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Australasian BioTechnology

The journal of AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

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PLUS

Trends in life sciences

Medtech

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CEO AND CHAIR REPORT

BY JULIE PHILLIPS, CHAIR; AND GLENN CROSS, CEO, AUSBIOTECH

New report qualifies sector for first time

A new Life Sciences Sector Snapshot, commissioned by AusBiotech to provide a comprehensive overview of the life sciences sector within Australia, has revealed the magnitude of the life sciences sector for the first time. It confirms that there are approximately 232,218 people employed in the Australian life sciences sector, across 1653 organisations. The research shows that 53 per cent of life sciences organisations in Australia are industry-based, with 875 companies in total. Approximately 30 per cent of the workforce in the sector is employed by industry – around 69,109 people.

Flagship conference demonstrates buoyant life sciences sector

The AusBiotech 2017 annual national conference, held late last year in Adelaide, demonstrated the buoyancy of the sector, attracting 985 delegates from 18 countries – the largest delegations from China, Japan, New Zealand, Singapore and South Korea, the United Kingdom and the United States – to network, collaborate, and discuss sector successes and prospects. The participants heard from world-class speakers on contemporary issues concerning the sector, and welcomed the new statistics showing the significance of the sector to the Australian economy. Highlights included the 2017 Johson & Johnson Industry Excellence Award winners and the announcement of a new round of federal grants.

MTPConnect, the Medical Technologies and Pharmaceuticals Industry Growth Centre, announced that it has selected 20 national projects to collectively receive $7.385 million in funding over two years, with proposed matched funding of $15.2 million coming from the sector.

Julie Phillips

Glenn Cross

MTPConnect's Project Fund Program is a competitive, dollar-for-dollar matched funding program investing in big, bold ideas to improve the productivity, competitiveness and innovative capacity of Australia's medical technology, biotechnology and pharmaceutical sector. MTPConnect is supported by the Australian Government's Industry Growth Centres Initiative.

AusBiotech is pleased to have been awarded funds for a new project, the 'Australia-China Life Sciences Partnership Program' (China Program).

The China Program is designed to increase awareness and opportunities for communication, collaboration and commercialisation between companies and MRIs in the life sciences sector in Australia and China; and to deliver high-quality, collaborative research and industry projects, as well as valuable data analytics on commercial engagement between the two countries.

The AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards recognised innovative companies and individuals in Australia's world-class biotechnology, medical technology and healthcare sectors:

- Industry Leadership Award: Mrs Lusia Guthrie
- Company of the Year: Planet Innovation
- Emerging Company of the Year: CancerAid.

For more than 30 years, the annual AusBiotech national conference has brought the global life sciences community together to reflect on what has been achieved and to look at what Australia must do to further expand and promote its leading biotech sector.

> The AusBiotech and Johnson & Johnson Innovation Industry Excellence Awards recognised innovative companies and individuals in Australia's world-class biotechnology, medical technology and healthcare sectors

In addition to presenting a vast and stimulating program of speakers, AusBiotech facilitated at least 1500 meetings between participants via the business partnering system.

AusBiotech 2018 will be held in Brisbane and this follows the announcement that the Queensland Government will support the event this year. Speaking at the BIO International Convention in San Diego in 2017, Premier of Queensland Annastacia Palaszczuk said almost 1000 business leaders, investors and scientists from Australia and overseas are expected to attend the AusBiotech 2018 national conference from 31 October to 2 November at the Brisbane Convention and Exhibition Centre.

AusBiotech confirms changes to Board line up

AusBiotech announced the election of Professor Jan Tennent as a Director at the Annual General Meeting – which continues the strong industry-research conduit to the AusBiotech Board – and the appointment of a new Director, Dr Megan Baldwin, CEO and Managing Director of Opthea Limited, bringing expertise in life sciences industry leadership.

Jan Tennent (PhD GCertMgt FASM GAICD) is a respected senior executive and networked business leader with international and national experience in the pharmaceutical, agricultural biotechnology and research sectors. She has a proven record of contribution and accomplishment in the governance and management of non-profit organisations, and highly matrixed organisations, including CSIRO, CSL and Pfizer. Jan is currently the CEO of Biomedical Research Victoria, the premier voice linking health and medical research with clinical care in Victoria.

In her previous role as Director for Business Development and Global Alliances at Pfizer Animal Health, Jan was responsible for maximising the growth and profitability of Asia-Pacific business units, and leading the due diligence and negotiation teams for a number of company and product acquisitions, and numerous technology licenses and collaborative research and development (R&D) agreements. As a member of the CSL Animal Health executive team,

“In addition to presenting a vast and stimulating program of speakers, AusBiotech facilitated at least 1500 meetings between participants via the business partnering system”

Jan was responsible for new product opportunity evaluation and leadership of product development, and the launch teams for unique vaccines in Australia and the United Kingdom.

Jan's research career included periods as Director of the CRC for Vaccine Technology and Program Manager for the Vaccines and Immunology group of CSIRO Animal Health. In these roles, she honed her innovation and management skills, having oversight of the research and vaccine clinical trial activities of a 20-strong team.

An alumnus of Monash and Deakin universities, Jan was appointed in 2017 as Collaborative Professor at the University of Osaka. She is a Principal Fellow at The University of Melbourne, Fellow of the Australian Society for Microbiology and graduate of the Australian Institute of Company Directors.

The election result saw Director Serina Cucuzza (Manager, Commercial Development and Industry Engagement at the Burnet Institute) depart the Board after three years' service to AusBiotech.

On behalf of the Board, we extend our sincere thanks to Serina for her valuable contribution over her Board tenure. She has brought strong governance skills, and a research and early commercialisation perspective to the Board, for which we are most grateful.

The Board has also welcomed Dr Megan Baldwin, whose appointment was based on the principle of diversity of perspective at the Board and balance in Board Director profiles, and with regard to membership engagement and needs.

Megan was appointed CEO and Managing Director of Opthea Limited in February 2014, and has more than 20 years' experience working on therapeutic drug development programs in both Australian and international biotechnology companies. Megan joined Opthea in 2008 and has held various positions, including Head of Preclinical R&D and Chief Executive Officer of Opthea Pty Ltd. Megan is now focused on advancing Opthea's OPT-302 clinical development program for the treatment of eye diseases, including wet age-related macular degeneration.

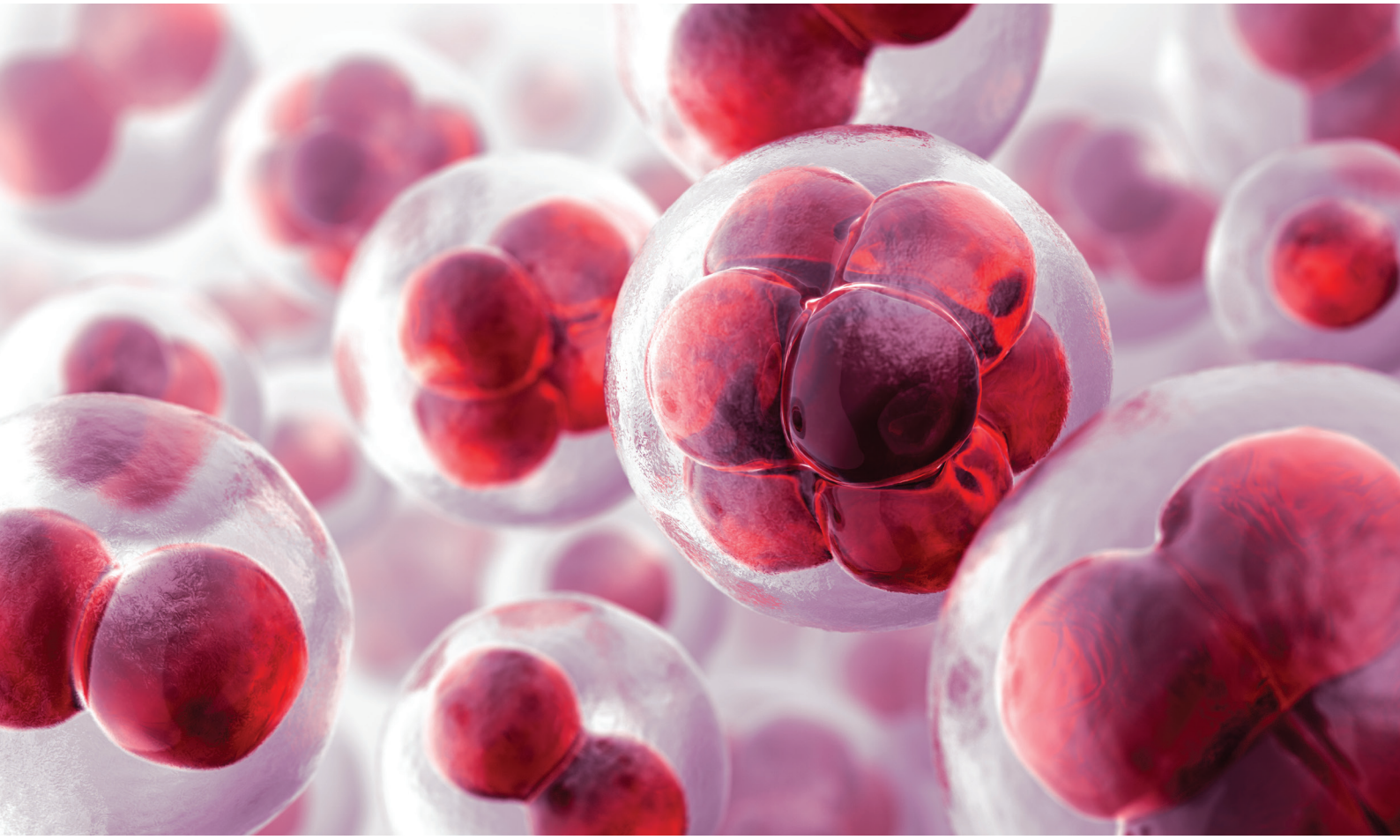
Prior to Opthea, Megan was employed at Genentech (now Roche), the world leader in angiogenesis-based therapies for cancer and other diseases. Her experience included several years as a postdoctoral researcher, before she moved to Genentech's commercial division, with responsibility for corporate competitive intelligence activities. In these roles, she developed extensive commercial and scientific knowledge in anti-angiogenic and oncology drug development.

The Board has also welcomed Dr Megan Baldwin and Professor Jan Tennent, whose appointments were based on the principle of diversity of perspective at the Board and balance in Board Director profiles, and with regard to membership engagement and needs

Megan holds a Doctor of Philosophy (Medicine) from The University of Melbourne, having conducted her doctoral studies at the Ludwig Institute for Cancer Research, and is a member of the Australian Institute for Company Directors.

The current Board comprises:

- Ms Julie Phillips, AusBiotech Chairman and CEO and Executive Director, BioDiem
- Dr Megan Baldwin, CEO and Managing Director, Opthea Limited
- Ms Michelle Burke, Principal and Director, Indigo Advisory
- Mr Glenn Cross, CEO, AusBiotech Limited
- Dr Andrea Douglas, Vice President, R&D Strategy and External Affairs, CSL Limited
- Mr Serg Duchini, Partner, Chief Strategy Officer, National Leader R&D and Government Incentives & Co. Director, Deloitte Touche Tohmatsu
- Mr Lawrence Gozlan, CEO, Scientia Capital
- Professor Jan Tennent, CEO, BioMedical Research Victoria
- Mr Barry Thomas, Director, Cook Medical Asia Pacific and Vice President, Cook Inc., Cook Medical / Cook Inc.



> The medical technology industry is growing worldwide, and Australia is poised to become a world-leader in medtech, supported by strong capabilities in areas such as genomic medicine, digital health and precision medicine

AusMedtech 2018

AusMedtech is an annual conference held by AusBiotech to bring together key stakeholders of the Australian and international medical devices and diagnostics sector to help prepare the industry sector for its changing landscape. AusMedtech 2018 will be held in Adelaide from 1–2 May 2018 at the Adelaide Convention Centre, South Australia.

The medical technology industry is growing worldwide, and Australia is poised to become a world-leader in medtech, supported by strong capabilities in areas such as genomic medicine, digital health and precision medicine. While the medical technology industry faces ongoing reforms, it also faces disruptive healthcare technologies that will have longer-term consequences. Check out the program at www.ausmedtech.com.au.

In closing, we have a challenging year ahead, including the expectation of the federal government's response to the review of the R&D Tax Incentive (RDTI) and the Innovation and Science Australia 2030 plan. The sector is growing, with policy stability being a key ingredient, and the RDTI providing an incentive for growing R&D, including clinical trials, in Australia.

AusBiotech is now collating the results of the 2018 CEO Industry Position survey and will launch the associated report at the end of April.

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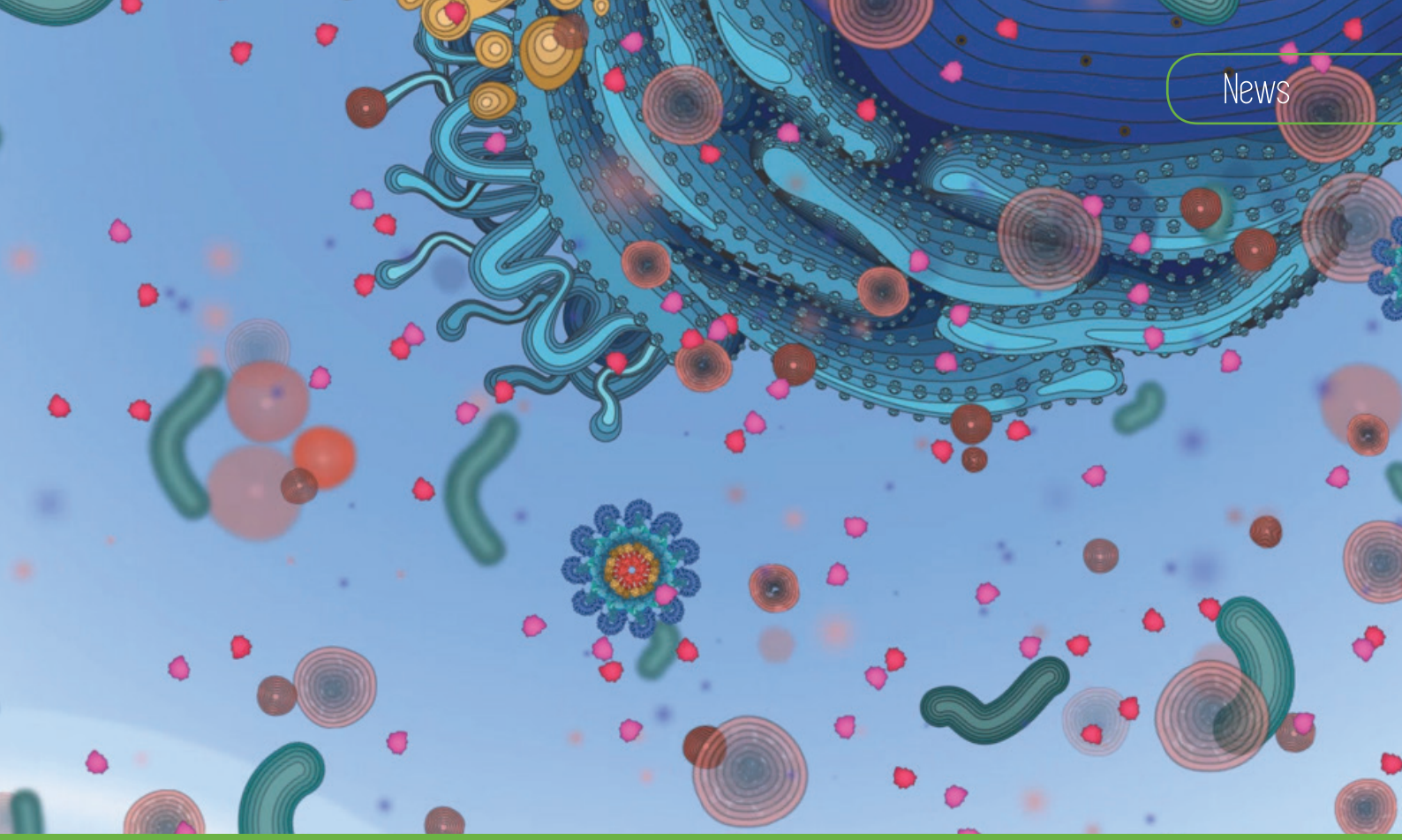
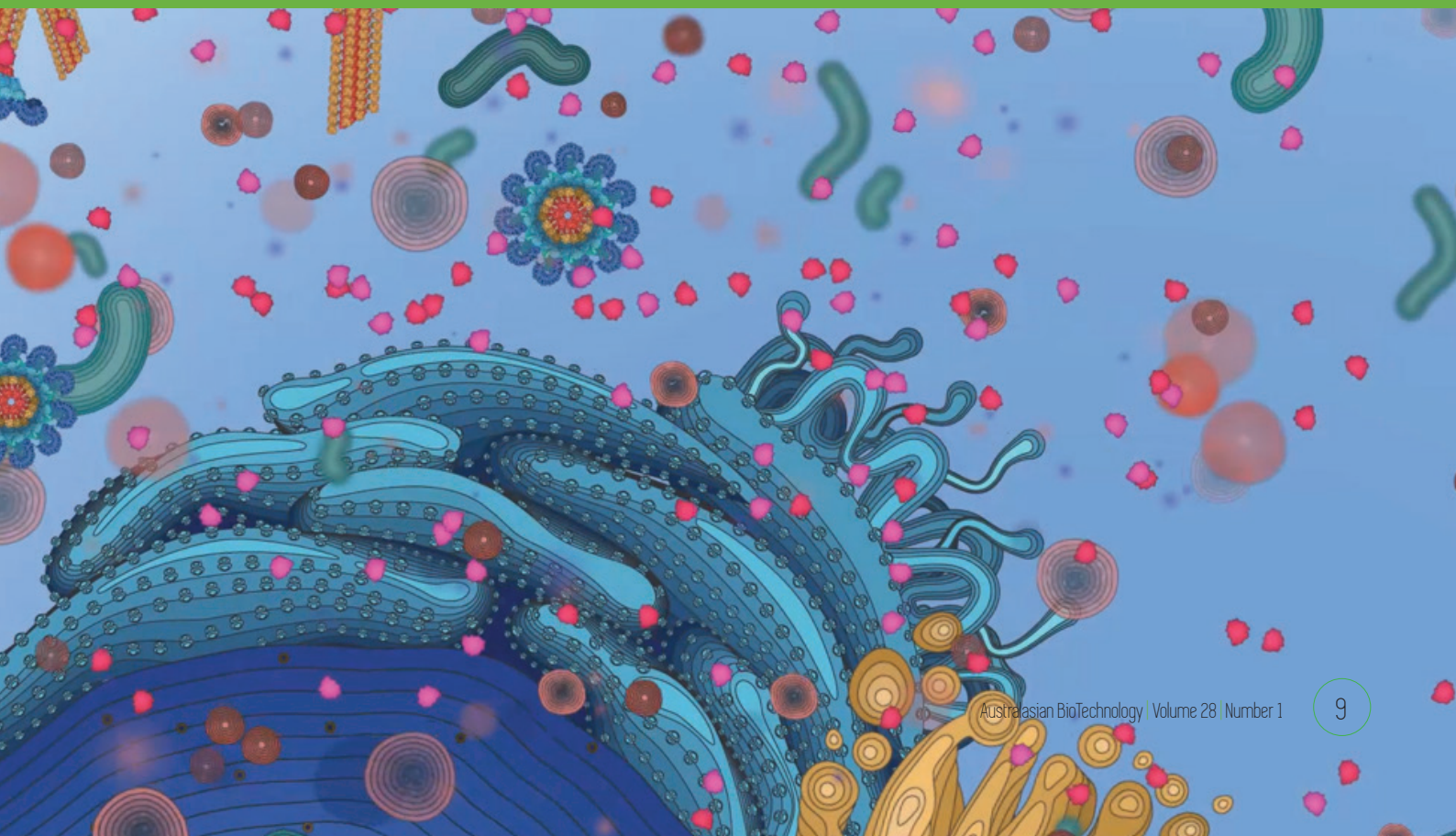


RESEARCHERS DISCOVER OFF SWITCH FOR DISEASE DRIVERS

BY THE UNIVERSITY OF QUEENSLAND



Kate Schroder

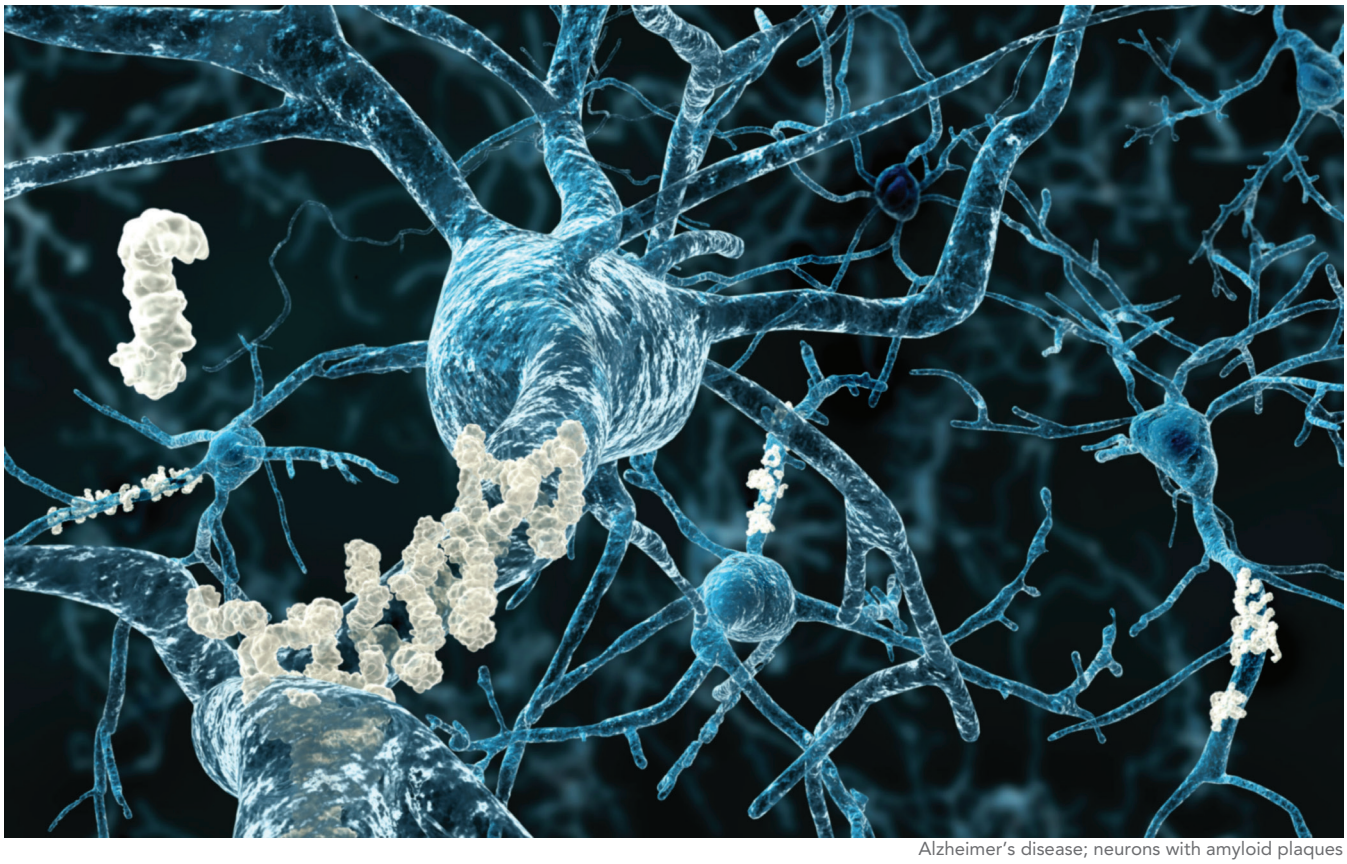
Unravelling the secrets of the immune system has become an urgent research priority, with uncontrolled inflammation implicated in myriad debilitating and devastating diseases. Neurodegenerative diseases such as Parkinson's and Alzheimer's disease, type 2 diabetes, heart and liver disease, rheumatoid arthritis, gout, and even some cancers, are all driven by prolonged or dysregulated inflammatory response. By defining the molecular processes behind inflammation, a laboratory at The University of Queensland's (UQ's) Institute for Molecular Bioscience (IMB) is laying the groundwork for new therapies to fight not just one disease, but many.

IMB's Inflammasome Lab focuses on the machine-like protein complexes formed when the immune system detects an infection, injury or other disturbance. Once assembled, inflammasomes send messages to immune cells, instructing them to respond. Group leader Associate Professor Kate Schroder says that during injury or infection, the immune response protects the body by creating inflammation to promote healing or to eliminate agents that may cause harm. It is when the disturbance cannot be cleared that inflammasomes damage healthy tissues, and this cycle of inflammation becomes the driver of disease.

'In the case of Alzheimer's, the immune system detects the presence of amyloid plaques, and fires off an inflammatory response; but the immune cells can't remove the plaques, so the inflammasomes continue to fire, and the sustained inflammation drives neurodegenerative damage,' Schroder says.

In gout, a common and painful form of arthritis, inflammasomes recognise uric acid crystals as the danger signal.

'With fatty liver disease, the immune system is initially responding to over-nutrition. For patients with this condition, the liver becomes increasingly fatty and inflamed, which can lead to cirrhosis or even liver cancer.'



Alzheimer's disease; neurons with amyloid plaques

Discovering how to switch off uncontrolled inflammation could be a silver bullet for a range of diseases driven by the uncontrolled firing of inflammasomes. But first researchers need a thorough understanding of how the system works when an otherwise healthy person has an infection or injury. Schroder's team has made important inroads into describing these processes, including the discovery of how the inflammasomes would usually turn themselves off.

'The inflammasome initiates the inflammation process by activating a protein that functions like a pair of scissors, and cuts itself and other proteins,' Schroder says. 'What we've recently found is that, after a period of time, this protein cuts itself a second time to turn off the pathway. This acts like an in-built timer switch, ensuring the inflammasomes only fire for a specific length of time after they are triggered. If we can find a way to tweak this system, we could turn it off manually in disease to stop the damage caused by sustained inflammation.'

The research, published in the *Journal of Experimental Medicine*, was supported by the Australian Research Council, and involved laboratories at IMB and the UQ School of Chemistry and Molecular Biosciences. Imaging for the project was performed in the IMB Cancer Biology Imaging Facility, funded by the Australian Cancer Research Foundation.

Schroder's laboratory has now begun studying the inflammasome in fatty liver disease, a rapidly growing health issue due to the increasing global incidence of obesity and diabetes. 'We are also working with collaborators to investigate how our research can be applied in neurodegenerative diseases.'

While the team's research could improve the lives of those suffering from some of the world's most challenging inflammatory diseases, it has another important aspect that could make a significant global difference. 'Inflammasomes form an important part of the immune response to infection, and microbes have evolved various mechanisms to evade this response,' Schroder says. 'We are defining how inflammasomes detect these bugs, and the strategies the bugs use to avoid this antimicrobial response. By understanding exactly how the body fights infection, we can help identify new drug targets or vaccines to combat infectious disease, which causes 13 million deaths around the world each year.'

Associate Professor Kate Schroder heads the Inflammasome Laboratory at the Institute for Molecular Bioscience, The University of Queensland, as an Australian Research Council Future Fellow. She is a Group Leader of IMB's Cell Biology and Molecular Medicine Division and Deputy Director, Centre for Inflammation and Disease Research.

WORKING HAND-IN-HAND WITH COLLABORATIVE ROBOTS

Robots don't necessarily have to be the bad guys when it comes to industry.

People often think of robots as job killers; however, the future of work will be a collaboration between humans and machines. Collaborative robotics is an emerging field that allows workers and robots to work side-by-side to improve efficiency and quality of the production process and output. These robots will have an influential effect on how Industry 4.0 affects the 'smart' factory of the future.

These robots reconfigure the machine/human relationship and allow workers to have more hands-on management of manufacturing processes. For instance, Australian winemaker Accolade Wines uses collaborative robots to shape cardboard to put into a machine to make boxes for its wine.

The robots create boxes for different-sized wine – from 180-millilitre bottles to 10-litre casks. Workers can program the robots to create the boxes to certain specifications. The robots do not need to be placed behind a fence to prevent damage to glass bottles on the production line.

Collaborative robots also improve the connectivity of factories and other workplace environments. In 2016, Microsoft joined forces with a robot manufacturer to develop a collaborative robot. It uses the Microsoft Azure Internet of Things, which works with the robotic system to send data to the Microsoft Azure cloud software.

A manufacturer can use the data from the cloud to ensure that production schedules and other key performance indicators are being met. This information sharing between the robot and the cloud ensures that the company can overcome any bottlenecks in the shop floor and thereby increase efficiency, productivity and quality assurance.

Bosch APAS Assistant is the company's collaborative robot solution. The APAS robot is an intelligent and flexible robot system for direct and safe collaboration between human and machine.

Its sensor skin is the first assistance system created for interaction with human operators without the need for a safety fence. Its 3D camera allows the APAS to identify objects and their spatial position, while the gripper automatically retracts in case it jams.

With the APAS assistant sensor-based, platform-independent distance-monitoring system, the robot can detect what is happening in its immediate vicinity. If it comes within 50 millimetres of another object the robot will stop. With its speed-switch function, the robot monitors the area around itself so that if someone enters the surrounding area, it automatically slows to a safer speed, avoiding any injury risk to employees.

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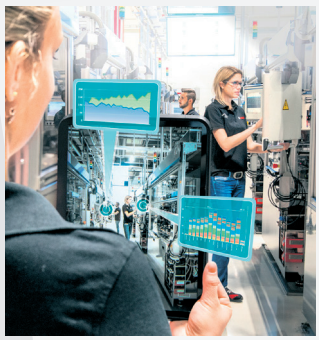

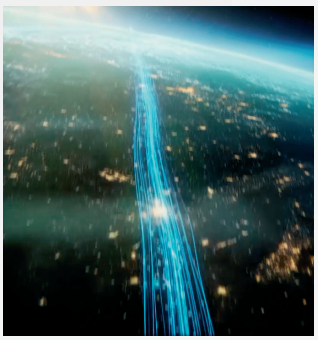


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Pictured here (left to right) are Aila Whittall, Eva Lengyelova, Lisa Sadetskaya, Rosanne Robinson, Dr Ellen van Dam and Dr Enid Eslick.

GENDER EQUITY IN LIFE SCIENCES

BY LISA SADETSKAYA, CLARITY PHARMACEUTICALS

In the 1970s, Charlotte Whitton, the first female mayor in Canada, commented on the problem of gender inequality: 'Whatever women do, they must do twice as well as men to be thought half as good. Luckily, this is not difficult.' Marie Skłodowska Curie is a great example. She was the major contributor to the early understanding of radioactivity, the first woman to win a Nobel Prize (1903), and was the first person (and the only woman) to win twice and in multiple disciplines: chemistry and physics. Her discoveries paved the way for innovation in several scientific fields, such as nuclear medicine, space science, energy and many others.

Despite her success, Marie Curie had to face numerous challenges, such as bias, financial struggles, a shortage of funding for her research, inadequate research equipment and the necessity to balance immense workload, family and numerous health issues related to her work with radioactive elements.

While we have seen improvements in gender equality in life sciences, there are still some painfully obvious inequities. While in Australia almost 50 per cent of science graduates are women, and they make up more than half of PhD graduates, only 17 per cent of senior academics in Australian universities and research institutes are female[1]. This reflects the notable pay gap in STEM in general – 32 per cent of men reach annual salaries of more than $100,000, compared to just 12 per cent of women[2].

Sadly, this trend carries over to the Australian public research sector. Men received 79 per cent of Australian Research Council Linkage Infrastructure, Equipment and Facilities (ARC LIEF) grants in the last 10 years, and 82 per cent of National Health and Medical Research Council (NHMRC) program grants in the last 15 years. But the problem runs even deeper – 84 per cent of all of those men who received NHMRC grants in the last 15 years worked in all-male teams, creating a deeper gender divide and making culture change a challenging task[3].

It is clear that to fix the gender equality problem in life sciences, more than a strong role model like Marie Curie is required. The change has to be a cultural one, and it is crucial for men to contribute to the solution. One of the vital steps is avoiding clusters of men working with men and altering the process of forming teams to account for diversity. The field of life sciences, much like any other field in science and technology, was originally set to a male default, so it is time to reset the system and create a culture where women can be integrated into the system, and discover their full potential without feeling marginalised and demoralised.

Creating the right funding opportunities, ensuring access to grants and supporting the culture change on the institutional level are important factors, as well. A number of initiatives to support this have been launched recently, such as Science in Australia Gender Equity (SAGE) initiative and the Women in Health Science initiative by NHMRC.

A study by the Peterson Institute for International Economics reveals that companies with at least 30 per cent of women in leadership positions had net profit margins up to six per cent higher than companies with no women in the top ranks[4]. Other benefits of gender equity include emotional intelligence, collaboration and an ability to adapt to change[5].

The benefits of creating an inclusive culture with gender-diverse teams are evident. At Clarity Pharmaceuticals, a personalised medicine company focused on the treatment of serious diseases, more than 50 per cent of employees are female, with women at all levels of management. Women are crucial in the clinical and preclinical development teams, as well as in corporate roles. For instance, Rosanne Robinson is a founding board member and has been integral to the development of the company, while Professor Suzanne Smith was one of the key chemists behind the development of Clarity's core technology.

Clarity has, to date, been successful in translating great Australian science from institutes such as the Australian Nuclear Science and Technology Organisation, and the University of Melbourne, into the clinic, and has been awarded a number of government grants both in Australia and abroad for the development of its pipeline of radiopharmaceuticals to treat cancer, and other serious diseases in children and adults.

Clarity uses the funding for clinical and preclinical development of its pipeline, as well as to employ and retain talent. And although Clarity takes a gender-neutral approach, the company has been able to attract and retain a high percentage of highly educated and qualified women. This has occurred by simply implementing pragmatic work practices that avoid a number of the rigid limitations of academia that disproportionately affect women. Some of these work practices include more flexible working arrangements to accommodate team members with young families, and providing a nurturing environment for those seeking broader experiences in the sciences or business, or wishing to further advance their education.

Clarity views these measures not merely as a way to support its employees, but as a vital strategic step towards sustaining the company's competitive edge, raising the next generation of successful scientists, contributing to the broader development of a deeper talent pool, and increasing Australia's competitiveness in the field of life sciences.

1 Gender Equity, Australian Academy of Science, <https://www.science.org.au/supporting-science/gender-equity>

2 Only 16% of Australians in Stem professions are women, and pay gap is 'unacceptable', The Guardian, <https://www.theguardian.com/australia-news/2016/mar/31/just-one-in-five-australians-working-in-stem-professions-are-women-and-theyre-paid-less>

3 Australian research 'has a Daversity problem': Analysis shows too many men work mostly with other men, ABC Science, <http://www.abc.net.au/news/science/2017-11-24/australian-research-has-a-daversity-problem/9178786>

4 Research on over 21,000 Companies Globally Finds Women in Corporate Leadership Can Significantly Increase Profitability, Peterson Institute for International Economics, <https://piie.com/newsroom/press-releases/new-peterson-institute-research-over-21000-companies-globally-finds-women?id=241>

5 New Research Shows Women Are Better at Using Soft Skills Crucial for Effective Leadership and Superior Business Performance, Finds Korn Ferry Hay Group, Korn Ferry, <https://www.kornferry.com/press/new-research-shows-women-are-better-at-using-soft-skills-crucial-for-effective-leadership/>; The Benefit of More Women in Leadership Roles, Women of HR, <http://womenofhr.com/the-benefit-of-more-women-in-leadership-roles/>

BIOTECH'S LEADING WOMEN

From an unacceptably low base, women have steadily been working towards equal representation in life sciences. Recent figures show that efforts to support women in life sciences are reaping results, but we're not there yet in achieving equity. Women represent 33 per cent of the industry, and this figure dwindles as the seniority level increases.

While pharmaceutical companies are leading the way with 45 per cent female representation, within the industry levels drop to 22 per cent at executive level, 16 per cent for CEOs and managing directors, and just 13 per cent at board level. This theme was consistent across the life sciences sector, research institutes, government and regulatory bodies, funding bodies and the services sub sector.

AusBiotech is focused on improving female representation in the life sciences at all levels. In March 2018, AusBiotech ran the AusBiotech Women in Life Sciences Luncheons to provide a forum for women to gather and support one another in their careers in life sciences in order to achieve a more equal standing. This year, the theme focused on the power of sisterhood and how this bond among women can further galvanise diversity in life sciences as essential to building a successful sector – a position supported regardless of gender.

With the theme 'Sisters in Life Sciences', the luncheons this year encouraged, supported and further developed women in the sector. Leaders in the sector connected with those aspiring to start or progress their career in the life sciences to bolster their efforts.

In this edition of *Australasian BioTechnology*, we profile five leading women in the life sciences, and learn more about their views on the industry.

Dr Jackie Fairley

Dr Jackie Fairley was appointed Starpharma CEO in July 2006. She has more than 25 years of operational experience in the pharmaceutical and biotechnology industries, working in business development and senior management roles in companies including CSL and Faulding/Hospira (now part of Pfizer). Under her leadership, Starpharma has advanced into the ASX300, attracted significant global investors and commercial partners, and developed new and valuable commercial products based on Starpharma's proprietary polymer technology. These include the world's first antiviral condom, VivaGel®BV for bacterial vaginosis (soon available in Australia as Fleurstat™) and DEP® docetaxel, an improved version of the leading cancer drug Taxotere®.

How can the life sciences industry attract more female leaders?

I don't so much see it as a need to attract female leaders, but the need to ensure that we develop both men and women as leaders, and work to remove any biases in selection and promotion. We also need to start early and foster girls' interest in STEM subjects and encourage younger female executives to seek out and pursue leadership roles.

Elaine Darby

AusCann Managing Director Elaine Darby has held leadership positions in digital health and biotechnology companies, practised as a lawyer with top-tier firm Clayton Utz, and has been a winemaker in the Margaret River region of Western Australia. She holds both science and law degrees, and brings expertise from both these fields of study into her work. Darby's unique background has prepared her for the multifaceted challenge of building one of Australia's first medicinal cannabis companies.

What do you love about your industry?

The most fulfilling aspect of this industry is helping patients to find effective treatments for refractory chronic conditions. Underpinning this, I enjoy the challenges of operating in an evolving industry and the satisfaction of being able to use science to dispel preconceived beliefs on the therapeutic uses of cannabinoids. I am also attracted to the diversity of the industry as it encompasses horticulture, pharmaceutical manufacturing, clinical studies, medical education and compliance with regulatory frameworks.

Kathy Harrison

Kathy Harrison has been CEO of Dimerix Limited since November 2016, having been recruited in March 2014 as sole employee to take Dimerix into the clinic.

Under Harrison's leadership, Dimerix has progressed to an ASX-listed company with positive Phase IIa clinical data and a strong patent position. Dimerix is poised to enter the clinic again with two further Phase II trials, further driving the value in the DMX-200 asset. Harrison's career has been built by combining her passion for science and intellectual property protection, and translating these into human healthcare products. Her background includes degrees in science, qualifications and private practice experience as a patent attorney, and biotechnology company experience. This blend of skills makes her well suited to tackling human healthcare needs in a commercial environment.

What do you love about your industry?

I love the opportunity biotechnology gives me to work with incredibly intelligent and capable people, and with world-leading science and technologies. Added to that is the opportunity to make a real difference in the lives of people suffering under the burden of disease. These factors make biotechnology a great place to be.

Sam Cobb

Sam Cobb founded AdAlta in 2007 and has seen AdAlta progress its i-body technology from bench to bedside, with its lead i-body candidate entering the clinic later this year. AdAlta listed on the ASX in August 2016, and Cobb was instrumental in the success of the oversubscribed listing. Under Cobb's leadership, AdAlta has refined its position as a next-generation antibody-type platform play and showed that AdAlta's 'i-body' scaffolds can be used for hitting targets that are yet to be drugged with antibodies. AdAlta is developing its lead i-body AD-114 for the treatment of fibrosis, a challenging disease area with high unmet patient need.

What do you envisage for the future of gender equity in your field?

50:50 throughout the entire organisation from bench to Board and, more importantly, at the executive role and on both sides of the investment table (CEOs, and then venture capital and broking on the other side). In addition, equal pay across the sector for the same role in all of the positions listed above.

Dr Leearne Hinch

Dr Leearne Hinch is CEO of BARD1 Life Sciences, and she brings a generalist background in operational management, strategic planning, fundraising, business development and commercialisation across therapeutics, devices, diagnostics and animal health. Hinch has driven the growth of several early-stage life sciences companies through advancing technology commercialisation from the research stage towards clinical development, to successfully raise funds, secure collaboration partners, negotiate commercial deals and grow shareholder value. She has previously held executive positions in ASX-listed biotechnology, multinational and private companies including Eustralis Pharmaceuticals, Immuron, OBJ, Holista Colltech and Virbac.

What do you envisage for the future of gender equity in your field?

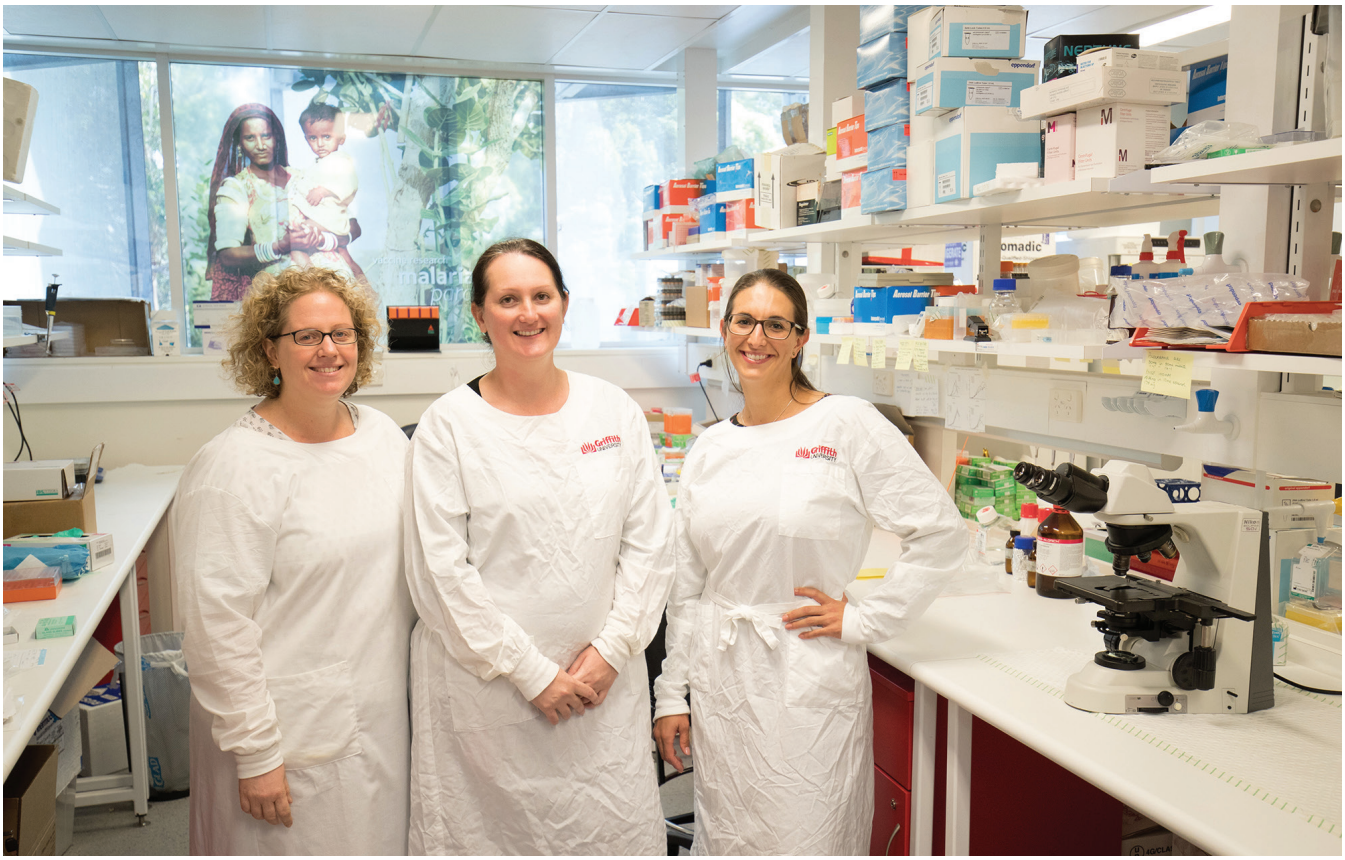
The ideal future is when the life sciences industry has evolved to a point where gender equity is no longer a governance issue, and recruitment and selection of prospective directors, CEOs and life sciences candidates is based on assessment of their qualifications, experience and achievements to put the right person in the right job to contribute to the long-term success of the business.

Leslie Chong

Leslie Chong, CEO of Imugene (ASX: IMU), was previously Senior Clinical Program Lead at Genentech, where she oversaw clinical development for Cotellic, an MEK inhibitor, FDA-approved in 2015, for the treatment of BRAF V600E mutated melanoma. She was also a part of the cancer immunotherapy team. Before Genentech, Chong was a clinical development head at the San Francisco cancer drug developer Exelixis, and before that she held clinical operation leadership roles at GSK and PPD. At Imugene, Leslie has put her clinical development skills to use, getting the HER-Vaxx B cell peptide vaccine into the clinic and developing the B cell–based mimotope pipeline while building the business.

Why is gender equity important in your industry?

Biotech tends to be extremely limited in terms of how many women are involved. I can't speak as to why that is exactly, but I have always thought that women in biotech don't just have to be the equal of their non-female colleagues; they have to be better. The women I looked up to as mentors were excellent role models for me because they were creative and had to think quite differently to their male counterparts. The problem-solving seems to me where women tend to be leap years ahead of their male counterparts because they had to be.



Dr Danielle Stanisic, Associate Professor Kate Seib and Dr Lara Herrero

LIFE SCIENCES HUB LED BY WOMEN

BY KATHY KRUGER, GOLD COAST HEALTH & KNOWLEDGE PRECINCT

As the Gold Coast hosts the 2018 Commonwealth Games, the emerging Gold Coast Health and Knowledge Precinct (GCHKP) will be a key legacy.

Supported by $5 billion in infrastructure, and home to Griffith University, the $1.76-billion Gold Coast University Hospital and the new Gold Coast Private Hospital, as well as the $550-million GC2018 Athletes Village, the 200-hectare GCHKP will be transformed post–Commonwealth Games into a vibrant community to live, work and learn.

A number of talented women are among life sciences leaders that are making a significant difference, and who'll take the GCHKP into its exciting future.

It's a golden moment for the Gold Coast, and GCHKP Project Director Di Dixon has an attractive investment proposition – not only the enviable lifestyle of Australia's fastest-growing major city, but also an emerging ecosystem that's growing life sciences and related health technologies.

The GCHKP boasts a combination of expertise, infrastructure, land and location unique in Australia – nine hectares are available for health and innovation investment, serviced by the Gold Coast light rail and with easy transport access, surrounded by 1250 residences and seven hectares of parkland.

High-speed fibre-optic cabling, promising some of Australia's fastest internet speeds, makes the precinct a seriously connected hub.

'Four sites will be developed immediately post-Games, and we have strong interest from international investors for a couple of other sites – development will be able to start from 2019,' says Dixon.

'GCHKP will be the key GC2018 legacy project and is crucial to the Gold Coast coming of age.'

Originally from the United Kingdom, and with a background in economic development and project management, Dixon has led the concept of creating a health and innovation hub since inception. The GC2018 has turbo-charged the project, with the opportunity to develop such prime greenfield land.

The GCHKP already boasts the Institute for Glycomics, with more than 200 researchers. The only institute of its type in Australia, and one of only six in the world, it's currently involved in clinical trials of four drug and vaccine technologies, and is active in commercial partnerships.

Recent licensing and co-development deals include a Group A streptococcus vaccine with Chinese company Olymvax Biopharmaceuticals; a therapeutic for viral-induced arthritis (Phase II clinical trials 2017) with Paradigm Biopharmaceuticals; and therapeutics for sepsis (Phase I clinical trials 2017) with Sirtex Medical Ltd.

'The key for the precinct is to ensure there is an R&D and commercial innovation aspect to the operations of companies we locate here, in order to grow a genuine global reputation in our areas of niche strength,' says Dixon.

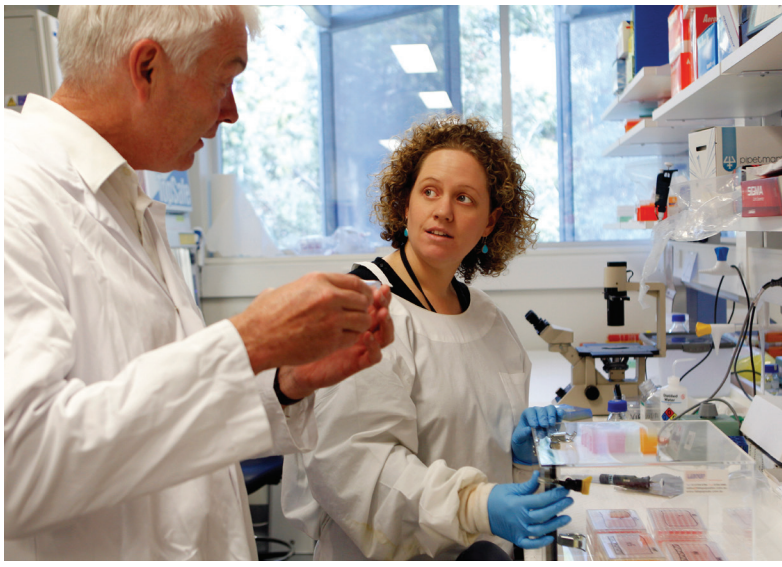
And when it comes to leveraging expertise and commercial connections in the precinct, there's a wealth of talent to choose from, much of it female.

The GCHKP is also home to the Menzies Health Institute Queensland (MHIQ) at Griffith University, headed by Professor Suzanne Chambers.

It's also developing a growing reputation for clinical trials, with Griffith's Clinical Trials Unit headed by Associate Professor Evelin Tiralongo. Griffith's Pro Vice Chancellor (Health), Professor Sheena Reilly, is also based in the precinct.

The National Centre for Neuroimmunology and Emerging Diseases sits within MHIQ, with leading immunologist Professor Sonya Marshall-Gradisnik its Co-director.

Marshall-Gradisnik and her team have discovered that chronic fatigue syndrome is potentially related to problems in the ion channels that allow calcium into the body's cells.



Dr Danielle Stanisic and Professor Michael Good

'Calcium is required by just about all cells, and is vital in helping the immune system destroy a virus or infection,' says Marshall-Gradisnik.

'We've reported that patients with ME (myalgic encephalomyelitis) have lower levels of calcium being transported into their immune cells, and the immune cells have lower calcium being stored inside.'

The NCNED is now working on a larger validation study, and investigating various drugs that can improve the function of these ion channel receptors.

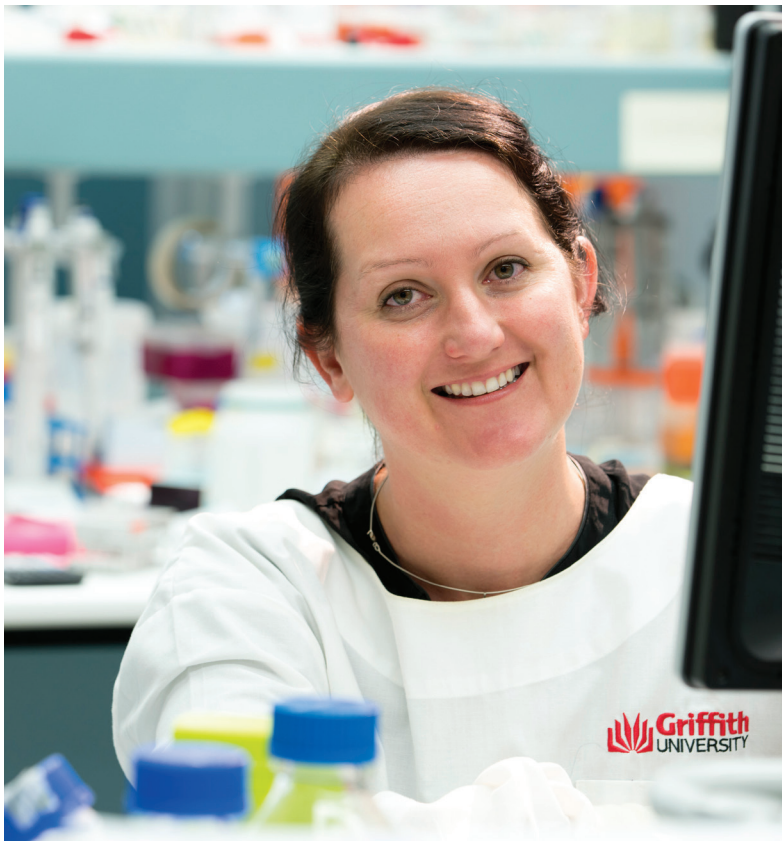
At the Institute for Glycomics, two of the Principal Research Leaders are women with vast life sciences experience. Professor Sue Berners-Price is also Dean of Griffith University's Graduate Research School, while Professor Nicolle Packer recently joined the Institute, following a distinguished career in industry and academia.

Microbiologist Associate Professor Kate Seib is a mid-career researcher, who joined the Institute in 2012 after returning home from seven years with Novartis in Italy.

She's previously been awarded an NHMRC Career Development Fellowship (CDF) and was the 2016 winner of the ASM Frank Fenner Award by the Australian Society for Microbiology (ASM).

In 2015, her team was awarded more than $1 million to find new vaccine targets for diseases that cause

Professor Sonya Marshall-Gradisnik



Associate Professor Kate Seib

meningitis, gonorrhoea and middle ear infections, and she's also enjoyed subsequent NHMRC success.

As convenor of this year's ASM national conference, Seib believes that it is important for women to have visibility outside of the lab, and not just in terms of publications.

'Involvement in professional organisations, mentoring and science communication are all ways to gain profile and encourage other women into science.'

Fellow Institute research leader Dr Lara Herrero (NHMRC CDF) was a finalist in the Women in Technology (WiT) 2017 awards for Life Science Research Award Leader.

A decade after contracting Ross River fever, from which she suffered ongoing and debilitating symptoms, she's enjoyed career success in supporting sufferers.

'My career highlight so far has been taking a drug from conception to the clinic,' says Herrero.

'Due to the extremely positive preclinical results from my pentosan polysulfate (PPS) research and a strong collaboration with an industry partner, we were able to show proof of principle, successfully treating several human patients with PPS under the Therapeutics Goods Administration Special Access Scheme.

'I think that attracting women to science is no longer an issue. Impressively, at least 50 per cent of undergraduates are female; however, retainment of women in science is a completely different issue and a real concern.'

For Senior Research Fellow Dr Danielle Stanisic, four years spent in Papua New Guinea shaped her career-long quest to beat Malaria.

'Having the opportunity to work in a country where malaria is endemic, and seeing the impact firsthand, really gives you a different perspective on your research,' Stanisic says.

Dr Stanisic has worked with Professor Michael Good since 2013 in the Institute's Laboratory of Vaccines for the Developing World, and oversees the clinical trials of the world-first whole blood-stage malaria parasite vaccine candidate PlasProtecT®.

HIGHLIGHTING POSSIBILITIES

an important step in retaining women in science

BY SUE JENNINGS, HR DIRECTOR, ABBVIE ANZ

With a female scientist (Professor Michelle Simmons) named 2018 Australian of the Year, there has never been a better time to encourage young women and girls to pursue a career in health and medical research. There is still much to be done, however, if we are to retain these women once they complete their qualifications.

Kate Weatherby spent nearly 10 years committed to her studies in biomedical science, graduating with a PhD in 2016. But it was during her studies that she realised that the typical path of pursuing postdoctoral qualifications and a career in academia was not for her.

I met Kate by chance at an AusBiotech Women in Life Sciences Luncheon in 2017, after she won a competition to attend the networking event. In her competition entry, she spoke of her passion for science and the words really resonated with me:

'My vision for women in STEM is that women of all stages of their careers actively support each other to fulfil their potential. Strong female role models demonstrate that women are just as capable as men, and should be entitled to the same opportunities and treatment. My hope is that with strong female STEM representatives, a shift will be made away from the idea that STEM is primarily for males, and we can reach the point as a society where female CEOs and directors of STEM-based corporations are not an anomaly, but a sign of equality.'

AbbVie is a company full of highly educated women, many of whom have formal qualifications in science. Supporting and retaining women in health and medical research is a core focus for us. So, I was compelled to reach out to Kate and I am really glad I did.

She explained that she was interested in clinical research, and so, after going through a formal interview process, AbbVie offered her a role as Assistant Clinical Research Associate. She is now part of a clinical operations team of more than 40 people, based in Sydney, who are dedicated to managing AbbVie's world-class clinical trial program.

Sue Jennings

Kate's experience really brings the value of women networking to life.

Kate Weatherby

'I'm an introvert, so it was really hard to put myself out there,' she says. 'But I found that taking a friend along is really helpful. It also helps to set a target for the number of new people you want to meet. It's important not to go into it purely expecting job offers, but just meeting new people and entering a different network, you never know what opportunities will come your way.'

Central to AbbVie's talent acquisition strategy is to look for emerging talent: those with great technical skills. Equally as important are passionate people who align with our cultural values and want to make a difference, both for our organisation, and for patients.

Young women need to be able to connect with future employers. Networking is a powerful tool, and it's a skill women need to continue to develop, as we know that around 70 per cent of roles are never formally advertised.

Initiatives such as the AusBiotech lunches are great opportunities for young women to find out about career possibilities that are open to them in biotechnology and the pharmaceutical industry.

Helping to highlight these opportunities is something I am focused on this year, and I challenge you to do it, too. So, next time you are at an AusBiotech event, reach out to the students in the room and ask them about their career aspirations. You might be surprised by the talent that you find right in front of you.

AusMedtech 2018

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INVESTING IN THE FUTURE

At the University of Sydney, we are driven by the pursuit of research excellence. We are currently ranked in the top 50 research universities in the world, and we plan to triple our investment in this area by 2020. At this point, The University of Sydney will be the leading comprehensive, research-intensive university in Australia and one of the best in the world.

Our research is driven by the big picture. We take a problem and look at it from all angles, combining the expertise and talents of scholars from many disciplines.

In the biotechnology space, academics like Professor Anthony Weiss AM are paving the way with their future-focused research. Along with a team of staff from the University of Sydney and the United States, Professor Weiss developed MeTro, a squirtable glue that can seal wounds in 60 seconds. This product could revolutionise the medical industry by replacing sutures and staples in hospitals and in war zones.

Plenty of innovative research is taking place in other areas too. University of Sydney researchers just launched Kinoxis Pharmaceuticals after $3.9 million was raised in an initial financing round to help find a treatment for drug addiction and substance use disorders, using oxytocin compounds.

Partnerships like this one help researchers to commercialise their discoveries by providing funding and necessary resources. If Kinoxis can find a suitable treatment this will alleviate substantial challenges faced by health care professionals and will greatly improve our society.

Pursuing research excellence at the university requires the latest innovative technology across all disciplines. This is why we're also investing in world-class and openly accessible core research facilities. With more than 70 research centres across Sydney already, the expansion continues to meet the needs of our researchers.

The University of Sydney's core research facilities provide access to high-end research infrastructure and offer a range of related services to assist researchers with specialist applications. These centralised, shared facilities span faculties and serve as focal points of research activity.

Speaking about our state-of-the-art infrastructure, Professor Simon Ringer, Director of Core Research Facilities at the university, says, 'These facilities are intimately linked to the search for solutions to the most significant challenges of our time in climate, health, food, water, energy, communications, transport, manufacturing, construction and national security'.

Of particular interest to the biotechnology community is Sydney Cytometry. Here, our researchers answer questions about cell biology and biomedical research, applied clinical research and the clinical diagnosis of cancer and other health disorders. Other relevant core facilities include the Sydney Informatics Hub, Sydney Mass Spectrometry and Sydney Microscopy and Microanalysis. All of these core facilities are located on our main campus in Camperdown.

By asking the big questions, we could change the world

With more than 70 research centres on campus and a vision to triple our investment by 2020, we are equipped to excel – our research is already rated at world standard or above.* Our researchers are uniquely placed to collaborate across disciplines and address some of society's greatest challenges.

What will you start here?

sydney.edu.au/research

THE UNIVERSITY OF SYDNEY

*Australian Government Excellence in Research for Australia 2015

CRICOS 00026A

THE POWER OF PARTNERSHIPS

BY DR SAMIH NABULSI, GENERAL MANAGER, COOK MEDICAL AUSTRALIA

Dr Samih Nabulsi

Australia is among the top countries in the world for biomedical research, producing approximately three per cent of the world's published medical research.

To realise the value of this opportunity, Australia needs to improve its ability to translate its world-class research into commercially viable health and medical technologies and treatments.

One way to achieve this is to ensure that local companies are encouraged to commercialise and manufacture locally by investing back into their business for research and development (R&D) purposes.

A greater emphasis on collaboration

A greater emphasis on collaboration will be critical to enabling this paradigm shift. With more than 30 years' experience working in partnership with industry, researchers, clinicians and government in Australia and across the region, Cook Medical Australia has a strong track record of developing innovative technologies that help to improve the quality of life for patients all around the globe.

We understand, however, that our future success will rely on our ability to innovate, making our capacity to collaborate critical.

As part of our commitment to deliver innovative solutions in advancing patient care, we actively seek opportunities to partner with physicians, innovators, research centres and universities; in fact, we seek partnerships with anyone who is willing to back themselves with an idea that aligns with that mission.

Our technology partnerships span the Asia-Pacific region, encompassing a broad range of R&D initiatives that work hand in hand with our commitment to the health outcomes of patients.

> Australia's medtech industry will be further sustained by ongoing investments in design and manufacturing processes that align with global industry phenomena, such as digital transformation and Industry 4.0

In addition to clinical research studies, we are engaged in initiatives focused on developing the skills and experience of our partners in areas such as advanced manufacturing and commercial operations, as well as increasing business investment and export capabilities.

Our success in the Asia-Pacific region is largely due to the achievements of the Asia-Pacific New Technologies Team (ANTT) – a dedicated team with a diverse range of backgrounds covering clinical, engineering, commercial and operations experience.

ANTT, along with the Asia-Pacific Commercialisation and Development Centre, is now part of Cook Medical's global New Ventures team, whose mission is to open the door for discovery, evaluation and creation of new solutions that enhance patient care. For example, one specific avenue we look to for partnership opportunities are programs that help accelerate medical solutions by validating clinical needs prior to developing solutions or technologies.

Advancements in progress

While Australia has traditionally not fulfilled its potential in the commercialisation of intellectual property (IP), there are promising signs.

Australia's manufacturing industry is undergoing a transformation, with the advancement of medical technologies (medtech) at the forefront of that change.

In its 2017 Annual Highlights report, MTPConnect released new sector metrics that showed jobs supported by the medical technology, biotechnology and pharmaceutical (MTP) sector had increased by 10 per cent to 62,000 from 2015 to 2016, and that manufacturing exports were up by 30 per cent to $5.2 billion.

MTPConnect's Annual Highlights report also showed that 1.4 billion was invested in the R&D space, with almost 50 per cent of that figure from industry. These figures point to the growth and commitment in the industry. This is largely due to the efforts of individuals that have worked to shape the industry, as well as policies that support its growth. Industry leaders, however, must encourage and support local production and manufacturing to ensure that the Australian medtech industry continues to mature and compete on a global scale.

It is increasingly evident that local advances in science, technology and materials will ensure a vibrant, advanced manufacturing sector for Australia that is capable of producing high-value and innovative medtech products.

Alongside those critical product innovations, Australia's medtech industry will be further sustained by ongoing investments in design and manufacturing processes that align with global industry phenomena, such as digital transformation and Industry 4.0.

With a mature, thriving advanced manufacturing sector, Australia will be well positioned to realise further export opportunities for IP derived from manufacturing process improvements.

This is an opportunity we understand very well at Cook Medical Australia. While our mission is to pursue innovative healthcare treatments that respond directly to patient needs, we are also focused on how we can continuously improve our manufacturing processes to maximise the efficiencies of production and reduce product lead times.

Partnering with the University of Queensland, Cook Medical Australia was instrumental in bringing together research and industry partners to establish the Australian Research Council (ARC) Research Hub for Advanced Manufacturing of Medical Devices (www.ammd.org.au). The Hub seeks to concurrently develop materials, methods and technologies for more efficient design and manufacturing processes, better devices, and improved clinical outcomes.

Research and industry partnerships are key to growing workforce capability in the medical device industry and increasing the translation of new technology. This will result in better outcomes for patients, growth opportunities for the sector, job creation, and increased output and market share of Australian manufactured medical technology.

TACKLING THE CHALLENGE OF PROSTATE CANCER DIAGNOSIS

Prostate cancer is the most commonly diagnosed cancer among Australian and New Zealand men, and current diagnostic screening tests are inadequate.

About one in seven men will develop prostate cancer in their lifetime. Prostate cancer is generally a slow-growing cancer though, and if it is diagnosed and treated early, the mortality rate among sufferers is greatly reduced.

The current first-line screening tool is the Prostate Specific Antigen test (PSA), which analyses the amount of the protein PSA in the blood. Higher levels of PSA are an indicator of prostate cancer, however, only one in four men with an elevated PSA (above 4ng/mL) will actually have cancer. Additionally, some prostate cancers do not cause an elevated PSA, which makes PSA test results misleading at times: the success rate is only 44 per cent. The test's ability to predict no cancer, on the other hand, is much higher at 92 per cent.

While PSA testing is currently the best option, the high rates of false positives make its use controversial for screening, and guidelines vary by country.

Now, Caldera Health is developing a non-invasive solution to accurately and reliably detect prostate cancer. Caldera Health is a New Zealand–based biotech company that was founded by Dr Jim Watson and Dr Richard Foster in 2009. Dr Watson and Dr Foster were both diagnosed with metastatic prostate cancer, and both were victims of the inaccuracy of the PSA test. The two men have since passed away; however, their vision of an accurate test to identify cancer early is now close to a reality that will see a reduction in the number of unnecessary invasive biopsies and missed diagnoses.

Caldera Health has identified and filed a patent for a specific RNA gene signature for prostate cancer, and developed a test to accurately detect these biomarkers in biopsy tissue. The test provides 97 per cent sensitivity and 97 per cent specificity. Caldera is now transitioning the technology to a non-invasive, urine-based laboratory test that will measure RNA biomarkers to screen for and diagnose prostate cancer. This gene signature in urine is currently being analysed in Caldera's third clinical study, which started in October 2017, with final results due towards the middle of this year.

Caldera Health's test utilises vesicles in the urine as its source of RNA biomarkers. The prostate sheds vesicles directly into the urine stream, which makes the sample a rich source of information. The diagnosis will require only a simple urine test, without the need for a digital rectal exam (DRE) beforehand, making it applicable to population-based screening.

Caldera Health is looking to replicate the tissue-based test results in a simple urine test that has the potential to become the new best practice in first-line prostate cancer screening.

To find out more about Caldera Health and the research program, please visit www.calderahealth.com, or email Jen Barnes, Business Development Manager, at jen.barnes@caldera.co.nz.

TAPPING INTO BETTER HEALTH AND INNOVATION

Can a medical app be patented?

BY ROBYN HEARD AND NADIA ODORICO, PATENT ATTORNEYS, GRIFFITH HACK

Medical software applications (apps) are becoming increasingly common and useful.

From measuring how far we've moved with mobility trackers to monitoring diabetes or epilepsy on a smartphone, medical apps are giving us greater awareness and control of our health needs.

But as the number of health-related apps grows, dealing with more conditions and situations, how do you protect the intellectual property behind them? Is a medical app patentable?

Software as a Medical Device (SaMD) is defined by the International Medical Device Regulators forum as 'software intended to be used for one or more medical purposes without being part of a hardware medical device'.

Regulation of SaMD is risk-based and depends on the intended purpose of the software, namely for diagnosis, prevention, monitoring treatment or alleviation of disease.

While international regulatory bodies seek to develop internationally harmonised guidance for SaMD, patent offices don't differentiate this software category.

Inventions implemented using software must pass a test for patent eligibility, before even assessing novelty and inventiveness. Patent eligibility (including for SaMD) typically has nothing to do with the purpose, efficacy or social value of the technology, and everything to do with how it works.

Where software is merely for record keeping or manipulation of data, this will typically not be considered SaMD, nor patentable. Where software provides a diagnostic or advisory function, this qualifies as SaMD, but is not necessarily patentable.

Regardless of where an app falls on the SaMD spectrum, if there is innovation in how the diagnostic or advisory function is implemented in the software app, it may be considered patent eligible.

To improve the likelihood of convincing patent examiners to treat your SaMD as patent eligible, specifications need to be drafted carefully to accommodate the current varying global assessment regimes, and anticipate changes in the future.

The problem for developers is lack of harmonisation and frequent change in patent eligibility tests across different jurisdictions.

For example, the United States requires 'something more' than generic software implementation.

Europe, on the other hand, allows patents for inventions that utilise technology to solve problems, and this may include software in certain circumstances. Patent eligibility is based on the methodology utilising technology to perform diagnostic or advisory functions – so the solution that underlies the app needs to be novel and not obvious.

Whereas in Australia, patent eligibility is based on the 'substance of the invention' and, under current practice, requires software implementation innovation to address a technical problem.

Currently, patent eligibility for medical apps is highly dependent on solution implementation, rather than fundamental concept or medical benefit – but this may change.

If you are a medical app developer, it is worth seeking advice from a patent attorney, as there may be more potential for protection than you realise.

griffith hack
IP Amplified

IS YOUR INTELLECTUAL PROPERTY PROTECTED?

Australia's medical technology sector is thriving, making a difference to the health and lives of people around the world.

It's also an area of intense competition and complex technology.

Ensuring you have a strong IP strategy and protection is critical.

Griffith Hack is at the forefront of protecting, managing, enforcing and commercialising clients' innovations in the medtech world.

Get in touch to find out how we can help you.

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MELBOURNE IS TAKING MEDTECH INNOVATION TO A NEW LEVEL

Renowned for the development of the cochlear implant and bionic eye devices, Melbourne has established a reputation as a premier medical technology (medtech) innovation hub.

Some years ago, the Victorian Government identified medical technology as a priority growth sector. It has since invested hundreds of millions of dollars in creating the infrastructure and environment for medtech companies to be supported and able to flourish, particularly in Melbourne.

Melbourne, Australia's epicentre of medtech innovation

Melbourne has become the natural centre of Australia's medical innovation ecosystem. Medtech communities have established themselves because of the incredible connections with local industry, and research and health organisations. This is founded on the presence of Australia's foremost research and education institutions in medtech, including The University of Melbourne, Monash University, RMIT University, La Trobe University and Swinburne University of Technology.

Two significant national medtech support programs with strong industry partnerships have also made Melbourne home. The Actuator accelerates and funds medical technology, while ANDHealth facilitates the development and commercialisation of clinically validated technologies. Both organisations have established their Australian headquarters in Melbourne, with The Actuator based at the multidisciplinary Victorian innovation hub at Melbourne's Goods Shed North.

Australia's largest medtech start-up competition, the annual MedTech's Got Talent, and the BioMelbourne Network Devices and Diagnostics Lab are both hosted in Melbourne. The latter is an annual symposium and this year's theme is how new technologies are disrupting traditional business models.

Melbourne's unique features are attracting not just local start-up stakeholders, but international businesses as well. LaunchVic's $60-million investment is encouraging entrepreneurs and start-ups across Victoria, with many bright minds contributing to the thriving start-up sector.

All of the above is coupled with Victoria's strong history of manufacturing capability, world-leading engineering, advanced medical research, rigorous patent protection, nanotechnology, attractive tax incentives, generous grants and bipartisan government support.

It is no wonder that Victoria is home to 25 ASX-listed medtech companies, with a combined market capitalisation of more than $6.2 billion. More than 270 medtech companies employ about 7000 people, most working out of Melbourne.

The naming of Melbourne in 2017 – for the seventh consecutive year – as the world's most livable city by the Economist Intelligence Unit – is a bonus for medtech companies relocating or setting up in Melbourne. The city received a perfect score for health care, education and infrastructure, as well as stability, culture and environment.

Government support

Over the past 12 months, a number of initiatives with global industry leaders have brought together the brightest minds to tackle medical challenges in Victoria.

Johnson & Johnson and Monash University

Early in 2018, a Johnson & Johnson Innovation Partnering Office at Monash (JJIPO@MONASH) was opened to connect Victorian entrepreneurs with the global Johnson & Johnson Innovation network. JJIPO@MONASH will deliver training and networking programs, and accelerate healthcare innovation. Johnson & Johnson Innovation also collaborated with the government on the new $300,000 Victorian QuickFire Challenge specifically designed to help innovators with devices at the early development stage.

Anatomics and CSIRO

This collaboration between Melbourne-based medical device company Anatomics and the CSIRO is developing and manufacturing the world's most advanced capabilities in reconstructive prosthetics. Its customisable 3D-printed body parts are cheaper, more durable and better-fitting than off-the-shelf models. Anatomics, winner of the 2017 Governor of Victoria Export Award for Small Business, has benefited from participation in the government's international trade mission program and is now exporting to 40 countries.

Medical Developments International and CSIRO

Melbourne manufacturer Medical Developments International (MDI) developed the 'green whistle', marketed

as Penthrox®, for emergency pain relief. In collaboration with CSIRO, MDI has improved the delivery of the active ingredient methoxyflurane – a fast-acting, powerful, non-narcotic inhaled analgesic – and reduced its manufacturing cost. With the support of the Victorian Government, MDI has increased its export performance and the green whistle is now used around the world.

4Dx Limited, Monash University and Hydrix

Lung-imaging company 4Dx Limited, in collaboration with the Laboratory for Dynamic Imaging at Monash University and Hydrix, a leading software and engineering company, is developing unique, non-invasive imaging technologies to improve the management of respiratory conditions. The government has helped 4Dx Limited to tap into the lucrative American market. The government is also assisting the consortium to manufacture preclinical scanners with 4Dx technology in a $2.4-million project that will create 56 new jobs and generate $6.7 million in export revenue for Victoria over two years.

Financial incentives

The government has funding options available: grants of up to $1 million are available through the $200-million Future Industries Sector Growth Program; and the Boost Your Business program offers Victorian manufacturers up to $6 million to assist them to innovate and grow export capability.

Several attractive research-and-development tax incentives are also available through the Australian Government, including a refundable tax credit of up to 43.5 per cent for clinical trials from first-in-human studies in patients and 'special needs' populations.

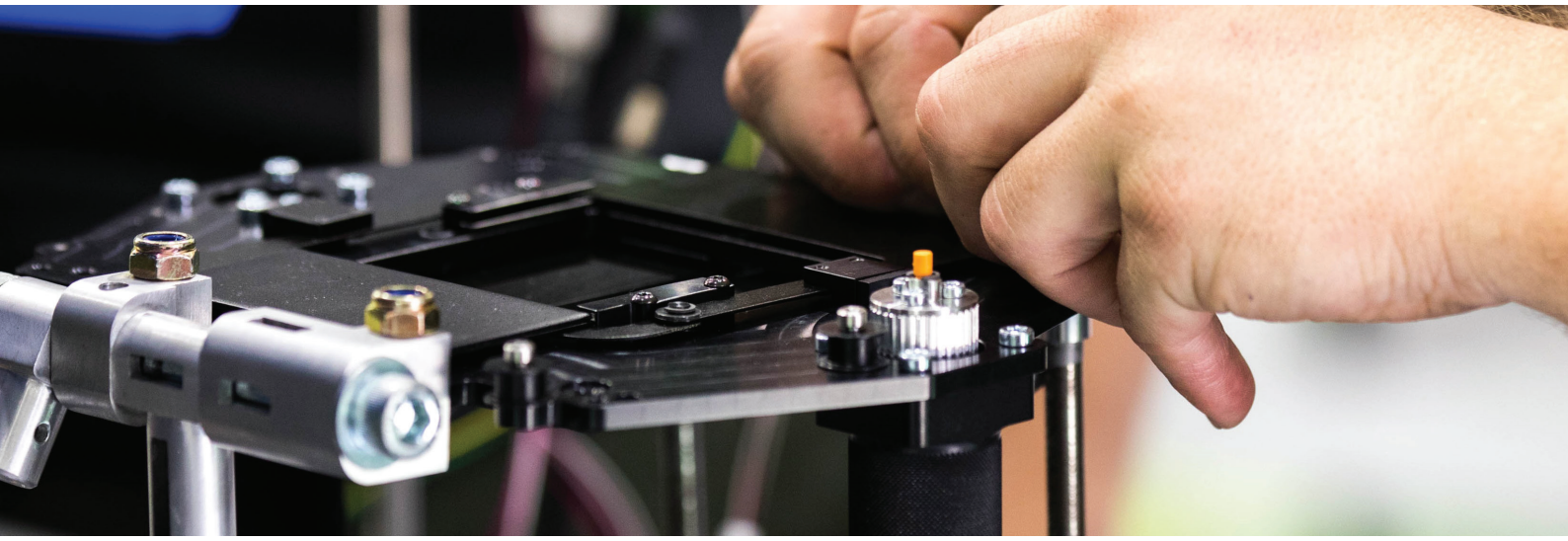
A cost-comparison study shows that Australia is 28 per cent cheaper than the United States before tax incentives, and 60 per cent cheaper after tax incentives for conducting clinical trials.

Attracting more business

Victoria's global healthcare spending is projected to grow by more than four per cent annually, and the government recognises the urgent need for new technologies, goods and services that will improve patient care.

The government's network of 22 international business offices, including a new Boston location, is identifying opportunities for international organisations to connect Victoria's medtech talent with the world's best.

To discuss opportunities for growing your business in Victoria, contact Andrew Wear at andrew.wear@ecodev.vic.gov.au.



UNPACKING SOURCES OF MEDICAL TECHNOLOGY INNOVATION IN SOUTH AUSTRALIA

BY DR LEANNA READ, CHIEF SCIENTIST OF SOUTH AUSTRALIA

This May, the spotlight will shine on South Australia as we host the prestigious AusMedtech 2018 conference in Adelaide, giving visitors an opportunity to learn about the world-class research and innovation taking place.

Medical technology innovation has always been part of South Australia's DNA. In the early 1900s, Australia's first recorded medical X-ray images were taken in Adelaide, thanks to research into X-ray crystallography developed by father and son team and Nobel Prize winners, Sir William Henry Bragg and Sir William Lawrence Bragg.

The groundbreaking work paved the way for many breakthroughs, including the discovery of DNA structure, advanced radiation therapy for cancer, solid-state electronics, modern pharmaceuticals, superconductivity and radio astronomy.

Our spirit of discovery continued through the 1950s, when pioneering plastics manufacturer Charles Rothauser responded to challenges in the medical

community by delivering new penicillin injections using moulded syringes made of polypropylene – a plastic that can be heat-sterilised, as opposed to the more expensive chemical sterilisation methods.

Medtech innovation in South Australia

Today, South Australia continues to be an important destination for medical technology innovation, as evidenced by the growing number of successful industry–research collaborations that have resulted in new products, services and better health outcomes for the community, attracting industry leaders and global investors to our state.

One success story comes from Adelaide-based Corporate Partners In Excellence Pharmacy Services (CPIE) – a pharmacy organisation supplying private and public hospitals, as well as being Hospital in the Home (HITH) providers.

The company, which fills and supplies infusion pumps with medicines (primarily compound antibiotic and chemotherapy for intravenous infusion) found that several customers were not receiving complete therapy as a result of faulty off-the-shelf infusion pumps.

CPIE General Manager Andrew Slugett says, 'Our internal team conducted a global search for a new infusion pump that would deliver our medicines to our patients in the right dose at the right time, but we couldn't find a pump that addressed all of our needs.

'We needed a pump that didn't mask the quality of our medicines and had the features needed by our patients at an affordable cost.'

With further research into HITH products, CPIE gained intimate knowledge of the infusion-pump market and developed a new infusion pump that addressed their needs, diversifying their business and product offering. It also sparked a new industry–research collaboration with Flinders University.

'Everyone at CPIE was involved in this new adventure and we all brought different skills to the process; but we knew our limits and asked for help,' he says.

With support from the South Australian Government's Innovation Voucher Program, the South Australian Early Commercialisation Fund (SAECF) and AusIndustry's Accelerating Commercialisation Fund, the company was able to commence their commercialisation journey.

A pilot human study for the smart brain biopsy nedle

A keen eye for market opportunities

A second example highlights the way our researchers now have a keen eye on market opportunities when designing their research programs.

Professor Robert McLaughlin and his team, originally from the University of Western Australia, relocated to the University of Adelaide to commercialise their 'smart needle' technology with support from the South Australian Government's Premier's Research and Industry Fund (PRIF) and SAECF.

Integrating a tiny imaging probe into a hypodermic needle, they have developed a needle that can see where it is going to help surgeons perform safer, more effective surgery. Reflecting on the source of innovation, Professor McLaughlin says that engaging with frontline healthcare workers was critical to the research and commercialisation success.

'We knew what our technology could do, but needed help to understand the needs we could address. So we spent time in surgery and in radiology clinics, working closely with the medical clinicians and learning about the reality of health care,' McLaughlin says.

Medical Device Partnering Program at Flinders University

'It's similar to any other market – you need to listen to your customers. The difference is that our customers, surgeons and radiologists are working to save lives.

'We learnt that if our research didn't help them do that, then they had no time for us. That sort of feedback quickly helped us to focus on innovations that could make a real difference in medicine, and we have now conducted a successful pilot human study in brain surgery.'

South Australian research is also blurring the divide between devices and drugs, seen recently through work conducted by the Cooperative Research Centre for Cell Therapy Manufacturing and its spin-off company, Carina Biotech Pty Ltd.

Carina's CEO, Dr Justin Coombs, says that they are now looking at genetically engineering immune T-cells to recognise solid cancers – an approach referred to as chimeric antigen receptor (CAR) T-cells, or CAR-T.

'Early successes with CAR-T therapies for blood-related cancers by global companies, such as Novartis, Kite Pharma and Juno Therapeutics, has paved the way for this exciting "fourth pillar" of cancer treatment – with more than 90 per cent complete remission rates being seen in some blood-cancer clinical trials,' Coombs says.

'Carina is now attacking the "holy grail" of CAR-T therapy by developing broad-spectrum or "universal" CAR-T cells that could potentially attack a broad range of solid cancers. The next step is to complete preclinical testing in a range of cancer models and get into clinical trials as quickly as possible. An exciting aspect of this area of medical technology is that new CAR-T therapies are getting accelerated approval by the United States' Food and Drug Administration – so, the time for us to get a product to market could be quite fast.'

South Australia has also led the way in developing an effective partnership model for medical technology innovation. Flinders University's Medical Device Partnering Program (MDPP) was established almost 10 years ago, with support from the South Australian Government, as an ideas incubator to connect industry with researchers to help translate ideas into new products and services.

MDPP's Director, Professor Karen Reynolds, says that, to date, the program has considered more than 350 ideas for medical or assistive devices and connected up to 120 of these ideas to a team of experts through the MDPP's valuable collaborative workshops.

'The ideas come from a range of sources rather than push technology towards applications,' Reynolds says.

'Through the program, we invite inventors, end users and clinicians who have identified problems to submit ideas for new innovations. The unique MDPP model ensures that all the pieces of the puzzle are brought together in the product development and commercialisation process to ensure the innovation is a success.

'It is about breaking down the barriers for invention and considering end users early in the development process.'

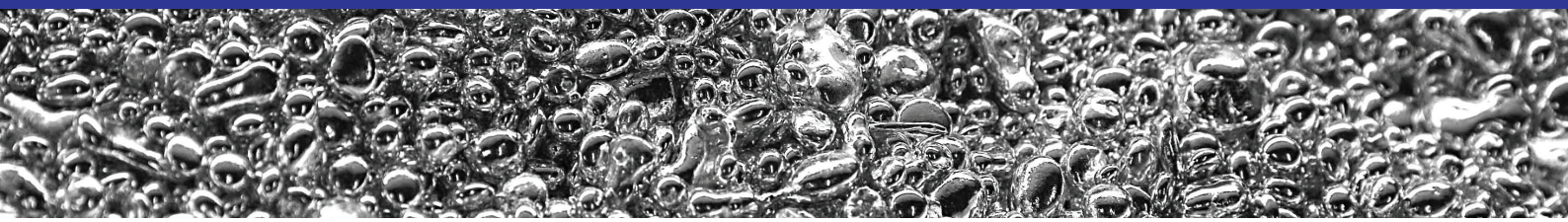
These examples are but a few of the many medtech success stories coming from South Australia. They underpin the importance of collaboration and focusing innovation efforts on global market opportunities.

Medtech is a key component of the advanced manufacturing sector that will play a pivotal role in the economic transformation of the state – and indeed Australia. High-value-add and knowledge-intensive medical technologies are exactly the types of products that will ensure Australia remains at the front of the pack in a globalised economy.

You can learn more about these commercialisation stories at the AusMedtech conference, 1–2 May 2018, in Adelaide.

For more information about innovation in South Australia, visit www.innovation.sa.gov.au.

JM Medical Components



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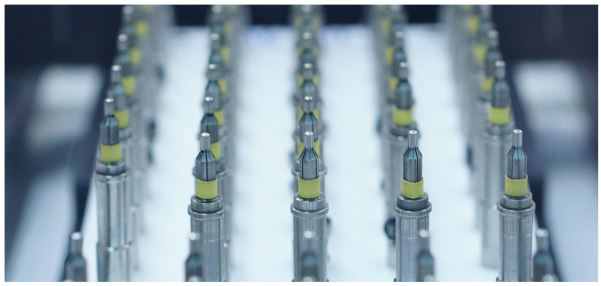

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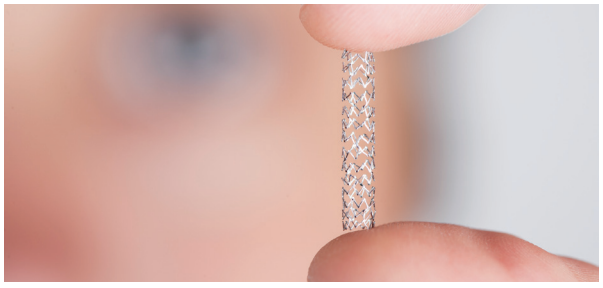

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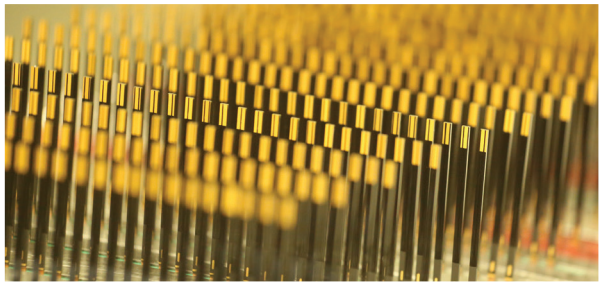

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IVD ACCESS TO EUROPE

The clock is ticking

BY MYRIAM BATTISTUTTA

The in vitro diagnostic medical devices (IVD) regulatory framework is changing in Europe, and you should understand how this could impact your business.

Prior to the formal adoption of the framework in 1998, the supply of IVDs to Europe was unregulated. For IVD manufacturers selling products in Europe at that time, it was a challenge to collect and prepare technical documentation to support their IVDs' safety and performance. The change was significant and many manufacturers had to make tough decisions, discontinuing those IVDs that would not provide sufficient return on investment, as it was an expensive transition.

Notified bodies (NBs), authorised representatives, and regulatory professionals all became a necessary part of supplying IVDs to the European Union. Some manufacturers floundered. Well, prepare yourselves: another wave of change has been triggered and is building momentum. On 5 April 2017, two new regulations on medical devices were adopted and on 25 May 2017, they became enforceable, effectively replacing the existing directives.[1]

IVD regulation has brought with it major changes for current and future IVD developers and manufacturers. The most significant changes are the way IVDs are classified and the requirements for conformity assessments. The regulation introduces a risk-based classification system with four classes: the lowest is Class A and the highest is Class D. For Class A IVDs, the conformity assessment remains the responsibility of the manufacturer; however, for Classes B, C and D an NB must be involved. The manufacturers hardest hit will be those with a large number of previously self-declared IVDs that will now require NB involvement – costs will go up, time frames for CE (European conformity) marking will increase and NBs will be swamped with work.

Myriam Battistutta

There is a five-year transition period from the time the regulation was adopted; transition must be completed by April 2022. The clock is ticking. This is not a generous time frame and manufacturers should start planning now. What is your transition plan? How are your IVDs classified? When should you transition existing products and what are the budget impacts? Will some products need to be dropped from your portfolio and what impact will this have on your bottom line? How is your NB preparing for the change? Have they applied for designation with the competent authorities for the new regulations? Are they resourcing appropriately based on their clients' transition plans? How do they plan to stay ahead of the tsunami that is coming?

As we move through this transition period, it is critical for manufacturers to become informed, undertake an impact assessment and start planning a clear and sensible path forward with their regulatory professional(s) and NBs. A good resource that provides an overview of requirements of the IVD regulation has been developed by MedTech Europe.[2]

Myriam Battistutta is Senior Consultant Quality and Regulatory at Fusidium. Visit www.fusidium.com for more information.

1 https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en

2 http://www.medtecheurope.org/sites/default/files/resource_items/files/MTE_IVDR_Flowchart-Dec-2017_FINAL.pdf

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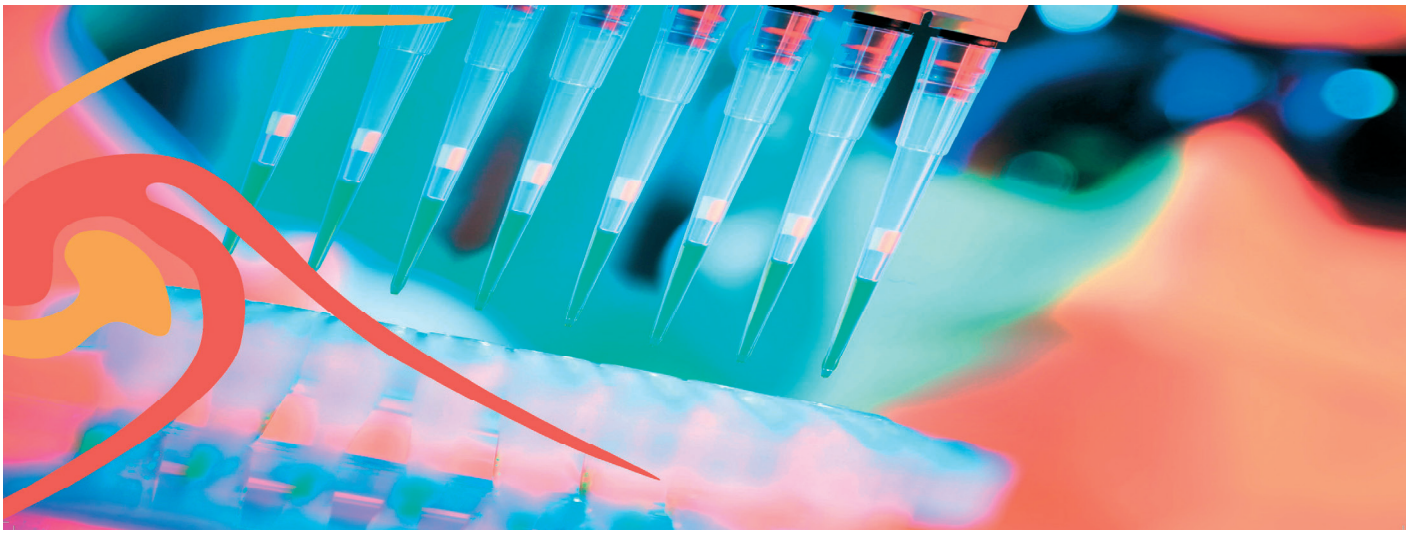


BENCH TO BEDSIDE

Queensland University of Technology (QUT) research and technology is behind the first ever 3D-printed shin bone implant.

A combination of vascularised tissue transfer and 3D scaffold technology is being used to repair large bone defects and is currently being trialled to regenerate 36 centimetres of tibial bone.

The new approach keeps the tissue-engineered bone alive and regenerating from the inside out.

After a decade of development by Distinguished Professor Dietmar W Hutmacher and his team at QUT, this first clinical application passed its six-month milestone.

The new technique was applied in a clinical case where the patient faced amputation.

A 27-year-old male initially experienced pain, with an initial diagnosis of complex regional pain syndrome. The patient developed an abscess and severe osteomyelitis requiring removal of 36 centimetres of tibia.

With amputation presented as the main solution, the patient and surgeons decided to try the new regenerative technique.

The 36-centimetre section of tibia was removed and a custom-designed scaffold was used to replace it.

QUT's research team, including Dr Marie-Luise Wille, Dr Nathan Castro and PhD student Sebastien Eggert, worked closely with Dr Michael Wagels, the Princess Alexandra plastic surgeon who performed the surgery in August 2017.

The QUT team used a 3D printer from Queensland-based company 3D Industries to print the models before sending the final scaffold design to Osteopore International, known for its clinical track record producing FDA-approved and CE-marked biodegradable scaffolds.

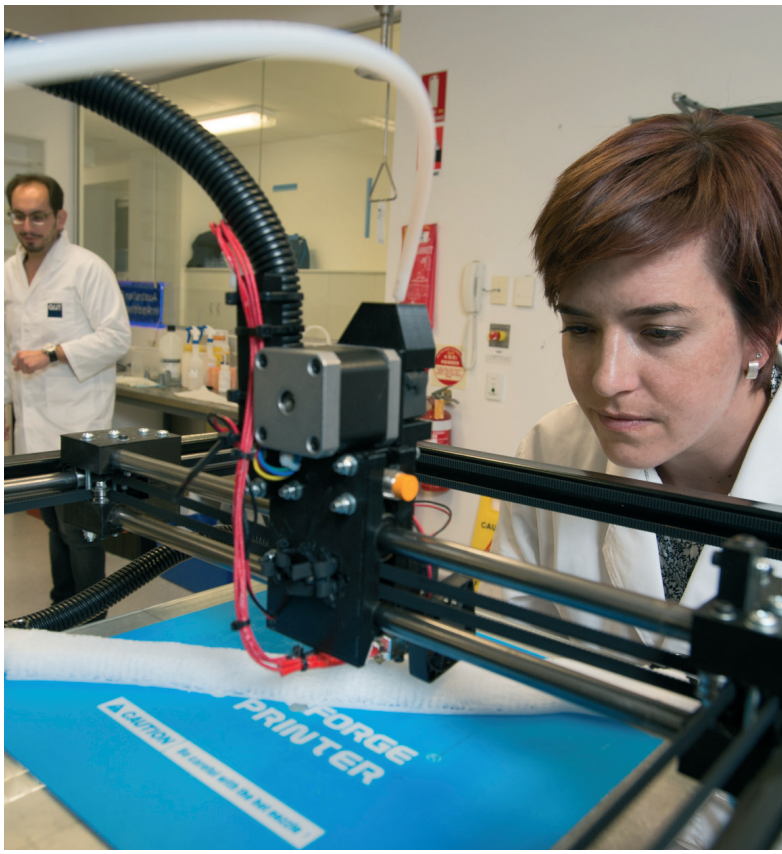
The surgical team used living pieces of bone and soft tissue inside the scaffold and stabilised the defect with an intramedullary nail.

Given the large nature of the replacement, the team took a conservative approach to rehabilitation and the patient is not yet walking.

Six months after the surgery, there is no sign of infection and CT imaging suggests that bone is forming.

More than eight years prior to clinical trial, the team used several regenerative approaches in animal models, combining 3D-printed polymer scaffolds, stem cells, growth factors and fixation devices in more than 300 procedures.

By combining scaffolds and growth factor, bone morphogenetic protein – 7 (BMP-7) – a three-centimetre tibial defect could be healed in sheep, resulting in strong new bone.



After one year, six-centimetre defects reached 60–70 per cent of the torsional strength of a normal tibia.

Work on large animal models at the QUT Medical Engineering Research Facility (MERF) has been invaluable in bringing the research into clinical application.

This is just the beginning of QUT's 3D printing pursuits, according to Professor Hutmacher, who is also director of the ARC Industrial Transformation Training Centre in Additive Biomanufacturing (ARC ITTC).

'Additive biomanufacturing is an emerging sector within advanced manufacturing and the technology allows us to 3D print scaffolds, customised to the patient, which are then slowly resorbed by the body and help guide the new bone formation,' says Professor Hutmacher.

QUT is flexible and open to a range of collaboration models. To discuss a research project, contact the Office of Research on 07 3138 5376, or email officeofresearch@qut.edu.au. For more information, visit www.qut.edu.au/research.

A giant leap towards
REGROWING BONES

QUT is at the forefront of the global regenerative therapies market and is a leader in medical biotechnology development. QUT has the capability to take concepts through research, development, in-vivo testing, clinical trials and training. We have teams in place to develop shared understanding between researchers and partners of project goals and timeframes, negotiate information sharing and IP requirements, access co-investment opportunities, and commercialise outcomes. Find out more at **www.qut.edu.au/research** or email **officeofresearch@qut.edu.au**

a university for the real world

QUT

MEDICAL DEVICE CLINICAL TRIALS OUTLOOK

BY MIE OHAMA, SENIOR CLINICAL QUALITY MANAGER FOR CORPORATE CLINICAL QUALITY AND COMPLIANCE, MEDTRONIC CLINICAL RESEARCH INSTITUTE

To ensure that a new medical device will become available as soon as possible for patients who are waiting for the new technology, many medical device companies are looking for ways to generate clinical evidence that could be used for regulatory submissions in multiple countries.

Increasing globalisation of clinical trials creates challenges for both regulators and industries. From a regulator's perspective, it is not clear how clinical data was generated in another country, or if it meets the clinical regulatory requirements of their own country.

While some regulators have started introducing the least burdensome approach and principles[1], many other regulators are still facing challenges on resource constraints that impact the number of foreign clinical site inspections that they can perform. From an industry perspective, it becomes a challenging task to develop a global protocol due to different regulations among different countries.

Mie Ohama

To address those challenges, ISO 14155 was created to harmonise the design, conduct, recording and reporting of medical device clinical investigations carried out in human subjects[2]. The standard became the gold standard for clinical trials that assess the safety or performance of medical devices for regulatory submission purposes. The standard is currently under revision, aiming to increase acceptance by countries that were not engaged in the development of the 2011 version. The revised version of the ISO 14155 is planned to be published in 2019.

As more and more regulators accept ISO 14155 as a gold standard for clinical trials with medical devices, it is important for trial sponsors to understand the upcoming changes to the next version.

Clinical development stages

Depending on the clinical development stage and the

1 'The Least Burdensome Provisions: Concept and Principles, Draft Guidance for Industry and Food and Drug Administration Staff', US FDA, 2017, available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf

2 ISO 14155:2011 Clinical investigation of medical devices for human subjects — good clinical practice

study design, requirements of the standard could apply differently. The next revision of the standard clarifies requirements during different stages of clinical trials to ensure adequate consideration is provided in terms of the subject's rights, safety and wellbeing, the scientific outcome, and the credibility of the clinical data.

Application of ISO 14971 to clinical investigations

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[3]. A clinical investigation is generally required when the currently available data is insufficient to demonstrate conformity with the essential principles[4]. To re-enforce risk management throughout the process of a clinical investigation from planning through to consideration of results, the next revision clarifies the relationship between the clinical investigation of a medical device and management of its associated risks.

Guidance on statistical considerations

Statistical consideration is vital for optimising a study design, evaluating a research hypothesis, interpreting research results and drawing conclusions. To minimise bias, maximise potential benefits and maintain the integrity of the analysis, this revision details statistical requirements to be considered during development of a clinical investigation plan.

Alignment with new and changing clinical requirements

Since the current version was released in 2011, many new and changing requirements (for example, European Union Medical Device Regulation, ICH Good Clinical Practice (GCP), US FDA guidance, China GCP) have been introduced in the global clinical regulatory environment. To have alignment with those requirements, the revision includes a summary section of GCP principles, a reference to registration of the clinical investigation in a publicly accessible database, a guidance with regards to clinical quality management, a guidance on risk-based monitoring, a guidance for ethics committees, and a guidance on clinical investigation audits.

3 ISO 14971, Medical devices — Application of risk management to medical devices

4 Global Harmonisation Task Force, Clinical Investigations [SG5/N3:2010], available at: http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n3-clinical-investigations-100212.doc

With these changes, ISO 14155 will continue to be the global standard that helps industries and regulators with assessing the safety or performance of medical devices for regulatory submission purposes.

About the author

Mie Ohama is responsible for clinical quality for 22 countries in the Asia Pacific region. She is an active steering committee member of the Asian Harmonization Working Party Working Group 5 (clinical evidence for performance and safety). She also became a member of ISO/TC 194/WG 4 and Standards Australia HE-030. She has provided training to several Asian regulatory agencies. Ohama is one of the two AusBiotech representatives on the Australian and ISO Standards Committee for medical device clinical trials. This article provides an update of her work on behalf of AusBiotech.

Disclaimer: The views expressed are those of the author. The author is an employee of Medtronic Australasia Pty Ltd, a manufacturer of medical technology.

CSIRO:

providing cutting-edge capabilities and research for industry

The global medical technologies and pharmaceuticals (MTP) sector is expected to be worth almost $3 trillion by 2025, as the world population ages and emerging markets seek better health care. The potential for Australia's biotech and medtech companies is vast.

As Australia's national science agency, the CSIRO delivers truly innovative solutions. We help our partners to increase competitiveness, reduce risk, expand markets and develop new industries. We do this through our groundbreaking research and by developing resources, equipment and expertise unavailable elsewhere in Australia.

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CSIRO's Protein Production Facility plays a key role in delivering recombinant protein–enabling technologies for Australia's biotech sector, as well as international partners.

That's being enhanced even further as we build a pilot-scale Current Good Manufacturing Practices (CGMP) fermentation facility, to support companies who are creating a biological drug pipeline.

Currently, Australian biotech companies have to head overseas for this capability, at great cost and with long waiting times.

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Our Precision Health and Probing Biosystems Future Science Platforms (FSPs) have the potential to help reinvent and create new medtech industries for Australia. Probing Biosystems is working to ensure life quality keeps pace with life expectancy, while investigating novel technologies in health surveillance and in-vitro diagnostics, as well as precision nanomedicine treatments.

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While Australia is home to more than 500 biotech and medtech companies, many are small and medium enterprises that sometimes struggle with the transition from research and development to a sustainable product.

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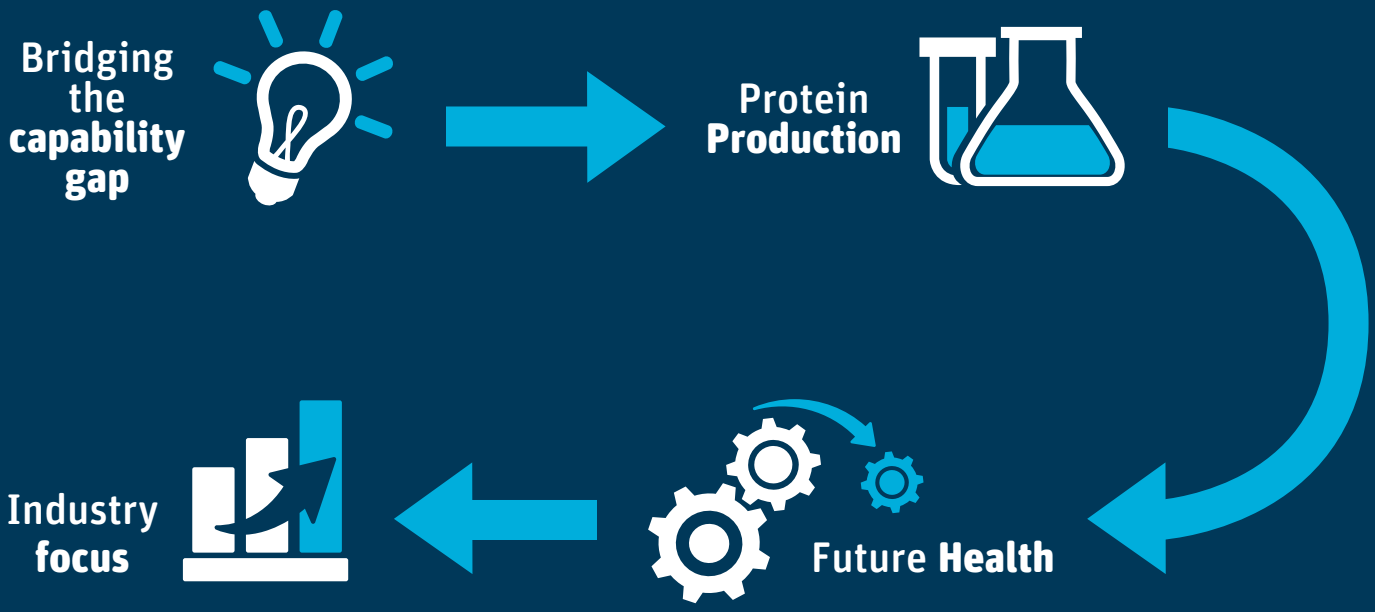

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SOUTH AUSTRALIA:

an ideal place for medtech innovation

South Australia has a thriving medical technology industry. According to Marco Baccanti, Chief Executive of Health Industries South Australia – a state government agency set up to assist interstate and international life sciences companies to establish operations in South Australia – key to this success are three main things: strong academic research, a strong health system and an automotive supply chain. This last point may seem unusual, but the components and skills required for production of medical devices are very similar to those used in automotive production – injection moulding, micromechanics and an ability to upscale for profitability.

'South Australia has all of these components, as well as a government and private sector that is willing to assist,' Baccanti says.

One major advantage for medical technology companies working in South Australia is access to the MedDev SA Alliance. A cluster of leading South Australian medical device companies, MedDev SA was established in June 2015 as an industry-led initiative with the support of the government. It facilitates meaningful connections leading to real-world commercial outcomes.

MedDev SA supports organisations with a validated value proposition. The main area of focus is providing access to investment, assisting with recruitment, and providing access to markets.

Since its inception, MedDev SA has activated projects with around $20 million worth of market value, and it is expected that this will approach $1 billion within the next five to 10 years. The cluster has sought to operate to global best practice. As a result, they are the first cluster in the Asia-Pacific region to be accredited by the European Secretariat for Cluster Analysis (ESCA).

Richard Barrett is the CEO of MedDev SA, and he and Baccanti both agree that South Australia's medtech companies are developing ways to address an ageing South Australian population.

'South Australia has been a leader in the medical technology sector in areas of vision and ophthalmology, implantables and digital health – especially artificial intelligence and machine learning for clinical decision support,' Barrett says. 'Each of these areas plays a significant role in age-related afflictions.'

The advances in technology are excellent, but Baccanti says that product innovation alone is not enough.

'For these technologies to work, there needs to be cooperation between the community, the doctor, healthcare workers, the insurance companies and the infrastructure surrounding them. Policy change is paramount,' Baccanti says.

South Australia's medical technology sector will be on show from 1–2 May at AusMedtech 2018, held at the Adelaide Convention Centre. The conference will bring together more than 300 delegates from across the Asia-Pacific region.

TechInSA, South Australia's high-tech accelerator for startups, is a major sponsor of the event. Supporting the development and scaling of early-stage technology companies, the organisation administers the SA Early Commercialisation Fund (SAECF), providing up to $500,000 for eligible projects, as well as business assistance.

'The grant fund and "sister" $50-million venture fund are designed to capitalise on deal flow from research and investment in artificial intelligence, additive manufacturing, and digital health, among other high-tech sectors,' says Dr Judy Halliday, Director Industry Development at TechInSA.

'Complementing the work of MedDev SA and HealthInSA with more mature companies, we have already had over 400 high-tech startups apply for funding in the last year. Of these, over 50 have received grants totalling $7.5 million, which has leveraged over $25 million in matched funding,' says Halliday.

TOP FIVE MEDICAL DEVICE TRENDS OF 2018

BY TERRY WALSH, DIRECTOR APAC, MASTERCONTROL

The speed at which the medical device industry is changing and evolving is perhaps unrivalled in the life sciences industry. Medical device manufacturers are experiencing disruption from small companies and start-ups entering the market[1]; tech giants, like Amazon, are investigating and investing in medical device expertise; and cybersecurity concerns are on the rise.

Despite uncertainty and challenges, however, the medical device industry continues to experience tremendous growth, potential and an abundance of opportunities for further technological innovation. Not only did *Investing News* predict that medical device manufacturers would capture major market share in 2017[2], but Evaluate Research estimates that, by 2022, medical technology sales will exceed $530 billion. Sales rates for medical devices are expected to grow annually by 5.2 per cent.

Taking this into consideration, we've identified five trends that industry professionals believe are likely to have the most significant impact on medtech this year.

1. Tech giants will continue to disrupt the life sciences space

Tech behemoths Apple, Google and Amazon have turned their gaze to the life sciences sector, including medical devices, and they're not alone. Other business sectors are investing in bioelectric medicines (for example, miniature implantable devices) to treat diseases, while major courier companies are advancing into healthcare logistics, shipping and mobile health (mHealth) devices, such as wearable smart devices[3].

'Times are still good for medtech – but the healthcare industry as a whole is undergoing a period of significant change,' says Alexander Belcredi, an editor with Boston Consulting Group[4]. 'These changes could create a downward spiral for companies that cling tightly to business as usual; but those that build their

capabilities and adapt their business models will find enormous opportunities to grow and thrive.'

2. Pharma and medical device products will continue to fuse

Every year, pharmaceutical and medtech industries become more interdependent. In an environment that requires more device manufacturers to conduct clinical trials, many firms are looking to ally with pharmaceutical companies to minimise the resources needed to conduct clinical evaluations and navigate non-traditional registrations.

Conversely, pharma and biotech companies are seeking opportunities to partner with medtech firms to capitalise on the growing drug-device combination products market, estimated to exceed $115 billion by 2018[5]. It's expected that pharmaceutical manufacturers will continue to transition from blockbuster drugs to mHealth and wearable technology products to gain a competitive edge and add new revenue sources.

3. Regulatory upheaval will continue to escalate in the United States, Europe and Australia

As consumers and industry stakeholders continue to demand better, safer products, government officials in the United States, Europe and Australia have insisted upon improved regulatory oversight of the medical device industry. Many of the changes are a concern to medical device manufacturers because they are significant.

For example, in the United States, ISO 13485: 2016 gives device makers until March 2019 to completely transition to a quality management system. Certification is voluntary in the United States, but mandatory in several other countries, including Canada and Japan.

The Australian Therapeutic Goods Administration (TGA) has introduced new guidance to prioritise the review designation for cutting-edge in vitro diagnostic device (IVD) technologies, considerably speeding up time to market. The TGA target for these novel IVDs is decisions on priority review designation applications that will take no more than 20 business days. This will help to push technologies like artificial intelligence (AI) and machine learning to the forefront[6].

Terry Walsh

4. Connected devices for seniors will continue to gain in popularity

With baby boomers entering their golden years, the market for interconnected medical devices is at an all-time high. It's been fuelled by devices, such as Fitbits, smartphones, and now smart speakers like Amazon's Alexa-controlled Echo speaker, which has the potential to audibly remind a person to take their medications.

According to a 2017 report by the Australian Bureau of Statistics (ABS), the proportion of Australians aged 65 and over increased from 12.1 per cent in 1997 to 15.4 per cent in 2017[7]. This population demographic is projected to increase more rapidly over the next decade, as more baby boomers turn 65. Moreover, a report from the Parliament of Australia estimates that the country's aged-care workforce will need to grow by two per cent annually, 'or triple its size for the next 30 years or so to meet demand[8]'.

Since many seniors won't be able to afford an assisted-living facility, tech-enabled home care will be expected to fill the gap.

'Ageing care is one of the most aggressive industries in innovation,' stated a report in the online trade publication *TechRepublic*[9]. In the first half of 2017 alone, $3.5 billion was invested in 188 digital health companies, setting a record[10].

5. 'Vigilant cybersecurity' will remain an industry watch phrase

The potential market for bioelectronics and internet-connected devices is significant, but the level of their success may depend on two critical issues – security and data privacy.

'Things are coming to the market very, very fast, and a lot of these organisations that are building these devices are trying to be first on the market,' says John Petersen, Senior Manager, The Chartis Group[11]. 'That's a huge risk to any organisation, as that's a starting point for really any type of breach into the network.'

Australia's Emergency Care Research Institute (ECRI) has listed ransomware and other cybersecurity threats to healthcare delivery among its top 10 health technology hazards for 2018 that can endanger patients[12].

According to a poll report from PricewaterhouseCoopers (PwC) Health Research Institute (HRI), 50 per cent of respondents said they would avoid using a connected medical device in the wake of a cyber breach[13]. Information Security Group reported in August 2017 that more than one-third of surveyed medical device manufacturers said that their organisations had experienced a cybersecurity incident in the past year[14].

Conclusion

While these trends in the medical device manufacturing industry could be viewed as potential challenges, it is important to remember that the industry is evolving quickly and adapting to meet these obstacles. Many of these 'obstacles' also present promising opportunities to expand medtech into new sectors well beyond 2018. The key for manufacturers is to remain nimble and adaptive, and to implement policies, practices and course corrections to navigate the fluidity within the industry.

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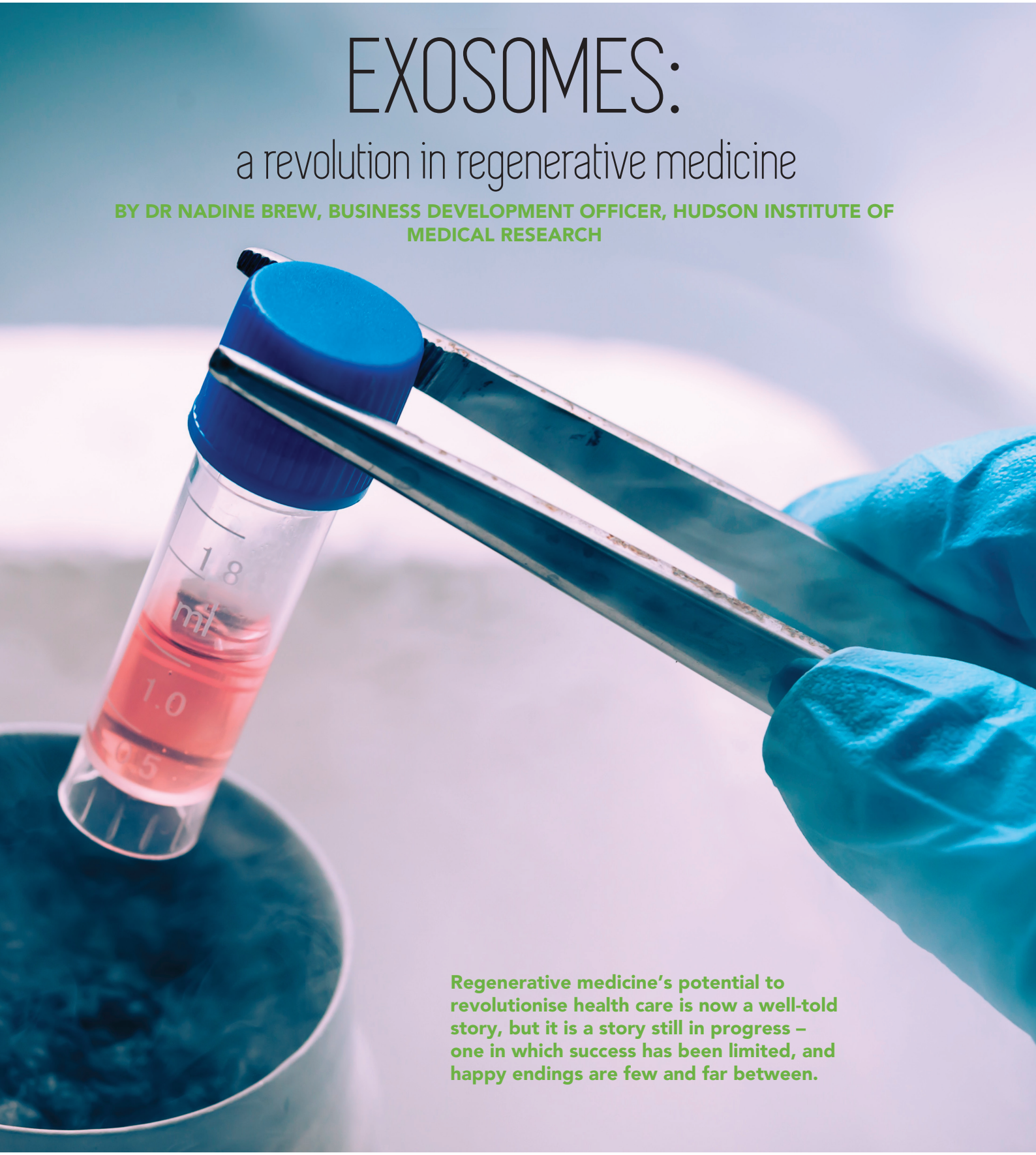
EXOSOMES:

a revolution in regenerative medicine

BY DR NADINE BREW, BUSINESS DEVELOPMENT OFFICER, HUDSON INSTITUTE OF MEDICAL RESEARCH



Regenerative medicine's potential to revolutionise health care is now a well-told story, but it is a story still in progress – one in which success has been limited, and happy endings are few and far between.

The tale of regenerative medicine is still being written. It's tremendous potential has been stymied by major drawbacks: labour intensity and expense, cold-chain dependence, inherent variation, and risks of immunogenicity and tumourigenicity. A new hero is being sought. Imagine a regenerative medicine therapy with the same promise as stem cells, but able to overcome the stumbling blocks currently preventing us from moving forward.

Such a therapy does exist in the form of stem-cell-derived exosomes. Exosomes are nanosized particles used by virtually all cell types to shuttle biological 'cargo', including proteins, RNA, cytokines and lipids, for intercellular communication. Exosomal cargo reflect their cell of origin or 'parent' cell. For example, the anti-inflammatory and immune-modulating mediators present within certain stem cells are also present in stem-cell-derived exosomes. Results in head-to-head studies using gold-standard disease models show that stem-cell-derived exosomes have regenerative and immune-modulating capacity in striking resemblance to their parent stem cells.

For these reasons, exosome-based therapies are now widely viewed as the future of regenerative medicine. Experts report that the exosome sector is at an inflection point; tipped to grow to the scale of other successful biologics – such as stem cells, monoclonal antibodies and chimeric antigen receptor T cells (CAR-T).

Within a few short years, about a dozen exosome biotech start-ups have launched, with seed backing and experienced biotech veterans at the helm. Presently, exosome products are undergoing large-scale good manufacturing process (GMP) and bio-manufacturing platform development in preparation for clinical use. Many promising preclinical exosome programs have been completed, encompassing a range of indications, from cancer to Alzheimer's disease to lung fibrosis.

The production of exosomes uses many techniques already well established in the cell therapy and biologics field. In broad terms, exosomes can be obtained from media exposed to the parent cell using four techniques: ultracentrifugation, precipitation, chromatography sorting or tangential flow filtration. Each of these methods has different advantages and drawbacks, with tangential flow filtration considered the most scalable and industrially applicable.

To create a viable platform technology that is scalable for clinical trials and cost-effective, suitable manufacturing approaches are being optimised. An additional manufacturing and commercial benefit of exosomes is that, being highly stable, they are far easier to transport and store than cells, and can be lyophilised for potential off-the-shelf use and administration as an inhaled formula. These inherent characteristics of exosomes will translate into cost savings, making them less expensive to produce than cell-therapy products.

Due to the unique properties of exosomes, there are some challenges to be resolved prior to their adoption as a viable mainstream therapy. What will a single dose of exosomes be and in what units will they be measured? How will the Therapeutic Goods Administration (TGA) and other regulatory agencies handle exosome approvals? How will exosome therapy pricing be determined? Reassuringly, previous generations of successful biologic medicines have paved the way, and similar questions have been dealt with by government and the medical research sector, enabling their current market successes.

Indeed, any market ambiguities have not slowed investment momentum in the sector. Even existing stem cell companies are also becoming aware of the benefits of exosomes and diversifying their pipelines with stem-cell-derived exosome programs. ReNeuron (Surrey, United Kingdom) is now producing exosomes derived from their neural stem cell line of CTX cells. The CTX cells are in clinical trials for stroke and critical limb ischemia but ReNeuron is yet to reveal their indication for exosomes. Celltex Therapeutics (Houston, United States), a stem cell bank provider, has licensed intellectual property (IP) from Texas A and M Institute to develop mesenchymal stem-cell-derived exosomes for a therapy to treat Alzheimer's disease.

Utilising exosomes for the delivery of drug or other biologic payload types (for example, vaccines and RNA) to target cancer has been a favoured approach to date. Codiak BioSciences (Cambridge,

United States) has engineered exosomes, termed 'iExosomes', to carry payloads directed at intracellular oncogenic targets. Their first indication for these engineered exosomes is pancreatic cancer. Targeting the KRAS mutation, iExosomes successfully suppressed cancer in numerous pancreatic cancer mouse models. ExoCyte Therapeutics (Singapore) combines immune cells with the patient's own tumour-derived exosomes to stimulate an anti-tumour immune response. Evox Therapeutics (Oxford, United Kingdom) is investigating exosome-mediated delivery of RNA in a recently announced partnership with Boehringer Ingelheim.

In Melbourne, Australia's life sciences capital, there is world-leading expertise and infrastructure at the forefront of the exosome field. Key players in the local sector form a thriving collaborative nexus between large multinational companies, emerging start-up biotechs, and university and medical research institutes.

The organisations driving exosome research and development (R&D) and bio-manufacturing programs include: Hudson Institute of Medical Research, Monash University, La Trobe University and the biomedical manufacturing stem cell facilities at the CSIRO; all supported by the recent launch of the Centre for Commercialisation of Regenerative Medicine Australia (based at Monash University).

At Hudson Institute and Monash University, Dr Rebecca Lim is collaborating with GE Healthcare and Scinogy Pty Ltd to validate and upscale the production of a proprietary exosome technology that her team has developed. Lim's work started with placental stem cells, which she and Professor Euan Wallace of Monash University characterised extensively and then validated in multiple preclinical animal models. Following their successful Phase I study, the placental stem cells are now about to enter Phase II trials.

Lim continued working with placental stem cells, to understand more precisely how they were functioning. In this process, she discovered exosomes originating from human placental stem cells. Lim has successfully isolated, purified and characterised the shed exosomes and administered them to disease animal models. Remarkably, she has found that the cell-free exosome treatment is just as potent as the placental stem cells themselves. Similar findings with other exosome types have now been confirmed by multiple groups around the world.

Lim is convinced that these particles are the future of regenerative medicine. As a key authority in this emerging field, she has been invited to meetings about exosome science and commercialisation around the world. She believes that her team is uniquely positioned to succeed in the exosome market. The team has attracted substantial grant funding from the National Health and Medical Research Council to accelerate therapeutic development of exosomes.

Their approach is to develop a technology platform strategically targeting diseases where placental stem cells and derivative exosomes have robust, validated efficacy. An initial target indication is lung fibrosis – a major area of unmet clinical need and, in comparison to oncology, one of much less research attention and competition.

At present, Lim's focus is on partnering with investors to fund the formal manufacturing program presently being embarked on in Melbourne. This will enable her to translate these findings into clinical trials as rapidly as possible.

OHSAS 18001:2007
DFR
ISO 14971 Risk Management
Product Cost Modelling
Human factors engineering
IEC62304 SW Life Cycle Development
Project Dashboards
ISO 14001:2004
New Product Introduction
IECEx
ISO13485 & ISO9001
System Definition
Ideation
Stage-Gate Development Process
Integrated design & manufacturing
Safety Critical Systems
IEC61508 Safety Related Electrical Systems

Software Engineering
Detection & measurement
PRINCE-II
ASDEFCON
Innovation
Mechatronic
Project Management
Thermal
Electrical Engineering
Electronics design
Test & Quality Assurance
Manufacturing support
Tooling strategy
Systems Engineering
Mechanical Engineering
PLC programming
Regulatory
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Supply Chain Management
Systems Integration
Usability & Ergonomics
Outsourcing Management
Optics
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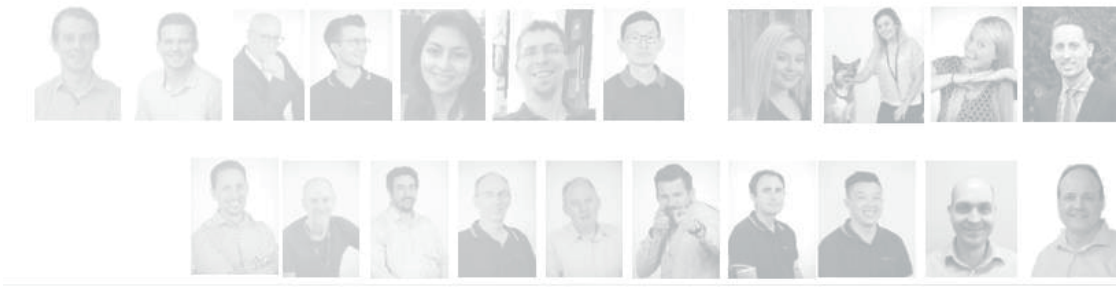
18 years medical device innovation



HYDRIX

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IN TOUCH WITH TECHNOLOGY

Engineers and medical professionals at The University of Western Australia (UWA) are collaborating on devices that enhance surgeons' abilities to touch, see or otherwise detect life-threatening conditions, such as tumours and aneurysms.

The human sense of touch is incredibly sensitive, with recent tests suggesting that differences as small as a single layer of molecules can be discerned through our fingertips. When it comes to health care, that astounding level of receptiveness is invaluable, providing information about the texture, stiffness and flexibility of parts of the body that, in turn, assists diagnosis and treatment.

As acutely sensitive as it is, however, there are times when touch is simply not enough to detect problems. When it comes to breast cancer operations, for example, a little technological assistance wouldn't go amiss. In such cases, surgeons routinely excise a portion of healthy tissue around a tumour and then resort to touch and their eyesight to establish whether or not any of the cancerous tissue remains.

'I was blown away when I learned that surgeons often still rely on the sense of touch to determine if a tumour has been completely removed during breast surgery,' says Dr Brendan Kennedy of the Department of Electrical, Electronic and Computer Engineering at UWA. 'In up to 30 per cent of cases here in Perth, the patient requires another surgery, which is obviously a terrible outcome for the patient and a huge expense for the healthcare system.'

Ultrasounds and X-rays, however, lack the resolution needed to pinpoint lingering malignant cells that are missed by the physical examination. So, as Head of the Bioimaging Research and Innovation for Translational Engineering Laboratory (BRITElab) at the Harry Perkins Institute of Medical Research, Kennedy has been working with a team of biomedical engineers to create a more sophisticated imaging technique capable of locating what touch cannot.

The result is a finger-mounted optical probe that will facilitate a survey of the 'surgical margin' – the thin rim of tissue around the site of an excised tumour. The probe will assist in the detection of cancer cells that are too small to see or feel, and will better establish whether or not all trace of them has been removed during surgery.

Known as micro-elastography, the technique uses optical coherence tomography (OCT), the same imaging modality

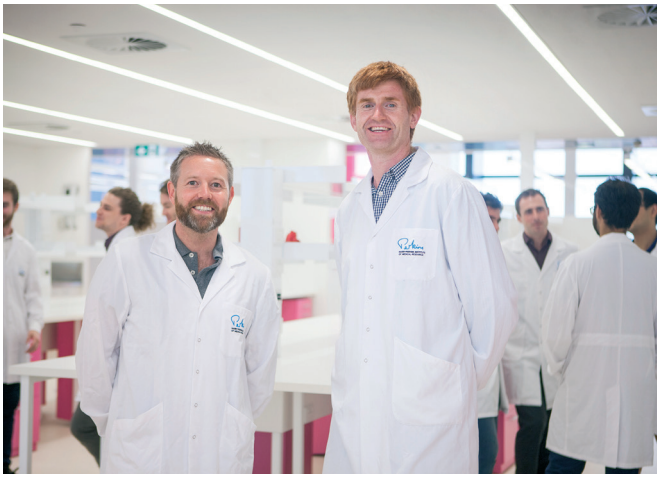


Image © Harry Perkins Institute of Medical Research

that underpins the breakthrough microscope-in-a-needle that originated within the same research team. The key difference, however, is that the images measure not how different tissues reflect light, but how these tissues react to being compressed by a surgeon's touch. The key indicator is that tumour tissue is stiffer, which makes its response to compression distinct from that of the tissue surrounding it.

'The tool will provide surgeons with feedback about whether malignant tissue exists in the surgical margin while the patient is still in the operating room,' explains Kennedy. 'Ultimately, we believe that the technology can be transplanted into a handheld probe that can be used during surgery.' This research has led to the creation of OncoRes Medical, a UWA startup that receives commercial funding from the Medical Research Commercialisation Fund (MRCF).

The device is the result of engineers working hand in hand with surgeons and pathologists. Such collaborations have been bearing fruit in other areas, too. At UWA's Vascular Engineering Laboratory (VascLab), Dr Barry Doyle conducts research into conditions such as coronary artery disease, aortic dissection and abdominal aortic aneurysms.

Dr Doyle and his team have been testing a combination of CT and MRI scans to generate 3D representations of aortic aneurysms. The study uses a software platform called BioPARR (Biomechanics based Prediction of Aneurysm Rupture Risk) to apply solid mechanics to the biological problem, and so assess the levels of biomechanical stress in a given blood vessel. The process can calculate where

Image © Harry Perkins Institute of Medical Research

an aneurysm is likely to rupture and, importantly, aims to predict if it is likely to rupture at all. By using data specific to individual patients, the results are unique to the patient, and treatment plans can then be tailored accordingly. Doyle and the VascLab team are also developing a new software platform to better understand the biomechanics in coronary artery disease and help predict patients at risk of a clinical event, such as a heart attack.

'That is the beauty of what engineering can bring to medicine,' says Doyle. 'It takes away any ambiguities and it focuses right down on the specific patient, helping to make better-informed clinical decisions.'

Other research undertaken by Doyle's team at VascLab makes use of bioprinting, which enables the creation of living constructs that can be tested and observed by scientists seeking solutions to medical problems.

'It is a huge interdisciplinary challenge for engineers and material scientists to print and understand the mechanical and cellular behaviour of the bioprinted structure,' says Doyle. 'Then, of course, each specific application requires a whole raft of people from different disciplines far beyond typical engineering.'

The work of doctors Kennedy and Doyle, and their teams, in creating cutting-edge new medical devices is just the latest in a succession of advances to emerge from UWA. As well as the groundbreaking microscope-in-a-needle, a number of other devices that combine hard science and medical research have emerged from the university.

Recently, for example, Associate Professor Tim Inglis and his team of researchers were responsible for a major breakthrough in testing levels of antibiotic resistance in microbes. Using flow cytometry, they were able to reduce the time taken to assess bacteria from 24 hours to just three hours.

Professor Tim St Pierre from UWA's School of Physics, meanwhile, devised cross-disciplinary technology that employs magnetic fields to detect parasite eggs in humans. Of particular use in detecting the organisms that cause schistosomiasis – second only to malaria in terms of globally devastating parasitic diseases – the low-cost device makes it possible to diagnose the presence of the eggs in much lower quantities, and so much earlier than ever before.

With the university dedicated to investing in biomedical research into the future, these successes will surely inspire the next generation of innovators to make more discoveries with global impact.

VALUING EMERGING TECHNOLOGIES AND TRENDS

BY DR KATHERINE WYNN, GREG WILLIAMS AND DR SHANE SEABROOK, CSIRO FUTURES

An effective research and development (R&D) strategy considers, among other things, how to allocate limited resources across different types of projects, and how to communicate R&D value to key stakeholders.

CSIRO's strategic advisory arm, CSIRO Futures, is using economic tools and techniques to estimate the value of emerging opportunities, and to develop scenarios across priority sectors for Australian businesses and governments.

We identified a number of exciting opportunities in the Medical Technologies and Pharmaceuticals Roadmap[1], ranging from smart devices, implants and bionics, to diagnostics, and informatics products and services. The market for some of these emerging technologies has been valued at the global level, and there are many market research companies that produce industry reports with global market values across a range of time frames. However, such reports rarely provide Australian-specific information that would be useful for Australian companies and research organisations when communicating to their stakeholders.

We have started estimating the value of the Australian market for some of these emerging technologies, such as genome sequencing services (which may generate A$740 million in expected revenues from 2017–21).

We also identified a number of trends in life sciences, such as precision health care, consumer control and integrated care, all of which are underpinned by a universal desire for better health and wellbeing. Attempting to quantify these trends is complex because of their breadth and interrelation. An example of this is the extensive range of targeted pharmaceuticals, as well as custom technologies and treatments, that provide precision health care tuned to the specific needs of the individual.

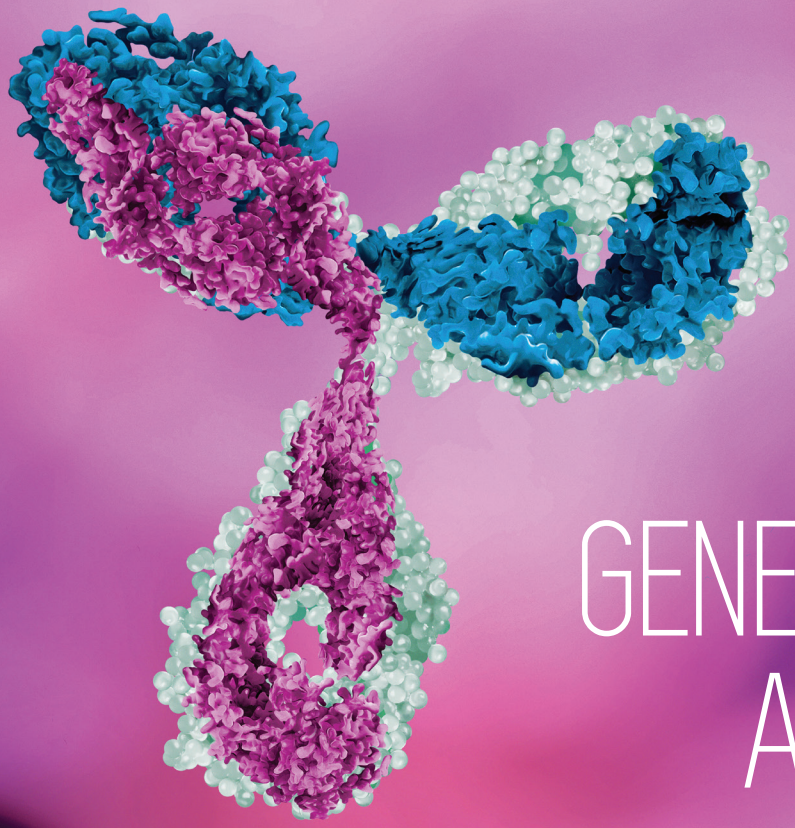
In spite of the complexity, we have started to develop techniques to scope and then quantify parts of these trends. A recent example is the sale of point-of-care and home diagnostics products, which are important revenue drivers for the broader precision healthcare trend, and which we estimate may generate A$770 million in expected revenues in Australia from 2017–21.

A number of tools and techniques can be used to estimate values, which support resource allocation and collaborative actions at the national, sector and business levels:

- Cost-benefit analysis: used when R&D impact can be assessed in monetary terms, where benefits include revenues and cost savings, while costs include money, time and resources spent. Often, future-expected revenues or R&D spend are useful metrics on their own.
- Multi-criteria analysis: a good alternative to cost-benefit analysis when R&D impacts are more difficult to quantify in monetary terms, as it can analyse impact with multiple objectives and criteria.
- Input-output analysis: used to estimate the impact of a new technology, investment or policy decision on economic activity and employment across all industries.
- Monte Carlo analysis: used to estimate R&D impact when subject to uncertainty (such as climate, scientific, regulatory or financial) providing the decision-maker with the full range of possible values and their probabilities, including the most likely outcome. It's also a great way to conduct sensitivity and scenario analyses.
- Real options analysis: This is used to value business budgeting decisions, such as expanding or staging an investment, and can help to allocate an R&D budget across diverse projects.

For more information, please contact CSIRO Futures at www.csiro.au/en/Do-business/Futures/Team.

1 CSIRO, 2017, Medical Technologies and Pharmaceuticals Roadmap, available at www.csiro.au/en/Do-business/Futures/Reports/Medical-Technologies-and-Pharmaceuticals-Roadmap.



THE NEXT GENERATION OF ANTIBODIES

BY SAM COBB, MANAGING DIRECTOR AND CEO, ADALTA

One of the greatest advancements in drug development in recent times has been antibody therapeutics. More than 50 monoclonal antibodies have been approved in the past 20 years, significantly improving treatment of high-burden diseases, such as cancer and inflammation.

The success of monoclonal antibody therapeutics is owed to their ability to specifically bind to a target with high affinity and specificity, avoiding the off-target effects synonymous with their small-molecule predecessors.

Monoclonal antibodies, however, still have their drawbacks, including high molecular weight, limited tissue distribution, instability and high potential immunogenicity. As such, there has been significant research and development (R&D) investment in next-generation antibody technologies that replicate specific target binding using smaller protein backbones. Approaches include the identification of species that naturally generate smaller, heavy-chain-only antibodies, including camels and llamas. European biotechnology company Ablynx developed a pipeline of llama antibodies, including caplacizumab, currently in Phase III for orphan indication thrombotic thrombocytopenic purpura (aTTP). Ablynx was recently acquired by Sanofi for A$6.1 billion, demonstrating the significant value in next-generation antibody platforms.

Other next-generation antibody approaches involve the generation of non-immunoglobulin scaffolds used to form vast protein libraries through randomisation of residues at the binding surface. These platform

technologies include the Affibody, and the Anticalin from Pieris AG, as well as OBodies from the New Zealand–based company of the same name.

Melbourne-based biotechnology company AdAlta has developed a next-generation antibody technology that has taken aspects from both approaches. AdAlta's technology, termed the i-body, is based on the structure of the shark antibody, which also only consists of a single heavy-chain domain; however, in contrast to Ablynx, which uses actual llama single-domain antibodies, AdAlta has developed a human scaffold protein that mimics the shark antibody, thus providing high-affinity binding with lower potential for immunogenicity. The long loop of the i-body and a shorter complementarity determining region (CDR) binding loop mimic the structure of the shark antibody binding regions, which have been engineered into the human protein. The long CDR loop is a key advantage of the i-body and, through randomisation of residues, AdAlta has created a library of more than 20 billion i-bodies, which are screened using phage display.

The long-loop CDR region of the i-body provides superior access and binding to drug targets compared to next-generation antibody approaches. The length of the binding loop allows the i-body to bind deep in the groove of drug targets, such as G-protein-coupled receptor (GPCR) and ion channels. The lack of specificity demonstrated by small molecule binders has contributed to the large amount of unexploited targets – and targets that are linked to pathologies of high unmet need.

Unique binding of the i-body and subsequent pharmacology has been demonstrated by AdAlta's lead candidate, AD-114, which binds to the GPCR CXCR4. Through screening the i-body library, a panel of candidate binders were originally identified that demonstrated nanomolar affinity to CXCR4. Epitope mapping revealed distinct interaction of each binder to specific residues in the binding groove of the GPCR and subsequent distinct downstream receptor activation. The candidates act as biased antagonists, selectively blocking specific pathways downstream of CXCR4, including the beta-arrestin pathway. The concept of biased agonism and antagonism has significant therapeutic potential in cases such as opioid receptors, where a biased agonist could elicit pain relief without causing respiratory depression and constipation. This work was published by Griffiths et al. in *The Journal of Biological Chemistry* (2016) 291:12641.

Sam Cobb

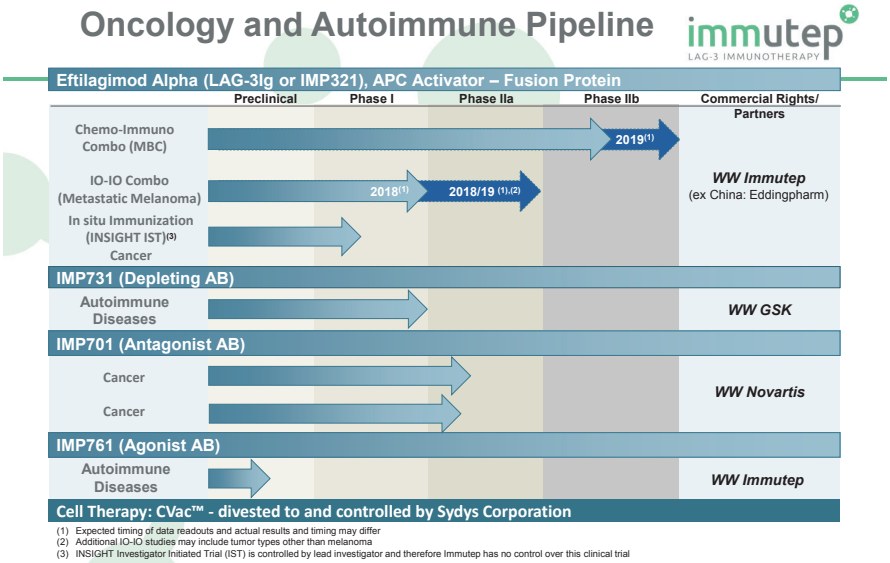
The unique pharmacology of AD-114 has also been demonstrated in a pathological setting. AD-114 is in preclinical development for idiopathic pulmonary fibrosis (IPF), a rare lung condition that affects 10,000 Australians but kills as many as breast cancer does. CXCR4 is highly expressed in the lungs of IPF patients. Fibrosis expert Cory Hogaboam observed anti-fibrotic activity of AD-114 in IPF patient tissue that was not replicated by the CXCR4 small- molecule drug AMD3100 or Mozobil. This work was recently published in *Scientific Reports*, by Griffiths et al. (2018) 8:3212. AdAlta has US FDA Orphan Drug status with AD-114 is progressing to the clinic in the second half of 2018.

AdAlta's next-generation i-body technology provides a new way to identify novel treatments that bind to difficult-to-access targets, including GPCRs and ion channels. The i-body, as a next-generation antibody technology, has the advantages of small molecules, such as stability and ability to access unique epitopes, and the advantages of antibodies, with their high affinity and specificity.

AdAlta is looking to expand the i-body pipeline, as well as to collaborate with pharmaceutical companies, biotech companies and academic partners with targets that have been considered undruggable, identifying high-affinity and uniquely specific binders without the unwanted side effects.

IMMUTEP CAPTURING GLOBAL ATTENTION

Immutep Limited – listed on the Australian Stock Exchange (IMM) and Nasdaq (IMMP) – is capturing the attention of the international biotech market with its concentration on the LAG-3 (Lymphocyte Activation Gene-3) immune checkpoint and combination therapies; expansive intellectual property; and global partnerships. The company's clinical trials in Europe and Australia are among the most advanced for a prospective immunotherapy drug related to LAG-3.



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Formerly Prima BioMed, the company was renamed Immutep (derived from Imhotep, the Egyptian god of medicine) in November 2017 following its acquisition of Immutep SA in December 2014. LAG-3, a protein involved in regulating the immune system, was discovered in 1990 by Immutep's Chief Medical and Scientific Officer, Professor Frédéric Triebel, who founded the original company.

Today, immune checkpoints like LAG-3 are considered a major target in immuno-oncology and the development of cancer treatments. The world's biggest pharmaceutical companies are investing in clinical-stage LAG-3 programs, with Bristol-Myers Squibb currently running 10 combination LAG-3 antibody clinical trials involving approximately 3500 patients.

Immutep currently has four LAG-3 product candidates, the most advanced being eftilagimod alpha (Efti or IMP321), based on the LAG-3 immune control mechanism that plays a vital role in regulating T cells. Efti is best described as an immune activator, boosting T cell responses to fight cancer in combination with chemotherapy or other immunotherapies. It is currently being trialled with Paclitaxel (Phase IIB trial in Europe) and with KEYTRUDA (Phase I trial in Australia).

To date, Immutep has also partnered with GlaxoSmithKline (GSK), Novartis, and Eddingpharm (EOC), with each holding a development licence for LAG-3-related product candidates. GSK is developing IMP731, a novel therapeutic antibody for the treatment of autoimmune diseases; Novartis is developing IMP701, an anti-LAG-3 antibody also known as LAG525; and Eddingpharm owns the exclusive rights to develop and market Efti in mainland China, Hong Kong, Macau, and Taiwan.

Novartis is currently recruiting for two clinical trials involving IMP701 for 675 patients in total, with advanced solid and hematologic malignancies. GSK has now fully recruited 67 patients for its Phase I, first-in-human clinical trial study. Both partners are responsible for all development costs, with Immutep entitled to receive royalty and milestone payments.

Novartis recently paid Immutep a US$1 million milestone payment, its second in relation to the development of IMP701. Immutep also recently received a milestone payment of US$1 million from EOC Pharma, an affiliate of Eddingpharm, in relation to the development of Efti in China.

Immutep will be filing an investigational new drug (IND) application with the US Food and Drug Administration in the first half of calendar year 2018, to assess the commercial pathway for Efti in the United States.

MEDICINAL MARIJUANA

commercialisation and innovation in a complex regulatory environment

BY SALLY J. DAVIS AND ALEX TZANIDIS, DAVIES COLLISON CAVE PTY LTD; AND DARRON SALTZMAN, DAVIES COLLISON CAVE LAW PTY LTD

As the regulatory framework for medicinal cannabis in Australia becomes more permissive for both producers and patients, there is an opportunity to develop a robust manufacturing and production industry to meet supply in both domestic and international markets. The ability of the Australian biotechnology industry to capitalise on this opportunity will depend on the ability of stakeholders to navigate the complex regulatory obstacles presented by overlapping federal and state legislation. Furthermore, Australian producers will also have to face strong competition from well-established players in the United States, Canada and Israel to establish a foothold in this booming global industry.

The legalisation of medicinal cannabis in Australia was largely enabled by the Narcotic Drugs Amendment Act 2016 (Cth) and the Narcotic Drugs Regulations 2016 (Cth), which permits research, cultivation, production and exportation of medicinal cannabis and related products. Corresponding amendments have also been made to the Therapeutic Goods Act 1989 (Cth) to facilitate regulatory approvals and alternative access schemes for unapproved medicinal cannabis products. Although the production, cultivation, importation, exportation and regulatory approval for the supply of medicinal cannabis are subject to federal legislation, the power to regulate patient access to medicinal cannabis remains with the states and territories. Ongoing lack of consistency between the jurisdictions has resulted in a complex web of legislative instruments for the prescription and use of medicinal cannabis across Australia.

In this article, we will outline some of the key issues that are likely to impact the growth of the Australian medicinal cannabis industry over the next year, including increased access to medicinal cannabis in Australia and internationally, cannabis education within the Australian medical profession and the results of ongoing clinical trials.

Competing in the global marketplace

Australia is by no means a leader in the legalisation of medicinal cannabis. Countries such as the United States, Canada and Israel have already positioned themselves as progressive in the legalisation of medicinal cannabis, while simultaneously developing robust domestic production and supply chains. There are a number of key differences, however, in the approach to legalisation that has been taken in Australia when compared to other jurisdictions, which may provide an opportunity for Australian producers to capitalise on a broader market, particularly in view of clinical data that is necessary within the Therapeutic Goods Administration (TGA) regulatory framework.

The legalisation of medicinal cannabis in a number of jurisdictions, in particular the United States, has not been accompanied by strict or consistent regulation. As a result, there is no requirement to obtain regulatory approval, and there is a lack of clinical data to evidence the benefits of cannabis and cannabis-derived products as therapeutic agents. While observational evidence to support the use of cannabis for a range of indications, such as pain, nausea and epilepsy, may be sufficient for a proportion of the population that is comfortable with cannabis use (for example, recreational cannabis users), this alone is unlikely to convince physicians or mainstream consumers to redefine cannabis as a therapeutic substance, rather than an illicit drug. It is arguable, therefore, that the more ad hoc approach to legalisation seen in the United States may restrict the consumer base of medicinal cannabis products to the 'low-hanging fruit' (again, recreational cannabis users), which may be problematic, particularly as mainstream consumers represent a much larger market.

Alex Tzanidis

Darron Saltzman

Sally J. Davis

By contrast, cannabis-derived compounds and formulations will only be available in Australia with a prescription (Therapeutics Goods Act, Appendix D). As such, these products will have to satisfy the strict regulatory requirements for prescription medical products, supported by quality data (composition, batch consistency, stability, sterility and impurity content); non-clinical data (pharmacology and toxicology data); and clinical data (results from clinical trials). All medicinal cannabis products derived from seeds, extracts, resins, plants and any part of the plant must also conform to the Therapeutic Goods Order 93 (Standard for Medicinal Cannabis).

In this context, the Australian industry is well placed to produce high-quality, medical-grade products that are supported by robust clinical data. On a

global scale, this strict regulatory approach is most similar to that of Israel, where extensive research and clinical analysis of medicinal cannabis is currently underway. The Israeli industry is seeking to capitalise on advanced research and development to build a strong clinical reputation to distinguish Israeli products in the marketplace. Taking a research-driven approach to medicinal cannabis in Australia is also likely to result in a more widely accepted product. There are also opportunities for the Australian research community to attract cross-jurisdictional collaboration and investment due to the favourable taxation incentives for clinical trials that are currently on offer under the Australian Government's R&D Tax Incentive Scheme.

Market acceptance in Australia

As mentioned above, medicinal cannabis will only be available to Australian patients by prescription. Therefore, in order to develop a strong domestic market for medicinal cannabis in Australia, medicinal cannabis products will have to be accepted by the medical profession; however, in view of the current lack of safety, quality and efficacy data, it is not surprising that medicinal cannabis is not considered to be a treatment of first choice.

Of course, market acceptance of medicinal cannabis is inherently linked to the outcomes of clinical research. As more data becomes available, medical practitioners will require additional training and education to ensure that patients are provided with safe and effective medications, and to support evidence-based decision-making. The need for education has been recognised by the TGA, which is working with the states and territories to assist medical practitioners in accessing quality evidence on medicinal cannabis, particularly for the treatment of epilepsy and palliative care, to better support them in making informed decisions about the use of medicinal cannabis.

Conclusion

The legalisation of cannabis for medicinal use in Australia provides a new economic market opportunity from what was previously an illegal trade. Importantly, the legalisation of medicinal cannabis in Australia has occurred in conjunction with an injection of funds to support clinical research, resulting in the establishment of a number of specialised research centres and clinical trial programs. The outcomes of this research activity is essential to develop a robust domestic market for the production and supply of medicinal cannabis products that are effective and safe for patients in Australia, and around the globe.

FAST DRUGS, NEW DRUGS

BY KIM O'CONNELL, PARTNER; AND SUZY MADAR, SENIOR ASSOCIATE, KING WOOD & MALLESONS

Businesses looking for overseas opportunities to expand in the healthcare industry should be aware of important regulatory changes that are taking place in both China and Australia.

The healthcare industry in both Australia and China is undergoing significant growth that has been accompanied by rapid regulatory change. Both countries have invested significantly in the industry, which increasingly caters for ageing populations that provide demand in a rapidly expanding market for prescription and non-prescription medicines. In 2016, the value of Australia's pharmaceutical market increased to US$22 billion, while China's is currently the world's second-largest, with a value of US$116.7 billion in 2016.

Growth in the sector has also been accompanied by significant regulatory shifts. Following global trends, regulators in both jurisdictions have become increasingly focused on finding ways to accelerate approvals for important new medications. Chinese regulators have been moving in this direction since 2015, and Australia is currently in the process of implementing major reforms.

Accelerating approvals in Australia

Increasing the speed of approvals for important new drugs has been a global regulatory trend in recent years. In Australia, the Therapeutic Goods Administration (TGA) – which regulates therapeutic goods, including medical devices, prescriptions, over-the-counter medicines and some complementary medicines – is in the process of introducing three expedited pathways for drug approvals.

Priority Review pathway

The Priority Review pathway, introduced in July 2017, permits sponsors to proceed under the accelerated review procedure if the application relates to a new medicine or the use of an old medication to treat 'a life-threatening or seriously debilitating condition'. To take advantage of the expedited review pathway, there must be no alternative treatment on the Australian Register of Therapeutic Goods (ARTG), or 'substantial evidence' to demonstrate that the new drug or treatment presents a significant improvement to currently available treatment options.

This new pathway was immediately utilised. In August 2017, Roche Products Pty Ltd was the first applicant to secure priority review designation for both Alecensa®, an anaplastic lymphoma kinase (ALK) inhibitor used in the treatment of non-small-cell lung cancer; and Hemlibra®, a prophylactic medication for haemophilia A (congenital factor VIII deficiency). In February 2018, Roche's Alecensa was the first medicine to be registered on the ARTG via the Priority Review pathway.

Provisional Approval

Complementing these accelerated reviews is the introduction of 'Provisional Approval' in the *Therapeutic Goods Amendment (2017 Measures No 1) Act* that amends the *Therapeutic Goods Act 1989* (Cth) ('*Act*') to create a class of 'Provisionally registered goods' that will be able to be released to the market on the basis of early clinical data on efficacy, quality and safety.

The maximum provisional registration period is two years, which may be extended by one or two years by application (up to a maximum of two extensions).

New assessment pathway for complementary medicines

Currently, listed complementary medicines contain lower-risk ingredients and are permitted to make lower-level assertions about medicinal capabilities (limited to usefulness in maintaining health and the treatment of non-serious conditions). Registered complementary medicines are considered higher risk on the basis of ingredients or indications.

The Bill introduces a new approval pathway that will enable sponsors to apply to list complementary medicines – including vitamins, minerals and nutritional supplements – on the ARTG with higher-level indications than are currently permissible.

Currently, listed complementary medicines are also not assessed prior to listing – listing merely requires an applicant to self-certify the safety and quality of the product. Under the proposed pathway, sponsors will continue to self-assess quality, safety and efficacy; however, the TGA will also assess evidence supporting the proposed claims and indications. In all other respects, these medicines must meet the current eligibility criteria for listed medicines in relation to manufacturing standards.

China prioritises specific foreign products

In China, where drug approvals generally take longer, there has been a similar regulatory focus on providing mechanisms to permit manufacturers to bring products to market more quickly.

In February 2016, the China Food and Drug Administration (CFDA) issued a notice stating that a priority review pathway would be implemented for certain categories of products, including innovative drugs, products in short supply, early generics, and drugs used to treat AIDS, tuberculosis, viral hepatitis, rare diseases and cancer.

Complementing this, in March 2017, the CFDA issued a draft rule, stipulating that foreign drugs will no longer require prior approval from overseas regulators or have to be in Phase II and III clinical trials overseas before trials in China are permitted. This is a significant change that will result in drugs being able to be released to the Chinese market much more quickly.

Kim O'Connell

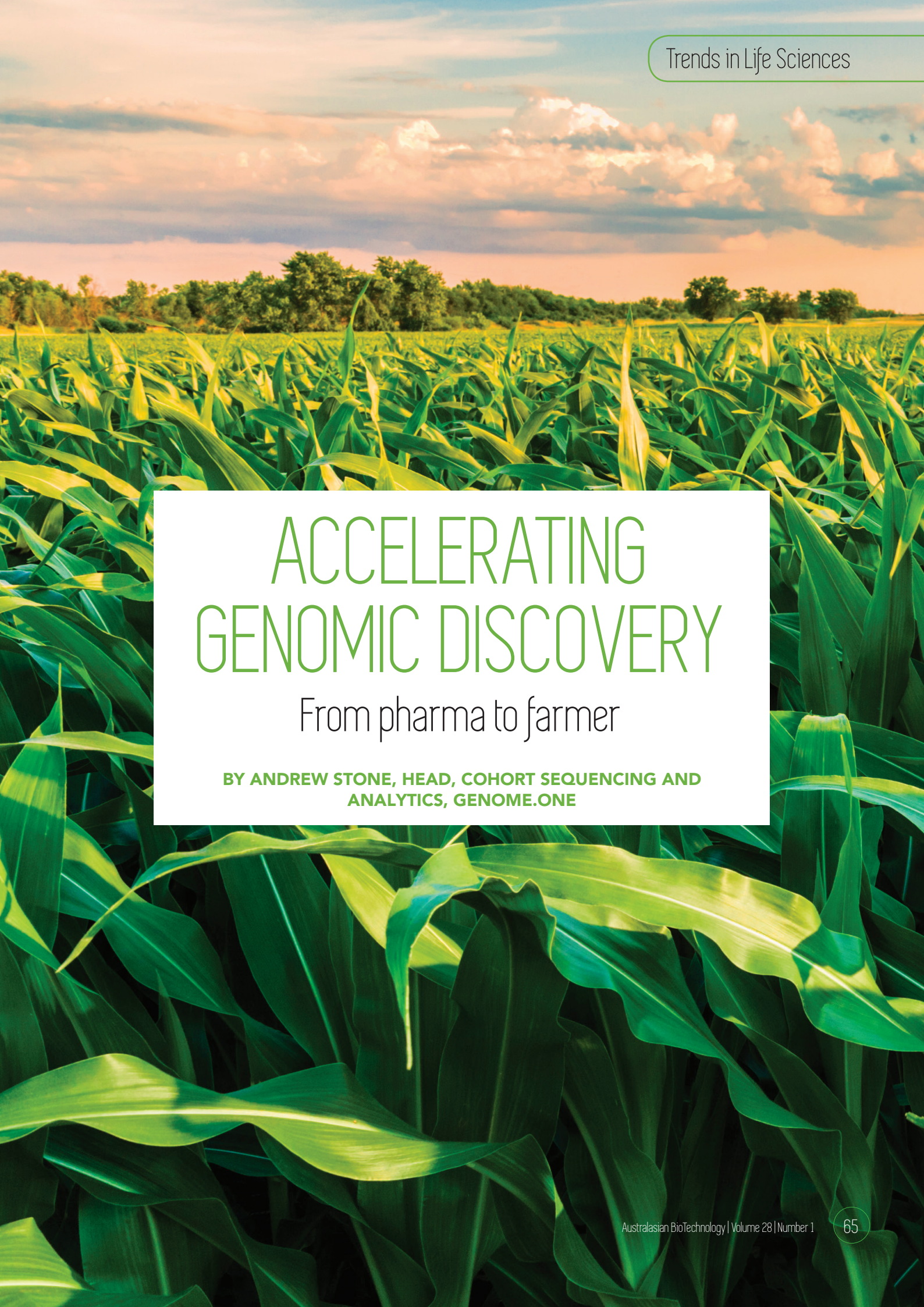
Suzy Madar

More recently, the Chinese Central Government released the Draft Administrative Measures for Drug Registration (Draft DDR) for public consultation. The Draft DDR includes a new Marketing Authorisation Holders (MAH) regime, aimed at addressing a shortage of authorised innovative drugs in China that is thought to be due to the reluctance of Chinese manufacturers to invest in the long approval periods for new drugs, that have instead focused on the production of generic drugs.

The Draft DDR also proposes separation of manufacturing and drug licences, which are currently linked, so as to permit research and development institutions with limited manufacturing capability to rely on third-party manufacturers. The scheme will be open to foreign pharmaceutical companies that appoint a local Chinese entity as an agent responsible for preclinical and clinical trials, manufacturing operations, side effects, pricing, labelling and advertising.

The opportunity

Regulatory changes that fast-track approvals in both countries and ease restrictions on foreign businesses in China present a significant opportunity for Australian pharmaceutical businesses looking to capitalise on the rapidly expanding markets in China and Australia.



ACCELERATING GENOMIC DISCOVERY

From pharma to farmer

BY ANDREW STONE, HEAD, COHORT SEQUENCING AND ANALYTICS, GENOME.ONE

Genome sequencing – analysing all of an organism's genetic information at once – is having a transformative effect across the biotechnology industry. The technology required to sequence a genome is more accessible than ever, in part due to a rapid decline in cost and an increase in speed over the past 15 years. In 2014, three genomics centres, including the Kinghorn Centre for Clinical Genomics at the Garvan Institute of Medical Research in Sydney, acquired Illumina HiSeq X Ten systems, which has the capability to sequence a whole human genome at a base cost below US$1000. Such high-throughput technologies are generating a wealth of genomic data, and are providing an increasingly valuable information source for both medical and agricultural research.

The pathway for the translation of medical research has traditionally been linear – discoveries are made in research that inform the development of a new drug or diagnostic test, which is then approved for use in the clinic after many phases of clinical trials. Recently, and especially with regard to genomics research, we are seeing a shift towards a more cyclical translation pathway of clinically driven research. Increasingly, candidates for genomic research are being identified in the clinic and their genomic data is being used to inform their own clinical care. Similarly, diagnostic information is playing a crucial role in discovery stages, leading to a blurred boundary between research and the clinic. This shift in the traditional research paradigm means that genomic discovery is playing a role at all stages of the translational pathway, rather than just at the beginning.

Many drug trials are adding translational arms alongside more traditional clinical endpoints so that the biochemical mechanisms that underpin clinical observations can be explored in depth. Others are using genomic information to stratify patients and inform how the trial is run. The Molecular Screening and Therapeutics (MoST) clinical trials being carried out at the Garvan Institute of Medical Research in Sydney use molecular information from tumours to match individual patients with treatments targeted to their specific cancer type. The trials also contain multiple clinical sub-studies of novel treatments, and patients are stratified into sub-studies based on what treatment is most appropriate for their tumour. The MoST trials sit between a traditional Phase I toxicity trial and Phase II efficacy trial, and represent the future of trial design in cancer, as genomic profiling of tumours will be essential for the next generation of targeted therapeutics.

Andrew Stone

Tailoring treatments based on a person's genetic make-up promises an era of better patient outcomes from more targeted and effective therapies. For this reason, pharmaceutical companies are beginning to incorporate genomics at all stages of the drug-development pipeline – from discovery through to late-stage clinical trials.

In 2016, AstraZeneca launched its Centre for Genomics Research with the aim of compiling genome sequences and health records from two million people over 10 years. AstraZeneca intends to discover rare variants associated with disease and response to treatment, and will use the data to inform drug development across their entire portfolio, which includes complex diseases such as asthma and diabetes. Much of the genetic contribution to complex diseases remains unexplained, and large-scale sequencing projects such as this could uncover the impact of rare variants that have not previously been identified.

Agricultural research is also undergoing a genomic revolution to combat rising populations and climate

change. The rate of annual yield increases from major staple crops must more than double by 2050 to keep up with population increases. Conventional breeding, which involves selection based solely on phenotype over a number of generations, is expensive and time-consuming. A rapid and efficient selection system is needed for the development of high-yielding and climate-resistant crop varieties for the future, and this is where genomics is becoming a powerful tool.

Genomic selection involves estimating the genetic worth of a plant by comparing its genomic profile with those of others that have grown in the same environment. This requires large reference libraries of molecular markers and phenotypic information to be built, but can save significant time and money in the long run by increasing the accuracy and efficiency of selection. Genomic selection is becoming routine in crop improvement, particularly for cereal crops, such as maize and rice. We are seeing a lot of genomic research that is focused on building or refining reference libraries for other crops, to accelerate the uptake of this technique.

A similar approach to breeding is being used for livestock, and is responsible for the dramatic increases in livestock productivity over the past 50 years. For example, milk production in Holstein cows doubled from approximately 6000 kilogams in 1960 to 12,000 kilograms in 2000 – and 75 per cent of this change was genetic.

Libraries of genome-wide markers are being used to predict performance traits of breeding stock, which allows producers to optimise the profitability and yields of their herds by making strategic breeding decisions. Genomic selection of livestock has been used commercially for more than a decade, so most of the work in this area is focused on adding to, or refining, the existing reference libraries.

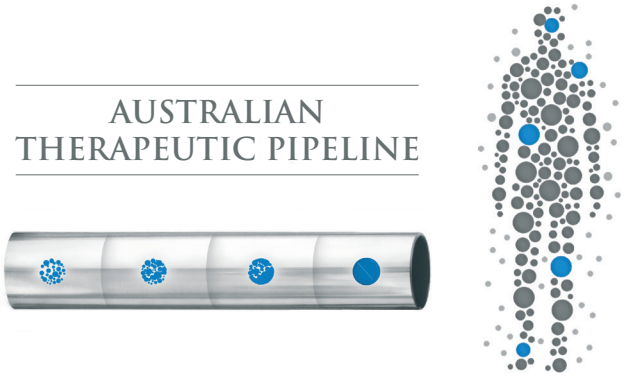
A key project is the 1000 Bulls Genome Project – an international effort to construct a large database of genetic variants from 1000 ancestor bulls of the most important domestic cattle breeds. The first 234 genomes sequenced have yielded 28.3 million variants, including several associated with embryonic loss and lethal chondrodysplasia. This type of database is invaluable for producers looking to maximise the health and viability of their herd.

Genome sequencing has moved from a prohibitively expensive and time-consuming research technique to a powerful tool for shaping the future of biotechnology. We are already seeing genomic information being used for the development of targeted therapeutics, the stratification of patients in clinical trials, and the improvement of crop and livestock breeding.

Additionally, we are seeing the emergence of pioneering genomics-focused companies, such as Australia's Genome.One, which provides genomic sequencing and genomic analysis to accelerate innovation in the biotech sector. Importantly, as the cost of sequencing continues to decrease, the amount of genomic data available for research will increase exponentially, providing even greater opportunities for researchers to realise the value of genomic information in their field.

THE AUSTRALIAN THERAPEUTIC PIPELINE

Australia has excellent therapeutic discovery and development capabilities, but they can be hard to identify and engage with. To remedy this, Therapeutic Innovation Australia (TIA), a not-for-profit company that supports access to translational research facilities, has established the Australian Therapeutic Pipeline (the Pipeline).



The Pipeline brings together the expert capabilities that make up Australia's ability to discover, develop and manufacture therapeutics for human health. These facilities provide access to research capabilities in the areas of small molecules, biologics and cell therapies, preclinical testing and clinical trial support.

Small molecule capabilities

Compounds Australia

Compounds Australia is Australia's national compound library. Its unique systems allow chemists to deposit small molecules into a central repository for access by drug discovery researchers, enabling high-throughput screening.

Walter and Eliza Hall Institute of Medical Research HTS Laboratory

The high-throughput screening (HTS) laboratory at the Walter and Eliza Hall Institute of Medical Research (WEHI) boasts Australia's foremost HTS capability and can kickstart drug discovery through rapid identification of chemical hits from large chemical libraries.

Australian Cancer Research Foundation (ACRF) Drug Discovery Centre for Childhood Cancer

The ACRF's unique facility is dedicated to developing new anti-cancer therapeutics. Its capabilities include high-throughput and high-content screening, and hit-to-lead, lead optimisation and compound libraries.

Community for Open Antimicrobial Drug Discovery (CO-ADD)

The CO-ADD, led by The University of Queensland, is an initiative to provide free screening of compounds for antimicrobial activity for academic research groups to find new compounds to combat drug-resistant infections.

Australian Translational Medicinal Chemistry Facility (ATMCF)

The ATMCF, located at Monash University, provides researchers with critical medicinal chemistry expertise to support chemistry-led drug discovery and development. ATMCF works closely with the CDCO (see below).

Biologics and cell therapies

National Biologics Facility (NBF)

The NBF offers world-class expertise in molecular biology, antibody engineering (including phage display), cell culture and biopharmaceutical development. The NBF operates nodes at The University of Queensland in Brisbane and the CSIRO in Melbourne.

Cell and Tissue Therapies, Western Australia

Licenced by the Therapeutic Goods Association (TGA), Cell and Tissue Therapies is a biotherapeutic manufacturing facility providing diverse clinical products and services, and producing material to support clinical trials.

Monash Antibody Technologies Facility

A globally recognised source of cost-effective, high-quality, high-affinity, custom monoclonal antibodies, the Monash Antibody Technologies Facility is experienced in robotics, antibody purification and characterisation. The facility assists customers with antibody production challenges.

Q-Gen Cell Therapeutics

Q-Gen is a fully integrated facility for translational research within QIMR Berghofer, providing good manufacturing practice (GMP), quality control and cell banking to support the manufacture of therapies for clinical trials.

Preclinical testing

Centre for Drug Candidate Optimisation (CDCO)

The CDCO provides world-leading preclinical translational expertise on absorption, distribution, metabolism and

excretion and pharmacokinetic properties of drug candidates to enable their further translation and entry into clinical trials.

Centre for Integrated Preclinical Drug Development (CIPDD)

The University of Queensland's CIPDD offers expertise for drug development, including good laboratory practice (GLP) preclinical studies, including pharmacokinetic and toxicology studies, and specialist expertise in in-vivo efficacy profiling.

Preclinical Imaging Research Laboratory (PIRL), South Australia

Based at the South Australian Health and Medical Research Institute (SAHMRI), PIRL offers a variety of preclinical services, including pharmacokinetic/pharmacodynamic (PK/PD), plus imaging and experimental surgery.

Centre for Clinical Diagnostics (CCD)

Located at The University of Queensland's Centre for Clinical Research, CCD provides ISO-accredited development and optimisation of in-vitro diagnostic medical devices.

Clinical trial support

Australia New Zealand Clinical Trials Registry (ANZCTR)

ANZCTR is an online register of clinical trials undertaken in Australia in a variety of areas, and provides a detailed picture of clinical trial research in Australia.

ACRF Cancer Genomics Facility

Based at the Centre for Cancer Biology, this facility provides a full range of genomics and bioinformatics services to support biomarker discovery and personalised medicine.

genomiQa

This facility within QIMR Berghofer offers ISO-accredited somatic and germline analysis by whole genome and exome sequencing, and gene expression services to clinicians, companies and researchers.

Kinghorn Centre for Clinical Genomics

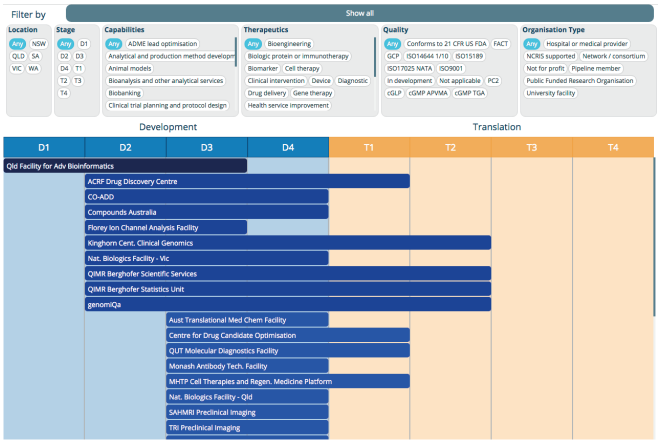
This centre, based at the Garvan Institute, offers ISO-accredited whole-genome sequencing to translate genomics to the clinic, as well as offering bioinformatics and data visualisation services.

Paediatric Trials Network Australia (PTNA)

PTNA brings together paediatric researchers in Australia to facilitate paediatric clinical trials using WebSpirit, which is advanced clinical-trial data-management software.

Peter MacCallum Molecular Pathology Laboratory

The Peter MacCallum Cancer Centre offers ISO-accredited, state-of-the-art protein, RNA and DNA molecular pathology, providing high-throughput diagnostic molecular services on multiple test platforms.



The Pipeline Navigator (above) is an interactive online map of Pipeline members and their capabilities.

Q-Pharm Clinical Trials

Q-Pharm specialises in early-phase clinical trials, including first-in-human, biosimilar, PK/PD, vaccine, and challenge studies. Q-Pharm operates state-of-the-art facilities within the Royal Brisbane and Women's Hospital.

Informatics and support services

BioGrid Australia

BioGrid operates a federated data-sharing platform for collaborative translational research, providing secure infrastructure that links privacy-protected and ethically-approved data with a network of health collaborators.

QIMR Berghofer Scientific Services

QIMR Berghofer's core suite of integrated scientific services are available to external users, including bioanalytics, flow cytometry, histology, microscopy, proteomics, sample processing and sequencing.

QIMR Berghofer Statistics Unit

This team of experts provides statistical consultancy and research collaboration services to medical and clinical researchers. Available services range from laboratory research to clinical trials, epidemiology and biomarker development.

Victorian Cancer Biobank (VCB)

The VCB is a not-for-profit consortium of tissue banks that provides high-quality, ethically obtained biospecimens for researchers. Since 2006, more than 19,000 individuals have donated to the Biobank, which has prepared more than 33,000 specimens.

Visit www.therapeuticpipeline.com to find out more about the Pipeline, including the Pipeline Navigator, an innovative online map of therapeutic capability providers, and the Pipeline Accelerator, a voucher-based scheme to support project access to Pipeline capabilities.

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Sunshine Coast University Hospital: A new benchmark in integrated research, training facilities & patient-centred care.

The multi-award-winning Sunshine Coast University Hospital is Australia's largest Greenfield hospital. Developed as part of a 20-hectare integrated health campus, its world-class design delivers a new benchmark in integrated research and training facilities, patient-centred care, and as a healthcare workplace for the Sunshine Coast community.

With over 700 beds, the hospital offers a wide range of tertiary level healthcare facilities, including an emergency department, comprehensive cancer centre, specialised medical and surgical services, a mental health unit, maternity rehabilitation and renal services, as well as interventional and diagnostic services.

Sunshine Coast University Hospital is an embodiment of patient-centred service that encourages family to support their loved ones and facilitates seamless teaching and learning. Its design demonstrates a sensitivity in response to the Sunshine Coast in terms of its culture, climate and distinctive vernacular architecture. The functionally flowing outdoor and indoor spaces, gently dappled with tranquil light and finished with the highest levels of craftsmanship, aid in the healing process and enhance the general wellbeing of visitors and users, while considering long-term operational efficiency and sustainability.

HDR is a world leader in health, research, education, science and technology facilities, designing and delivering more projects across these sectors than any other firm in the world including, in Australia: Liverpool Hospital, Westmead, the award-winning Lifehouse Integrated Cancer Centre at the Royal Prince Alfred Hospital, UNSW's Material Sciences and Engineering Building, Australian School of Advanced Medicine at Macquarie University, and the National Measurement Institute.

Stemming from its philosophy that great design creates value in terms of financial, emotional, environmental and aesthetic performance, HDR is consistently recognised among the highest ranked firms across multiple sectors in international rankings.

HDR and Architectus Brisbane completed Sunshine Coast University Hospital as Sunshine Coast Architects.

Honoured to be awarded the
F.D.G Stanley, Karl Langer & Gabriel Poole 'Building of the Year' Awards

Australian Institute of Architects NAA 2017

2017 Australian Institute of Architects National Architecture Awards
- *Public Architecture*

2017 Australian Institute of Architects (QLD) Awards
- *Public Architecture – F.D.G Stanley Award*
- *Urban Design – Karl Langer Award*

2017 Australian Institute of Architects Regional Awards
- *Gabriel Poole Building of the Year*
- *People's Choice Award*
- *Regional Commendation*

Concrete Institute of Australia
- *Queensland Division Excellence Award, Infrastructure Category*

Building Industry Consulting Services International (BICSI) South Pacific Excellence Awards
- *BICSI South Pacific Professional ICT Design Award*

Consult Australia Awards for Excellence
- *Gold Award Winner for Sustainability in Design Category*

Sustainability Awards 2017
- *Public Category*

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THE SOCIAL INVESTMENT OF EARLY-STAGE BIOMEDICAL INNOVATION

BY ASSOCIATE PROFESSOR KEVIN PFLEGER, CHAIR OF ACCELERATING AUSTRALIA EXECUTIVE COMMITTEE, UNIVERSITY OF WESTERN AUSTRALIA

Universities and medical research institutes around the country have missions that stress lasting health benefits for both local and global communities. Indeed, this is why medical researchers sign up to the career in the first place. As individuals and institutions, we are passionate about improving people's health and wellbeing. Why, then, is it so hard to bridge the gap between the world-leading academic research that is so highly regarded by international peers, and tangible benefits for patients?

The MedTech and Pharma Growth Centre (MTPConnect) Sector Competitiveness Plan (SCP) clearly articulates key constraints in this regard, and three that I would like to focus on are skills, collaboration and funding. Our country's leading researchers are, by definition, exceptional at research. They collaborate well with like-minded souls nationally and internationally in their chosen field of expertise, and they are also highly successful at obtaining grants to fund their research teams. So, what is missing?

The challenge is that research translation requires different types of skills, collaboration and funding, knowledge of which tends not to be readily available to researchers in an academic environment. Progressing down the path towards patient benefit firstly requires an understanding of patient needs that are not adequately addressed by current treatments. It requires engagement with clinicians, patient groups and industries that are at the coalface working to provide solutions.

This does not in any way diminish the importance of fundamental research, which has the potential to generate important game-changing advances; however, such advances will only benefit patients if the value of applying those novel research findings is realised in an appropriate context, and individuals

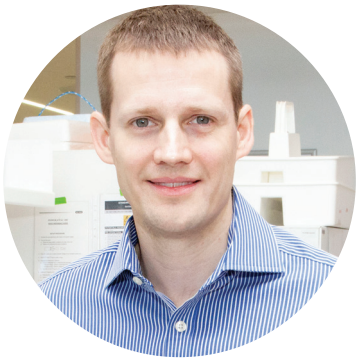
and/or organisations are able to progress their application towards a real-world outcome.

Does that mean that researchers need to become experts in many new disciplines? The answer is 'no', as this is impossible – there are not enough hours in the day. Instead, we need to feel comfortable working and collaborating across boundaries, whether that is between research disciplines; between research, engineering, clinical and businesspeople; or between academia, industry and government. We have to value everyone in the ecosystem and rely upon each other's expertise in different areas. This can be daunting, but it is also incredibly exciting, as it enables us to collectively achieve far beyond our individual abilities.

The term 'translation' is especially apt, as being able to translate terminology of specialised technical research to the requirements of a patent application, regulatory affairs or an investor pitch is critical in itself. We don't all need to retrain as patent attorneys, regulatory affairs specialists or venture capitalists, but we do need to know enough to stay on the right path, avoid pitfalls, and ask the right people to help us at the right time. This is where the ecosystem comes in. There is enormous expertise out there, and the trick is knowing how to access it in a way that works for everyone involved. The problem, of course, then comes down to time and money, something researchers are always lacking.

The medical research funding system is set up on the basis of generating publications to get grants, to then generate more publications, to get more grants, et cetera. Why? Because publications are a very important way of disseminating research findings, demonstrating output from the research and obtaining peer review of the work (experts in the field critiquing the research and ensuring that it is up to standards of best practice). Publications are also easy to measure, so they become the major assessment tool for quality and quantity of research output when comparing individuals, research groups and universities.

So, why is this a problem? It isn't if, as a society, Australia is content being a world leader in generating exceptional medical research output that adds to the sum total of knowledge in the world; however, if we, as a nation, want to do more to see that exceptional research tangibly benefit society, either socially or economically, we need to support the next step, in addition to publishing the research outcomes. And the exciting thing is that this is happening more and more.



Associate Professor Kevin Pfleger

In 2016 and 2017, MTPConnect, supported by the Australian Government Industry Growth Centres Initiative, committed funds , which were matched by the sector, to 'invest in big, bold ideas to improve the productivity, competitiveness and innovative capacity of the medical technology, biotechnology, and pharmaceutical (MTP) sector'. This has bolstered the interconnectivity of the ecosystem through the funding of initiatives such as Accelerating Australia, a national consortium of biomedical research institutions, universities, healthcare providers and companies that boost the biomedical entrepreneurship and translation of medical research through experiential entrepreneurial courses, brokerage and early-stage commercialisation support services.

Such endeavours are only possible due to the incredible generosity of professionals in the broader medtech and pharma ecosystem, from patent attorneys and tax accountants, to regulatory affairs and clinical trials specialists, to health economists and venture capitalists, to university executives and government officials, to medicinal chemists and large pharma executives. All of these people see the amazing research that is happening in Australia that struggles to cross the so-called funding valley of death, and collectively they are building a bridge.

The final piece of the puzzle is early-stage investment from those willing to take a chance on very high-risk projects that could be very financially rewarding after perhaps a decade or more of incubation, but with little guarantee of success. In many ways, this could be regarded as 'philanthropy with benefits'. What can be guaranteed is that, overall, more patients will benefit from the enormous investment in Australian medical research if greater strategic investment at this early translation stage is made, either directly though funding projects, or indirectly by upskilling our workforce, thereby fostering jobs and growth in a critical sector of our transitioning high-skill economy.

ARC

linking industry and research to empower Australian innovation

BY PROFESSOR SUE THOMAS, CEO, AUSTRALIAN RESEARCH COUNCIL

The Australian Government, through the Australian Research Council (ARC), provides targeted support to researchers who collaborate with industry and business to address pressing issues with commercial implications, and responds to the needs and priorities of our society and economy.

The ARC is the primary Commonwealth entity responsible for awarding competitive, non-medical research grants in Australia, through the National Competitive Grants Program. The ARC awards a significant portion of this funding to stimulate research-industry collaborations, principally through the Linkage Projects scheme, and the Industrial Transformation Research Program.

The Linkage Projects scheme is one of the foundation programs of the ARC, and has been in place since 2001. The ARC has awarded more than $1.6 billion through the Linkage Projects scheme to stimulate research–industry linkages in its lifetime. In 2017 alone, 117 new collaborative research projects were awarded under the ARC's Linkage Projects scheme. These projects represented $46.5 million in ARC funding to support new collaborative research, with 274 partner organisations that pledged to provide a further $79.7 million to support the research projects.

The scheme aims to create research–industry connections, which can endure beyond the duration of ARC funding. Like any other working collaboration, these linkages build lasting associations and professional relationships, which expand the scope of our national research activity. An internal 2010 evaluation of the scheme found that the creation of long-term professional relationships was seen as one of the primary benefits of the scheme by its stakeholders.

A significant change to the operation of the Linkage Projects scheme occurred in 2016, when there was a shift to a continuous submission cycle for applications. The continuous application process was implemented as an outcome of the Australian Government's National Innovation and Science Agenda (NISA), in order to allow a closer connection between proposal submission and outcome announcement. Proposals can be submitted at any time, and are progressed for assessment once submitted, rather than having to wait for a scheduled annual selection meeting. This new cycle is to allow for more nimble and responsive funding in response to industry time frames.

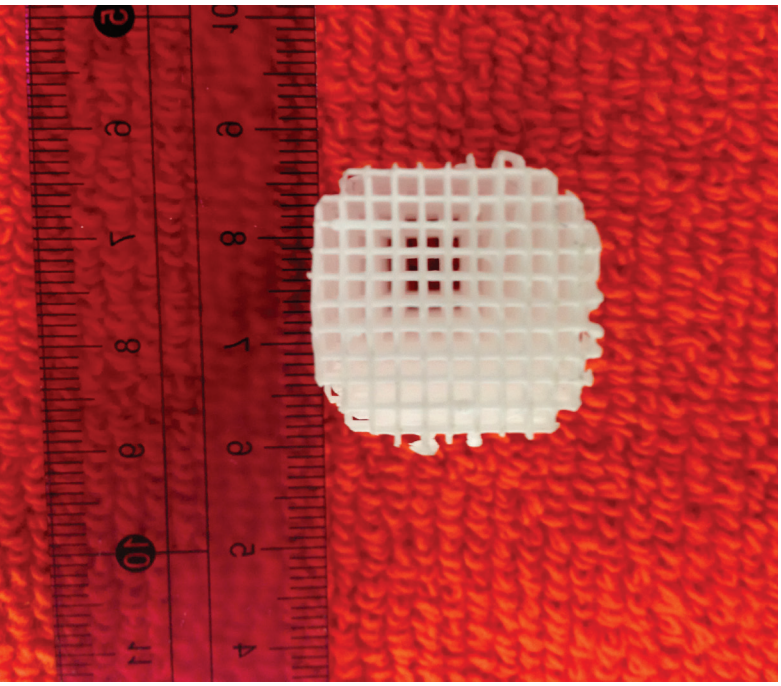
To complement the Linkage Projects scheme, in 2011 the ARC announced a new research program that was designed to build significant new research partnerships and expand existing partnerships in key areas of national importance. This program, called the Industrial Transformation Research Program (ITRP), has quickly demonstrated its impact to industry and to the research sector.

The ITRP is designed specifically to transform the way that research and industry interact. It is designed to leverage investment from the local and international business community into targeted industry sectors. It is also designed to foster new collaborations, and to reinforce the fabric of our varied industries to solve challenging industry issues.

The current priorities are:

- advanced manufacturing
- cybersecurity
- food and agribusiness
- oil, gas and energy resources
- mining equipment, technology and services
- medical technologies and pharmaceuticals.

The program has two funding schemes: Industrial Transformation Research Hubs and Industrial Transformation Training Centres.



The new 3D-printed ceramic implant will ultimately replace grafts and metal hardware in mending broken bones. Image courtesy of Tissue Engineering and Biomaterials Research Unit, University of Sydney

The Industrial Transformation Research Hubs scheme engages Australia's best researchers in issues facing the new industrial economies and training the future workforce. The scheme supports collaborative research between the Australian higher education sector and industry, designed to focus on strategic outcomes that are not independently achievable. These research hubs receive funding of $500,000 to $1 million per year for three to five years.

The Industrial Transformation Training Centres scheme fosters close partnerships between university-based researchers and other research end users to provide innovative Higher Degree Research (HDR) and postdoctoral training for end-user-focused research industries that are vital to Australia's future. Training Centres receive up to $1 million per year for three to five years.

There have now been six rounds of Research Hubs announced, and five rounds of Training Centres, with 57 Research Hubs and Training Centres awarded more than $200 million between them. These Research Hubs and Training Centres are located all around the country, and are proving to be significant powerhouses of research ingenuity.

For instance, the ARC Industrial Transformation Training Centre for Innovative BioEngineering, at the University of Sydney and led by Professor Hala Zreiqat, is developing 3D-printed ceramic implants to replace bone grafts and metal hardware in mending broken bones. The implants, which actually induce bone formation, have already been demonstrated to effectively heal broken bones in animals, and are stronger than any currently available on the market.

Professor Sue Thomas

The ARC Training Centre for Innovative Wine Production, led by Professor Vladimir Jiranek at the University of Adelaide, has collaborated with industry partners to tackle sector challenges, including responding to changes in climate and consumer preferences. The funding has enabled the Training Centre to establish new HDR and postdoctoral research projects aimed at improving the productivity and profitability of Australian wine production. Already, the Training Centre has created lower-alcohol-content wines without compromising on flavour or quality, and has developed technologies to improve wine yield and quality.

The ARC Dairy Innovation Hub, led by Professor Sally Gras at The University of Melbourne, has worked to address significant technical challenges facing the dairy manufacturing industry. The Research Hub has addressed practical questions relevant to the industry, such as: What makes mozzarella stretchy? What happens to cheese as it ages? How can the shelf life of dairy products be extended for domestic and export markets?

Other research areas have focused on dairy products with improved taste and spreadability, and reduced-fat cheeses that really do 'taste like real cheese'. The research hub has also developed a new technique to separate the different components of whey from milk to recover high-value ingredients, reduce disposal costs, increase sustainability and maximise commercial returns.

The ARC is pleased to be able to showcase the Linkage Projects scheme and Industrial Transformation Research Program, and highlight their importance in research innovation and translation in Australia today.

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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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Caldera Health Ltd is a private New Zealand–based molecular diagnostic company that is initially targeting prostate cancer diagnosis, addressing a major global unmet clinical need that arises out of the limitations of the current prostate-specific antigen (PSA) test. Caldera is in the final stages of developing a non-invasive, highly accurate screening test for prostate cancer using urine as the sample source. Once achieved, Caldera strongly believes this technology package has application to many other conditions.

Jen Barnes, Business Development Manager
+64 21 529 151 | Jen.barnes@caldera.co.nz | www.calderahealth.com

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CMAX Clinical Research is a specialist in Phase I–II clinical research, including first-in-human studies. CMAX has a brand-new, custom-built, 50-bed dedicated, self-contained facility, and also participates in Phase III–IV studies as an investigative site. CMAX has more than 24 years' experience, making it Australia's first established and dedicated Phase I facility; it also has strong relationships with pharmacologists and medical experts across a wide variety of therapeutic areas, with easy access to Adelaide's new BioMed City.

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Alistair Cumming CEO/MD
T: +61 417 711 141 | E: ceo@gretals.com

Imagion Biosystems Ltd

Imagion Biosystems Ltd is an Australian medical device developer with a US-based research and development operation, listed on the Australian Securities Exchange (ASX: IBX). Imagion has developed a new medical imaging technology that can detect specific cancers non-invasively. The proprietary technology uses magnetic nanoparticles with tumour-targeting antibodies to 'tag' specific cancers. Only those particles that are attached to the tumour are measured by the sensors, while unattached nanoparticles are not detected, greatly improving sensitivity.

Leanne Daly, Business Development
+61(0)418 570 917 | www.imagionbiosystem.com

Immutep Limited

Immutep is an Australian biotechnology company developing novel immunotherapy treatments for cancer and autoimmune diseases, with operations in Europe, Australia and the United States. Its lead product, eftilagimod alpha, is a LAG-3 product candidate that is currently in multiple clinical trials, including a Phase IIB trial in combination with chemotherapy to boost the immune system response in cancer. Immutep is listed on the Australian Stock Exchange (IMM) and on the NASDAQ (IMMP).

E: enquiries@immutep.com | W: www.immutep.com

Lucid Health Consulting Pty Ltd

Lucid Health Consulting was founded in 2016 by the three directors, George Papadopoulos, Michael Aristides and Steve Crowley, each with over 25 years of experience across pricing, reimbursement, health economics and market access. The company specialises in health technology assessment for reimbursement and submission preparation; pricing strategy, including negotiations and price defence; and market access, including advisory boards, commercial assessments and stakeholder mapping.

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Byron Darroch, Executive VP, Global, Next Science
info@nextscience.com | www.nextscience.com

Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (Telix) is a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or molecularly targeted radiation (MTR). The company is headquartered in Melbourne, with international operations in Brussels, Kyoto and Indianapolis. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. Telix is listed on the Australian Securities Exchange (ASX:TLX).

E: info@telixpharma.com | W: www.telixpharma.com

Upside Biotechnologies Ltd

Upside Biotechnologies Ltd is a private, New Zealand–based, preclinical company developing what it believes will be the treatment of choice for large burns. Its product, PelliCel®, is a full-thickness, autologous, engineered skin product that can be grown in large, robust sheets to definitively cover a large burn in 16 days. Upside aims to initiate a clinical trial in the first quarter of 2020.

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INTRODUCING JAMES FLETCHER

With the retirement of Joanna Hill, who created the regular Index section for this journal for many years, we are pleased to introduce James Fletcher, who is now producing this feature.

Fletcher is a financial adviser at Baillieu Holst, a Melbourne-based stockbroking firm. With a background in economics, he worked as a tax adviser before spending more than two decades in the financial markets, including nine years trading equities for large international banks in Japan. More recently, Fletcher returned to the University of Melbourne to pursue postgraduate studies in history.

His interest in life sciences came about when he saw a gap in the investment market for many retail investors looking at the biotech sector. 'Most investors either pick one or two small stocks, like a once-a-year horse punter, or they ignore the sector entirely,' says Fletcher. A portfolio approach is required, along with realistic expectations of the time line to success. Fletcher notes: 'Warren Buffett says that "The stock market is a device for transferring money from the impatient to the patient." I think that is particularly pertinent to the biotech industry'.

Successful investing in this sector also requires a properly managed portfolio of stocks, with products in different stages of development. 'An index-tracking exchange-traded fund would not work in this sector,' Fletcher believes. 'Ideally, a closed-end fund for retail investors would be the most appropriate structure.'

Fletcher also encourages his clients to be classified as 'sophisticated' if possible, by passing either an asset or an income test. 'Increasingly, the compliance requirements and regulatory risks of dealing with retail ("unsophisticated") clients will result in fewer products and services being offered to them.'

Fletcher looks forward to the opportunity to be involved with *AusBiotech*.

Baillieu Holst
Since 1889

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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	28.2	0.35	0.40	0.20	-4		4	
AusCann Group Holdings Ltd	AC8	Cultivation, manufacture and distribution of medicinal cannabis products and targeting of medications for neuropathic and chronic pain	3-May-89	222.9	1.62	1.86	0.33	-1		5	
AtCor Medical Holdings Limited	ACG	Developer and international marketer of blood pressure at the heart device SphygmoCor	9-Nov-05	7.0	0.03	0.06	0.02	-2	-2	1	
Alchemia Limited	ACL	Drug discovery and development, including the fondaparinux anticoagulant drug	23-Dec-03	3.6	0.01	0.03	0.01	0	-9	1	
Acrux Limited	ACR	Transdermal drug delivery platform technology	29-Sep-04	25.8	0.16	0.32	0.13	-9	-2	21	
Actinogen Ltd	ACW	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders, including Alzheimer's disease	16-Oct-07	38.1	0.05	0.09	0.04	-1	-7	1	
Anteo Diagnostics Limited	ADO	Multi-component coatings for solid phase of immunoassays for biomarker development	7-Apr-00	17.3	0.01	0.04	0.01	-1	-2	0	
Adherium Ltd	ADR	Developer of digital technologies to monitor medication use in chronic respiratory conditions	26-Aug-15	22.6	0.12	0.25	0.07	-8	0	10	
AFT Pharmaceuticals	AFP	Develops, licenses and sells a range of medical products globally	22-Dec-15	204.3	2.10	2.61	1.95	14		10	
Apiam Animal Health Ltd	AHX	iVet technology for real-time animal health monitoring, including on-farm welfare assessments	15-Dec-15	81.8	0.81	1.26	0.61	4		-3	1.60
Admedus Ltd	AHZ	Tissue engineering and vaccine development for herpes and human papillomavirus	24-Mar-04	76.4	0.30	0.44	0.20	-5	-6	7	
Analytica Limited	ALT	eHealth devices, including the PeriCoach system for stress urinary incontinence	25-Oct-00	19.7	0.01	0.01	0.00	-0	-4	0	
Allegra Orthopaedics Ltd	AMT	Prosthetic implant tools	5-Dec-07	13.9	0.14	0.05	0.02	0	-6	7	
Antisense Therapeutics Ltd	ANP	Drug discovery and development, including the antisense compounds for MS, DMD and acromegaly	20-Dec-01	6.9	0.04	0.04	0.01	-2	2	1	
Antara Lifesiences Ltd	ANR	Natural, plant-based therapeutics for gastrointestinal diseases	16-Oct-14	79.6	1.60	1.83	0.72	-6	-26	21	
Avita Medical Ltd	AVH	Skin regeneration technology for the treatment of wounds, scars and skin defects	11-Aug-93	60.1	0.06	0.09	0.05	-2	-3	1	
AirXpanders Ltd	AXP	AeroForm tissue expander for breast reconstruction	29-Sep-04	143.9	0.48	2.63	0.75	-13	8	8	
Bio-Gene Technology Ltd	BGT	Insecticide product development, including Qcide and Flavocide, and insect control in agriculture and animal health	29-Nov-17	18.6	0.17	0.28	0.17	-1		6	
Biotron Limited	BIT	Antiviral drug development, focused on HIV and hepatitis	24-Jan-01	10.6	0.03	0.05	0.02	0	-8	0	
Benitec Limited	BLT	Development of a proprietary therapeutic technology platform to provide long-lasting silencing of disease-causing genes	17-Feb-97	41.0	0.20	0.34	0.12	-4	-5	8	
Botanix Pharmaceuticals Ltd	BOT	Development and commercialisation of therapeutics for bone and joint disease	24-Jan-85	60.4	0.12	0.21	0.04	-1	0	1	
Bionomics Limited	BNO	Small molecule development in areas of cancer and central nervous system disorders	21-Dec-99	229.1	0.50	0.51	0.32	-1	-41	5	
BPH Energy Ltd	BPH	Commercialising a portfolio of Australian biomedical technologies emerging from collaborative research from universities, medical institutes and hospitals	6-Aug-04	1.9	0.00	0.01	0.00	0		1	
Brain Resource Limited	BRC	Provider of international database for human brain function	28-Aug-01	22.8	0.05	0.12	0.04	-7	-1	2	

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)
BTC Health Ltd	BTC	Biopharmaceutical company focused on product development and commercialisation	29-Aug-00	26.1	0.20	0.24	0.11	-1		2	
Bioxyne Ltd	BXN	Gut and immune system health probiotic products, including a patented probiotic range	14-Dec-00	51.2	0.08	0.14	0.01	0	-20	0	
Capitol Health Ltd	CAJ	Provider of diagnostic imaging services to the Australian healthcare market	9-Jun-06	216.7	0.27	0.33	0.15	-1		8	0.40
Cann Group Ltd	CAN	Research, development and cultivation to facilitate the supply of medicinal cannabis	4-May-17	329.0	2.97	4.55	0.45	-1		53	
Cellmid Limited	CDY	Development of therapies targeting midkine in cancer, fibrosis and chronic inflammatory disease	9-Dec-05	27.3	0.46	0.80	0.35	-8	-6	5	
Cogstate Ltd	CGS	Diagnosis and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's)	13-Feb-04	102.4	0.90	1.22	0.78	-3	0	9	
CropLogic Ltd	CLI	Technology platform that improves crop yield	12-Sep-17	4.1	0.05	0.18	0.05	-1		6	
Clover Corporation Limited	CLV	Supplies science-based oil products to the medical food market for infants and children	30-Nov-99	105.7	0.64	0.74	0.36	2	0	18	1.00
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	60.2	0.34	0.74	0.31	1		10	
Cochlear Ltd	COH	Manufacture and sale of cochlear implant system for impaired hearing	4-Dec-95	11,064.1	189.51	192.80	129.18	388	49	401	280.00
CannPal Animal Therapeutics Ltd	CP1	Pet pharmaceutical company developing cannabinoid-based medicines for cats, dogs and horses	25-Oct-17	9.9	0.23	0.31	0.16	-1		6	
Creso Pharma Ltd	CPH	Development and production of cannabis and hemp-derived therapeutic products, and treatments for humans and pets	20-Oct-16	71.2	0.78	1.65	0.39	-18		19	
CSL Limited	CSL	Development, manufacture and marketing of pharmaceutical and diagnostic products	8-Jun-94	74,882.4	165.08	167.66	119.01	445	37	617	192.02
Cryosite Limited	CTE	Collection, processing and long-term storage of blood stem cells	9-May-02	5.2	0.11	0.19	0.10	-2	-6	4	
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	457.3	10.10	9.60	5.91	13	80	57	
Cyclopharm Limited	CYC	Manufacturer and distributor of radiopharmaceuticals for imaging technology; lead product is Technegas, a lung ventilation imaging drug	18-Jan-07	75.1	1.20	1.10	0.71	-2	-53	21	1.00
Cynata Therapeutics	CYP	Stem cell and regenerative medicine platform technology, Cymerus, for production of mesenchymal stem cells	20-Dec-07	113.1	1.25	1.35	0.37	-6	-20	10	
Dorsavi Ltd	DVL	Motion analysis device technologies for clinical, elite sports and OHS	11-Dec-13	36.1	0.22	0.48	0.20	-3	0	5	
Dimerix Ltd	DXB	Development of therapeutic treatments identified using drug discovery platform, Receptor-Heteromer Investigation Technology	4-Feb-93	20.2	0.01	0.01	0.00	-3	-4	0	
Ebos Group Ltd	EBO	Distributor of healthcare products	6-Dec-13	2593.2	17.18	17.94	15.45	86	0	38	53.98
Ellex Medical Lasers Ltd	ELX	Production of opthalmic instruments for treatment of impaired vision	12-Sep-94	125.7	0.88	1.25	0.78	-4	0	37	
eSense Lab Ltd	ESE	Create 'virtual plants' with commercial and medicinal applications; first plant targeted for re-engineering is cannabis	14-Feb-17	6.3	0.17	0.57	0.15	-4		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	29.9	0.04	0.07	0.04	-1	-5	1	
Genera Biosystems Limited	GBI	Develops and commercialises molecular diagnostic tests based on AmpaSand bead technology	11-Jun-08	17.2	0.16	0.23	0.12	-3	-5	-5	
GI Dynamics, Inc	GID	EndoBarrier; endoscopically delivered treatment for the management of obesity and type 2 diabetes	7-Sep-11	19.6	0.03	0.07	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	35.4	0.34	0.59	0.12	-15		3	
Genetic Signatures Ltd	GSS	Molecular diagnostics company focused on development and commercialisation of its proprietary platform technology, 3Base	31-Mar-15	27.4	0.25	0.46	0.26	-3		14	
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	26.8	0.01	0.02	0.01	0	-3	0	
Holista Colltech Ltd	HCT	Development and commercialisation of food ingredients and ovine collagen	26-Feb-04	21.9	0.11	0.20	0.07	-2		1	

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Imagion Biosystems	IBX	Detection and localisation of cancer and other diseases using nano particle technology; proprietary MagSense bio-imaging detection technology	22-Jun-17	7.6	0.07	0.20	0.06	-5		3	
IDT Australia Ltd	IDT	Manufacturer of pharmaceuticals and clinical trial management services	24-Sep-93	17.9	0.07	0.16	0.07	-12	-1	1	
Innate Immunotherapeutics	IIL	Immunomodulator microparticle technology	23-Dec-13	6.8	0.03	0.83	0.03	-3		2	
Immuron Ltd	IMC	Oral immunotherapy products that target the human gut immune system and gut microbiome	30-Apr-99	53.8	0.40	0.70	0.14	-5	-9	4	
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	68.1	0.02	0.04	0.02	0		0	
Imugene	IMU	Developer of HER2+ gastric and breast cancer immunotherapies	2-Dec-93	79.9	0.03	0.03	0.01	0	-37	0	
Impedimed Limited	IPD	Diagnostic devices for lymphoedema, muscle wasting and metabolic disorders utilising bioimpedance technology	24-Oct-07	283.5	0.74	1.07	0.54	-8	-10	11	
ITL Limited	ITD	Design and manufacture of healthcare devices, biological sampling systems	29-Oct-03	28.2	0.33	0.66	0.31	12	0	17	
Invitrocue Ltd	IVQ	Provider of bio-analytic solutions, including in-vitro cell-based testing technologies and image analytics software for use in digital pathology	14-Dec-91	51.0	0.11	0.13	0.06	-1		0	
Invion Ltd	IVX	Developer of treatments for inflammatory diseases	15-Feb-10	103.6	0.02	0.02	0.00	0	0	0	
Kazia Therapeutics Ltd	KZA	Development of anti-cancer drugs	1-Sep-94	36.3	0.79	0.79	0.34	-13		22	
LBT Innovations Limited	LBT	Automated systems for the preparation, screening, interpretation and streaking of microbiological specimens	31-Jul-06	26.1	0.15	0.37	0.14	-1	-14	6	
Living Cell Technologies Limited	LCT	Developer of live cell therapy products for treatment of neurological and metabolic disorders	1-Sep-04	14.3	0.03	0.28	0.02	-1	-4	1	
LifeHealthcare Group	LHC	Distributor of critical care medical devices and implantable devices	5-Dec-13	161.8	3.60	3.70	2.00	15	25	25	15.00
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	6.4	0.14	0.35	0.11	-3		6	
Mach7 Tech Ltd	M7T	Imaging IT solutions, 3D printing and holographic projection provider	30-Nov-05	38.1	0.28	0.38	0.11	-15	-2	3	
Medlab Clinical Ltd	MDC	Research and development of novel bio-therapeutics to improve health outcomes in chronic diseases, such as chronic kidney disease and obesity	14-Jul-15	143.5	0.69	1.20	0.50	-2		1	
MedAdvisor Ltd	MDR	Mobile and web apps for individuals and carer to manage all aspects of prescription medication use	26-May-11	37.5	0.05	0.06	0.03	0		1	
MediBio	MEB	Diagnostic tests for depression and other mental health disorders	29-Jan-01	42.5	0.21	0.46	0.19	-8	-2	6	
Medigard Limited	MGZ	Retractable safety devices for injection and blood collection	5-Feb-04	2.4	0.02	0.03	0.01	-1	-4	-1	
Medical Australia Limited	MLA	Distributor of medical devices, IV systems, blood banking laboratory collection of human and animal biologics	20-Dec-04	11.6	0.09	0.09	0.05	0	28	4	
MMJ PhytoTech Ltd	MMJ	Aims to commercialise medicinal cannabis and high-value-based cannabis therapeutics	22-Jan-15	90.6	0.41	0.84	0.31	-8		18	
Mesoblast Limited	MSB	Commercialisation of adult stem cell technology	16-Dec-04	804.5	1.66	3.41	1.19	-16	-10	16	
Monash IVF Group	MVF	Assisted reproductive technologies, genetic testing and ultrasound services	26-Jun-14	274.2	1.15	2.12	1.16	11	10	-38	7.90
Medical Developments International Limited	MVP	Medical and veterinary equipment, including pain management, resuscitation and asthma management products	15-Dec-03	446.2	7.35	8.07	4.61	3	283	-10	4.00
Micro-X Ltd	MX1	Develops and manufactures a range of mobile X-ray imaging systems for medical applications	22-Dec-15	57.7	0.40	0.55	0.32	-8		6	
MGC Pharmaceuticals Ltd	MXC	Innovator in phytocannabinoid-based medicines within the biopharmaceutical industry	21-Dec-06	107.5	0.09	0.13	0.04	-1		0	
MyFiziq Ltd	MYQ	Smartphone app to provide accurate circumference measurements to assist with management of diabetes and weight	17-Aug-15	59.3	0.77	1.65	0.03	-17		1	
Mayne Pharma Ltd	MYX	Pharmaceutical commercialisation and manufacturing. Development of oral drug delivery systems	29-Jun-07	1,136.1	0.74	1.46	0.59	-11	-7	8	
Nanosonics Limited	NAN	Ultrasound probe disinfection – Trophon device	17-May-07	805.2	2.65	3.40	2.15	2	124	26	

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)
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	5.1	0.15	0.38	0.11	-1		5	
Neuren Pharmaceuticals Limited	NEU	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders	3-Feb-05	301.0	3.11	3.60	1.10	-2	0	1	
Novita Healthcare Ltd	NHL	Cognitive training program for children with attention difficulties	23-Sep-04	12.9	0.04	0.06	0.02	0		1	
Noxopharm Ltd	NOX	Development of drugs to make radiotherapy more effective. NOX66 is the company's pipeline product	9-Aug-16	64.8	1.01	1.80	0.27	-15		4	
Memphasys Ltd	MEM	Cell and protein separation systems	14-May-07	8.9	0.00	0.00	0.00	0	0	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	14.1	0.17	0.37	0.15	-4		4	
Nufarm Ltd	NUF	Crop protection and specialist seed company. Manufacturing and marketing of products to help farmers protect crops against damage	10-Nov-98	2,787.9	8.52	10.20	7.74	39		267	12.67
OBJ Limited	OBJ	Developer of transdermal drug delivery technology in pharmaceutical and cosmetic industries	29-May-00	63.2	0.03	0.08	0.03	0	-18	0	-
Orthocell Ltd	OCC	Soft tissue cellular therapies for restoration of tendon and cartilage injuries	12-Aug-14	24.0	0.29	0.52	0.28	-2	-14	0	
Orion Health Group Ltd	OHE	Technology solutions advancing population health and precision medicine, including data management and creating personalised healthcare plans	26-Nov-14	146.6	0.75	1.80	0.75	-21		15	
Optiscan Imaging Ltd	OIL	Microscopic imaging technologies for medical markets	8-Aug-97	31.0	0.08	0.13	0.06	0		1	
Oneview Healthcare Plc	ONE	Software platform for patients in hospital and aged care facilities, including dietary services and care management	17-Mar-16	108.7	2.00	5.71	1.82	-71		64	
Opthea Ltd	OPT	Developer of novel therapy OPT-302 for treatment of eye diseases	18-Apr-91	121.5	0.19	0.28	0.07	-8	-30	22	
Oncosil Medical Ltd	OSL	Brachytherapy device that implants a dose of beta radiation into a pancreatic tumour	15-Aug-05	68.9	0.14	0.18	0.08	-2	-8	1	
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	79.8	0.24	0.51	0.21	-6	-4	12	
Oventus Medical Ltd	OVN	Medical devices for sleep apnoea treatment incorporating Oventus Airway Technology	19-Jul-16	25.8	0.38	0.78	0.31	-8		15	
PharmAust Ltd	PAA	Developer of targeted cancer therapeutics for humans and animals, specialising in repurposing marketed drugs	2-Oct-01	11.0	0.06	0.09	0.05	-2	-4	2	
Patrys Limited	PAB	Developer of natural human antibody-based therapies in the oncology area	13-Jul-07	50.3	0.07	0.07	0.00	0		0	
Paradigm Biopharmaceuticals Ltd	PAR	Biopharmaceutical company focused on repurposing the drug 'pentosan polysulphate sodium' for the treatment of inflammation	19-Aug-15	33.8	0.28	0.72	0.23	-4		4	
Probiotec Limited	PBP	Manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, medicines and consumer health products	14-Nov-06	58.7	0.95	1.07	0.37	5	18	30	2.25
Prana Biotechnology Limited	PBT	Developing first-in-class therapies to treat neurodegenerative diseases, such as Alzheimer's, Parkinson's and Huntington's disease; lead candidate PBT2	28-Mar-00	29.4	0.06	0.08	0.05	-1	-4	4	
Painchek Ltd	PCK	Smartphone app to provide pain assessment for those who are unable to communicate	1-May-12	34.0	0.06	0.10	0.02	0		1	
Paragon Care Ltd	PGC	Provider of medical equipment, devices and consumables to the healthcare market	15-Oct-99	195.7	0.72	0.96	0.68	6		-12	2.98
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	13.6	0.24	0.36	0.15	-2		1	
Pro Medicus Ltd	PME	Provider of radiology information systems and diagnostic imaging	10-Oct-00	847.6	8.30	9.04	4.63	9		25	5.00
PolyNovo Ltd	PNV	Developer of biodegradable polymers for use in medical devices; lead product is NovoSorb technology, which is used in the treatment of burns, surgical wounds and Negative Pressure Wound Therapy	26-Nov-98	327.0	0.50	0.59	0.17	-1	0	4	

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)
Phosphagenics Limited	POH	Targeted Penetration Matrix built from vitamin E; delivery technology for small and large molecules; products include gels, skin care and a nutritional feed additive for animals	11-Aug-93	22.1	0.01	0.02	0.01	-1	0	0	
Papyrus Australia Ltd	PPY	Sustainable technology that produces products from the trunk of the banana palm	15-Apr-05	5.1	0.02	0.05	0.00	0		0	
Prescient Therapeutics Ltd	PTX	Developer of anti-cancer drugs; lead drug candidate PTX-200	2-Jan-92	18.0	0.09	0.11	0.05	-1	0	3	
pSivida Corp.	PVA	Long-term sustained drug delivery to treat back-of-eye diseases – Durasert technology	12-Jun-08	9.5	1.63	3.23	1.30	-82	-2	0	
Pharmaxis Ltd	PXS	Drug discovery to treat inflammatory and fibrotic diseases using amine oxidase inhibitor chemistry platform	10-Nov-03	111.9	0.34	0.37	0.23	0	-71	3	
Phylogica Limited	PYC	Development of intracellular biological therapeutics using its Functional Penetrating Phylomers (FPP)	30-Mar-05	64.2	0.03	0.05	0.02	0	-12	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		0	
Race Oncology Ltd	RAC	Development of chemotherapy drug Bisantrene for cancer, particularly Acute Myeloid Leukemia	13-Jul-16	13.5	0.35	0.52	0.17	11		3	
ResApp Health Ltd	RAP	Developer of mobile medical applications for the diagnosis and management of respiratory diseases	12-Jan-05	82.4	0.13	0.39	0.06	-1	0	1	
Recce Pharmaceuticals Ltd	RCE	Development of synthetic antiobiotics to address the threat of antiobiotic resistance	15-Jan-16	14.0	0.16	0.26	0.14	-3		1	
Roto-Gro International Ltd	RGI	Automated farming system for producing high-quality plants indoors, including medicinal cannabis, pharmaceuticals and food products	10-Feb-17	26.2	0.39	0.71	0.25	-1		2	
Regeneus Ltd	RGS	Cellular therapies focusing on osteoarthritis and other inflammatory conditions, cancer and wound healing	19-Sep-13	23.0	0.11	0.16	0.11	-2	-7	3	
Reproductive Health Science	RHS	Developer of chromosomal abnormality embryo testing in IVF cycles	5-Mar-87	24.3	0.27	0.30	0.08	-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	9.7	0.02	0.04	0.02	0	-40	0	
Rhythm Biosciences Ltd	RHY	Development of an affordable blood test for the early detection of colorectal cancer – 'ColoSTAT'	7-Dec-17	89.0	0.17	0.37	0.17	-1		0	
Ridley Corporation Ltd	RIC	Production of animal nutrition solutions, including feed ingredients; and marketing and provision of rural products	13-Aug-87	454.0	1.48	1.62	1.27	8		59	4.25
ResMed Inc	RMD	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing	25-Nov-99	17,861.5	12.69	12.81	8.94	38	34	0	12.56
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	14.0	0.12	0.29	0.09	-7	-2	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	13.8	0.44	0.67	0.30	0		0	
RSH Respiri Ltd	RSH	Devices for detecting and monitoring respiratory disorders	14-Jul-00	41.2	0.10	0.11	0.02	0	-29	0	
Reva Medical, Inc	RVA	Bioresorbable coronary scaffolds for the treatment of cardiovascular disease	23-Dec-10	169.1	0.42	1.11	0.34	2	19	29	
Stemcell United Ltd	SCU	Growth, reproduction and extraction of plant stem cells for medical and healthcare products	13-Jun-00	12.8	0.03	0.30	0.02	-1		0	
SDI Limited	SDI	Research and development, manufacturing and marketing of specialist dental materials	7-Nov-85	67.8	0.56	0.69	0.42	4		36	2.40
Science Developments Pty Ltd	SDV	Research, development and commercialisation of polymers for dairy and food product manufacturing	2-May-02	3.5	0.01	0.02	0.01	0		0	
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	17.9	0.12	0.20	0.10	-1		0	
Sonic Healthcare Limited	SHL	Laboratory medicine/pathology, radiology/ diagnostic imaging and primary care medical services	30-Apr-87	10,092.5	23.74	24.97	20.61	110	22	-349	78.00
SciGen Limited	SIE	Develops, manufactures and markets human healthcare biotechnology derived products. Focuses on endocrinology, gastroenterology and immunology	15-Nov-02	1.1	0.02	0.07	0.02	0	5	-15	

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SomnoMed Ltd	SOM	Specialises in products for sleep apnoea; lead product SomnoMed mandibular advancement splint (MAS)	27-Aug-04	191.3	3.15	3.93	2.74	-15	-20	29	
Starpharma Holdings Limited	SPL	Developer of dendrimer products; lead products VivaGel for bacterial vaginosis, dendrimer-enhanced docataxel in clinical development for solid tumours	28-Sep-00	468.7	1.22	1.67	0.65	3	41	15	
Sirtex Medical Limited	SRX	Novel technology for liver cancer treatment; radioactive particle, SIR-spheres	24-Aug-00	1,542.1	27.65	27.82	10.45	-40	-70	202	30.00
Suda Ltd	SUD	Oromucosal sprays for drug delivery treatment of off-patent drugs	24-Jan-02	19.5	0.02	0.03	0.01	0	-7	0	
Simavita Ltd	SVA	Wearable and disposable technologies for elderly incontinence	22-Feb-14	6.2	0.02	0.08	0.01	-2	-1	0	
TBG Diagnostics Ltd	TDL	Development, manufacture and marketing of molecular diagnostic kits, instruments and services	22-Dec-95	15.7	0.26	0.30	0.14	-3	-3	7	
The Hydroponics Company Ltd	THC	Development and delivery of medicinal cannabis	4-May-17	54.6	0.60	1.15	0.19	-3		12	
Telix Pharmaceuticals Ltd	TLX	Development and commercialisation of molecularly-targeted radiation in the management of prostate, renal and glioblastoma (brain) cancer	15-Nov-17	62.4	0.50	0.85	0.46	0		0	
TPI Enterprises Ltd	TPE	Processor of Narcotic Raw Material (NRM) for the international pharmaceutical industry	13-Aug-15	124.9	1.50	2.94	1.28	-23		43	
Universal Biosensors Inc.	UBI	Specialist medical in-vitro diagnostic tests for point-of-care; blood test C-reactive protein test	13-Dec-06	44.1	0.27	0.48	0.24	0	-62	7	
Uscom Limited	UCM	Non-invasive medical devices in the field of cardiac, vascular and pulmonary monitoring	10-Dec-03	35.0	0.26	0.29	0.15	-2	-15	3	
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	23.5	1.01	1.72	0.99	-13		-3	
Volpara Health Technologies	VHT	Research, development and manufacturing company that provides digital health solutions for personalised breast cancer screening	27-Apr-16	65.3	0.69	0.80	0.30	-5.77		6	
Viralytics Limited	VLA	Development and commercialisation of oncolytic immunotherapies; lead product candidate CAVATAK	15-Oct-86	466.1	1.68	1.72	0.59	-6	-28	13	
Virtus Health Ltd	VRT	Assisted reproductive services, diagnostics, genetic testing and day hospitals	11-Jun-13	460.6	5.72	6.33	4.97	37	15	-168	26.00
Vita Life Sciences Limited	VLS	Development and distribution of over-the-counter medicines, complementary, alternative, dietary supplements and health foods	23-Aug-07	44.1	0.81	1.16	0.69	5	16	43	3.75
Wattle Health Australia Ltd	WHA	Health and wellness products with scientific and nutritional benefit	15-Mar-17	243.7	2.69	2.90	0.23	-10		10	
XRF Scientific Ltd	XRF	Manufacturer and marketer of instrumentation for scientific industries, including commercial laboratories	31-Oct-06	25.4	0.19	0.23	0.16	1		11	0.24
Zelda Therapeutics	ZLD	Investing in research and clinical trials to study medical cannabis for a variety of ailments	28-Jul-03	61.1	0.12	0.16	0.05	0		1	

Data current at 19 March 2018. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Baillieu Holst Stockbroking Ltd and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.

This quarter's top ASX healthcare sector performers

ASX CODE	Company Name	Last Price	Quarter Return %
IVX	Invion Ltd	$0.02	144
PAB	Patrys Limited	$0.07	105
VLA	Viralytics Limited	$1.68	95
RSH	Respiri Limited	$0.10	93
AC8	Auscann Grp Hlgs Ltd	$1.62	88
KZA	Kazia Therapeutics	$0.79	81
IMC	Immuron Limited	$0.40	79
IMU	Imugene Limited	$0.03	76
CYP	Cynata Therapeutics	$1.25	73
BOT	Botanix Pharma Ltd	$0.12	68
RHS	RHS Limited	$0.27	62
SRX	Sirtex Medical	$27.68	55
WHA	Wattle Health Au Ltd	$2.69	54
ANP	Antisense Therapeut.	$0.04	49
UCM	Uscom Limited	$0.26	49
ADR	Adherium Ltd	$0.12	47
RAP	Resapp Health Ltd	$0.13	47
1AD	Adalta Limited	$0.35	41
SVA	Simavita Ltd	$0.02	36
CUV	Clinuvel Pharmaceut.	$10.10	32

This year's top ASX healthcare sector performers

ASX CODE	Company Name	Last Price	Year Return %
MYQ	Myfiziq Limited	$0.77	273
WHA	Wattle Health Au Ltd	$2.69	238
PAB	Patrys Limited	$0.07	228
IVX	Invion Ltd	$0.02	185
BXN	Bioxyne Ltd	$0.08	183
PPY	Papyrus Australia	$0.02	134
RHS	RHS Limited	$0.27	128
AC8	Auscann Grp Hlgs Ltd	$1.62	93
CYP	Cynata Therapeutics	$1.25	82
NOX	Noxopharm Limited	$1.01	80
PCK	Painchek Ltd	$0.06	80
RSH	Respiri Limited	$0.10	76
BOT	Botanix Pharma Ltd	$0.12	73
IMU	Imugene Limited	$0.03	70
NEU	Neuren Pharmaceut.	$3.11	66
PBP	Probiotec Limited	$0.96	65
SPL	Starpharma Holdings	$1.22	64
PNV	Polynovo Limited	$0.50	62
CAJ	Capitol Health	$0.27	59
RAC	Race Oncology Ltd	$0.36	57

Data current at 19 March 2018. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Baillieu Holst Stockbroking Ltd and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.

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