2007	131.72	0.07	0.21	0.05	-1.28	-5.78	3.00	-

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IPL	Incitec Pivot Limited	A manufacturer and distributor of industrial explosives, industrial chemicals and fertilisers to the agriculture and mining industries.	28/7/2003	7,186.23	3.70	4.17	2.62	25.60	14.45	133.00	18.30
IQ3	Iq3Corp Limited	A corporate finance and advisory firm that provides capital raising and corporate advisory services to listed and unlisted companies in the life science industry.	18/5/2015	12.52	0.12	0.17	0.07	-5.44	-2.21	-7.00	-
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	13.14	0.08	0.13	0.06	-0.66	-11.82	2.00	-
IRX	Inhalerx Limited	InhaleRx Limited focuses on developing inhalation medicinal therapies in Australia and internationally. It offers medical inhalation devices for the delivery of prescribed medicines.	11/1/2017	140.07	0.08	0.13	0.06	-0.66	-11.82	2.00	-
IVQ	Invitrocue Limited	Provider of bio-analytic solutions including in vitro cell-based testing technologies and and image analytics software for use in digital pathology.	14/12/1994	34.71	-	-	-	-1.36	-	-	-
IVX	Invion Limited	Developer of treatments for inflammatory diseases.	15/2/2010	64.17	0.01	0.03	0.01	-0.03	-31.67	-	-
IXC	Invex Therapeutics Limited	A biopharmaceutical company, focused on the research and development of Exenatide as an efficacious treatment for neurological conditions.	5/7/2019	42.09	0.56	0.82	0.44	-4.00	-14.00	41.00	-
JHL	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	1.50	0.01	0.03	0.00	-1.70	-0.35	-2.00	-
KZA	Kazia Therapeutics Limited	Development of anti-cancer drugs.	1/9/1994	37.41	0.25	1.65	0.23	-11.10	-2.21	3.00	-
LBT	LBT Innovations Limited	Automated systems for the preparation, screening, interpretation and streaking of microbiological specimens.	31/7/2006	23.99	0.08	0.16	0.06	-2.68	-2.80	1.00	-
LCT	Living Cell Technologies Limited	Developer of live cell therapy products for treatment of neurological and metabolic disorders.	1/9/2004	12.85	0.01	0.01	0.00	-0.26	-3.46	1.00	-
LDX	Lumos Diagnostics Holdings Limited	Lumos Diagnostics specialises in rapid, cost-effective and complete point-of-care (POC) diagnostic test solutions to help healthcare professionals more accurately diagnose and manage medical conditions.	5/7/2021	13.22	0.06	1.23	0.05	-7.38	-0.85	13.00	-
LER	Leaf Resources Limited	Leaf Resources Limited manufactures and supplies pine chemicals in Australia. It provides natural wood rosin and turpentine; and cellulose and cellulosic fuels.	5/1/1999	42.28	0.04	0.10	0.02	-0.86	-4.30	1.00	-
LGP	Little Green Pharma Limited	Little Green Pharma Limitedd engages in the cultivation, production and distribution of medicinal cannabis products in Australia and internationally. It offers cannabis flower products.	20/2/2020	84.20	0.35	0.84	0.22	12.00	2.92	37.00	-
M7T	Mach7 Technologies Limited	Imaging IT solutions, 3D printing and holographic projection provider.	30/11/2005	158.82	0.67	1.07	0.45	-1.08	-61.57	10.00	-
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	29.69	13.00	30.00	6.45	-475.50	-2.73	524.00	-
MEB	Medibio Limited	Diagnostic tests for depression and other mental health disorders.	29/1/2001	4.13	0.00	0.01	0.00	-0.08	-1.25	-	-
MEM	Memphasys Limited	Cell and protein separation systems.	14/5/2007	30.10	0.04	0.13	0.03	-0.22	-17.27	-	-
MSB	Mesoblast Limited	Commercialisation of adult stem cell technology.	16/12/2004	648.67	0.88	2.07	0.61	-20.89	-4.21	-6.00	-
MVF	Monash IVF Group Limited	Assisted reproductive technologies, genetic testing and ultrasound services.	26/6/2014	407.17	1.05	1.27	0.89	5.90	17.71	3.00	4.30
MVP	Medical Developments International Limited	Medical and veterinary equipment, including pain management, resuscitation and asthma management products.	15/12/2003	159.11	1.96	5.36	1.37	-26.97	-7.27	25.00	-
MX1	Micro-X Limited	Develops and manufactures a range of mobile X-ray imaging systems for medical applications.	22/12/2015	69.23	0.15	0.35	0.11	-4.31	-3.36	-	-
MXC	MGC Pharmaceuticals Limited	Innovator in phytocannabinoid-based medicines within the biopharmaceutical industry.	21/12/2006	50.95	0.02	0.07	0.02	-0.68	-2.65	-	-
MYX	Mayne Pharma Group Limited	Pharmaceutical commercialisation and manufacturing. Development of oral drug delivery systems.	29/6/2007	643.73	0.37	0.43	0.20	-4.76	-7.77	11.00	-
NAN	Nanosonics Limited	Ultrasound probe disinfection – trophon device.	17/5/2007	1,494.27	4.95	7.52	2.87	3.65	135.62	42.00	-

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)
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	10.72	0.07	0.15	0.06	-1.19	-6.05	1.00	-
NEU	Neuren Pharmaceuticals Limited	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders.	3/2/2005	680.21	5.40	5.99	1.63	-6.60	-81.82	33.00	-
NGS	Nutritional Growth Solutions Limited	Nutritional Growth Solutions Limited develops, produces and sells pediatric protein supplements in the United States and internationally. It offers its products under the Horlicks, Healthy Height and Pro Up brand names.	30/10/2020	8.31	0.12	0.28	0.10	-6.89	-1.74	-	-
NOU	Noumi Limited	Noumi Limited engages in sourcing, manufacturing, selling, marketing and distributing plant-based beverages, as well as dairy and nutritional ingredient products to wholesale and consumer markets.	7/11/1985	73.43	0.27	0.53	0.10	-34.21	-0.77	-28.00	-
NOX	Noxopharm Limited	Development of drugs to make radiotherapy more effective. NOX66 is the company's pipline product.	9/8/2016	65.75	0.23	0.63	0.17	-3.39	-6.64	11.00	-
NSB	Neuroscientific Biopharmaceuticals Limited	NeuroScientific Biopharmaceuticals Limited develops diagnostic and therapeutic treatments for neurodegenerative diseases through preclinical studies of patented technologies.	27/7/2018	35.87	0.25	0.54	0.16	-4.70	-5.32	7.00	-
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	69.77	0.10	0.12	0.04	-1.12	-8.93	-	-
NUF	Nufarm Limited	Crop protection and specialist seed company. Manufacturing and marketing of products to help farmers protect crops against damage.	10/11/1988	2,018.70	5.31	6.93	4.09	27.65	19.20	261.00	8.00
NXS	Next Science Limited	Next Science Limited is a medical technology with a research and development centre in Florida, United States.	18/4/2019	214.79	1.00	1.48	0.70	-6.55	-15.27	6.00	-
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	23.40	0.15	0.31	0.13	-2.33	-6.44	8.00	-
OCC	Orthocell Limited	Soft tissue cellular therapies for restoration of tendon and cartilage injuries.	12/8/2014	81.84	0.42	0.59	0.30	-4.70	-8.83	7.00	-
OIL	OptiScan Imaging Limited	Microscopic imaging technologies for medical markets.	8/8/1997	74.35	0.12	0.29	0.09	-0.54	-22.22	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	82.98	0.15	0.52	0.11	-2.96	-5.07	3.00	-
OPL	Opyl Limited	Opyl Limited (formerly ShareRoot Limited) provides biopharma and health organisations access to emerging AI-assisted technologies and professional guidance to understand and improve healthcare design, development and delivery.	7/3/1996	3.26	0.06	0.20	0.03	-5.58	-1.08	2.00	-
OPT	Opthea Limited	Developer of novel therapy OPT-302 for treatment of eye diseases.	18/4/1991	440.19	1.25	1.48	0.79	-21.87	-5.72	59.00	-
OSL	OncoSil Medical Limited	Brachytherapy device that implants a dose of beta radiation into a pancreatic tumour.	15/8/2005	63.44	0.06	0.08	0.03	-1.43	-4.48	1.00	-
OSP	Osprey Medical Incorporated	Based in Minnetonka. Technologies to reduce the amount of dye injected into patients during heart catheterisation procedures – DyeVert PLUS Contrast Reduction System.	2/5/2012	5.13	0.20	1.40	0.20	-113.23	-0.18	55.00	-
OVN	Oventus Medical Limited	Medical devices for sleep apnoea treatment incorporating Oventus Airway Technology.	19/7/2016	4.83	0.02	0.16	0.02	-5.24	-0.38	2.00	-
PAA	PharmAust Limited	Developer of targeted cancer therapeutics for humans and animals. Specialise in repurposing marketed drugs.	5/10/2001	26.62	0.08	0.12	0.07	-0.55	-15.27	2.00	-
PAB	Patrys Limited	Developing novel antibody therapies for a range of oncology indications.	13/7/2007	53.48	0.03	0.05	0.02	-0.35	-7.43	-	-
PAL	Palla Pharma Limited	Palla Pharma Limited (formerly TPI Enterprises Limited) is involved in the production and distribution of narcotic raw material for supply to international pharmaceutical markets, and the production and distribution of poppy seed for supply to international culinary markets.	13/8/2015	47.76	-	0.41	0.20	-42.86	-	11.00	-
PAR	Paradigm Biopharmaceuticals Limited	Biopharmaceutical company focused on repurposing the drug 'pentosan polysulphate sodium' for the treatment of inflammation.	19/8/2015	298.68	1.31	2.67	0.85	-19.44	-6.74	22.00	-
PBP	Probiotec Limited	Manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, medicines and consumer health products.	14/11/2006	182.98	2.25	2.42	2.02	10.57	21.29	-20.00	5.00

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)
PCK	PainChek Limited	Smartphone app to provide pain assessment for those who are unable to communicate.	1/5/2012	36.30	0.03	0.07	0.03	-0.59	-4.75	1.00	-
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	348.38	0.43	1.61	0.42	-2.42	-17.77	12.00	-
PGC	Paragon Care Group Limited	Provider of medical equipment, devices and consumables to the healthcare market.	15/10/1999	222.27	0.35	0.49	0.26	2.47	13.97	-7.00	1.60
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	101.52	0.96	1.35	0.72	-3.81	-25.20	5.00	-
PME	Pro Medicus Limited	Provider of radiology information systems and diagnostic imaging.	10/10/2000	5,643.07	54.10	70.00	36.54	42.60	127.00	54.00	18.00
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 (NPWT).	26/11/1998	1,402.78	2.12	2.34	0.84	0.09	2,355.56	-	-
PTX	Prescient Therapeutics Limited	Developer of anti-cancer drugs. Lead drug candidate PTX-200.	19/12/1986	121.13	0.19	0.31	0.12	-0.77	-24.03	2.00	-
PXS	Pharmaxis Limited	Drug discovery to treat inflammatory and fibrotic diseases using amine oxidase inhibitor chemistry platform.	10/11/2003	42.83	0.08	0.15	0.07	-2.71	-2.88	1.00	-
PYC	PYC Therapeutics Limited	Development of intracellular biological therapeutics using its functional penetrating Phylomers (FPP).	30/3/2005	200.40	0.06	0.16	0.06	-0.51	-12.35	1.00	-
RAC	Race Oncology Limited	Development of chemotherapy drug Bisantrene for cancer, particularly Acute Myeloid Leukemia.	13/7/2016	323.66	2.03	3.83	1.45	-6.49	-31.28	24.00	-
RAD	Radiopharm Theranostics Limited	Radiopharm Theranostics Limited develops radiopharmaceutical and nuclear medicine products for diagnostic and therapeutic uses. Radiopharm Theranostics Limited was incorporated in 2021 and is based in Carlton South, Australia.	25/11/2021	24.35	0.21	0.50	0.13	-16.00	-1.28	6.00	-
RAP	ResApp Health Limited	Developer of mobile medical applications for the diagnosis and management of respiratory diseases.	12/1/2005	159.04	0.19	0.20	0.04	-0.88	-21.02	-	-
RCE	Recce Pharmaceuticals Limited	Development of synthetic antiobiotics to address the threat of antiobiotic resistance.	15/1/2016	154.55	0.87	1.38	0.55	-4.77	-18.24	9.00	-
RGI	Roto-Gro International Limited	Automated farming system for producing high quality plants indoors, including medicinal cannabis, pharmaceuticals and food products.	10/2/2017	3.77	0.01	0.04	0.01	-4.22	-0.26	1.00	-
RGS	Regeneus Limited	Cellular therapies focusing on osteoarthritis and other inflammatory conditions, cancer and wound healing.	19/9/2013	15.93	0.05	0.09	0.04	-1.70	-3.06	1.00	-
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	32.26	0.07	0.20	0.05	-0.09	-77.78	2.00	-
RHY	Rhythm Biosciences Limited	Development of an affordable blood test for the early detection of colorectal cancer – 'ColoSTAT'.	7/12/2017	280.58	1.31	2.08	0.88	-4.43	-29.57	2.00	-
RMD	ResMed Incorporated	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing.	25/11/1999	14,085.92	34.09	40.79	27.37	77.46	44.01	-	16.78
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	50.00	0.18	0.48	0.10	-2.52	-6.94	-	-
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	3.00	0.00	0.01	0.00	-0.57	-0.70	-	-
RSH	Respiri Limited	Devices for detecting and monitoring respiratory disorders.	14/7/2000	39.62	0.05	0.10	0.03	-1.06	-4.91	-1.00	-
SCU	Stemcell United Limited	Growth, reproduction and extraction of plants stem cells for medical and healthcare products.	13/6/2000	14.92	0.01	0.02	0.01	-0.32	-4.11	1.00	-
SDI	SDI Limited	Research and development, manufacturing and marketing of specialist dental materials.	7/11/1985	98.06	0.83	1.14	0.73	5.93	13.91	47.00	3.15
SDV	Scidev Limited	Research, development and commercialisation of polymers for dairy and and food product manufacturing.	2/5/2002	63.51	0.34	0.97	0.16	0.61	54.92	12.00	-

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)
SHG	Singular Health Group Limited	Singular Health Group Limited, a medical technology company, develops and commercialises volumetric rendering platform (VRP) for the 3D and virtual reality (VR) visualisation of anatomy using standard radiological imagery.	12/2/2021	10.77	0.17	0.36	0.09	-3.27	-5.05	-	-
SHL	Sonic Healthcare Limited	Laboratory medicine/pathology, radiology/ diagnostic imaging and primary care medical services.	30/4/1987	16,371.19	34.10	46.95	31.96	306.20	11.14	-4.00	95.00
SOM	SomnoMed Limited	Specialises in products for sleep apnoea. Lead product SomnoMed mandibular advancement splint (MAS).	27/8/2004	104.28	1.26	2.65	1.14	-5.91	-21.32	13.00	-
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	292.04	0.72	1.50	0.62	-4.39	-16.29	14.00	-
TD1	TALi Digital Limited	Cognitive training program for children with attention difficulties.	23/9/2004	6.16	0.01	0.04	0.01	-0.57	-0.88	-	-
TDL	TBG Diagnostics Limited	Development, manufacture and marketing of molecular diagnostic kits, instruments and services.	22/12/1995	58.75	-	-	-	-1.60	-	3.00	-
TLX	Telix Pharmaceuticals Limited	Development and commercialisation of molecularly-targeted radiation in the management of prostate, renal and glioblastoma (brain) cancer.	15/11/2017	2,074.64	6.63	8.82	3.55	-40.01	-16.57	16.00	-
TRJ	Trajan Group Holdings Limited	Development and manufacture of analytical and life sciences instruments and devices.	7/6/2021	329.95	2.17	4.59	1.91	0.12	1,808.33	19.00	-
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	15.67	0.34	0.83	0.23	-12.52	-2.68	44.00	-
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	16.33	0.05	0.11	0.04	-2.03	-2.22	1.00	-
TTB	Total Brain Limited	Provider of international database for human brain function.	28/8/2001	6.02	0.05	0.30	0.04	-5.95	-0.76	2.00	-
UBI	Universal Biosensors Incorporated	Specialist medical in-vitro diagnostic tests for point-of-care and blood test C-reactive protein test.	13/12/2006	61.43	0.29	1.04	0.28	-9.14	-3.17	15.00	-
UCM	Uscom Limited	Non-invasive medical devices in the field of cardiac, vascular and pulmonary monitoring.	10/12/2003	12.32	0.06	0.15	0.06	-1.00	-6.20	4.00	-
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	31.19	0.86	2.20	0.82	-14.46	-5.95	-15.00	-
VHT	Volpara Health Technologies Limited	Research, development and manufacturing company that provides digital health solutions for personalised breast cancer screening.	27/4/2016	163.81	0.65	1.32	0.40	-6.08	-10.69	5.00	-
VLS	Vita Life Sciences Limited	A pharmaceutical and healthcare company, mainly engaged in formulating, packaging, sales and distribution of over-the-counter (OTC) medicines, health supplements, vitamins and investments.	23/8/2007	106.81	2.01	2.60	1.08	15.75	12.76	52.00	5.75
WNX	Wellnex Life Limited	Wellnex Life Limited (formerly Wattle Health Australia Limited). Health and wellness products with scientific and nutritional benefit.	15/3/2017	26.69	0.09	0.15	0.06	-4.06	-2.17	1.00	-
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	75.03	0.59	0.86	0.48	-8.13	-7.20	21.00	-
XRF	XRF Scientific Limited	Manufacturer and marketer of instrumentation for scientific industries, including commercial laboratories.	31/10/2006	87.65	0.65	0.77	0.49	4.10	15.73	17.00	2.00
ZLD	Zelira Therapeutics Limited	Investing in research and clinical trials to study medical cannabis for a variety of ailments.	28/7/2003	16.76	1.75	8.75	0.90	-150.50	-1.16	105.00	-

This quarter's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Quarter Return %
PNV	Polynovo Limited	$1.81	106.86
TLX	Telix Pharmaceutical	$7.75	90.89
NTI	Neurotech International	$0.09	77.36
RAP	ResApp Health Limited	$0.19	65.22
AVR	Anteris Technologies	$27.50	64.18
LCT	Living Cell Technologies	$0.01	50.00
IMU	Imugene Limited	$0.26	50.00
AUA	Audeara	$0.12	48.15
GLH	Global Health Limited	$0.35	45.83
NEU	Neuren Pharmaceuticals	$5.27	42.43
PTX	Prescient Limited	$0.17	41.67
PAR	Paradigm Biopharma	$1.51	33.63
ZLD	Zelira Therapeutics	$1.90	31.03
OPT	Opthea Limited	$1.33	30.39
NAN	Nanosonics Limited	$4.82	28.19
RMD	ResMed Incorporated	$34.36	23.84
CUV	Clinuvel Pharmaceutical	$19.50	23.73
CU6	Clarity Pharma	$0.59	22.92
ADR	Adherium Limited	$0.01	22.22
CHM	Chimeric Therapeutic	$0.14	21.74

This year's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Year Return %
RAP	Resapp Health Limited	$0.19	287.76
AVR	Anteris Technologies	$27.50	241.19
NEU	Neuren Pharmaceuticals	$5.27	229.38
CAU	Cronos Australia	$0.30	160.87
AGN	Argenica	$0.42	112.82
VLS	Vita Life Sciences	$2.12	104.46
NTI	Neurotech International	$0.09	88.00
RIC	Ridley Corporation	$1.69	52.98
CTE	Cryosite Limited	$0.67	52.87
RHY	Rhythm Biosciences	$1.42	49.09
TLX	Telix Pharmaceutical	$7.75	46.23
IPL	Incitec Pivot	$3.67	39.60
XRF	XRF Scientific	$0.61	27.55
PGC	Paragon Care Limited	$0.32	26.79
MVF	Monash IVF Group Limited	$1.08	23.41
AUA	Audeara	$0.12	20.00
EMD	Emyria Limited	$0.21	20.00
NUF	Nufarm Limited	$5.21	19.68
EBO	Ebos Group Limited	$35.23	18.09
VRT	Virtus Health Limited	$8.10	17.13

Data current at 4 August 2022. 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. James Fletcher can be contacted at jfletcher@evansandpartners.com.au or on 03 9235 9716.

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