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Australasian BioTechnology

The journal of AusBiotech
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CEO AND CHAIR REPORT

BY LORRAINE CHIROIU, CEO, AUSBIOTECH;
AND JULIE PHILLIPS, CHAIR, AUSBIOTECH

The momentous Research and Development (R&D) Tax Incentive Inquiry win for the sector, a plethora of Therapeutic Goods Administration (TGA) submissions, a partnership with the Biotech Showcase in San Francisco and a series of BioCheers events with CSIRO are all significant highlights in the AusBiotech calendar so far this year.

AusBiotech launched its new strategic plan in the second half of 2018, and we have been busy rolling out our plans to best represent, advocate and deliver services and benefits to our members. We also welcomed our newest AusBiotech Director, Dr Dean Moss, at our Annual General Meeting (AGM) at the National Conference held in Brisbane in October 2018. Dean brings to AusBiotech more than 30 years of global experience in science, academia, business, management and commercialisation in Australia, the United States and the United Kingdom. He is currently the Chief Executive Officer of UniQuest, Australia's leading university commercialisation entity that manages the intellectual property of The University of Queensland.

The AGM also saw the departure of Director Lawrence Gozlan, Chief Executive Officer of Scientia Capital, from the Board after five years' service to AusBiotech. Lawrence gave an invaluable contribution over his Board tenure. Alongside applying his experience in global capital markets and specialist life sciences investment knowledge, Lawrence led AusBiotech's Remuneration and Nomination Committee, which has included implementing a thorough governance process around the recent Chief Executive Officer appointment. We are most appreciative of Lawrence's contribution over the past five years.

Championing advocacy through member engagement

We were proud to start this year with a momentous sector win. After two and a half years of key AusBiotech advocacy work alongside our members, the Senate Inquiry deliberating over the changes to the R&D Tax Incentive released their report. The Committee recommended that the Senate defer consideration of the Bill until further examination and analysis of its impact has been undertaken. The R&D Tax Incentive is a crucial mechanism for the Australian life sciences sector and is recognised by the government through carving clinical trials out in the R&D Tax Incentive reform package, so the success in retaining it is vital to realising our nationally significant economic and social potential.

Lorraine Chiroiu

Julie Phillips

During the R&D Tax Incentive Inquiry, it became clear that the federal government has used 'judgement' rather than evidence-based modelling to assess the impact of proposed changes to the R&D Tax Incentive program. AusBiotech gave evidence at the Senate Inquiry, together with others in the sector, so the voice of industry was strong and united in its feedback. The strong opposition to the Bill also speaks volumes about the strength of the Australian life sciences sector, and the work that has gone in across the country to promote its success, value and further potential.

In February, we launched our ninth CEO Biotechnology Industry Position Survey 2019,

> The strong opposition to the Bill also speaks volumes about the strength of the Australian life sciences sector, and the work that has gone in across the country to promote its success, value and further potential

which formally seeks opinions and information from industry leaders in order to build a comprehensive view of the Australian biotech sector. A federal budget and a federal election are all expected shortly. The contributions to the Survey and the related roundtable discussions are key to preparing AusBiotech's advocacy platform for the year ahead. The CEO Biotechnology Industry Position Survey Report will be released in early May.

Alongside the roundtable discussions aligned with our Survey, we have also been actively responding to a plethora of TGA consultations on medtech and clinical trials. This led to two additional roundtable discussions inviting members to a briefing and seeking their input on several of these key medtech proposals. Much like our industry, these proposals move quickly and we were grateful to those who gave their time at short notice. As they present themselves, we will continue to use these issues-based opportunities to seek and share your views, knowledge and experience.

Finally, we want you, our members, to have your say, and we are committed to active and persuasive policy representation. Therefore, building on AusBiotech's strong policy foundations, we have pledged to implement new initiatives: new quarterly policy updates, a register of key policy issues and policy papers, and to hold an annual CEO policy forum in Canberra. We will also provide additional opportunities for members to provide input into AusBiotech's policy positioning.

> Companies connected with international capital markets presented their business case to over 100 potential investors and partners at each event

You can read more about our work at www.ausbiotech.org/policy-advocacy.

Facilitating global development

2019 began with a bang as we officially partnered with the Biotech Showcase in San Francisco alongside the enormous J.P. Morgan Healthcare Conference, where we presented the strengths of Australian life sciences to the world. We could not have been more pleased that attendance at the session was at standing-room only; it validates our belief that Australia is highly attractive in the life sciences arena and that we rightly own our place among the global leaders.

This success was followed by our Asian Investment Series, where we took a delegation of Australian life sciences companies to two major investment hubs, Shanghai and Hong Kong, at the end of March. Companies connected with international capital markets presented their business case to over 100 potential investors and partners at each event. At the same time, we also ran our inaugural Australia–China Life Sciences Symposium, where early-stage spin-outs and start-ups looking to raise funding or secure collaborative partnerships joined us in China. This was the first time we have run this event, and interest in collaborating and engaging with Asian markets, such as China, proved strong.

Coming up

We are joining Austrade and MTPConnect in April at BioKorea 2019. AusBiotech will be boosting Australia's connections and reputation by supporting

the Australian pavilion and two dedicated conference sessions where we will showcase Australia's life sciences strengths, including regenerative medicine and clinical trial opportunities. The Korea Health Industry Development Institute (KHIDI), has led large Korean delegations to the AusBiotech National Conference over the past three years, demonstrating the strong interest Korean companies have in collaborating with Australia's biotech industry. BioKorea 2018 included over 700 biotech and medtech companies, including an Australian presence.

We are also headed back to America – this time to Philadelphia for our annual BIO mission in June. Last year, we were among the top 10 largest delegations, standing strong with over 350 Australians in attendance. If you are interested in exhibiting or attending, please contact us. Participation will help your company by leveraging the strength of the Australian brand and by gaining traction among biotechnology's global leaders.

Facilitating these international opportunities for investment discussions, collaborations and partnerships is crucial for the growth of the Australian life sciences sector and ultimately for continuing Australia's position within the top five countries in the life sciences sector globally. Alongside the AusBiotech National Conference, the mission to BIO each year is one of the most significant events on our calendar, and provides a platform to showcase our members and demonstrate Australia's life sciences' strengths to the world.

Focusing on growth

Working to increase opportunities for the sector to network and celebrate, and enabling access to talent, expertise, education and partnerships, AusBiotech was pleased to hold the New South Wales, Queensland and Victoria BioCheers events with CSIRO in February. This partnership is significant as AusBiotech continues strengthening its alliances with key stakeholders in the industry and connecting the pipeline of innovators who work in the sector. These three events welcomed over 400 members and non-members across the country. BioCheers events in South Australia and Western Australia were also strongly supported.

For the first time, AusBiotech and Medicines Australia partnered together to present this year's annual New South Wales Women in Life Sciences Luncheon, held on International Women's Day (8 March). Gender inequality in life sciences leadership is well documented and globally recognised; this luncheon connected the community to drive action and empower them to make a difference. It also included an hour-long discussion: 'An hour to empower'. This luncheon brought over 320 women together to be inspired by stories of challenge and achievement, and to consider what, together as a powerhouse of minds, they could do to make a difference. Diversity is the foundation to building a successful sector – a position supported regardless of gender.

Evolving customer needs and new regulations continue driving incredible innovation within the medtech sector. We are looking forward to showcasing local and international examples of real-world benefits being delivered to patients at our annual AusMedtech 2019 conference, Bionics and Beyond, in Melbourne on 14–15 May. Topics include medtech in space, the brain–machine interface, the bionic eye and the bionic ear, digital health, funding opportunities, clinical trials, market access, reimbursement and our new AusBiotech Future Forum where we traverse the horizon, identifying future science and trends that are expected to evolve or disrupt our current medtech environment. Thank you to the Victorian Government, our host state partner for 2019.

We hope that the articles in this edition of the *Australasian Biotechnology* journal help whet your appetite, and that we see you at AusMedtech 2019.

For more information on AusMedtech 2019, visit www.ausmedtech.com.au.

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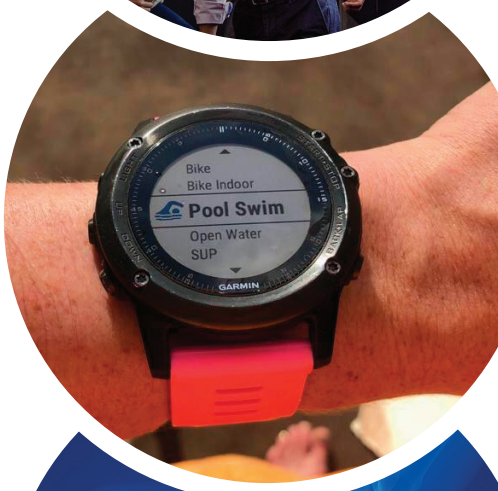

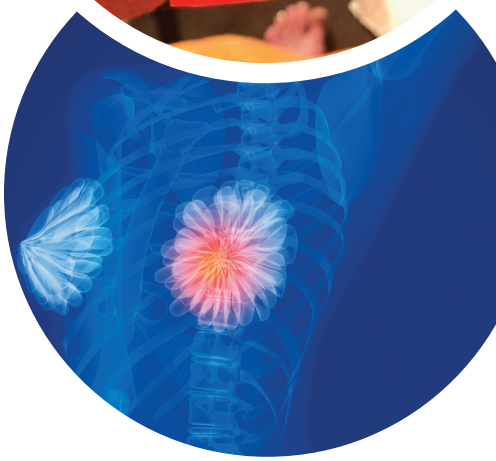

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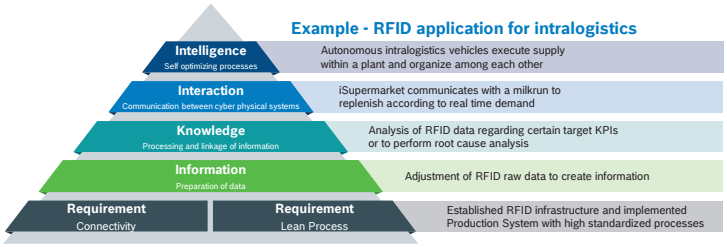
BRINGING INDUSTRY 4.0 TO LOCAL COMPANIES

The connected world has arrived, and it continues to grow and evolve every day. With an expected 7 billion people and 50 billion connected devices by 2020, the Internet of Things (IoT) is transforming the way we live, work, communicate, and interact with one another.



It is also enhancing processes and procedures in the manufacturing, transportation and warehousing of goods. The Fourth Industrial Revolution is setting new standards, enabling manufacturing to be simpler, more efficient and more flexible. It is called Industry 4.0.

Why is it important?

Historically, many different processes were used for the manufacture of products. These processes acted interdependently; however, the connecting of all of these via the internet creates a fully integrated ecosystem delivering faster, more customised products for the end user.

Industry 4.0 gives more control to the people at the core of making things. It allows for richer collaboration and rapid flow of information, and it cross-references in real time to automatically correct errors or optimise systems.

What makes the Bosch approach to Industry 4.0 different?

Bosch is both a provider and a user of Industry 4.0 technologies. With 290 manufacturing plants across the world, application of Industry 4.0 is an evolution not a revolution. Bosch's own reference projects for implementation range from large-scale mass production to multi-variant assembly quantities.

For example, the introduction of radiofrequency identification (RFID) technology is a good first step. The prerequisites for implementation are a standardised process in the context of lean principles and IT foundations that allow for basic connectivity and the exchange of data or different systems. Standardised processes enable the targeted capture of important information based on the RFID raw data. In turn, KPIs can be generated and monitored in real time.

This approach starts with a small hardware and connectivity investment that opens up possibilities for understanding and optimisation, and can lead to covering the entire value stream and a wide variety of processes through subsequent investments.

Some of Bosch's own reference projects have started in this way as 'pilots' and expanded upstream and downstream as process steps, ultimately rolled out in an international production network.

What can other manufacturers take away from this?

Bosch's Industry 4.0 applications all have one thing in common; they are customised to the requirements of the respective plants and integrate existing equipment. The process is iterative, with short control loops. Small steps reduce the complexity, achieve desired results faster and are measured against KPIs.

What about Australian manufacturers?

Australia has a rich manufacturing environment, comprising approximately six per cent of GDP; however, 97 per cent of Australian manufacturers are considered small to medium enterprises by global standards. Like Lean Philosophy, Industry 4.0 principles will become the norm; however, the journey will start with the introduction of small steps, such as RFID connectivity, which will then expand and improve productivity with additional measures.

Bosch Australia Manufacturing Solutions (BAMS) develops special purpose equipment that leverages the extensive global manufacturing footprint of Bosch and brings Industry 4.0 knowledge, solutions and services as a core competency tailored to local companies.

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REFLECTING ON AUSBIOTECH 2018

AusBiotech 2018 saw over 1100 delegates from 20 countries congregate in Brisbane in October for the largest life sciences conference in Australasia.

The conference forms a very special part of AusBiotech's broader work positioning Australia's biotechnology industry for growth. As a leaders' forum, it is also a key opportunity to connect with potential partners and investors, reflect on the sector's achievements and exchange ideas to further advance the sector's standing both nationally and globally. AusBiotech 2018 saw three days of speakers; an exhibition space holding 73 supporters; the largest number of AusPartnering meetings yet, with over 1300 booked; a vivacious gala dinner; and the industry's governmental support through the presence of the Hon. Kate Jones, Minister for Innovation and Tourism Development, and the Hon. Leeanne Enoch, Minister for Environment and the Great Barrier Reef, Minister for Science and Minister for the Arts.

AusBiotech 2018 presented issues critical to industry – global biotech trends, breakthroughs, challenges and success stories featured prominently on the program. With 142 speakers, the discussions were diverse and challenging; panel discussions and key themes covered regulation and reimbursement, research translational strategies, new markets, business development and capital access, emerging technologies, clinical trials, regenerative medicine, women in life sciences, agriculture, and commercialisation.

Keynote speakers included: John Carroll, Editor-in-Chief at Endpoints News (United States), with an industry update and an apprise on global life sciences investing; Dr Charmaine Gittleson, Chief Medical Officer at CSL Limited (United States), on keeping the balance in your clinical portfolio – prioritisation versus doing it all; and Professor Doug Hilton, Institute Director, Division Head of Molecular Medicine, Walter and Eliza Hall Institute (WEHI), who delivered the annual Millis Oration on the three pillars of WEHI's activities: science, translation and entrepreneurship.

With such prominent leaders gathering, it was also the ideal time to recognise our industry's leading lights through the annual AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards. The Awards recognise innovative companies and individuals in Australia's world-class biotechnology, medical technology and healthcare sectors, celebrating the highest achievers in Australian life sciences and demonstrating what is possible when vision and dedication come together.

The decisions of 2018 were extremely difficult to make, with the greatest number of nominations in the award's history – a result AusBiotech believes is down to both the strength of the industry, as well as the positive environment that the government is providing industry to do business within.

For the first time ever, joint winners were awarded for the Emerging Company of the Year category. Congratulations to 2018's winners: Dr Anna Lavelle (Industry Leadership award), Medicines Development for Global Health (Company of the Year award), and to Telix Pharmaceuticals and Microba (Joint Emerging Company of the Year). You can read more about the winners in their company profiles later in the journal.

The national conference included a one-day early-stage investment forum featuring 22 presentations on human therapeutics and enabling technologies from local research institutes, universities, hospitals and pre-series A companies. Pitches were made to an expert investor panel that included international big pharma representatives as well as corporate VCs and early-stage investors. The day proved popular amongst presenters, investors, and observers, and was the perfect extension on AusBiotech's annual Australia Biotech Invest & Partnering seminar, which was held two days earlier in Melbourne on 30 October. The annual Melbourne event also connected biotech with

investors, providing 29 companies with an opportunity to take centrestage in front of a 300-strong audience.

AusBiotech launched an interactive online platform at AusBiotech 2018 – The BioExchange platform – for international science-funding matching. The online platform aims to increase the potential Chinese investment and partner pool for Australian life sciences companies. It serves as a database for life sciences projects and as a platform for the exchange of ideas, resources and opportunities between Australian life sciences companies, and Chinese funding and industry partners. It combines direct messaging, translation services and project matching functions, allowing companies a risk-reduced, staged market entry into China.

BioExchange is the first major milestone for AusBiotech's wider Australia–China Life Sciences Partnership Programme, which aims to increase awareness and opportunities for communication, collaboration and commercialisation between the life sciences sector in Australia and China. The Programme is supported by MTPConnect and consortium partners China BlueSky Partners, Therapeutic Innovation Australia, KPMG, King & Wood Mallesons, Asialink Business and FB Rice.

With regenerative medicine being an area of potential significant growth for Australia, AusBiotech 2018 dedicated an all-day stream to the topic. Australia's regenerative medicines field now accounts for approximately 10 per cent of our medical researchers across Australian medical research institutes and universities, and there are more than 30 companies in Australia developing products with a regenerative medicine focus. Australia is well-placed to capitalise on our country's strong research base in developmental biology, genetics and tissue manufacturing, all of which underpin regenerative medicine, and to secure an even more prominent share of the global regenerative medicine market, which industry experts believe will be worth A$120 billion by 2035.

The conference included three regenerative medicine-related launches.

The 'Regenerative Medicine: Opportunities for Australia' report was launched, mapping out the Australian regenerative medicine sector in detail, and identifying priority areas and goals to make Australia globally competitive. Initiated by AusBiotech's Regenerative Medicine Advisory Committee, the project was conducted by LEK with funding from MTP Connect, and developed by AusBiotech member companies and research institutes. The report is being used to identify ways to improve and engage the national regenerative medicine sector, and to address key advocacy areas.

Together with the Forum for Innovative Regenerative Medicine (FIRM) in Japan, a regenerative medicine directory was launched, listing all members in Japan and Australia who work within the sub-sector to better enable global access to talent, expertise, education and partnerships. AusBiotech and FIRM signed a memorandum of understanding at AusBiotech 2017; maximising their international partnerships, the new directory is a member-only benefit available on our respective websites.

Also launched, in collaboration with the NSW Stem Cell Network, was the Snapshot of Stem Cell and Regenerative Medicine Companies in Australia 2018, a directory compiling public information on Australian stem cell and regenerative medicine companies across Australia into one document. The Snapshot is the fourth version of the directory and this year expanded to include regenerative medicine organisations.

The three-day conference was packed to the brim with new information, technologies, partnerships and, most of all, fun. Some say it takes a village to raise a child. The same applies to the successes of health care; the translation of our world-class research into real-value therapeutics requires us all to work together. To build relationships and collaborate together – that's what AusBiotech2018 was all about.

The 2018 conference was held at the Brisbane Convention Centre from 31 October – 2 November. The event was made possible with the support of the Queensland Government as the event's host state partner.

AusBiotech 2019 is being held at the Melbourne Convention Centre from 30 October – 1 November, with the support of the Victorian Government as AusBiotech's host state partner. For more information, visit www.ausbiotechnc.org.

Celebrating 10 years of dedication: LORRAINE CHIROIU

Working in a fast and challenging sector, and in an era where moving on after a few years has become the norm, giving 10 continuous years of commitment to an organisation is rare and we are proud to celebrate the achievements and leadership of AusBiotech's Chief Executive Officer Lorraine Chiroiu.

During her career, Lorraine has exemplified what it means to be a business and communications professional working in the realm of people, patient and biotechnology advocacy. It takes not just empathy and compassion to advocate for those in need, nor just a tenacious spirit to endure the rough times, but a combination of adaptability, diligence, integrity and passion to maintain a fight for the rights of others. It takes an insightful leader to empower and an earnest heart to inspire: Lorraine Chiroiu embodies both.

You may know Lorraine through her original AusBiotech role of Communications Manager, from her time as Chief Industry Affairs Officer, where she focused on both policy and communications, as Deputy Chief Executive Officer, or more recently as the Chief Executive; but you may not know how she came to be at AusBiotech. Rewind 20 years and Lorraine was entering the communications world, inspired by journalism and fixed on her principle dream of becoming an advocate, writer, and interpreter. Having honed these skills well since then, she puts them effectively into play as the Chief Executive Officer of AusBiotech.

After graduating, Lorraine was involved with the StigmaWatch program as a journalist, where she worked to improve the portrayal of people with serious mental illness in the media by advocating for those who were being marginalised and interpreting their experiences. It was also the stepping stone into what would become a career devoted to the progression of policy development and advocacy for the wellbeing of others.

Having undertaken positions with SANE Australia, Bristol-Myers Squibb, University of Melbourne and

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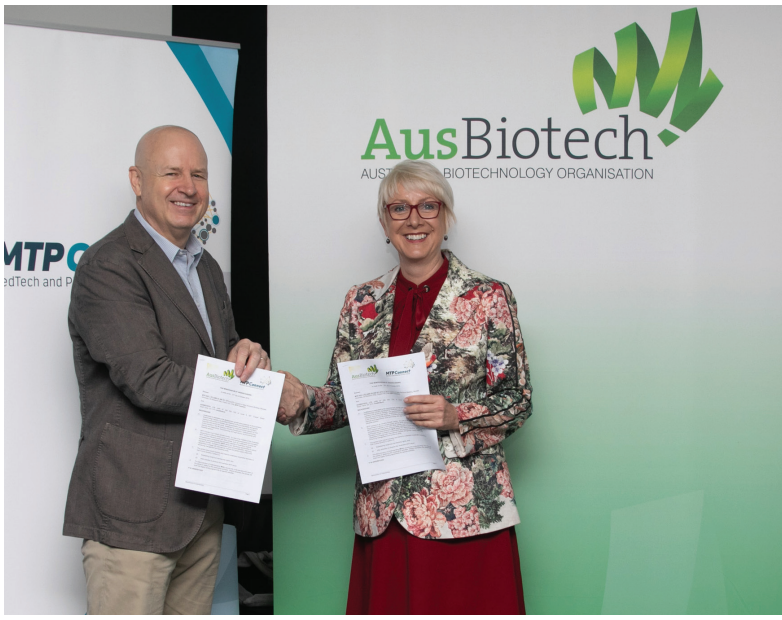
Pharmacy Guild of Australia, Lorraine has navigated a career encompassing both corporate and public affairs responsibilities, which led her to find a home for the past decade among leading companies working with AusBiotech.

Key achievements

When asked of her triumphs over her tenure, Lorraine batted away the question with humility, 'The nature of advocacy means that no-one can take sole credit for the results; however, we can each be very proud of the collaboration and the many people that drew together to make it happen'.

That said, Lorraine has been key to the success of many campaigns. At the time of joining AusBiotech, the biotech sector was in a backward slide from the global financial crisis. Half of the ASX–listed sector and many good technologies were falling victim to the sudden dearth of much-needed capital in the Australian and international environment. Lorraine managed the media campaign advocating for what we now call the Research and Development (R&D) Tax Incentive, under the leadership of the then Chief Executive Officer, Dr Anna Lavelle. The R&D Tax Incentive has been a game changer for the industry, and put Australia on the map globally as a key destination for the conduct of clinical trials and investment. In turn, this has added to our already high global standing in medical research and science, and to the recognition of biotech as a key industry within Australia. The life sciences is now a growing and mature sector that employs 232,000 people. Late in 2018, Lorraine gave evidence at the R&D Tax Incentive Senate Inquiry and, after two and a half years of key AusBiotech advocacy work alongside



our members, the Inquiry's Economics Legislation Committee recommended that the Senate defer consideration of the Bill until further examination and analysis of its impact has been undertaken. The R&D Tax Incentive is a crucial mechanism for the Australian life sciences sector, so the retention of it is vital to realising our nationally significant economic and social potential. Ultimately, the R&D Tax Incentive – and the advocacy work to support it – has resulted in life-saving technologies being progressed, the attraction of hundreds, if not thousands, of clinical trials, and patients getting access earlier to cutting-edge treatments.

An additional stand-out movement that Lorraine has led was AusBiotech's advocacy for the visionary Medical Research Future Fund, a $20-billion capital fund that aims to provide $1 billion per annum perpetually for medical research within Australia.

Leading the way

AusBiotech has an ambitious strategic plan to deliver over the next four years, and Lorraine will no doubt utilise her tenacity, adaptability, authenticity and dedication as she works with members, and leads her team, to deliver it and help shape the future of Australian biotech.

From all of the Board, happy 10 years Lorraine. Thank you for your dedication and contribution to AusBiotech and to improving the biotechnology sector. We look forward to continuing to work together and, ultimately, to being pivotal in growing our sector to provide economic and social benefits to Australians and, importantly, to help technologies reach patients in future.

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Industry Leadership Award winner:
DR ANNA LAVELLE FTSE

With an illustrious career history throughout the Australian biotechnology sphere, there is undeniable cause for Dr Anna Lavelle to receive 2018's Industry Leadership Award at the AusBiotech 2018 conference. The prestigious AusBiotech and Johnson & Johnson Industry Excellence Awards spotlight the leading lights of Australia's world-class biotechnology and medical technology sectors.

During her 11 years as AusBiotech's CEO, Dr Lavelle strongly advocated for policy changes, including the research and development tax incentive (RDTI), small business reform and intellectual property (IP) protection. Dr Lavelle is the only Australian to be recognised by Nature Scientific America as one of the world's top 100 visionaries in global life sciences, as determined through nominations and selections from an international panel of experts and peers. To date, Dr Lavelle is the only Australian to ever receive this recognition. In 2016, she was awarded an AusBiotech Life Membership in acknowledgment of her excellent service to the biotechnology sector, and her meritorious service to AusBiotech.

Dr Lavelle's present positions and ongoing responsibilities are equally numerous and relevant to today's biotechnology environment. A graduate of the Australian Institute of Company Directors, Dr Lavelle is an experienced director, having served for over 25 years on the boards of not-for-profit, government and for-profit entities. Working as both an executive director and a non-executive director, she has a lengthy track record in healthcare delivery, technology and business development, and negotiating government policy.

Previously holding positions as Non-Executive Director at Research Australia, the Agricultural Biotechnology Council of Australia, BioMedVic and Haemokinesis, Dr Lavelle continues to advocate and lead in the innovation sector within the Australian biotechnology industry across a range of organisations. Her current

roles include: Independent Director at the SoilCRC, Chairman of Avatar Brokers, Non-Executive Director of Hemideina, committee member of the National Health and Medical Research Council (NHMRC, HIAC), Chairman of the Australia National Digital Health initiative (ANDHealth), Chairman of the Medicines Australia Board and Fellow of the Academy of Science Technology and Engineering ATSE.

Looking through the titles and the awards, Dr Lavelle is a talented, tenacious and dedicated advocate for our industry. Her dogged determination was particularly important through difficult times, such as during the GFC, when many of the industry innovation programs were impacted. She played a key role in keeping the sector moving forward even during this period. She has a big heart, is truly compassionate and she's always there to defend and support the people around her.

Dr Lavelle's rich history and continuous commitment to the biotechnology sector are far and beyond extraordinary. She is by her own merit a woman of excellence: an impeccable candidate and recipient of the Industry Leadership Award.

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MICROBA

In the annual AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards, Microba was joint winner (with Telix Pharmaceuticals) of the Emerging Company of the Year award.

Microba specialises in the analysis of the human gut microbiome and is Australia's first company to offer gut microbiome profiling to the public using metagenomic sequencing. Originating from technology developed at the University of Queensland, Microba draws on the expertise of Professor Gene Tyson and Professor Phillip Hugenholtz, who are pioneers and world leaders in the analysis of metagenomic data. With a growing body of global research indicating that the gut microbiome plays a central role in health and disease, Microba has positioned itself to be a leading force in the development of new pathology services, therapeutics and diagnostics based on the gut microbiome.

Its first consumer product, the Microba Insight™ Sampling Kit, is an information tool that shows the abundance and functional potential of the microorganisms living in the gut with unprecedented precision. This product has empowered more than 4000 individuals and healthcare professionals to access new information on an individual's gut health and to tailor dietary recommendations according to an individual's gut microbial profile.

Utilising Microba's proprietary Metagenomic Analysis Platform (MAP™), a bioinformatic data analysis pipeline, Microba is developing new pathology products alongside leading healthcare professionals to enable microbiome testing to become a part of routine clinical care. Microba has also established a research service to make its MAP™ technology accessible to research groups and corporates across the globe to accelerate research and commercialisation in the microbiome sector.

Microba has built the Microba Discovery Database (MDD), one of the world's richest population databases containing microbiome profiles and key metadata on medical history, lifestyle and diet for more than 2500 individuals. Using this extensive database in combination with artificial intelligence to identify lead therapeutic and companion diagnostics,

Blake Wills

Microba has established its therapeutics division focused on pursuing the development of a pipeline of intellectual property assets. As a result of this focus, Microba is quickly progressing towards its mission of creating life-enhancing healthcare products.

As CEO of Microba, Blake Wills has made world-leading technology available to Australian consumers, providing them with significant new insight into their gut microbiome. Wills continues to drive the strategy of expanding Microba's capabilities into the infectious disease, gastroenterology, general practitioner and research markets. Wills and the scientific founders of Microba have a strong interest in the role of the gut microbiome in modulating the immune system and the potential therapeutic applications of key microbes and their metabolites. Microba has leveraged big data and machine learning to develop a pre-clinical asset pipeline. The first program developed by Microba is for inflammatory bowel disease (IBD).

Using machine learning and artificial intelligence to establish new diagnostic signatures in the microbiome is an exciting project that Wills is working on with Associate Professor Lutz Krause. This project has already yielded groundbreaking insights including gut health and age predictors, as well as IBD and cancer signatures. The future goal of the project is to evaluate an individual's specific microbiome to tailor dietary recommendations, diagnose disease states and predict response to therapeutic interventions.

Microba's ultimate aim is to further our knowledge of the gut microbiome for improved health and wellbeing. Bringing science to life and developing real-world applications for technology is a passion for Wills, who is a proven leader and company executive who has worked in the finance, life sciences and education sectors. During these roles, he launched and acquired multiple businesses in Australia and internationally. Notably, Wills was COO of an ASX–listed company that, during his tenure, grew to over 300 employees and operated in multiple jurisdictions.

Moxidectin, approved by the US FDA in 2018, is the first new treatment for onchocerciasis in more than 20 years

MEDICINES DEVELOPMENT FOR GLOBAL HEALTH

The annual AusBiotech Johnson & Johnson Innovation Industry Excellence Awards recognise Innovative Companies and individuals in the Australian biotechnology, medical technology and healthcare sectors. Medicines Development for Global Health won the Established Company of the Year award.

Medicines Development for Global Health (MDGH) is an independent, not-for-profit biopharmaceutical company headquartered in Melbourne, Victoria. Founded in 2005, MDGH uses all funds in excess of running costs to develop medicines and vaccines that address important unmet medical needs, but may have limited, or non-existent, commercial opportunities.

The company's focus is the development of new medicines to treat the neglected tropical diseases (NTDs) endemic in many of the world's poorest countries. The World Health Organization (WHO) estimates that more than a billion people worldwide are affected by NTDs and, in addition to disabling clinical symptoms, NTDs also contribute to significant economic and social privations.

Onchocerciasis (river blindness) is an NTD of high priority for MDGH. This debilitating condition is caused by the parasitic worm *Onchocerca volvulus*. Transmitted by a black fly, it causes severe itching, disfiguring skin conditions and visual impairment, including permanent blindness. Up to 200 million people, primarily in sub-Saharan Africa, are at risk of this disease, with an estimated 20 million infected.

Mark Sullivan

In June 2018, MDGH received US Food and Drug Administration (FDA) approval for moxidectin to be used to treat onchocerciasis in individuals aged 12 and older. The drug demonstrated superiority to the current treatment standard (ivermectin). It is thought that moxidectin will help accelerate the eventual elimination of this disease.

Moxidectin also holds promise for the treatment of several other neglected diseases, including scabies, soil-transmitted helminths, strongyloides and elephantiasis, and MDGH is planning development programs to support registration of moxidectin for these conditions.

MDGH was the recipient of several notable awards in the last year, including 2018 AusBiotech and Johnson & Johnson Innovation Industry Excellence Award (Established Company of the Year Award category). Mark Sullivan, Founder of MDGH, was named 2019 Victorian Australian of the Year and New York-based *Fast Company* magazine recently named MDGH in its annual list of the World's Most Innovative Companies.

CEO-REPORTED REMUNERATION FOR FY2018

BY LEE ROCHESTER, CLIENT PARTNER, WEXFORD HAYES EXECUTIVE SEARCH & BOARD ADVISORY

With chief executive remuneration continuing to remain in the spotlight and being one of the more complex issues that boards are required to manage, the Wexford Hayes annual review of CEO remuneration provides an insight into remuneration trends across the top 100 public ASX-listed companies in the healthcare and biotechnology sectors.

With continued challenges facing the industry, including pressure on revenue/margins, government funding, demand for infrastructure upgrades, and investment in technology, it should come as no surprise that chief executive total remuneration has been under pressure. Across the sector, we witnessed a 19.6 per cent decline (compared to 2017) when the total average remuneration fell to $935,000 per annum.

The reduction experienced was the result of sliding short-term (-15.6 per cent) and long-term incentives (-48.8 per cent) predominantly across larger organisations (for example, market capitalisation in excess of $1 billion) in the sector; however, we note that the average was significantly impacted by one of the larger organisations due to a change in chief executive significantly impacting reported long-term incentives. Adjusting for this organisation, and excluding them from our calculations, total average remuneration declined by a more modest 4.2 per cent to $849,000 per annum.

In contrast, fixed remuneration increased throughout 2018 by 3.8 per cent to an average of $548,000 per annum.

Market capitalisation of over $1 billion

Organisations in this sector experienced a reduction in total average remuneration of 43.1 per cent to $3.4 million; however, as noted previously, this reduction was impacted by one organisation reporting a large reduction in long-term incentives. When excluding this outlier, total average remuneration declined by 17.4 per cent compared to the previous period.

Fixed average remuneration held steady at an average level of $1.6 million per annum. The majority of chief executives in this segment received a short-term incentive over the course of the year; however, this incentive reduced by an average 26.5 per cent to $0.9 million.

Market capitalisation between $100 million and $1 billion

The mid-market also experienced downward pressure on total average remuneration with a 6.2 per cent reduction to $812,000 per annum, from $866,000 per annum. This reduction was driven by a decline in both average short-term and long-term incentives of 23.9 per cent and 8.6 per cent respectively.

Over the last four years, total average remuneration has contracted by an average of 6.9 per cent per annum due to pressure on both short-term and long-term incentives. In 2015, total average remuneration was approximately $1.024 million per annum and is now $812,000 per annum.

Fixed average remuneration remained steady with a slight increase of 0.1 per cent to an average level $519,000 per annum.

Market capitalisation under $100 million

In contrast to the large and medium-sized organisations in the sector, smaller organisations continued to experience an increase in total average remuneration.

Total average remuneration for this segment increased by 9.5 per cent to $568,000 per annum, with the rise resulting from growth in both fixed remuneration and short-term incentives of 10.6 per cent to $370,000 per annum, and 58.8 per cent to $68,000 per annum respectively. Reportable long-term incentives decreased by eight per cent to $130,000 per annum. Approximately 75 per cent of companies paid a long-term incentive over this period, and 50 per cent paid a short-term incentive.

Over the last four years, total average remuneration has grown by a yearly average of 13.6 per cent to $568,000 per annum due to consistent growth in both fixed- and short-term incentives.

If you are interested in receiving the full report, please contact Lee Rochester at lee.rochester@wexfordhayes.com

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MEDICAL AI: CAN PATENT LAW KEEP UP WITH THE TRAJECTORY OF INNOVATION?

BY DR RENEE WHITE, PATENT AND TRADEMARKS ATTORNEY, WATERMARK

Technologies that were once only seen in science fiction movies are now becoming reality.

A surge in the applicability of artificial intelligence (AI) to mainstream life has occurred over the past 30 years, particularly in medicine. Techniques such as artificial neural networks, fuzzy expert systems, evolutionary computation and hybrid intelligent systems are being applied more than ever before to assist the medical community in patient diagnosis, with a success rate similar to or better than their human counterparts.

The speed of innovation in the field of AI diagnostics is rapid. One concern for innovators is whether patent law can keep up. There are patent eligibility challenges aplenty in major innovation destinations for both computer-based technologies and diagnostics. This article reviews examples of AI diagnostics, recent changes to patent subject matter eligibility and

best practice in navigating these changes to protect medical AI in Australia and the United States.

What is medical AI?

According to the *English Oxford Living Dictionary*, AI is 'the theory and development of computer systems able to perform tasks normally requiring human intelligence, such as visual perception, speech recognition, decision-making and translation between languages'.

The World Intellectual Property Organization (WIPO) recently reported AI as one of the 'technology trends of 2019', providing detailed data on the rise of AI-related patents and key players seeking AI-related patent protection.

Of the top 20 fields of application identified in the analysis, 12 per cent of filed AI patents contained subject matter related to life and medical sciences, falling just behind telecommunications at 15 per cent.

It is no surprise that large multinationals like Siemens, Philips and Samsung hold the largest patent portfolios in the life and medical sciences. Universities and public research organisations (such as Combined Associated Schools (CAS), University of California and Zhejiang University) are also represented among the top 20 players, particularly in the field of neurosciences and neurorobotics.

Dr Renee White

Late last year, Siemens announced the release of AI-Rad Companion Chest CT, just one of their latest AI diagnostics in medical imaging. The product assists radiologists in the interpretation of chest images. While typically radiological images display a wide variety of information, due to time constraints and skill shortfalls, a radiologist's analysis is often limited to the primary medical indication. The software algorithm of AI-Rad Companion Chest CT can differentiate between various structures in the chest region, including lungs, heart, aorta, and coronary arteries, identifying potential abnormalities outside the primary concern, including lung lesions and total calcium volume in the coronary arteries. AI-Rad Companion Chest CT then automatically generates a standardised, reproducible and quantitative report based on these findings.

The technology comes with the promise not to replace radiologists of the future, but rather to enhance their work. The same potential exists for most AI technology; the benefit of intelligent automation is an increase in efficiency, accuracy and productivity as well as a reduction in potential human error.

Is patent law moving at the same pace as medical AI innovation?

Australia

For many years, certain subject matters have been ineligble for patent in Australia, including laws of nature, abstract ideas and mathematical algorithms. Recent seminal cases like *D'Arcy v Myriad Genetics Inc [2015], Research Affiliates LLC v Commissioner of Patents [2014], and Commissioner of Patents v RPL Central Pty Ltd [2015]* have added isolated naturally occurring nucleic acid molecules, cDNA, RNA and the implementation of a method by a computer or the internet to the list of ineligible subject matter.

It is interesting to note that claims directed to diagnostic methods have not directly been considered by an Australian court just yet; however, judges in the Myriad case made brief comments on the patentability of Myriad's methods of diagnosis, opining:

'[It] is not disputed that a process or method of detecting the increased likelihood of certain kinds of malignancy… may be patentable subject matter as a process.'

While diagnostics per se are safe from the patentability chopping block, where does this leave diagnostics deriving the benefit of 'computer-implemented invention' like AI technology?

> Early indications are that the guidelines have constructively softened the approach to patenting computer-implemented inventions and that many will now pass the first of the two-step Alice/Mayo test

Algorithms themselves and their integration with a computer are not necessarily off limits. Recent evidence suggests that the most likely way forward is through the careful drafting of a patent specification, with an emphasis on detailed technical description of the applicability of AI to the diagnostic outcome and how the use of AI is transformative rather than simply a substitute for extended human endeavour.

United States

Turning to the United States, the situation becomes a bit more complex. The US Supreme Court has invalidated patents directed to diagnostics and computer-implemented inventions in the following seminal cases: *Mayo Collaborative Servs. v. Prometheus Labs Inc. [2012], Alice Corp. Pty Ltd v. CLS Bank Int'l [2014]* and in the US equivalent, Myriad (BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation [2014]).

In Mayo, the plaintiff – specialty pharmaceutical and diagnostics company Prometheus Laboratories – had patented a suite of tests for assessing the correct dosages of certain Crohn's disease medications. When Mayo Clinic developed its own similar tests and began using them, Prometheus sued Mayo for infringement. The US Supreme Court invalidated Prometheus's method patent and provided a framework for determining patent eligibility in two steps. In 2014, the US Supreme Court went on to clarify Mayo in Alice, which resulted in the so-called Alice/Mayo test.

As part of the two-step test, it is first determined whether the claims are a law of nature, natural phenomenon or an abstract idea (known as 'the judicial exceptions'). What constitutes an abstract idea is relevant when considering computer-implemented inventions based on AI, for example, because US courts have invalidated patent claims covering subject matter that could be performed through an 'ordinary mental process', 'in the human mind' or by 'a human using a pen and paper'. When one considers the development of AI technology, particularly medical AI, this is in fact what the invention is – the supplementation of the human mind with intelligent software.

Cases including *Ex Parte Kirshenbaum [2013]* can inform approaches to achieve patent protection in AI-based technologies. Specifically, the US Patent Appeal Board stated that eligible inventions are those that have a feature or limitation that produces a 'useful, concrete and tangible result', without pre-empting an abstract idea like a mathematical algorithm. Furthermore, patent-eligible inventions that can be described in terms of structure (what it is) rather than functionally (what it does) will have a better chance of allowance.

Since the Alice decision, the United States Patent and Trademark Office (USPTO) has issued several iterations of practical guidance for evaluating subject matter eligibility. Throughout this period, concerns have been expressed that different examiners within and between technology centres have applied inconsistent standards due to a lack of clarity on how the 'judicial exception' to subject matter eligibility should be applied. This has created a challenging environment for inventors and companies trying to reliably predict the outcomes of patent examination. Public demand for clarity and consistency has led to the latest 'Revised Patent Subject Matter Eligibility Guidance', released by USPTO Director Andrei Iancu in January this year.

The 2019 Guidance is just that – a set of guidelines with no legislative changes; however, an optimistic view suggests that the recent changes will provide consistency and clarity to what was essentially a roll of the dice approach that a US examiner might take in claim interpretation, especially in the area of AI diagnostics. Early indications are that the guidelines have constructively softened the approach to patenting computer-implemented inventions and that many will now pass the first of the two-step Alice/Mayo test.

While patent law is perhaps not moving at the same pace as the growth of AI techniques in diagnostic testing, the signs in the United States are positive for the patentability of this subject matter. Since the US courts, at least in the past, have led the world in advancing the technology cover afforded by patent law, and since Australian courts have tended to follow their US brethren, although we might be waiting a while, Australian innovators in the field of artificially intelligent diagnostics can be optimistic.

IMPACTS OF EUROPEAN MEDICAL DEVICE REGULATION

2017/745 (MDR)

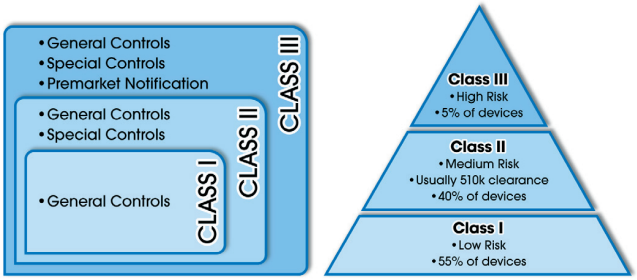
As time goes by, European Medical Device Regulation (MDR) is getting closer. Potential Notified Bodies (NBs) are currently being assessed in order to be prepared for the big changes affecting the requirements on manufacturers, products and the procedures of NBs. A major change is that any refused or withdrawn application must be reported to the European Database on Medical Devices. This largely impacts how applicants are recognised by other NBs after a refusal or withdrawal of an application.

For the manufacturers, one of the biggest changes is to the requirements covering the management system. For example, each manufacturer must be able to demonstrate that at least one competent person has the required expertise for complying with regulatory requirements and requirements of the law. The competent person absorbs the legal responsibility for the key tasks. This may include things like adequate verification of the conformity of the products, availability of appropriate and up-to-date technical documentation, and post-market monitoring of the devices, to name a few.

Now, Unified Device Identifiers (UDI) mark any product placed on the market. While aspects like 'general safety and performance requirements' and 'a beneficial risk analysis and risk management' are already implemented under the Medical Device Directive (MDD) by harmonised standards, under MDR their meaning is emphasised to evaluate and safeguard the continuous and permanent safety and effectiveness of medical devices. Items like Post Market Surveillance Plan (PMSP), Periodic Safety Update Report (PSUR) and Post Market Surveillance Report (PMSR) are completely new.

Transition rules are in place to help kickstart MDR and most products can be transitioned smoothly to MDR, but some will experience a hard cut. For example, reusable surgically invasive medical devices fall under a new classification that does not exist under the current MDD 93/42/EEC: class I – reusable. Meanwhile, conformity evaluation of software will experience major changes that will lead to reclassification from I to IIa, IIb or even III, which will then lead to the involvement of an NB. Another new product group has been implemented for medical devices consisting of substances or components of substances. All of these changes result in a cut-off point from the effective date of the European MDR – 25 May 2020.

DQS MED (Notified Body) – Under Corporate Directive CD 93/42/EEC provides system certification assessments under ISO 13485, MDSAP, ISO 15378, ISO 9001 as well as CE certification of medical devices. For more information, visit www.dqs-med.de/en.



SHOULD FITNESS WATCHES BE REGULATED AS MEDICAL DEVICES?

BY MEAGAN RYAN, INTELLECTUAL PROPERTY DISPUTES LAWYER IN MELBOURNE

The functionality of fitness watches is rapidly expanding alongside the market for wearable technology in general. This article identifies the advantages and disadvantages of increasing the regulation of fitness watches, and explores whether these watches should be subject to regulation as medical devices. Regulation is needed to address concerns arising from user privacy, data ownership and data usage. Whether it is currently necessary for fitness watches to be regulated as medical devices is debatable, although this need is likely to eventuate in the future.

Why regulation is necessary

The market for fitness watches is growing. This growth stems from the combination of a health-conscious population with the colossal industries of technology, and health and fitness. The global sales revenue for such devices was US$2.49 billion in 2016 and is estimated to be worth US$3.33 billion in 2022. The functionality of fitness watches is also increasing, particularly compared to the first generation of devices, which were essentially just clocks and pedometers.

Fitness watches now track and record a multitude of data points. The recorded data is often assimilated with a smartphone application and linked to other applications (like Strava and MyFitnessPal). This creates bulk data about wearers' daily lives, including what they ate (when tracked by the user), where they were, their activity levels and how much they slept, as well as the important physiological measure of heart rate and function.

The regulatory framework in Australia that impacts fitness watches includes privacy law, information law, consumer law and insurance law. Whether or not fitness watches should be regulated as medical devices depends on many factors, including the accuracy of the data collected and the context of the use.

Types of regulation

Meagan Ryan

Regulation can take many forms. It can occur through hard top-down regulation imposed by the government through statute. Regulation can also occur through soft bottom-up regulation imposed through compliance with industry standards. The line between fitness watches as consumer devices compared to medical devices is increasingly blurred. Accordingly, it may now be appropriate to view fitness watches as medical devices rather than consumer devices and to regulate them accordingly.

The current definition of a medical device could already encompass fitness watches where fitness watches are used to alleviate symptoms through exercise. Fitness watches are an instrument (used alone or in combination with others, including the software necessary for its proper application) intended by the supplier to be used by people for the purpose of one or more of the following: diagnosis; prevention; monitoring; treatment or alleviation of disease; investigation; replacement or modification of a physiological process; and that does not achieve its principal intended action on the human body by pharmacological, immunological or metabolic means.

The exception for 'metabolic means' does not exclude fitness watches from the definition of medical devices. Simply wearing a fitness watch does not impact the metabolism. Rather, it impacts the wearer's motivation to exercise. Exercise is part of the treatment for many illnesses, including depression, obesity, diabetes and cardiovascular diseases. Fitness watches and affiliated applications are already being used in a medical setting, with patients using such devices to self-report activity levels to general practitioners. The use by medical professionals of the data from the devices

will be the next step, particularly with the widespread introduction of electronic health records. Fitness watches perform functions similar to existing medical devices – for example, an implantable loop recorder, which is a cardiac monitor placed in the patient that provides the cardiologist 24/7 access to a patient's heart rate data.

Companies who produce fitness watches are already envisaging the use of their products in the provision of medical care. For example, Garmin has a subsection called Garmin Health, which 'provides enterprise solutions that leverage Garmin wearables and the high-quality sensor data they produce for applications in the corporate wellness, population health and patient monitoring markets'. Regulators also need to see fitness watches as part of the future of the health industry and regulate accordingly.

The current regulation of therapeutic goods is facing significant reform, including a review of the cybersecurity of medical devices and the scope of the medical device regulatory framework. This reform should include consultation on regulating fitness watches as medical devices, as well as the control, usage and ownership of data collected from fitness watches. Effective public health systems rely on access to population health data. The Australian Government recognises this, as is evidenced by its push towards gaining access to Australians' electronic health records. The data collected by fitness watches and held by private companies should be shared with the government for the purpose of public health.

Advantages and disadvantages of increasing regulation

An advantage of fitness watches being regulated as medical devices is that the Therapeutic Goods Administration (TGA) would be responsible for their regulation. This would ensure fitness watches meet requisite standards for safety and accuracy, as the TGA requires clinical and scientific evidence prior to the registration of medical devices.

Regulating fitness watches as medical devices may also make them eligible for government subsidies. This will increase accessibility to fitness watches and increase their positive health impact. Further, fitness watches classified as medical devices will have to comply with the outcome of the consultation on medical device cybersecurity.

A disadvantage of regulating fitness watches more strictly on data provisions or as medical devices is that such regulation could reduce Australian consumer choice. Regulations may result in the multinational producers of fitness watches not entering the Australian market with new products. This could lead to Australian consumers sourcing such devices from overseas. Regulation as medical devices could also curb innovation; however, companies that are conscious of consumer concern about their data will likely seek to avoid consumer backlash, and will adopt new regulations protecting data and controlling usage.

It's time

Fitness watches should be regulated as medical devices. Further regulation is required to address concerns arising from user privacy, data ownership and data usage. Increased regulation is appropriate given the type and accuracy of the collected data and the increased use of the data in medical settings.

The views expressed in this article are those of the author alone.

Meagan Ryan is an Intellectual Property Solicitor. She studied at Bond University as a Vice-Chancellor's Scholar gaining a Bachelor of Laws/Bachelor of Biomedical Science. Ryan has a Master of Laws (Intellectual Property and Information Law) from King's College London.

UNTAPPED MEDICAL TECHNOLOGY OPPORTUNITIES IN ASIA A HUGE POTENTIAL

BY ELIZA CHONG, MANAGEMENT CONSULTANT, MEDTECH, IQVIA ASIA PACIFIC; AND ANDRE TAN, BUSINESS DEVELOPMENT MANAGER, MEDTECH, IQVIA AUSTRALIA & NEW ZEALAND

The Asia-Pacific (APAC) is the fastest-growing region for medtech, home to nearly 4.4 billion people (60 per cent of the world's population), and by 2025, 1.1 billion people will be over the age of 50. There is greater need for healthcare solutions, driven by socio-economic developments, ageing populations, growing demand for more effective treatments and expansion of universal healthcare programs.

The APAC medtech market is evolving and growing rapidly. The market is expected to expand between eight and 12 per cent compound annual growth rate (CAGR) in the coming years, outgrowing the United States and European Union, which are only growing between four and five per cent, driving the total size from US$88 billion in 2015, up to US$133 billion in 2020. Along the way, APAC will surpass the European Union to become the second-largest medtech market. This growth is underpinned by technological progress and recognition of the fact that these products create value for patients and payers. Increasingly, technologies are being introduced that treat a fast-growing number of diseases and meet the needs of increasingly value-focused healthcare systems.

Within the APAC region, Australian and New Zealand (ANZ) medtech companies are in an advantageous and competitive position to develop relevant products to take advantage of opportunities in Asia, due to several favourable local (but not entirely exclusive) factors, including:

- traditionally strong links to high-quality research institutions and therapeutic subject matter expertise within ANZ, and globally though collaboration networks
- close geographical proximity to other markets within the APAC region
- a talented local workforce that has historically developed niche products across key areas of innovation
- a local heritage of commercialising products with relatively lower levels of access to transformative capital compared to other markets, resulting in companies that are highly capital-efficient and have know-how of driving value growth with limited capital
- strong ties with Asia, including multiple free trade agreements, encouraging greater access to markets.

A shift in perspective: the sensibilities of making Asia the first stop on the way to global domination

Though the United States and European Union had been the conventional primary target markets for new product commercialisation, the challenges of navigating reimbursement/payer-provider dynamics and the geographical separation between ANZ and those markets present well-known and persistent challenges for nascent companies trying to enter. This had led to a 'survival of the fittest' phenomenon whereby many promising early medtech start-ups fail prematurely due to their inability to achieve financial sustainability in their budding days.

It is imperative that ANZ companies adopt a new set of lenses when considering their global go-to

market strategy. The attractiveness of Asian markets is obvious and within reach for a flourishing ANZ medtech industry.

Therefore, developing products and services that cover both the needs of APAC and more mature healthcare markets is a strategic position that may bring into view broader commercial opportunities. There are many benefits of an 'Asia-first, followed by mature-market' entry strategy, including:

- reduced time to revenue by selecting markets with greater unmet needs and shorter regulatory timelines, with reduced need for dilutive capital raises
- an established sustainable revenue from Asia, which can help to support higher-risk product development activities aimed at other mature regions
- the mitigation of regulatory risks in the European Union: Substituting/supplementing EU revenue with Asia, as the regulatory changes in the European Union with the switch to the Medical Devices Regulation framework, continues to drive compliance uncertainty for many manufacturers
- synergy in clinical pursuits: Companies with new technologies can easily gain access to a large number of treatment-naive patients and willing collaborators for clinical trials across the region. This is reflected in the rapidly increasing number of clinical trials undertaken by medical device companies; 393 unique trials were conducted in Asian countries in 2015, and this number is expected to grow by 28 per cent as more local regulators are demanding local data. ANZ companies can take advantage of its multi-ethnic population and close academic ties to facilitate the generation of relevant clinical evidence, which can be used to expedite registrations and market access in Asian markets
- the growing population purchasing power of Asian countries: By 2025, more than half of 1.5 billion people in developing countries will be of a 'consuming class' with disposable income of more than $3600
- the availability of financing: As Asian investors look to other non-traditional investment assets, and as health care is often perceived as a 'safety' asset, the availability of such financing is instrumental to enable companies to scale and grow rapidly within Asia
- the ability to leverage benefits in clinical education and training: With the rapid development of healthcare infrastructure, healthcare professionals from developing countries will look to advanced systems for training and education. ANZ's world-class facilities and capabilities are much more appreciated by Asian healthcare professionals looking to reference and learn from rather than those from more mature countries. This will allow ANZ's fledging companies with innovative technologies an opportunity to train from their home ground and leverage ANZ's key opinion leaders and other assets in a cost-effective and impactful way.

Forging ahead to unleash the opportunities in Asia

Along with the advantage of operationally leveraging the favourable factors previously mentioned, there are a plethora of resources that ANZ companies can utilise. For instance, in funding, companies can apply for various sources of incentives such as Australian Research and Development (R&D) Tax Incentive, Biomedical Translation Fund and Medical Research Future Fund. There are also heightened network effects being part of a vibrant medtech, biotech and pharmaceuticals (MTP) ecosystem consisting of public and private establishments across academia, industry, government and other areas.

ANZ companies that are keen to capitalise on Asia's growth prospects should aim to develop an expanded mindset to learn about the uniqueness and nuances of this highly heterogenous region. While there is no one-size-fits-all approach, the region can be stratified to take advantage of the opportunities that each market presents. ANZ's innovation-driven companies are uniquely placed to develop alongside their neighbours to unlock opportunities that are within easy access.

NEUROSCIENCE TRIALS AUSTRALIA

Understanding the nuances of neuroscience clinical trials

The challenges that exist in the neuroscience clinical trials space are often unique to neuroscience. With the limited understanding of the biology of neurological diseases and conditions, due to the inaccessibility of the brain and the consequent lack of validated biomarkers and molecular targets, the cost and failure rates of clinical trials in this field are often high. With the exponential increase in basic neuroscience research activity, it is vital that clinical trials are optimised to increase the chances of success, to drive health outcomes and to improve the lives of patients.

Neuroscience Trials Australia is uniquely placed in this niche as a highly specialised contract research organisation. As a wholly owned subsidiary of The Florey Institute of Neuroscience and Mental Health at the renowned University of Melbourne, Neuroscience Trials Australia is located in the largest research centre of its kind in the Southern Hemisphere, with access to world-leading brain researchers.

The Australian Government currently offers incentives to encourage research and development (R&D) activities to nurture productivity, prosperity and innovation. The R&D Tax Incentive helps companies by being better targeted at genuine R&D, more generous in financial support, more predictable by decoupling incentive from the company tax rate, and less complex and restrictive through the removal of intellectual property requirements. This in turn has made Australia among the top 10 most competitive locations for R&D investment and presents Australia as the place for conducting clinical trials.

However, to fully capitalise on this generous tax incentive in the neuroscience clinical trials space, a working knowledge of the complexities of neuroscience is paramount. We have a thorough understanding of the nuances of neuroscience clinical trials and with our experience, we continually work to address the evolving challenges that arise in this area. With this, we work across a variety of therapeutic areas, which include epilepsy, stroke, multiple sclerosis, dementia, mental health, Parkinson's disease, Huntington's disease, neurosurgery, pain and migraine. We have expertise in first-in-human drug, device and cell therapies trials.

Our state-of-the-art facilities in Melbourne include platforms such as laboratories (including diagnostic laboratories for amyloid and tau protein assessment), preclinical work, imaging facilities (including MRI, CT and PET) and translational research, as well as access to over 200 sites around Australia. Our staff, with an average of more than 14 years' industry experience, has global management expertise in all phases of clinical research, including studies sponsored by pharmaceutical and device companies, granting bodies, institutions and investigator-initiated studies.

At Neuroscience Trials Australia, our mission is to improve lives through brain research, while our vision is to be a world leader in brain research. We value innovation, excellence, commitment, passion, integrity, rigour, collaboration and teamwork.

neuroscience trials australia

Neuroscience Trials Australia (Neuro Trials) is a niche contract research organisation, committed to ensuring the highest quality conduct of clinical studies in accordance with Good Practices (GxP) that meet or exceed our client's expectations. Quality is the role of every Neuro Trials employee and is woven throughout all stages of our clinical development process.

AREAS OF EXPERTISE

Stroke and stroke-related conditions, multiple sclerosis, epilepsy, Parkinson's disease, spinal cord injuries, Huntington's disease, neurosurgery, pain, neuromuscular disease, ALS/MND, Alzheimer's disease, paediatric indications, orphan indications and migraine.

- DIRECT ACCESS TO CLINICAL TRIAL NETWORKS
- WHOLLY OWNED SUBSIDIARY OF THE FLOREY
- EXPERIENCED & MOTIVATED SITES IN AUSTRALIA & NEW ZEALAND
- LOCAL SPONSORSHIP
- STATE OF THE ART FACILITIES
- IMAGING STUDIES EXPERTISE
- EMPLOYER OF CHOICE
- VENDOR ASSURANCE
- DATA MANAGEMENT
- KEY OPINION LEADERS IN NEUROSCIENCE & CLINICAL TRIALS
- NTA PROFITS ARE REDIRECTED TO NEUROSCIENCE ACADEMIC RESEARCH
- RISK MANAGEMENT APPROACH TO MONITORING
- ACCESS TO R&D TAX INCENTIVE
- BIOMARKERS AND BIO BANKING

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THE POWER OF PRECISION MEDICINE TO DELIVER BREAKTHROUGHS IN KIDNEY DISEASE

BY PROFESSOR DARREN KELLY, CEO, CERTA THERAPEUTICS, AND ENTREPRENEUR IN RESIDENCE AT THE MEDICAL RESEARCH COMMERCIALISATION FUND (MRCF); AND PROFESSOR ROBYN LANGHAM, MONASH UNIVERSITY

Kidney disease and injury, or chronic kidney disease (CKD), is becoming more prevalent worldwide, largely attributed to the rise in a number of chronic health issues in modern society. Diabetes, obesity and hypertension are all on the rise, each contributing to the development of CKD.

It has been estimated that one in 10 adults show signs of CKD, and with the associated co-morbid complications of cardiovascular disease, together with the risk of development of kidney failure, the global health implications of these numbers are staggering. With the global spend on CKD estimated to exceed $1 trillion, it's clear that the treatment and management of kidney disease needs to be addressed urgently.

With a lack of new kidney disease treatments over the last 30 years, and a raft of recent failed clinical trials, it's clear that we need to rethink our approach, and precision medicine is revealing a demonstrable way forward.

Precision medicine is a well-developed approach in the oncology field, essentially utilising a convergence of genomic sequencing of tumour samples, biomarker research, bioinformatics and big data analysis. In oncology, precision medicine promises improved patient outcomes by better identifying those who may be suitable for new treatments. In applying elements of precision medicine to kidney disease, we can realistically expect to develop a far greater understanding of the pathogenesis of CKD, and ultimately see a greater response rate in new clinical trials, with more precise molecular-based inclusion criteria.

The value of precision medicine

Prior to the application of precision medicine to clinical trials for cancer patients, treatments were broadly aimed at retarding rapidly dividing cancer cells in tumours, resulting in negative effects on other healthy cells within the body. As tumours could only be classified on the basis of their appearance under the microscope, treatments were broad-based, with no subtle variation within the same tumour cohort.

Professor Darren Kelly

Professor Robyn Langham

With the recognition of oncogenes, a mutated gene within all cells of a specific tumour, as central to the development of a number of cancers, treatments to specifically block the action of the oncogenes were developed. Successful response to treatment was increased, as only patients with tumours that expressed the oncogene were included in the clinical trial process.

Over the last decade or so, more complex and increasingly sophisticated biomarkers have been identified, with the ability to stratify patient populations with increasing granularity and greater numbers of treatments to match. Trial design has evolved to include so-called 'basket designs', where prospective treatments are matched to the genetic abnormalities identified in tumours.

Precision medicine for non-cancer diseases

The development of precision medicine in non-cancer cohorts of all descriptions has lagged behind what has been achieved in cancer studies because of the inherent differences in the tissues involved and in the mechanisms driving disease. In the case of kidneys, around 20 or so different cell types make up the normal kidney, with an influx of additional cells in most disease states – a far cry from the uniform cell population of a tumour sample.

In addition to more complex and diverse cell types and tissue structure, there are also many different possible mediators of disease, with complex response pathways resulting from each insult (be it diabetes or hypertension) often different in each cell type. Precision medicine in non-oncology cohorts utilises more in-depth analyses of cell function, moving beyond genomics into transcriptomics, proteomics and metabolomics.

Collectively, study of the '–omics' comprises a systems biology approach, which is heavily reliant on computational analysis of the huge datasets that are generated from complex tissue studies – a multilayer molecular signature, if you like. In some parts of the world, researchers are collecting rapidly growing patient cohorts that now have robust and extensive systems biology analyses: large disease groups of patients each with well-characterised molecular signatures. Existence of these patient cohorts are now enabling a precision medicine approach to kidney disease where previously not thought possible.

Implications for clinical trials

The experience of clinical trials in CKD over the last few years has emphasised the need to not only understand the cellular target of the new agent, but also to measure the action of the agent from the perspective of the whole tissue. Early transcriptomic studies of a novel Certa Therapeutics compound have identified the complex downstream pathways that are affected by the new drug in the preclinical setting. And like the precision medicine oncology approach, the complex downstream molecular effects of treatment can then be matched to disease states where specific molecular signatures have been identified from within patient kidneys.

This cutting-edge research by Certa Therapeutics, in collaboration with the team at University of Michigan led by Professor Matthias Kretzler, will enable a more tailored approach to a clinical trial in kidney disease than was previously possible. Clinical trial recruitment will include a consideration

of a disease's molecular signature to align with drug effect, providing more effective treatment at an individual level, rather than mildly effective treatments under a 'one size fits all' approach.

Conducting clinical trials featuring large cohorts is expensive, and the lack of significant developments in kidney medicine makes it clear – there's no silver bullet. Testing targeted compounds on specifically identified patient populations yields far better results for less money.

Precision medicine–based clinical trials are smaller, with higher response rates expected, and are therefore less expensive.

Ultimately, targeted drugs with higher response rates will benefit the community not only through better clinical outcomes, but also by lowering the cost to the health system. Most importantly, clinical trials informed by precision medicine deliver better results for the patients, who will have a louder, clearer voice in regard to the direction of their treatment.

The economic cost alone of operating a large-scale clinical trial is phenomenal. Forbes recently reported that the cost of developing a drug through to clinical trial can cost up to US$1 billion. A hefty price tag for a compound that may only work for a certain percentage of the trial group.

Prioritising a precision medicine approach to clinical trials will result in drastic improvements to patient treatment – this is already happening. I expect that as precision medicine in the non-oncology field has demonstrated utility in clinical trials, more and more companies will adopt the approach in order to maximise outcomes, ultimately driving this to become the standard approach to clinical trials.

THE FUTURE OF SAFE REFUGE

BY MINEARC

Can life be sustained in space? The future of safe refuge and designing systems to be able to support human and plant life indefinitely is already underway.

While Hollywood movies, such as *The Martian*, use drama and computer graphics to highlight our ability to survive in a hostile environment, the technologies depicted are not too far from reality.

As leaders in refuge chamber technology, we have extended this knowledge to the development of state-of-the-art monitoring and control technologies: GuardIAN and Biora. These developments, with the aid of Controlled (Closed) Ecological Life Support Systems (CELSS), form the basis for providing significant refuge periods. The future of safe refuge, and designing systems to be able to support human and plant life indefinitely, requires some key considerations.

CELSS

CELSS are highly involved, bioengineered systems that rely on plant growth to provide the principal elements of life-support – from food production and gas conversion, to water reclamation. During the 1960s, the Soviet Union pioneered CELSS during experiments for a regenerative life-support system for space colonies. Even now, 50 years later, colony proposals for Mars and the Moon would undoubtedly require very long-duration space station refuge volumes.

The general principle of CELSS is that plant growth chambers provide oxygen, food and fuel requirements for extended periods of refuge. Further to this, the plants would work to consume carbon dioxide and bodily wastes from the occupied areas of the refuge/living chamber, as well as providing humidity control through the condensation of an air conditioner feeding water into the plant area

Plant growth and environment control

MineARC Systems have been developing controlled environments for a variety of plant growth scenarios, from LED lighting design with a focus on capturing and manipulating as much of the usable light spectrum as possible, to the manipulation of gases and temperature within a chamber to maintain optimal growth and sustainability.

Similarly, hydroponic and aeroponic techniques are being trialled in conjunction with the development of control software and measurement instruments that best suit growth control.

Key areas of plant growth environmental control

A plant growth chamber, such as Biora, will require key elements to be controlled within its volume, despite any growing techniques employed through hydroponics. These include:

Light: An artificial light source (in MineARC's case, generally LED) provides or supplements the light spectrum required for each stage of the plant growth, ultimately for photosynthesis of larger-foliage plants and algae.

Temperature: Plants grow within a limited temperature range, effectively within the survivable limits of human occupation. Coupled with relative humidity, which is usually higher than human comfort levels, this aspect of plant growth compliments the current designs MineARC have developed through long-term refuge chamber manufacture.

Water: Good-quality water needs to be provided to plants. Filtration and pH levels, as well as precise amounts of water by weight, all need to be controlled to ensure proper plant growth.

Carbon Dioxide: Carbon dioxide can be added to the system for periods of time to help stimulate plant growth; however, not all plants will thrive in these conditions and not many will survive with sustained (continuous) high levels of elevated carbon dioxide.

Oxygen: Plants, like humans, still require oxygen during respiration and water intake. Without sufficient oxygen and periods of rest, an effective plant habitat cannot be maintained.

System Control: It's clear that the systems required to maintain plant life, in conjunction with any human life support, will be complex. Control systems will need to continually monitor and analyse environmental conditions and CELSS over prolonged living periods.

Moving into the future, MineARC Systems will be investigating the limitless possibilities of refuge chamber technology. We are committed to the continual development and exploration of current technologies, for the enhancement of mankind, to infinity and beyond.

mineARC SYSTEMS

biora

RESEARCH GRADE CHAMBERS

Biora Research Grade Chambers are designed to provide the capability of replicating extreme environmental conditions. The facilities are custom-engineered to offer complete control to efficiently sustain precise testing conditions for plant science and agricultural biotechnology applications.

Brought to you by MineARC Systems; the leading global manufacturer of refuge chambers and controlled environment technologies.

PC Certifiable Chamber Solutions

Full Spectrum LED Lighting

Gas Monitoring and O_2/CO_2 Control

Built-in HVAC System

Security and Real-Time Remote Monitoring

Airlock & Anteroom Options

- RESEARCH GRADE REACH-IN AND WALK-IN SOLUTIONS
- CUSTOM ENGINEERED, WITH CLIENT CONSULTATION
- AUSTRALIAN DESIGNED AND MANUFACTURED

20 CELEBRATING YEARS mineARC SYSTEMS

For more information go to WWW.MINEARC.COM

A HOME FOR medtech manufacturing

'Innovation lives in places. It needs a home,' says John Kao, US innovation expert, author and former Harvard Business School Professor.

In an era where connectedness is paramount to drive innovation and entrepreneurship, collaboration and co-location are essential to support Australia's growing health, medical devices and assistive technologies sector.

Adelaide has one of the Southern Hemisphere's largest clusters of medtech companies and research institutions, making South Australia a leader in this field.

BioMed City provides research, education, clinical care and business development, while Tonsley Innovation District – just 10 kilometres to the south – has become Australia's home of medtech manufacturing.

Tonsley has been transformed into Australia's most awarded innovation district since redevelopment of the site, a former Mitsubishi car plant, began in 2010. With an emphasis on high-value manufacturing, Tonsley unites individuals, businesses and researchers to collaborate and grow in a flexible and supportive environment.

Health, medical devices and assistive technologies is one of four focus sectors at Tonsley, capitalising on South Australia's advanced manufacturing and health industries skill sets.

Professor Karen Reynolds, Director of Flinders University's Medical Device Research Institute at Tonsley, says the district has a lot to offer manufacturers in the sector.

'What we are trying to achieve through Tonsley is a growing ecosystem in medical devices: a cluster of research, industry, service providers and government organisations, centered around the Tonsley development,' says Reynolds.

'I think to identify opportunities for manufacturing, you need to be part of that ecosystem.'

Tonsley has attracted innovative medtech businesses that understand the benefits of this model, including:

- Micro-X – designs and manufactures ultra-lightweight, mobile x-ray imaging systems for medical and security applications. It is now undergoing significant growth and doubling its footprint at Tonsley.

- ZEISS – international optical and optoelectronics firm, a leading developer, producer and distributor of measuring technology, microscopes, medical technology, eyeglass lenses and more.

- Somark – manufactures systems and technology to analyse animal data for pre-clinical research.

The Medical Device Research Institute (MDRI) is committed to high-quality research, encompassing assistive technology and rehabilitation engineering; biomechanics and implants; computational biomechanics; devices, sensors and signals; health informatics; medical image analysis; and medical simulation.

The MDRI facilitates collaboration across engineering, medicine and science, and works closely with the medical device industry. Its Medical Device Partnering Program (MDPP) is an ideas incubator that supports early innovation and technology development by bringing together researchers, clinicians, end users and manufacturers.

The Global Centre for Modern Ageing is closely connected to the health, medical devices and assistive technologies sector. It helps organisations and individuals to devise, build and commercialise products and services that enable older people to live and age well. Its LifeLab is a real-time test facility, which allows businesses to invent and trial products and services in a simulated 'real life' environment.

Tonsley is also close to Flinders Medical Centre, Flinders Private Hospital and Flinders University's main campus, while its College of Science and Engineering is at Tonsley.

For more information, please visit www.tonsley.com.au/health.

JOIN OUR LEADING MEDTECH HUB

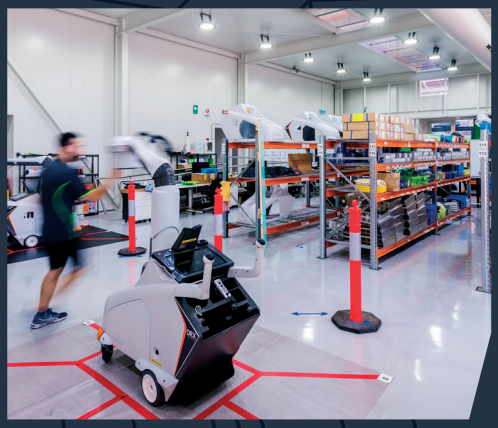
Want the benefits of being co-located with other innovative companies and researchers in the thriving medtech sector?

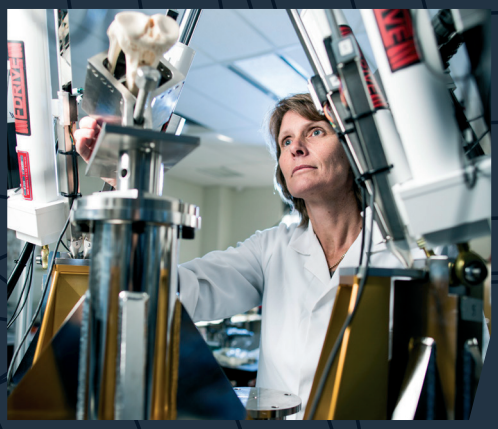
Australia's most awarded innovation district, Tonsley, is already home to companies and organisations such as global optical leader ZEISS, portable X-ray pioneer Micro-X, medical research technology developer Somark, the Global Centre for Modern Ageing, and Flinders University's Medical Device Partnering Program and Medical Device Research Institute.

Join these like-minded organisations on our 61ha mixed-use site, just 10km south of Adelaide's city centre and booming Adelaide BioMed City and only 1.5km from Flinders Medical Centre.

Choose from office and manufacturing spaces and become a part of an exciting future at Tonsley Innovation District.

More: tonsley.com/health





Tonsley
Innovation District

RenewalSA

Government of South Australia

THREE GUIDING PRINCIPLES FOR SUCCESSFUL COLLABORATIVE PARTNERSHIPS

BY DR SAMIH NABULSI, MANAGING DIRECTOR, COOK MEDICAL

The common theme that underpins more than five decades of successful innovation at Cook Medical is collaborative partnerships.

In the early days, collaboration with physicians led to the development of the company's first medical devices. The process would start with a physician identifying a problem and approaching Cook to work together to solve an immediate clinical or patient need.

Today, Cook Medical still views innovation through the 'patient first' lens, but our partnerships are significantly more diverse. Collaborations with researchers, inventors and entrepreneurs exist across every imaginable facet of product design and development, and clinical applications, and we are now able to make connections between seemingly disparate fields to drive medical device innovation.

Although the pathway to innovation is anything but linear, there are three guiding principles that are central to the success of collaborative partnerships in the medical device industry. Where there is alignment on these three principles, there is a foundation for collaborative partnerships to thrive. These principles are:

1. Clarity of purpose

To build a solid foundation for an effective working relationship over the long term, there must be clarity of purpose on two levels: at a project level and at an organisation level. By truly understanding what each party is seeking, there can be no confusion as to the motivations of each partner.

To assess shared purpose, first consider the potential partner's track record – what they have done in the past and who they have collaborated with – and simply ask what they are seeking from the collaboration. If their answer is, 'We'll do whatever it is that you want us to do', this illustrates that the potential partner either does not know what they want or that they lack a vision and therefore the passion for their ideas. This is different to 'I don't know and want to explore the potential for a partnership'.

Samih Nabulsi

Regardless of whether a partner's motivation is financial, discovery-driven or patient-centred, clarity of purpose ensures that everyone is on the same page from the start. The approach to each partnership will naturally be different and reflective of that potential partner.

It is also important to remember that people are central to collaborative partnerships. Getting the right people involved from a technology point of view is only one piece of the puzzle. Establishing whether you can work effectively with the same people is the other. No matter how good an opportunity may appear, a partnership will never really work if there is no connection.

To this end, partnerships can also be stress tested. Before taking on a large collaborative project, consider smaller initiatives – for example, a number of projects over several years – in order to lay the foundation for larger opportunities.

2. Openness and access

Openness is the foundation for building trust. This requires potential partners to establish a common understanding of all aspects of the partnership.

Unsurprisingly, the most common source of misalignment with potential partners centres on the value of what each party brings to the partnership. We see this time and again in complex or highly regulated industries, such as medical devices.

Where there is no background in medical devices, specifically high-risk devices, ensuring that potential partners understand the complexities of the industry, especially in the areas of risk and scalability, is critical to ensuring alignment on value.

Depending on the nature of the product or technology, alignment on valuation can take weeks, months or even years. This is where being a privately held company has a distinct advantage when it comes to working in partnerships, choosing to invest the time required and being open to the possibilities.

Exposure and education close the knowledge gap, and also provide the foundation for what becomes a realistic conversation about the true market value of the idea, which is required to take a new product or technology from concept to commercialisation.

To reach alignment on value, consider providing potential partners with access to people and resources across the entire business, including clinical trials, reimbursement, regulatory and manufacturing, for example. Although time- and resource-intensive, this is one of the most effective ways to educate, build trust and gain consensus on value up-front.

3. Sustainability

The nature of partnerships in the medical device industry has changed, and collaborations across a diverse network of partners is proving vital to advancing and accelerating innovation.

Medical device companies are now entering into collaborative partnerships in the fields of materials science, robotics, photonics and sensing. Commonly, these are disruptive technologies from the university sector, as well as entrepreneurs who have graduated from the growing number of venture-capital-backed incubator programs.

The value of these collaborative partnerships is generally realised over the long term. Focusing on sustainability, and creating an environment with the right conditions and frameworks for these partnerships to thrive, is key to realising this value.

There are numerous partnership and funding models to consider, each with their own pros and cons. Cook Medical's model has evolved into a platform of shared risk and shared reward, and aligns with our focus on building sustainable and socially responsible partnerships. In this model, our experience shows that commitment of parties tends to be greater, therefore the strength of the partnerships is inherently greater.

It is, however, important to remember that not all successful collaborative partnerships result in successful projects, but the advantage is that they often open the door to new opportunities.

MICROSCOPY SUPPORTING AUSSIE MEDTECH START-UPS

BY DR JENNY WHITING, MARKETING AND BUSINESS DEVELOPMENT MANAGER, MICROSCOPY AUSTRALIA

Getting a product to market can be a long and hard road, no matter how innovative your ideas may be. In the medtech sector, a new scheme is already helping start-ups to access heavily subsidised, essential analysis to help them validate their products and processes.

Little Green Pharma (LGP) is one of the first recipients of Microscopy Australia's Technical Vouchers. LGP is developing and producing Australian-made therapeutic cannabinoid formulations for the medical market.

Little Green Pharma

LGP is the first company to produce and bring 100 per cent Australian-made, pharmaceutical-grade medicinal cannabis formulas to the Australian market. This privately held pharmaceutical start-up was founded in 2016 in Perth, Western Australia. After securing the necessary permits and establishing manufacturing partnerships in 2017, LGP is developing new pharmaceutical-grade medicinal cannabis formulations for Australians with unmet clinical needs.

Damian Wood, Head of Pharmaceuticals, says, 'The first product we introduced to the Australian market was an oral oil formulation, where each millilitre contains 10 milligrams tetrahydrocannabinol (THC) and 10 milligrams cannabidiol (CBD) derived from medicinal cannabis whole plant. This THC and CBD in a 1:1 ratio is a common starting point for medical practitioners. We have recently started to expand our range of oil formulations, and we will also introduce novel, patented formulations made possible through collaboration with academic partners. We will continue to work with these partners to conduct preclinical and clinical development research and development (R&D) work with these new medicinal cannabis formulations, which will offer patients an equally efficacious product with fewer active ingredients, which we believe could lead to fewer side effects and better outcomes'.

This is where sophisticated electron microscopy has been able to help. Lilly Bojarski, Medical Science Liaison (NSW), explains the process: 'Engaging with Microscopy Australia through their facility at University of New South Wales (UNSW), we have been able to validate the physical make-up of some of our novel investigational formulas. This work, supported by a Microscopy Australia Technical Voucher, was very timely, as we were able to use world-class resources, including the new Talos Arctica cryo-EM instrument, to image our samples'.

LGP has subsequently been granted another voucher to continue research, enabling it to monitor formulas for any degradation during various storage conditions. The company's continuing engagement with academic research partners is allowing it to develop novel approaches to delivering cannabinoid-containing formulas as efficiently as possible for maximum clinical effect.

Bojarski continues, 'We intend to maintain our association with Microscopy Australia as we are committed to continuing R&D in the medicinal cannabis space'.

Find out more about Microscopy Australia's Technical Vouchers at: http://ammrf.org.au/industry-services.

SABRE MEDICAL PTY LTD

providing solutions for your medical devices

As medical device developments continue along a path of design, testing and refinement, Sabre Medical provides a landing pad for the developer where they can use our systems and products to help manufacture their device.

We offer the following services:

- device design and consultation; we have mechanical, chemical and biomedical professionals – as well as microbiologists – all in-house
- manufacturing assembly, cleaning and packaging
- cleanroom facility and technicians for hire or contract
- packaging design, testing, validations, device ageing and conditioning
- sterilisation with ethylene oxide
- finished product storage and distribution
- consumables: pouches, trays, foams and cartons, cleanroom consumables and disinfectants
- heat sealing machines.

With access to these services and experts, we can smooth out the process of device manufacturing and the associated validations, helping to bring your product to the market sooner.

Sabre has made significant investments into a humidity-controlled class-seven cleanroom and ethylene oxide sterilisers. There is no need to invest in expensive equipment for end-of-line packaging; our team of engineers and scientists will engage with your activities to take each project through the stages of product realisation to market readiness.

The package design process offers more than just a pouch or a bag. Packaging solutions can incorporate pouches, trays, single or double barriers, foam, polyurethane and other protective packaging materials to provide the best packaging configuration for your device. We have stocks of pre-validated, ready-to-go packaging pouches or trays, and can manufacture custom sizes with very short lead times.

We offer heat sealing machines for sale or hire that will seal a wide range of medical device materials: films, foils, papers and polymers. Our machines are compliant with ISO11607 Sterile Barrier Medical Device requirements for packaging. Validatable pouch or tray sealers and machines that integrate gas flushing or vacuum functions are on offer. We also provide the option of regular maintenance and calibration of machines.

Sabre has proven experience in developing package validation plans, executing the plan in short time frames and providing a significant portion of your design dossier.

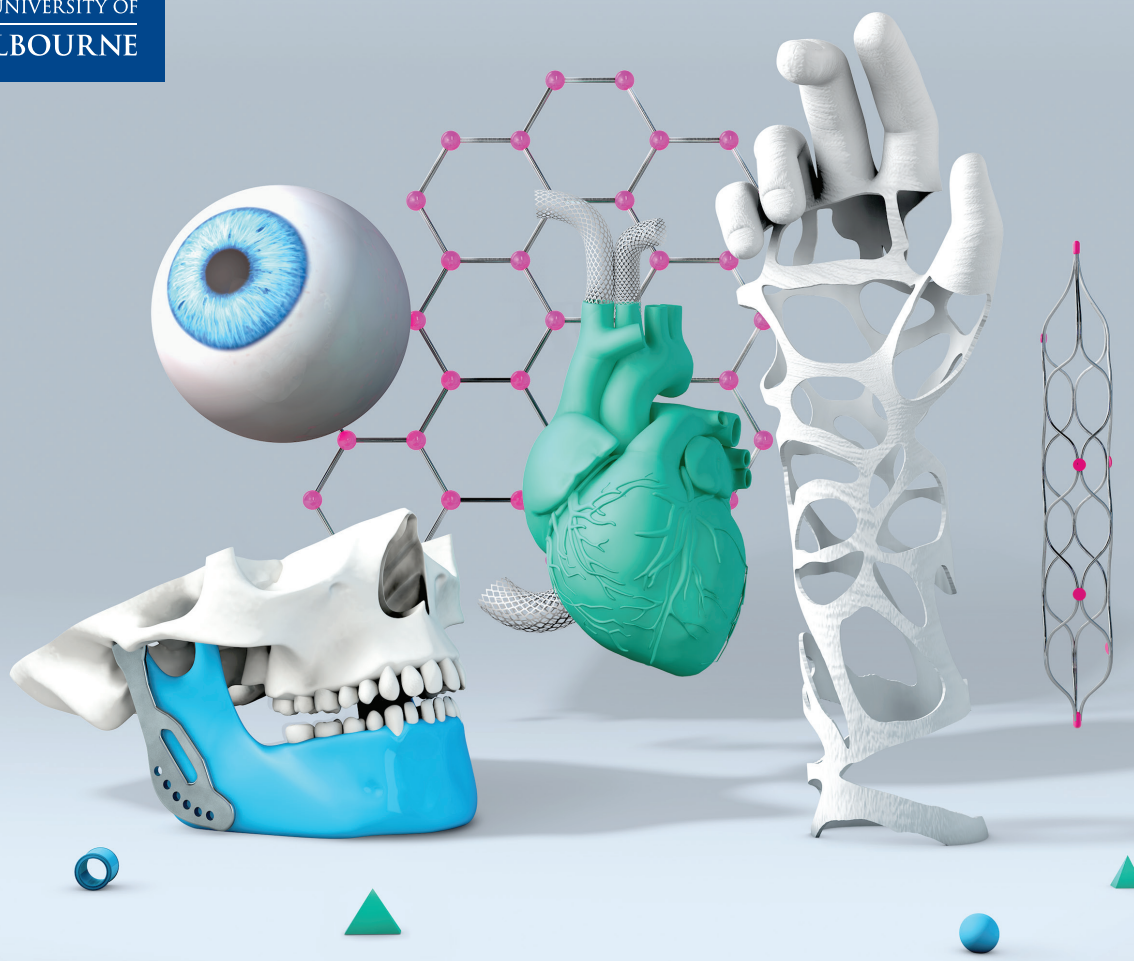
Our packaging testing services will slot into your validation plans. We understand that proving the reliability of your package and packaging systems provides the foundation for your sterilisation validation, and is critical in providing you sterility assurance.

We offer a class-seven cleanroom and associated packaging rooms within our facilities in Lane Cove and hepa filtration with the capacity to accommodate up to five operators. The cleanroom facility can be used with either your own team or Sabre's staff. To ensure that only the highest standards are maintained, we provide orientation and training in accordance with ISO 14698-1.

The facility operates both a small and large ethylene oxide sterilising chamber. We offer a full validation, or simply a gas exposure cycle, for trials and developments.

We are listed on the FDA website as a contract steriliser, which will enable you to make the transition to a global market while still staying close to home.

THE UNIVERSITY OF MELBOURNE



JOIN US AT THE LEADING EDGE OF AUSTRALIAN INNOVATION

OUR RESEARCH IS REVOLUTIONISING BIOMEDICIAL ENGINEERING TO CREATE REAL-WORLD IMPACT

We are driving research, education, innovation and commercialisation in:

- Implant systems and biomaterials
- Cell, tissue and organoid engineering
- Bionics and neural engineering
- Nanomedicine and antimicrobial materials
- Pharmaceutical manufacturing
- Systems and synthetic biology
- Biomedical imaging
- Biomechanics and mechanobiology

FIND OUT MORE

biomedical.eng.unimelb.edu.au
clarkinstitute.unimelb.edu.au

BIOMATERIALS, BIOFABRICATION AND REGENERATIVE MEDICINE

The Department of Biomedical Engineering and the Graeme Clark Institute combine materials science and engineering with biology and clinical expertise. This collaboration enables us to engineer tissues that can provide insights into diseases, assist in natural repair processes, enable regeneration of natural tissues and develop superior materials for use in next generation biomedical devices.

Engineering of human tissues is challenging at human scale and biomaterials for medical devices and implants must meet stringent design criteria. Drug-resistant infections and the formation of biofilms on medical implants are major issues that we are tackling with novel antimicrobial nanomaterials, composites and coatings for use in medical devices and regenerative medicine.

We design and fabricate biomaterial constructs with tailored 3D architecture, surface characteristics, mechanical properties and optimised molecular transport properties tailored for cell culture and tissue regeneration. This includes uses in wound repair, cardiovascular and blood-contacting devices, and eye and breast reconstruction.

Our program focuses on:

- design and fabrication of polymeric biomaterial scaffolds and devices
- synthesis of porous, mechanically tuneable 3D hydrogel systems for cell culture and tissue engineering
- development of antimicrobial nanoparticles, composites and coatings that resist biofilm formation
- design of microfluidic platforms for in-vitro cell analysis and cell-processing
- evaluation of host response to material implants
- scale up of stem cell culture
- physicochemical characterisation and in vitro testing of biomaterial constructs

IN-SILICO MODELLING OF CELL SYSTEMS BIOLOGY

Development of effective drugs to combat disease requires an in depth knowledge of the cellular and molecular processes that govern tissue and organ function.

The Department of Biomedical Engineering and the Graeme Clark Institute have deep expertise in developing computer models of biological processes within cells and the three-dimensional environment in which they occur. The models are informed by state-of-the-art experimental data and provide powerful new insights into how different chemical and mechanical signals within cells interact in health and disease. The models can be used to predict the efficacy of drugs that target molecular interactions underlying disease progression.

Our program focuses on:

- cellular processes underlying heart diseases such as hypertrophy and diabetes-induced cardiomyopathy
- validating models based on stem-cell derived tissue cultures for cardiac drug discovery
- the mechanobiology of cell-cell adhesions in cancer
- mechanics and shape of red blood cells in malaria
- new technologies for quantitative cell systems modelling

SYSTEMS NEUROPSYCHIATRY

Systems Neuropsychiatry is an interdisciplinary group of engineers and psychiatrists located across engineering and medicine at the University of Melbourne. Our research focuses on the brain as a system of interacting elements with the aim of understanding why, how and when these interactions break down or fail to develop properly in people with mental illness. Our goal is to use this knowledge to engineer improved treatments for serious mental disorders.

Studying the brain as an integrated system is a huge challenge with more connections present in the human brain than there are stars in the universe. This underpins our belief in the fundamental importance of an interdisciplinary approach to clinical brain science combining clinical and computational expertise.

The network-based statistic, a method developed by our team, has been used in hundreds of published neuroscience and psychiatry studies globally to localise brain network pathology. As founders of the Australian Connectomics School, we have established an international reputation for providing training to researchers and clinicians in the use of advanced methods for analysing brain networks.

Our program focuses on:

- developing computational tools to analyse brain images and map brain networks
- understanding the neurobiological basis of psychiatric disorders with brain imaging
- personalising and improving transcranial magnetic stimulation (TMS) therapies
- undertaking clinical trials and brain imaging studies in psychiatric populations

PERSONALISED IMPLANTS

Advances in 3D printing technology are revolutionising medical technologies, providing the ability to personalise healthcare and improve the wellbeing of people around the world as never before.

We are internationally recognised in the design, testing and manufacture of 3D printed personalised implantable devices to treat end-stage bone and joint conditions, including osteoarthritis, tumour resection, trauma and congenital abnormalities.

Our research is supported by state-of-the-art equipment for additive manufacturing and biomechanical evaluation including the Motekforce Link CAREN system, a fully-integrated, six-degree-of-freedom motion platform and treadmill surrounded by immersive virtual reality with high-speed motion capture cameras.

We are developing an innovation hub for personalised implant with the establishment of the ARC Training Centre for Medical Implant Technologies involving 24 organisations from industry, hospital and research sectors.

Our program focuses on:

- advanced patient-specific biomechanical modelling for device design, surgical planning and virtual clinical trials
- assessment of implant functional performance under physiological loading
- advanced 3D-printed personalised implantable devices

TAKING AUSTRALIAN TECHNOLOGY TO THE WORLD

ARTICLE PROVIDED BY ONCORES MEDICAL AND BRANDON CAPITAL PARTNERS

Breast cancer is the most commonly diagnosed form of the disease in Australia, affecting one in eight women.

While breast cancer is treatable, around one in four women undergoing breast conservation surgery (or lumpectomy) require repeat surgery to remove all of the malignant tumour.

Of the two million diagnoses of breast cancer globally, around 65 per cent are diagnosed early enough to just have the lump removed; however, with around 25 per cent of those requiring repeat surgery, the need to improve outcomes for a large number of patients is enormous, both in Australia and internationally. And that's not to mention the vast savings health systems would accrue from reduced hospital admissions.

A Western Australian medical technology company seems to have found an answer to improving the tumour removal process. OncoRes Medical, a Perth-based start-up, is developing an imaging probe and console to provide real-time intraoperative guidance to surgeons to help identify tumorous tissue, with the aim of improving the outcome of breast conservation surgery.

OncoRes Medical is a prime example of Australian research translation and entrepreneur-led medical innovation done impeccably well. What initially began as research by surgeon Professor Christobel Saunders AO, from the University of Western Australia (UWA), and engineer Dr Brendan Kennedy, from UWA and the Harry Perkins Institute of Medical Research, formed the basis of one of the most impressive medtech companies in operation today. OncoRes was catapulted to the world stage late last year after its technology gained praise and recognition from Prince Andrew, Duke of York, at international start-up competition Pitch@Palace Global 3.0.

Saunders and Kennedy had been collaborating on technology to solve the issue of repeat surgeries in breast cancer removal for eight years. Dr Kath Giles was an Investment Manager at Brandon Capital, the fund manager of the Medical Research Commercialisation Fund (MRCF), when the idea was first brought to her. The MRCF, Australasia's leading life sciences investment fund, is a unique collaboration between major Australian superannuation funds, the Australian and New Zealand governments, Australian state governments, and over 50 leading medical research institutes and research hospitals. As part of her role as a Perth-based investment manager, Giles was tasked with identifying research and assets with strong commercialisation potential from within the MRCF's Western Australian member institutes.

(L to R:) Dr Brendan Kennedy, Dr Katharine Giles and Professor Christobel Saunders

Formerly a doctor, assistant surgeon and an entrepreneur in medical apps, diagnostics and fitness devices, the technology resonated with Giles, now the CEO of OncoRes Medical.

'In my experiences as a [surgical] doctor, I'd often see surgeons have to rely purely on their own judgement, including touch and feel, when removing tumours during surgery. As technologies continue to develop, there is a growing desire and expectation from surgeons to be able to access and operate imaging tools autonomously, without having to wait on other specialists,' she says.

Seeing an opportunity to improve the tumour removal process, together Saunders, Kennedy and Giles created OncoRes Medical, with a Series A investment of A$6 million from the MRCF in late 2016.

Since the Series A investment, the team has developed cutting-edge, high-resolution imaging technology, in collaboration with surgeons and pathologists from the Western Australia Department of Health, using a novel combination of Optical Coherence Tomography and Elastography to provide a rapid evaluation of tissue microarchitecture at a scale comparable to histology. This means OncoRes's handheld probe and console will provide real-time intraoperative guidance to surgeons by assisting to delineate tumour from healthy tissue, ultimately reducing the need for further surgery.

What was a team of three is now a team of 26. Giles has joined OncoRes full-time as the CEO, taking a

> During proof of concept, OncoRes's imaging tool showed remarkable diagnostic accuracy in its study

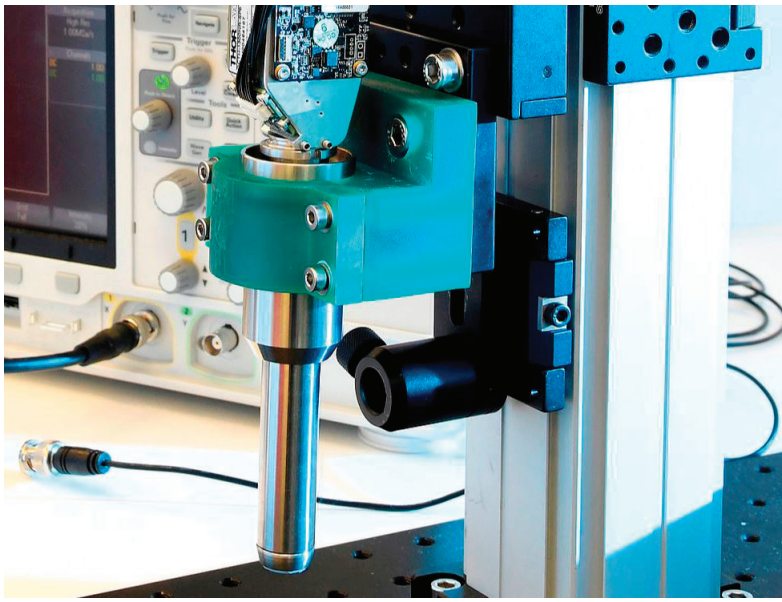
leave of absence from her role at Brandon Capital. OncoRes has bolstered its team with the addition of three new researchers, a product manager, a regulatory and quality manager, and an office manager, and now they're recruiting for a business analyst. The team is focused on building a strong advisory board, which includes Australian medtech entrepreneur Stewart Bartlett and Boston-based NinePoint Medical CEO Dr Eman Namati.

OncoRes Medical recently completed its proof of concept, which has been two years in the making. During proof of concept, OncoRes's imaging tool showed remarkable diagnostic accuracy in its study. A study of 92 patients (which included the training dataset of 21 patients) and 153 images showed its tool provided exquisite accuracy in detecting cancerous tissue in a benchtop setting, far better than competitors in the market or any other products in testing. Proof of concept also showed that the technology can be implemented into a handheld probe setting with comparable image quality to the benchtop setting.

And the timing couldn't be better for OncoRes, which received worldwide recognition after being named the joint winner of Pitch@Palace Global 3.0 in December last year. Pitch@Palace Global 3.0 saw 23 finalists representing 15 countries congregate in London for the international finale. Entrepreneurs had two minutes to pitch their ideas to a prestigious audience convened by the Duke of York, comprising CEOs, influencers, mentors and potential investors. The win was one of the major highlights to round out 2018 for OncoRes, and speaks to the strength of the biotechnology and start-up culture in Western Australia.

'It was beyond our wildest dreams to take a Western Australian-developed technology and showcase it in a global setting at a leading start-up competition. The calibre of the competition was very high, so to be declared joint-winner was recognition of the value our technology can bring to the world. The opportunities that have come from it and that will continue to arise are unparalleled,' Giles says.

OncoRes Medical is now moving into the product development phase for its technology. OncoRes has



a fully operational imaging probe in-house. Now the team is finalising the second version of its handheld probe, which has been developed to be suitable for use in the surgical cavity. Ethics has been approved for this study and the team is planning to take first in-human scans in May this year.

OncoRes has achieved its goals for the Series A investment under budget and ahead of time, which has been a 'massive high for us and a win for all of our stakeholders'. Further complementing this, OncoRes received a Cooperative Research Centres Project (CRC-P) Grant to tune of A$3 million in December 2018' which will provide vital funding for the team over the next three years.

But for OncoRes to get its technology to market, further capital is crucial. Giles says the company needs to raise a further A$14–18 million in Series B financing to help progress the technology through pivotal clinical studies and regulatory approvals.

'The CRC-P grant gives us recognition that what we're doing is addressing a significant clinical problem that Australians want solved. It also provides a drawcard for investors coming into the Series B round, as they can be satisfied that significant funding has already gone into the company,' Giles says.

Over the next two to three years, OncoRes will focus its energy on developing its tools and gaining approval for use in the United States by the Food and Drug Administration (FDA). After FDA approval, the company hopes to run its pivotal clinical trial across both Australia and the United States. OncoRes hopes its technology will be cleared for entry into the market in the next two-and-a-half to three years' time, before seeking a potential partnership with a medical device company.

ENABLING FUTURE MEDICINES

360biolabs is a contract service organisation providing pharmacokinetic (PK) and pharmacodynamic (PD) services to support the development of new therapeutics, vaccines or diagnostics in a quality-assured environment.

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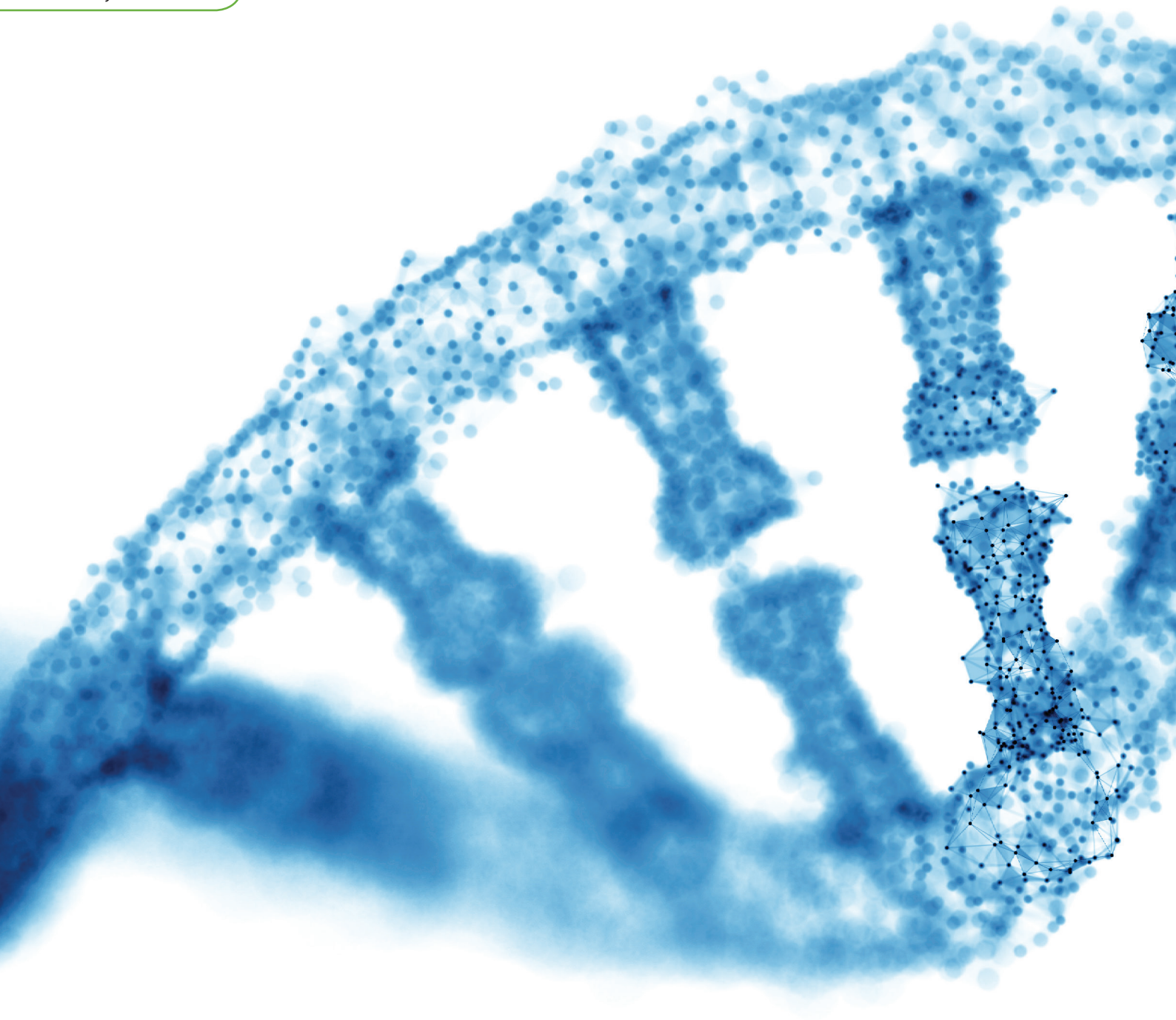

CHANGING STANDARDS IN CLINICAL TRIALS

BY MIE OHAMA, PRINCIPAL CLINICAL QUALITY SPECIALIST,
MEDTRONIC CLINICAL RESEARCH INSTITUTE

Arthur Brandwood and Mie Ohama both represent AusBiotech on Standards Australia's HE-30 committee – which looks after Australian national input to the ISO 10993 biocompatibility and ISO 14155 clinical trials standards. In this article, Mie Ohama updates us on the new ISO 14155 – what's changed and what it means for your clinical studies. In the next issue, Arthur Brandwood will provide an update on the changes in ISO 10993.

Medical device regulation is fundamentally standards-based. Whether you are submitting a Technical File for a CE marking assessment, or a TGA application or a US FDA 510(k) filing, the core of the submission will always be laboratory testing and clinical evaluations conducted in compliance with ISO and regional standards.

ISO 14155 has been the global standard for clinical trials that assess the safety or performance of medical devices for regulatory submission purposes. The standard was created to clarify worldwide the design, conduct, recording and reporting of clinical investigations carried out in human subjects, thereby providing a crucial framework that allows the medical technology companies to generate clinical evidence that can be used for regulatory submission around the world.

Regulations of the following countries clearly indicate that regulators accept ISO-compliant data for regulatory submission:

- The United States
- Europe
- Korea
- Japan.

Mie Ohama

According to the 'Statement regarding Use of ISO 14155:2011 "Clinical investigation of medical devices for human subjects – Good clinical practice" by the International Medical Device Regulators Forum (IMDRF), compliance with ISO 14155:2011 is not mandated by the participating countries; however, the standard is referenced as a recognised one to facilitate the regulatory review of medical device licence application.

From the Australian clinical regulatory environment perspective, the Therapeutic Goods Administration (TGA) released the *Australian Clinical Trial Handbook* version 2.0 in March 2018. In the handbook, ISO 14155 was recognised as the medical device Good Clinical Practice (GCP) in Australia, as well.

The 2011 version of ISO 14155 is currently under revision, aiming to increase the acceptance of the standard by countries that were not engaged in the development of the 2011 version. It is important for trial sponsors to understand the upcoming changes to the next version.

Re-enforcing risk management throughout a clinical investigation

ISO 14971 specifies a process for a manufacturer to identify potential hazards associated with medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls throughout the life

cycle of a medical device. A clinical investigation is generally required when the currently available data is insufficient to demonstrate conformity with the Essential Principles. All parties involved in clinical investigations (including the sponsor, investigators and data-monitoring committee members) play an important role in the risk management process. The next revision clarifies when and how potential safety concerns in a clinical investigation shall be managed throughout the investigation.

Expanding scope from pre-market clinical investigation to all types of clinical investigations, including the post-market phase

Depending on a result of risk assessment, three different stages of clinical development (e.g. the pilot stage, the pivotal stage and the post-market stage) apply to a medical device. Requirements of the standard vary depending on clinical development stage and the study design. The next revision of the standard clarifies requirements during different stages of clinical trials to ensure that adequate consideration is provided in terms of a subject's rights, safety and wellbeing, scientific outcome and credibility of the clinical data.

Clarifying minimum statistical considerations for all types of clinical investigations

Statistical consideration is vital for optimising a study design, evaluating a research hypothesis, interpreting research results and drawing conclusions. Depending on clinical development stage as well as how clinical investigation data will be utilised by the manufacturer, statistical consideration could be different. To minimise bias, maximise potential benefits and maintain the integrity of the analysis, this revision details statistical requirements to be considered for all types of clinical investigations during development of a clinical investigation plan.

Aligning the standard requirements with new and changing clinical requirements

Since the current version was released in 2011, many new and changing requirements (e.g. EU MDR, ICH GCP, US FDA guidance, China GCP) have been introduced in the global clinical regulatory environment. To align with those requirements, the revision includes:

- a summary section of GCP principles
- reference to registration of the clinical investigation in a publicly accessible database
- guidance with regards to clinical quality management
- guidance on risk-based monitoring
- guidance for ethics committees
- guidance on clinical investigation audits.

A definition of 'vulnerable population' was updated in alignment with ICH GCP E6 rev. 2.0.

With the changes above, ISO 14155 will continue to be the global standard that helps medical technology companies to create clinical evidence that can be used for regulatory submission in multiple countries.

Disclaimer: The views expressed are those of the author. The author is an employee of Medtronic Australasia Pty Ltd, a global leader in medical technology, services and solutions.

AusBiotech

Business Solutions Program

AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

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AusBiotech has selected Avatar Brokers as its endorsed broker for life science companies. The key advantage Avatar offers is objective, in-depth research on industry-specific exposures. Avatar understands the unique requirements of your industry and takes the time to understand the specific issues and challenges facing your business. Nil commission, fee for service and fully transparent. AusBiotech members are offered a free confidential assessment of their insurance needs against industry best practice.

CHUBB

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

FROST & SULLIVAN

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

Biotech Daily

Biotech Daily covers the major announcements from ASX-listed biotech companies, as well as the major research institutes and developments in government policy.

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

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ACTI is a new and unique-to-market accelerator providing access to the Chinese healthcare market. The programs it runs are open to Australian companies in the medtech and life sciences sectors, and are supported by a team with significant experience in start-up and business mentoring in Australia and China. These skill sets include registering, launching and marketing medical devices, in-vitro diagnostic devices (IVDs) and innovation-led products in both markets.

Melvin Lee | Incubator Manager
Australia China Technology Incubator (ACTI) Pty Ltd | Mobile: 0411 679 888 | Email: melvin@acti.asia

Almac Clinical Services

Almac Clinical Services, part of the Almac Group, the global contract manufacturing and development organisation, has over 30 years' experience deploying clinical supply-chain expertise and delivering a full suite of end-to-end clinical solutions to global clients. By listening to customers, Almac understands their challenges, creating patient-centric solutions that meet evolving study and industry needs. Almac champions integrated clinical supply and technological experience to make their customers' clinical trials more effective and efficient.

Helen Leiton | Regional Support Manager
Email: Helen.leiton@almacgroup.com | Mobile: 0431 095 984 | Web: www.almacgroup.com

Australian Clinical Labs - Specialised Trials

Clinical Labs performs around eight million pathology episodes across its national network each year. The company has over 900 accredited collection centres, 88 NATA-accredited laboratories and is the largest private provider of pathology services to public hospitals in Australia. In January 2019, Clinical Labs established a specialised trials division, offering clients customised pathology testing for Phase I–IV trials including collection, testing, kit supply, storage and data management.

Tim Wells | Business Development Manager
Mobile: 0499 801 450 | Web: www.clinicallabs.com.au/specialisedtrials

FLEDGE Innovation Labs

FLEDGE Innovation Labs is Australia's first and only incubator dedicated to the development and commercialisation of medical devices. Based at the CSIRO Manufacturing and Materials facility in Lindfield, FLEDGE provides premium collaborative working spaces for medtech start-ups, with guidance by experienced mentors drawn from executive ranks within the Australian medtech community. Fledge will soon launch its ISO-13485-compliant Quality Management System, essential for the commercialisation of medical devices, and does not require its members to sacrifice equity.

Gary Jones | Founder/CEO
Email: info@fledge.com.au | Website: www.fledge.com.au

Hall & Wilcox

Hall & Wilcox is a pre-eminent Australian independent business law firm of more than 650 people, including 78 partners, with offices in cities across Australia. Smarter Law is its response to the changing legal market and how it helps clients achieve their business objectives. Members of the firm's specialist Health & Community Industry Group have a deep understanding of the life sciences sector, including having had in-house industry roles.

Alison Choy Flannigan | Leader, Health & Community
Email: Alison.choyflannigan@hallandwilcox.com.au | Mobile: 0411 04 9459 | Web: www.hallandwilcox.com.au

NEW AUSBIOTECH MEMBERS

Indee Labs

Indee Labs is developing a non-viral gene delivery technology for the scalable manufacture of gene-modified cell therapies. Gene delivery via microfluidic vortex shedding (μVS) enables fast processing of small and large volumes of human primary immune cells. This mechanical technology can achieve high yield with a simple workflow and does not change immune cell activation or exhaustion profiles. Indee Labs is located in both Sydney and San Francisco.

Dr Warren McKenzie | CEO & Director
Email: Warren@indeelabs.com | Mobile: 0400 059 509 | Web: www.indeelabs.com

Institute for Molecular Bioscience (IMB)

The University of Queensland's Institute for Molecular Bioscience is a global leader in multidisciplinary life sciences research. As a discovery-based research environment, IMB is committed to working with partners to translate discoveries into real-world solutions. Together, we connect the dots between scientific knowledge and new health and industry applications to provide tailored and sustainable solutions, delivering knowledge leadership for a better world.

Email: partner@imb.uq.edu.au

Life Biosciences

Life Biosciences addresses eight pathways of age-related decline as a systemic breakdown of the body, not as isolated symptoms and conditions. Its daughter companies around the world work independently and collaboratively to attack these pathways through pioneering research and product development. Life Biosciences provides daughter companies with centralised resources, including an AI data platform for ageing, and LifeLabs, its 24,000-square-foot, state-of-the-art research facility. Life Biosciences seeks to increase health spans for everyone.

info@lifebiosciences.com

Living Cell Technologies Ltd

LCT is listed on the Australian (ASX:LCT) and US (OTCQX:LVCLY) stock exchanges. The company is incorporated in Australia, with its operations based in New Zealand. LCT has completed two clinical studies in Parkinson's disease, with its lead cell therapy product NTCELL®. LCT is also advancing research collaborations with the University of Auckland to identify products that are candidates for out-licensing. It has identified lead compounds ready for development as treatments for migraine and obesity.

Ken Taylor | Chief Executive Officer
Phone: +64 9 270 7946 | Mobile: +64 21 796 000 | Email: ktaylor@lctglobal.com | Web: www.lctglobal.com

Molecule2Market

Molecule2Market (M2M) is a boutique CRO. Our team of clinical research professionals is dedicated to advancing Australia's contribution to the research and development of innovative medical treatments. Combining our expertise and experience, we provide high-quality services across all phases of clinical research and a broad range of therapeutic areas. M2M offers the simplicity of support through one organisation, and can assist with clinical, regulatory, quality assurance/audit, data management/statistics, medical monitoring and local sponsorship services.

Anne De Luca | Director
Mobile: 0409 210 902

NEW AUSBIOTECH MEMBERS

OncoRes Medical

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Dr Katharine Giles | CEO
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Paul Carboon | Founder and CEO | Mobile: 0404 806 405 | Email: pcarboon@solentropy.com.au | Web: www.solentropy.com.au

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The SPD Company Pty Ltd is a boutique consulting organisation in pharmaceuticals, medical devices, biotechnology, OTC and complementary medicines. For over 15 years, SPD has provided technical advice in regulatory affairs, pharmacovigilance, QMS implementation, GMP/ISO audit readiness, new product development, supply chain and manufacturing, due diligence and legal-related issues. From complex projects to simple questions, its team of technical specialists and support staff all strive to offer the best value in every job they do.

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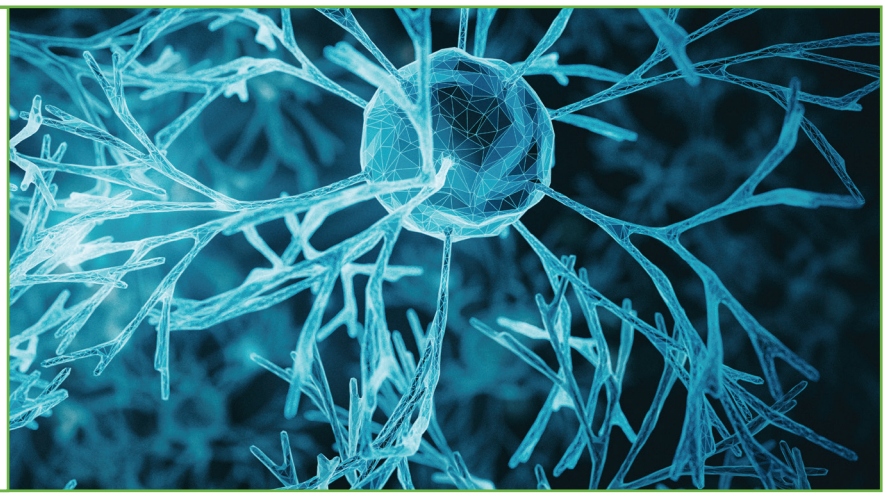

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BY JAMES FLETCHER, FINANCIAL ADVISER,
BAILLIEU HOLST

Issuer Name	ASX	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
AdAlta	1AD	Drug discovery and development using its technology platform to generate a promising new class of protein therapeutics, known as i-bodies	22-Aug-16	28.7	0.25	0.40	0.22	-4	-7	4	
AusCann Group Holdings Ltd	AC8	Cultivation, manufacture and distribution of medicinal cannabis products. Targeting medications for neuropathic and chronic pain	3-May-89	100.5	0.33	1.80	0.30	-3	-12	14	
AtCor Medical Holdings Limited	ACG	Developer and international marketer of blood pressure at the heart device SphygmoCor	9-Nov-05	28.5	0.04	0.07	0.02	-1	-5	1	
Alchemia Limited	ACL	Drug discovery and development. Fondaparinux anticoagulant drug	23-Dec-03	2.9	0.01	0.02	0.01	0	-7	1	
Acrux Limited	ACR	Transdermal drug delivery platform technology	29-Sep-04	30.8	0.19	0.32	0.14	-5	-3	16	
Actinogen Ltd	ACW	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders including Alzheimer's	16-Oct-07	62.6	0.06	0.07	0.04	-1	-6	1	
Anteo Diagnostics Limited	ADO	Multi-component coatings for solid phase of immunoassays for biomarker development	7-Apr-00	20.9	0.02	0.02	0.01	0	-9	0	
Adherium Ltd	ADR	Developer of digital technologies to monitor medication use in chronic respiratory conditions	26-Aug-15	4.7	0.03	0.20	0.02	-8	0	2	
AFT Pharmaceuticals	AFP	Develops, licences and sells a range of medical products globally	22-Dec-15	192.2	1.98	2.41	1.98	-10	-20	4	
Apiam Animal Health Ltd	AHX	iVet technology for real time animal health monitoring including on-farm welfare assessments	15-Dec-15	49.5	0.47	0.82	0.46	3	16	-5	1.60
Admedus Ltd	AHZ	Tissue engineering and vaccine development for herpes & HPV	24-Mar-04	24.2	0.04	0.40	0.03	-8	-1	3	
Analytica Limited	ALT	eHealth devices. PeriCoach system for stress urinary incontinence	25-Oct-00	13.3	0.00	0.01	0.00	0	-7	0	
Allegra Orthopaedics Ltd	AMT	Prosthetic implant tools	5-Dec-07	11.9	0.12	0.05	0.02	-1	-13	6	-
Antisense Therapeitics ltd	ANP	Drug discovery and development. Antisense compounds for MS, DMD, acromegaly	20-Dec-01	16.4	0.04	0.04	0.01	-1	-4	1	
Antara Lifesiences Ltd	ANR	Natural, plant-based therapeutics for gastrointestinal diseases	16-Oct-14	26.4	0.54	1.72	0.35	-8	-7	13	
Avita Medical Ltd	AVH	Skin regeneration technology for the treatment of wounds, scars and skin defects	11-Aug-93	494.1	0.27	0.27	0.05	-2	-11	2	
AirXpanders Ltd	AXP	AeroForm tissue expander for breast reconstruction	29-Sep-04	17.3	0.04	2.63	0.75	-30	0	11	
BioGene Technology Ltd	BGT	Insecticide product development. 'Qcide' and 'FLAVOCIDE' focused on insect control in agriculture and animal health.	29-Nov-17	11.5	0.10	0.21	0.09	-2	-4	4	
Biotron Limited	BIT	Antiviral drug developer, HIV and hepatitis	24-Jan-01	53.0	0.09	0.45	0.01	0	-21	1	
Benitec Limited	BLT	Development of a proprietary therapeutic technology platform to provide long-lasting silencing of disease-causing genes	17-Feb-97	33.4	0.13	0.34	0.09	-1	-19	11	

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Botanix Pharmaceuticals Ltd	BOT	Development and commercialisation of therapeutics for bone and joint disease	24-Jan-85	84.2	0.12	0.19	0.07	-2	-5	2	
Bionomics Limited	BNO	Small molecule developer in areas of cancer and CNS disorders	21-Dec-99	89.9	0.17	0.64	0.10	-5	-3	2	-
BPH Energy Ltd	BPH	Commercialising a portfolio of Australian biomedical technologies emerging from collaborative research from universities, medical institutes and hospitals	6-Aug-04	2.5	0.00	0.00	0.00	0	2	0	
Brain Resource Limited	BRC	Provider of international database for human brain function	28-Aug-01	13.8	0.03	0.06	0.02	-1	-3	1	
BTC Health Ltd	BTC	Bipharmaceutical company focused on product development and commercialisation	29-Aug-00	15.0	0.12	0.23	0.09	0	-48	2	
Bioxyne Ltd	BXN	Gut & immune health probiotic products, including a patented probiotic range.	14-Dec-00	12.8	0.02	0.09	0.02	0	-15	0	
Capitol Health Ltd	CAJ	Provider of diagnostic imaging services to the Australian healthcare market	9-Jun-06	172.8	0.22	0.35	0.15	0	-98	1	0.90
Cann Group Ltd	CAN	Research and development and cultivation to facilitate the supply of medicinal cannabis	4-May-17	234.3	2.10	3.88	1.53	-6	-35	60	
Cellmid Limited	CDY	Development of therapies targeting midkine in cancer, fibrosis and chronic inflammatory disease	9-Dec-05	18.5	0.22	0.57	0.19	-9	-2	8	
Cogstate Ltd	CGS	Diagnosis and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's)	13-Feb-04	30.4	0.23	0.93	0.25	-2	-14	4	
CropLogic Ltd	CLI	Technology platform that improves crop yield	12-Sep-17	7.3	0.03	0.08	0.01	-3	-1	2	
Clover Corporation Limited	CLV	Supplies science-based oil products to the medical food market for infants and children	30-Nov-99	330.4	2.02	2.04	0.83	5	38	23	1.88
Compumedics Ltd	CMP	Designs and manufactures technologies for the diagnosis of sleep disorders; neurodiagnostics solutions and Brain Research technologies through the Compumedics Neuroscan brand	21-Dec-00	67.3	0.38	0.72	0.32	2	22	11	-
Cochlear Ltd	COH	Manufacture and sale of cochlear implant system for impaired hearing	4-Dec-95	10,324.8	177.36	221.80	155.22	458	39	493	315.00
CannPal Animal Therapeutics Ltd	CP1	Pet pharmaceutical company developing cannabinoid-based medicines for cats, dogs and horses	25-Oct-17	5.4	0.13	0.26	0.10	-2	-8	5	
Creso Pharma Ltd	CPH	Development and production of cannabis and hemp derived therapeutic products and treatments for humans and pets	20-Oct-16	43.5	0.33	0.89	0.30	-15	-2	13	
CSL Limited	CSL	Development, manufacturing and marketing of pharmaceutical and diagnostic products	8-Jun-94	89,345.8	195.62	232.69	154.75	572	34	945	248.14
Cryosite Limited	CTE	Collection, processing and long-term storage of blood stem cells	9-May-02	1.6	0.04	0.12	0.04	-4	-1	-3	
Clinuvel Pharmaceuticals Limited	CUV	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-Feb-01	1,249.5	25.23	29.99	9.39	33	76	90	2.00
Cyclopharm Limited	CYC	Manufacturer and distributor of radiopharmaceuticals for imaging technology. Lead product is Technegas, a lung ventilation imaging drug	18-Jan-07	78.7	1.15	1.30	0.85	0	-2290	18	1.00
Cynata Therapeutics	CYP	Stem cell and regenerative medicine platform technology, Cymerus, for production of mesenchymal stem cells.	20-Dec-07	120.2	1.15	1.85	0.94	-6	-19	12	
Dorsavi Ltd	DVL	Motion analysis device technologies for clinical, elite sports and OHS	11-Dec-13	8.2	0.04	0.22	0.03	-2	-2	3	
Dimerix Ltd	DXB	Development of therapeutic treatments identified using drug discovery platform, Receptor-Heteromer Investigation Technology	4-Feb-93	13.8	0.01	0.01	0.00	-2	-4	3	

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Ebos Group Ltd	EBO	Distributor of healthcare products	6-Dec-13	3,142.3	20.30	21.50	16.00	89	23	76	58.14
Ellex Medical Lasers Ltd	ELX	Production of ophthalmic instruments for treatment of impaired vision	12-Sep-94	89.0	0.62	0.90	0.50	-4	-17	34	-
eSense Lab Ltd	ESE	Create 'virtual plants' with commercial and medicinal applications. First plant targeted for re-engineering is cannabis	14-Feb-17	3.4	0.02	0.17	0.02	-4	-1	4	
Factor Therapeutics Ltd	FTT	Development of wound care therapeutics. Lead therapeutic VF-001 is a targeted growth factor being developed to treat venous leg ulcers	19-Mar-04	3.6	0.00	0.09	0.00	-1	0	0	
Genera Biosystems Limited	GBI	Develops and commercialises molecular diagnostic tests based on AmpaSand bead technology	11-Jun-08	17.6	0.16	0.20	0.14	-4	-4	-8	
Gi Dynamics, Inc	GID	EndoBarrier; endoscopically delivered treatment for the management of obesity and type two diabetes	7-Sep-11	18.2	0.02	0.04	0.02	-2	-1	1	
G Medical Innovations Holdings Ltd	GMV	Remote healthcare monitoring technology. Develops and markets clinical and consumer medical-grade health monitoring solutions	10-May-17	37.3	0.29	0.45	0.18	-7	-4	3	
Genetic Signatures Ltd	GSS	Molecular diagnostics company focused on development and commercialisation of its proprietary platform technology, 3Base	31-Mar-15	124.8	1.20	1.40	0.24	-3	-38	11	
Genetic Technologies Limited	GTG	Molecular diagnostics specialising in women's health. Lead product BREVAGen Plus is a risk assessment test for non-hereditary breast cancer	30-Jul-87	19.8	0.01	0.02	0.01	0	-4	0	
Holista Colltech Ltd	HCT	Development and commercialisation of food ingredients and ovine collagen	26-Feb-04	16.9	0.07	0.12	0.04	-1	-9	2	
Imagion Biosystems	IBX	Detection and localisation of cancer and other diseases using nano particle technology. Proprietary MagSense bio-imaging detection technology	22-Jun-17	6.6	0.03	0.08	0.02	-4	-1	1	
IDT Australia Ltd	IDT	Manufacturer of pharmaceuticals and clinical trial management services	24-Sep-93	35.5	0.15	0.19	0.07	-1	-15	12	
Innate Immunotherapeutics	IIL	Immunomodulator microparticle technology	23-Dec-13	5.7	0.14	1.35	0.12	-10	-1	4	
Immuron Ltd	IMC	Oral immunotherapy products that target the human gut immune system and gut microbiome	30-Apr-99	35.1	0.25	0.42	0.20	-2	-12	5	
Immutep Ltd	IMM	Developer of novel immunotherapy agents treatments for cancer and autoimmune disease. Lead product candidate is eftilagimod alpha for breast cancer and melanoma	23-Jun-88	118.4	0.04	0.06	0.02	-1	-6	0	
Imugene	IMU	Developer of HER-2+ gastric and breast cancer immunotherapies	2-Dec-93	68.6	0.02	0.04	0.02	0	-10	1	-
Impedimed Limited	IPD	Diagnostic devices for lymph oedema, muscle wasting and metabolic disorders utilising bioimpedance technology	24-Oct-07	81.6	0.21	0.77	0.18	-6	-3	6	
ITL Limited	ITD	Design and manufacture of healthcare devices, biological sampling systems	29-Oct-03	10.3	0.15	0.39	0.08	3	4	14	
Invitrocue Ltd	IVQ	Provider of bio-analytic solutions including in vitro cell-based testing technologies and and image analytics software for use in digital pathology	14-Dec-91	36.0	0.07	0.12	0.06	-1	-5	0	
Invion Ltd	IVX	Developer of treatments for inflammatory diseases	15-Feb-10	71.5	0.01	0.05	0.01	0	-14	0	
Kazia Therapeutics Ltd	KZA	Development of anti-cancer drugs	1-Sep-94	29.8	0.47	0.79	0.33	-25	-2	7	
LBT Innovations Limited	LBT	Automated systems for the preparation, screening, interpretation and streaking of microbiological specimens	31-Jul-06	12.3	0.06	0.15	0.06	-2	-3	7	
Living Cell Technologies Limited	LCT	Developer of live cell therapy products for treatment of neurological and metabolic disorders	1-Sep-04	22.3	0.04	0.08	0.02	0	-127	1	
Lifehealthcare Group	LHC	Distributor of critical care medical devices and implantable devices	5-Dec-13	175.7	3.68	3.70	2.02	15	25	25	

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Lifespot Health Ltd	LSH	Medical diagnostic and monitoring technology using smartphones. BodyTel system for management of chronic diseases and My-Lifespot system for skin disease diagnosis	11-Jan-17	4.5	0.06	0.15	0.05	-2	-2	3	
Mach7 Tech Ltd	M7T	Imaging IT solutions, 3D printing and holographic projection provider	30-Nov-05	25.9	0.18	0.30	0.17	-4	-4	2	
Medlab Clinical Ltd	MDC	Research and development of novel biotherapeutics to improve health outcomes in chronic diseases such as chronic kidney disease and obesity	14-Jul-15	78.1	0.37	0.74	0.34	-3	-13	9	
MedAdvisor Ltd	MDR	Mobile and web apps for individuals and carers to manage all aspects of prescription medication use	26-May-11	59.9	0.04	0.05	0.03	-1	-9	1	
MediBio	MEB	Diagnostic tests for depression and other mental health disorders	29-Jan-01	4.2	0.02	0.22	0.02	-7	0	14	
Medigard Limited	MGZ	Retractable safety devices for injection and blood collection	5-Feb-04	2.7	0.02	0.03	0.02	-1	-3	-1	
Medical Australia Limited	MLA	Distributor of Medical devices, IV system, blood banking lab and collection of human and animal biologics	20-Dec-04	11.6	0.09	0.09	0.05	0	28	4	
MMJ Phytotec Ltd	MMJ	Aims to commercialise medical cannabis and high-value based cannabis therapeutics	22-Jan-15	57.5	0.24	0.41	0.19	13	2	31	
Mesoblast Limited	MSB	Commercialisation of adult stem cell technology	16-Dec-04	690.6	1.33	2.47	1.02	-25	-5	-14	-
Monash IVF Group	MVF	Assisted reproductive technologies, genetic testing and ultrasound services	26-Jun-14	256.8	1.07	1.28	0.88	8	13	-36	5.60
Medical Developments International Limited	MVP	Medical and veterinary equipment including pain management, resuscitation and asthma management products	15-Dec-03	284.5	4.37	7.56	3.48	0	1093	13	4.00
Micro-X Ltd	MX1	Develops and manufactures a range of mobile X-ray imaging systems for medical applications	22-Dec-15	37.9	0.26	0.42	0.20	-12	-2	0	
MGC Pharmaceuticals Ltd	MXC	Innovator in phytocannabinoid-based medicines within the biopharmaceutical industry	21-Dec-06	43.7	0.04	0.09	0.03	0	-88	1	
MyFiziq Ltd	MYQ	Smartphone app to provide accurate circumference measurements to assist with management of diabetes and weight	17-Aug-15	25.6	0.29	0.75	0.22	-5	-5	-2	
Mayne Pharma Ltd	MYX	Pharmaceutical commercialisation and manufacturing. Development of oral drug delivery systems	29-Jun-07	1,084.3	0.68	1.43	0.65	3	23	8	
Nanosonics Limited	NAN	Ultrasound probe disinfection - trophon device	17-May-07	1,367.8	4.47	4.58	2.26	4	126	30	
Nanollose Ltd	NC6	Uses industrial organic and agricultural waste products to produce plant-free cellulose for use in the food and medical industries	18-Oct-17	2.3	0.07	0.20	0.07	-3	-3	3	
Neuren Pharmaceuticals Limited	NEU	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders	3-Feb-05	115.2	1.13	3.48	1.01	3	36	24	
Novita Healthcare Ltd	NHL	Cognitive training program for children with attention difficulties	23-Sep-04	9.9	0.02	0.04	0.02	-1	-2	0	
Noxopharm Ltd	NOX	Development of drugs to make radiotherapy more effective. NOX66 is the company's pipline product	9-Aug-16	37.4	0.41	1.08	0.36	-9	-5	5	
Memphasys Ltd	MEM	Cell and protein separation systems	14-May-07	8.4	0.02	0.07	0.01	0	-7	0	
Neurotech International Ltd	NTI	Development and commercialisation of technological solutions for the diagnosis and treatment of neurological conditions. Flagship device is Mente Autism	4-Nov-16	3.0	0.02	0.21	0.02	-4	-1	1	
Nufarm Ltd	NUF	Crop protection and specialist seed company. Manufacturing and marketing of products to help farmers protect crops against damage	10-Nov-98	1,757.7	4.61	9.45	4.15	-13	-36	143	10.92
OBJ Limited	OBJ	Developer of transdermal drug delivery technology in pharmaceutical and cosmetic industries	29-May-00	34.4	0.02	0.04	0.02	0	-17	0	-

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Orthocell Ltd	OCC	Soft tissue cellular therapies for restoration of tendon and cartilage injuries	12-Aug-14	13.1	0.15	0.38	0.13	-6	-2	1	
Orion Health Group Ltd	OHE	Technology solutions advancing population health and precision medicine, including data management and creating personalised healthcare plans	26-Nov-14	101.2	1.13	1.16	0.56	-16	-7	2	
Optiscan Imaging Ltd	OIL	Microscopic imaging technologies for medical markets	8-Aug-97	20.8	0.05	0.08	0.04	-1	-9	1	-
Oneview Healthcare Plc	ONE	Software platform for patients in hospital and aged care facilities including dietary services and care management	17-Mar-16	27.0	0.36	2.08	0.37	-47	-1	19	
Opthea Ltd	OPT	Developer of novel therapy OPT-302 for treatment of eye diseases	18-Apr-91	180.8	0.19	0.28	0.07	-8	-9	16	
Oncosil Medical Ltd	OSL	Brachytherapy device that implants a dose of beta radiation into a pancreatic tumour	15-Aug-05	100.9	0.04	0.26	0.12	-2	-3	2	
Osprey Med Inc	OSP	Technologies to reduce the amount of dye injected into patients during heart catheterisation procedures - DyeVert PLUS Contrast Reduction System	2-May-12	45.3	0.11	0.29	0.09	-12	-1	9	
Oventus Medical Ltd	OVN	Medical devices for sleep apnoea treatment incorporating Oventus Airway Technology	19-Jul-16	29.7	0.28	0.41	0.23	-6	-4	7	
Pharmaaust Ltd	PAA	Developer of targeted cancer therapeutics for humans and animals. Specialise in repurposing marketed drugs	2-Oct-01	7.2	0.04	0.06	0.03	-1	-5	2	
Patrys Limited	PAB	Developing novel antibody therapies for a range of oncology indications	13-Jul-07	25.7	0.02	0.06	0.02	0	-38	0	
Paradigm Biopharmaceuticals Ltd	PAR	Biopharmaceutical company focused on repurposing the drug pentosan polysulphate sodium for the treatment of inflammation	19-Aug-15	219.6	1.55	2.15	0.28	-6	-28	7	
Probiotec Limited	PBP	Manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, medicines and consumer health products	14-Nov-06	95.6	1.60	1.80	0.85	25	6	58	3.00
Prana Biotechnology Limited	PBT	Developing first-in-class therapies to treat neurdegenerative diseases such as Alzheimer's, Parkinson's and Huntington's diseases. Lead candidate PBT2	28-Mar-00	25.0	0.05	0.06	0.03	-2	-2	203	-
Painchek Ltd	PCK	Smartphone app to provide pain assessment for those who are unable to communicate	1-May-12	28.5	0.03	0.09	0.03	0	-11	0	
Paragon Care Ltd	PGC	Provider of medical equipment, devices and consumables to the healthcare market	15-Oct-99	160.1	0.45	0.89	0.43	2	19	-1	3.10
Proteomics International Laboratories Ltd	PIQ	Focused on proteomics. Developed a platform technology for discovering diagnostic tests based on the differences in the protein make-up of people	16-Apr-15	26.2	0.33	0.49	0.18	-2	-14	6	
Pro Medicus Ltd	PME	Provider of radiology information systems and diagnostic imaging	10-Oct-00	1,784.3	17.00	17.70	6.85	16	105	22	6.00
PolyNovo Ltd	PNV	Developer of biodegradable polymers for use in medical devices. Lead product is NovoSorb technology in the treatment of burns, surgical wounds and Negative Pressure Wound Therapy.	26-Nov-98	489.2	0.74	0.80	0.46	-1	-105	4	
Phosphagenics Limited	POH	Targeted Penetration Matrix (TPM) built from vitamin E. Delivery technology for small and large molecules. Products include gels, skincare and a nutritional feed additive for animals	11-Aug-93	6.3	0.00	0.03	0.00	0	-2	0	-
Papyrus Australia Ltd	PPY	Sustainable technology that produces products from the trunk of the banana palm	15-Apr-05	1.2	0.01	0.02	0.01	0	-10	0	
Prescient Therapeutics Ltd	PTX	Developer of anti-cancer drugs. Lead drug candidate PTX-200	2-Jan-92	11.9	0.05	0.19	0.06	-1	-4	2	
pSivida Corp.	PVA	Long-term sustained drug delivery to treat back of eye diseases - Durasert technology	12-Jun-08	17.6	2.99	3.23	1.30	-82	-4	0	

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Pharmaxis Ltd	PXS	Drug discovery to treat inflammatory and fibrotic diseases using amine oxidase inhibitor chemistry platform	10-Nov-03	102.5	0.26	0.35	0.25	-3	-8	5	
Phylogica Limited	PYC	Development of intracellular biological therapeutics using its Functional Penetrating Phylomers (FPP)	30-Mar-05	56.2	0.02	0.04	0.02	0	-10	0	
Qrxpharma Ltd	QRX	Development and commercialisation of biopharmaceutical products. Clinical program with dual opioids, morphine and oxycodone - Moxduo	25-May-07	4.6	0.03	0.00	0.00	0	-12	0	
Race Oncology Ltd	RAC	Development of chemotherapy drug Bisantrene for cancer, particularly Acute Myeloid Leukemia	13-Jul-16	5.9	0.07	0.38	0.07	-7	-1	3	
ResApp Health Ltd	RAP	Developer of mobile medical applications for the diagnosis and management of respiratory diseases	12-Jan-05	52.0	0.08	0.28	0.07	-1	-8	1	
Recce Pharmaceuticals Ltd	RCE	Development of synthetic antiobiotics to address the threat of antiobiotic resistance	15-Jan-16	21.4	0.20	0.21	0.13	-2	-11	0	
Roto-Gro International Ltd	RGI	Automated farming system for producing high quality plants indoors, including medicinal cannabis, pharmaceuticals and food products.	10-Feb-17	25.3	0.25	0.56	0.23	-5	-5	4	
Regeneus Ltd	RGS	Cellular therapies focusing on osteoarthritis and other inflammatory conditions, cancer and wound healing	19-Sep-13	21.9	0.12	0.27	0.10	-3	-5	-2	
Reproductive Health Science	RHS	Developer of chromosomal abnormality embryo testing in IVF cycles	5-Mar-87	24.7	0.28	0.28	0.10	-2	-12	1	
Resonance Health Ltd	RHT	Non-invasive medical imaging software services. MRI for liver fat, liver iron concentration, iron levels in bone marrow	2-Jan-92	37.4	0.09	0.12	0.02	0	35	1	
Rhythmn Biosciences Ltd	RHY	Development of an affordable blood test for the early detection of colorectal cancer - ColoSTAT	7-Dec-17	10.3	0.17	0.27	0.13	-2	-7	6	
Ridley Corporation Ltd	RIC	Production of animal nutrition solutions including feed ingredients; and marketing and provision of rural products	13-Aug-87	414.0	1.36	1.57	1.25	7	20	61	4.25
Resmed Inc	RMD	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing	25-Nov-99	5,605.6	14.16	16.57	12.13	44	32	0	14.04
Rhinomed Limited	RNO	Nasal, respiratory and breathing technologies - Mute, a nasal device to assist with breathing through the nose, and Turbine, a nasal dilator	21-Sep-07	24.1	0.17	0.42	0.11	-4	-4	3	
Roots - Sustainable Agricultural Technologies Ltd	ROO	Developing and commercialising technologies to address problems faced by agriculture including plant climate management and shortage of water for irrigation	7-Dec-17	4.2	0.09	0.47	0.07	-7	-1	0	
RSH Respiri Ltd	RSH	Devices for detecting and monitoring respiratory disorders	14-Jul-00	40.5	0.08	0.17	0.07	-1	-6	0	
Reva Medical, Inc	RVA	Bioresorbable coronary scaffolds for the treatment of cardiovascular disease	23-Dec-10	70.6	0.17	0.40	0.12	82	0	-22	
Stemcell United Ltd	SCU	Growth, reproduction and extraction of plants stem cells for medical and healthcare products	13-Jun-00	10.8	0.02	0.06	0.02	0	-4	0	
SDI Limited	SDI	Research and development, manufacturing and marketing of specialist dental materials	7-Nov-85	99.3	0.82	0.90	0.49	6	13	40	2.60
Science Developments Pty Ltd	SDV	Research, development and commercialisation of polymers for dairy and food product manufacturing	2-May-02	5.1	0.06	0.10	0.03	3	2	4	
Sienna Cancer Diagnostics Ltd	SDX	Clinical translation of biomarkers using novel diagnostic technologies. First on-market product is based on technology for the detection of the biomarker telomerase	3-Aug-17	17.0	0.07	0.10	0.05	-1	-8	0	
Sonic Healthcare Limited	SHL	Laboratory medicine/pathology, radiology/ diagnostic imaging and primary care medical services	30-Apr-87	11,670.6	24.51	27.00	21.26	110	22	-222	82.00

Issuer Name	ASX	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
SciGen Limited	SIE	Develops, manufactures and markets human health care biotechnology derived products. Focus on endocrinology, gastroenterology and immunology	15-Nov-02	3.6	0.07	0.07	0.02	0	17	-15	
Somnomed Ltd	SOM	Specialises in products for sleep apnoea. Lead product SomnoMed mandibular advancement splint (MAS)	27-Aug-04	116.2	1.78	3.21	1.46	-27	-7	18	
Starpharma Holdings Limited	SPL	Developer of dendrimer products. Lead product VivaGel for bacterial vaginosis. Dendrimer-enhanced docetaxel in clinical development for solid tumours	28-Sep-00	371.7	0.96	1.67	0.87	-3	-31	13	
Sirtex Medical Limited	SRX	Novel technology for liver cancer treatment. Radioactive particle and SIR-spheres	24-Aug-00	1,893.7	33.55	33.58	13.33	74	45	271	
Suda Ltd	SUD	Orormucosal sprays for drug delivery treatment of off-patent drugs	24-Jan-02	12.9	0.01	0.01	0.00	0	-2	0	
Simavita Ltd	SVA	Wearable and disposable technologies for elderly incontinence	22-Feb-14	7.1	0.02	0.06	0.01	-2	-1	1	
TBG Diagnosticas Ltd	TDL	Development, manufacturing and marketing of molecular diagnostic kits, instruments and services	22-Dec-95	8.5	0.26	0.30	0.14	-2	-2	5	
The Hydroponics Company Ltd	THC	Development and delivery of medical cannabis	4-May-17	48.9	0.55	0.79	0.42	-7	-8	19	
Telix Pharmaceuticals Ltd	TLX	Development and commercialisation of molecularly-targeted radiation in the management of prostate, renal and glioblastoma (brain) cancer	15-Nov-17	98.9	0.66	1.03	0.54	-7	-10	6	
TPI Enterprises Ltd	TPE	Processor of Narcotic Raw Material (NRM) for the international pharmaceutical industry	13-Aug-15	86.0	1.06	1.64	0.90	-7	-15	43	
Universal Biosensors Inc.	UBI	Specialist medical in-vitro diagnostic tests for point-of-care; blood test C-reactive protein test.	13-Dec-06	35.9	0.20	0.31	0.20	21	1	29	
Uscom Limited	UCM	Non-invasive medical devices in the field of cardiac, vascular and pulmonary monitoring	10-Dec-03	21.3	0.16	0.25	0.11	-1	-13	2	
Vectus Biosystems Ltd	VBS	Drug discovery and development company. Lead product VB0004 has anti-hypertensive properties, and anti-fibrotic activity in the heart and kidneys	23-Feb-16	10.5	0.45	1.19	0.29	-10	-5	-11	
Volpara Health Technologies	VHT	Research, development and manufacturing company that provides digital health solutions for personalised breast cancer screening	27-Apr-16	212.5	1.15	1.55	0.61	-6	-20	-10	
Viralytics Limited	VLA	Development and commercialisation of oncolytic immunotherapies. Lead product candidate CAVATAK	15-Oct-86	485.6	1.75	1.75	0.59	-6	-29	13	
Virtus Health Ltd	VRT	Assisted reproductive services, diagnostics, genetic testing and day hospitals	11-Jun-13	329.6	4.06	5.93	3.91	36	11	-218	24.00
Vita Life Sciences Limited	VLS	Development and distribution of over-the-counter medicines, complementary, alternative, dietary supplements and health foods	23-Aug-07	48.0	0.88	1.05	0.65	4	20	39	3.75
Wattle Health Australia Ltd	WHA	Health and wellness products with scientific and nutritional benefit	15-Mar-17	109.7	0.85	2.37	0.80	-5	-17	29	
XRF Scientific Ltd	XRF	Manufacturer and marketer of instrumentation for scientific industries, including commercial laboratories	31-Oct-06	21.4	0.16	0.19	0.13	1	13	12	0.30
Zelda Therapeutics	ZLD	Investing in research and clinical trials to study medical cannabis for a variety of ailments	28-Jul-03	40.8	0.05	0.13	0.03	0	-13	1	
Zelda Therapeutics	ZLD	Investing in research and clinical trials to study medical cannabis for a variety of ailments	28-Jul-03	37.2	0.07	0.16	0.07	0	-31	1	

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This quarter's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Quarter Return %
AVH	Avita Medical Ltd	$0.26	120
CLI	Croplogic	$0.03	73
FTT	Factor Theraptcs Ltd	$0.00	69
ANP	Antisense Therapeut.	$0.04	53
BOT	Botanix Pharma Ltd	$0.12	51
PBT	Prana Biotechnology	$0.05	50
NAN	Nanosonics Limited	$4.49	49
PAR	Paradigm Bio.	$1.55	47
RHT	Resonance Health	$0.09	46
BNO	Bionomics Limited	$0.17	44
PME	Pro Medicus Limited	$17.01	43
AXP	Airxpanders Inc.	$0.04	42
ZLD	Zelda Therapeutics	$0.05	41
GSS	Genetic Signatures	$1.20	41
CLV	Clover Corporation	$2.02	41
KZA	Kazia Therapeutics	$0.47	32
CDX	Cardiex Limited	$0.04	31
CUV	Clinuvel Pharmaceut.	$25.24	30
BLT	Benitec Biopharma	$0.13	29
GTG	Genetic Technologies	$0.01	29

This year's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Year Return %
PAR	Paradigm Bio.	$1.55	164
GSS	Genetic Signatures	$1.20	159
AVH	Avita Medical Ltd	$0.26	150
RHT	Resonance Health	$0.09	144
BIT	Biotron Limited	$0.09	129
SIE	SciGen Limited	$0.07	113
CUV	Clinuvel Pharmaceut.	$25.24	94
CLV	Clover Corporation	$2.02	74
PME	Pro Medicus Limited	$17.01	74
IDT	IDT Australia Ltd	$0.15	69
PVA	pSivida Corp	$2.99	63
LCT	Living Cell Tech.	$0.04	59
OHE	Orion Health Grp	$1.13	57
PBP	Probiotec Limited	$1.60	54
NAN	Nanosonics Limited	$4.49	53
VHT	Volpara Health Tech	$1.14	49
CDX	Cardiex Limited	$0.04	48
IMM	Immutep Ltd	$0.04	45
PIQ	Proteomics Int Lab	$0.33	44
SDI	SDI Limited	$0.82	40

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