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Australasian BioTechnology

The journal of AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Special conference edition:

AusBiotech 2017 national conference

Policy's role in biotech innovation

Next-generation cell-based therapies

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The Queensland delegation to BIO International, led by Premier Palaszczuk

CEO AND CHAIR REPORT

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

Welcome to this special edition of *Australasian BioTechnology*, where we update you on key happenings at AusBiotech, and explore what's in store as the industry event of the year, AusBiotech 2017, returns to Adelaide, with national and global industry leaders convening for the annual flagship conference.

Your organisation has continued to execute its strategic plan, focused on international engagement, attraction of investment and advocacy in regards to government policy.

BIO 2017

AusBiotech has recently led the Australian delegation to the world's largest and most influential global biotechnology meeting, the 2017 BIO International Convention, held in San Diego, California, from 19–22 June 2017. AusBiotech has been managing Australian delegations to BIO for more than a decade and, in 2017, Australia was again among the top 10 largest international delegations in attendance, with close to 300 attendees and 40 exhibiting companies.

Julie Phillips

Glenn Cross

This event is key to positioning Australia's unique capabilities in biotechnology innovation.

In managing the Australian delegation to BIO, AusBiotech worked with the Federal Department of Industry, Innovation and Science (AusIndustry, Entrepreneur's Programme), the Victorian and Queensland state governments, and a committee of other state representatives to bring a strong collaborative and national approach to the 2017 Australian representation.

The four intensive days of global learning, sharing and connecting offered by BIO can't be found on this scale in any other forum. As a truly international

event, BIO also provides valuable opportunities for Australia to host and participate in joint activities with other countries.

AusBiotech surveyed the exhibitors who participated as part of the Australian delegation to BIO 2017, and almost 100 per cent said the Australia Pavilion contributed to Australia's presence.

Without the Australian Government underwriting the costs and state governments providing base funding, Australia's strong presence at this global biotechnology showcase would not be possible. In this context, the strong support from the federal government and from the Victorian and Queensland state governments in 2017, and in previous years, is greatly appreciated by the industry.

BIO continues to grow every year, and the 2017 event offered unparalleled opportunities for Australia to develop meaningful and lasting connections with global biotechnology and pharmaceutical companies, academic research institutions and investors from around the world.

Global Investment Program

This time last year, we were pleased to report that AusBiotech, along with its partners KPMG, DibbsBarker, WE Buchan and the ASX, obtained MTPConnect and received funding to undertake a Global Investment Program. The program utilises a three-pronged approach to increase the quantity and quality of investment in the sector by doing the following:

1. Educating private and institutional investors about the unique ecosystem of the life sciences sector via the production of a Guide to Life Sciences Investing, and the implementation of corresponding workshops and events.
2. Providing companies and researchers with the training and access they need to attract investors, via the provision of training and resource materials.
3. Pitching to investors workshops, as well as the production of a Roadmap to a successful IPO (for life sciences companies), and the implementation of corresponding workshops. Life sciences companies need to ensure that they have a strategic and well-designed investment strategy so that they can attract appropriate investment opportunities.

The program provides increased access to global capital markets by allowing the upscaling and enhancement of AusBiotech's current Global Investment Series in Australia (see below details on Australia Biotech Invest 2017), Hong Kong and Singapore. Currently, there is no other event that focuses on bringing Australian life sciences companies to Asia to source investment from local investment companies. While AusBiotech has held investment events in Singapore and Hong Kong previously, the program enabled the expansion to China, marking the first foray of an investment event focusing on Australian life sciences companies in China.

Under the program, investment events will also be held in the United States and Europe. The expansion of the Series will facilitate access to more international investors, global capital markets and opportunities for collaborations and partnerships, thus providing Australian life sciences SMEs at various stages of development with increased investment and alternative funding opportunities.

Progress on the project has been significant with the Roadmap to a successful IPO for life sciences companies launched recently in Melbourne and Sydney, and the Guide to Life Sciences Investing ready for consultation, which will roll out in the coming months. The Guide will provide potential novice life-sciences investors with factual, relevant and independent information about the sector.

Better investor understanding of the sector will lead to not only increased investments, but also increased investors' participation in the wider life sciences community. As companies learn to better source, connect and communicate with investors, they will be better equipped to successfully attract funding. The follow-on effect of better funding is increased stability and productivity from those companies, and therefore overall sector growth and confidence. As investment in the sector grows, and the value and benefits of that investment are seen, it is envisaged that this would foster a self-perpetuating growth cycle, with Australian life sciences research and SMEs seen as a viable and attractive investment option for Australian and overseas investors.

Australia Biotech Invest

The annual Australia Biotech Invest 2017, themed 'Connecting Capital with Innovation', will be held on 24 October 2017 at the Sofitel Melbourne on Collins. The event will include a full-day program of company presentations, which will showcase the potential of life sciences companies to an anticipated 200 investors. A dedicated exhibition area will enable companies to display detailed information about their business case and technologies, and engage directly with prospective partners.

Participating in Australia Biotech Invest will provide your company with a unique opportunity to connect

with investors from Australia and around the world, and to take your business to the next level. We urge you to take advantage of this opportunity.

AusAg & Foodtech Summit

The AusBiotech AusAg & Foodtech Summit 2017 was recently held in Adelaide, putting the spotlight on investment in agritech and foodtech innovation to help bridge Australian science and business.

The Summit drew together the agritech and foodtech ecosystem to advance commercialisation opportunities and foster relationships between stakeholders from each stage of the sector's value chain.

Breaking away from the Summit's traditional framework, a greater focus on investment saw a limited number of investor-ready organisations provide eight-minute pitches, and the exhibition, named The Marketplace, was presented in a new format, consisting of compact displays with spaces for representatives to talk with prospective investors and partners.

Keynote speakers included Michael Dean, Co-Founder and Chief Investment Officer at AgFunder; Professor Steve Swain, Research Director at CSIRO; and Dr Leanna Read, Chief Scientist of South Australia.

Thanks goes to Dr Paul Wood, who chairs AusBiotech's Ag and Food Advisory Group, and led the Summit's program development, which attracted almost 200 delegates.

Policy update

The policy environment in the past months has been marked by the wait for news on the government's response to the Review of the Research and Development (R&D) Tax Incentive, the Productivity Commission's review of Australia's intellectual property provisions, and a flurry of work on visa provisions.

The R&D Tax Incentive program is of critical importance to the life sciences sector, and AusBiotech is watching developments closely.

Following the welcome restoration of a number of sector-related occupations on the list for skilled migration visas announced in June (effective 1 July), the government has opened a public consultation on reforming Australia's visa system and designing a new and more simple system.

As part of the June announcement regarding the occupations list, the government noted that it will review the list every six months, and it is understood that at each review point, public consultation will form part of the process.

“The R&D Tax Incentive program is of critical importance to the life sciences sector, and AusBiotech is watching developments closely”

Beyond the 30 June announcement, AusBiotech members have raised several further issues: 'Patent Attorney' and 'Trade Mark Attorney' have been removed from the occupations list; a number of occupations have been returned to the short-term list, which provides no pathway to residency; and details of how industry might be consulted moving forward are unclear.

The list of occupations and the designation on the short or medium to long-term list proved to be a critical issue for the attraction of highly skilled individuals in the biotechnology, pharmaceutical and medical technology industries, which supports Australia's competitive advantage in life sciences innovation.

In addition to the occupation list for skilled migration visas and the investor visa review, the government has tasked the Department of Immigration and Border Protection with making the visa system easier to understand and navigate, and therefore more responsive to 'Australia's economic, social and security interests'.

The government has provided a well-considered response to the recommendations covering pharmaceutical patent term extensions, innovation patents, trade agreements, pay for delay, fees, the inventive step, competition law, open access and policy.

The response accepted the recommendation to further amend sections 7(2) and 7(3) of the *Patents Act 1990*, covering what constitutes an 'inventive step', and the recommendation for reform of the patent filing process to require applicants to identify the technical features of the invention in the set of claims. This will require further consultation, which is expected to commence shortly.

The Productivity Commission also recommended reform of patent fees to 'promote broader intellectual property policy objectives, rather than the current primary objective of achieving cost recovery', with fees rising each year at an increasing rate, including during the patent-term extension period. The government noted but essentially rejected the recommendations,

> Government accepted the recommendation to abolish the innovation patent system after the commission found that the majority of SMEs that use the innovation patent system do not obtain value from it

saying it was not convinced of the need to move away from a cost recovery framework.

Government accepted the recommendation to abolish the innovation patent system after the commission found that the majority of SMEs that use the innovation patent system do not obtain value from it, and that the system imposes significant costs on third parties and the broader Australian community.

The government noted and undertook to further discuss the recommendation to abolish the current five-year patent term extension, saying: 'Any consideration of changes to the extensions of term regime must strike a balance between ensuring that new pharmaceutical products are developed, and that they are safe and effective, but also ensuring that they are accessible and affordable'.

The government will reform competition law to remove the current exemption covering IP licensing arrangements, and noted the recent establishment of a dedicated policy unit focused on IP in the Department of Industry, Innovation and Science.

The recommendation to avoid the inclusion of provisions covering IP in bilateral and regional trade agreements was clearly rejected.

IMNIS

The award-winning Industry Mentoring Network in STEM (IMNIS) MedTech-Pharma Program has now been launched across Australia, after the program was funded on the back of a successful pilot.

IMNIS is an initiative of the Australian Academy of Technology and Engineering (ATSE) that connects motivated second-year PhD students (mentees) with outstanding industry leaders (mentors). The program provides mentees with the opportunity to increase their understanding of the industry sector, develop the skills needed to be successful within the broader STEM sector (industry, academia, government) and extend their professional network. It also provides mentors the opportunity to give back to the sector.

The IMNIS pilot, part of which was led by AusBiotech, demonstrated success in multiple universities across three states. The program is supported by consortium partner AusBiotech, and sponsored by CSL and KPMG.

In 2016, IMNIS was recognised with a prestigious Business Higher Education Round Table Award and was awarded funding from MTPConnect to expand the program nationally.

Australia is ranked lowest among OECD nations in collaboration between business and research – not just in large businesses, but also in SMEs. Only 30 per cent of Australia's PhD students go into industry or government, compared to more than 70 per cent in most industrialised countries. The program aims to raise Australia's level of industry-university collaboration, and foster a culture of research and innovation.

IMNIS seeks to develop a new generation of industry-savvy PhD graduates who can engage with industry, kickstart collaborations and transition between sectors.

AusBiotech 2017 national conference

The conference forms a very special part of AusBiotech's broader work to position Australia's biotechnology industry for growth. As your representative, we are working on your behalf to leverage the rapidly changing dynamics of the Australian economy to raise biotechnology's role and profile in jobs and the economy of the future – and to maintain and improve our standing as ranked in the top five in the world.

This year's conference will be held at the Adelaide Convention Centre from 25–27 October, attracting some of the world's brightest biotech experts, as 1000 delegates are expected to gather to connect on new and challenging ideas in their fields to advance our world-class biotech sector.

The following pages will provide a comprehensive overview of AusBiotech 2017, including a number of articles from the speaker line-up. The event has been made possible with the support of the South Australian Government's TechIn SA, which we are pleased to have as the event's host state partner.

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Metabolic phenotyping is a powerful tool for wide ranging biological studies, offering a greatly enhanced range of metabolic analysis.

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murdoch.edu.au

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BIOMED CITY TO BENEFIT HEALTH AND ENTREPRENEURS

With the opening of the new Royal Adelaide Hospital in September 2017, South Australia has positioned itself at the forefront of biomedical technology, research and innovation.

The state-of-the-art hospital is the centrepiece of the $3.6-billion Adelaide BioMed City, one of the largest health and life sciences clusters in the Southern Hemisphere. Located along North Terrace in the heart of the CBD, the new Royal Adelaide Hospital sits alongside the South Australian Health and Medical Research Institute (SAHMRI), the Universities of Adelaide and South Australia, and the soon-to-be developed Proton Beam Therapy Centre (dubbed SAHMRI 2).

'We are proud to be providing South Australians with a new standard of healthcare facility in which world-class healthcare can be provided,' says Jenny Richter, Chief Executive Officer, Central Adelaide Local Health Network.

'The new Royal Adelaide Hospital is one of Australia's most technologically advanced healthcare facilities, and has been planned, designed and built around the needs of patients. Our geographic location within the BioMed precinct will see new innovative healthcare, clinical research and integrated teaching programs complementing the work, with all members of the precinct, attracting the best in clinicians, researchers and academics.'

Professor Steve Nicholls, acting Executive Director, SAHMRI, agrees.

'At the end of the day, what we are looking to achieve is better outcomes for patients,' Professor Nicholls says. 'New discoveries at the bench lead to new therapies and new ways to treat patients. Co-location makes this process exponentially better by bringing everyone closer together.'

Professor Nicholls also commented that the precinct will develop technologies and applications that will be used to provide world-class health care across the state, not just for the sites in the CBD.

'South Australia is uniquely placed to offer a state-wide healthcare system that can reach virtually all of our population,' Professor Nicholls says. 'Healthcare systems should evolve, and that is exactly what we are seeing here.'

Wider benefits to the state due to co-location

More than just improving the health of patients, Marco Baccanti, Chief Executive, Health Industries South Australia, said that the BioMed precinct will also enhance the health of the South Australian economy.

'Put yourself into the shoes of an investor,' says Baccanti. 'Around 10,000 people will be using the BioMed City facilities on a daily basis. The combination of this level of activity, along with the proximity of the sites, is something that makes the precinct unique; in short, it makes Adelaide an extremely desirable place to work. Through this development, we are fostering a sustainable, knowledge-intensive industry where we will see an increase in the probability of medical discoveries, which will, in turn, improve the likelihood of economic growth. Ongoing, this cycle will fuel itself and Adelaide will continue to reap the benefits.'

The co-location of these health and medical sites is also expected to generate ideas, technologies and companies stemming from the activity in the precinct.

TechInSA, South Australia's high-tech start-up agency that directly fosters entrepreneurs and start-up companies, is positioned to assist with that growth. The agency provides funding to a range of industries to grow the state's hi-tech sector, administering the Early Commercialisation Fund grants program (SAECF), which provides early-stage companies and entrepreneurs up to $500,000 to commercialise eligible projects.

CONNECTING BIOTECH STUDENTS WITH INDUSTRY

A growth industry like biotech needs to employ new people with new ideas, who can step into the industry with the knowledge and confidence to make a positive impact. The University of Melbourne has positioned itself as a leading provider of fundamental and applied training for the next generation of biotech professionals through its Master of Biotechnology.

Professor Herbert Kronzucker, Head of the School of BioSciences at the University of Melbourne, says that the Master of Biotechnology program capitalises on Melbourne's central position within Australia's biotechnology hub.

'Our biggest strength in the Master of Biotechnology is the set of industrial partners we've lined up,' says Kronzucker.

These include CSL, Cell Therapies, Sienna and many other companies in Victoria's burgeoning biotech industry.

All University of Melbourne Master of Biotechnology students do an industry project in their second year of study, and many also complete an internship with an industry partner.

'This is working in real-life, on live business issues that we're trying to address today,' says Paul Davies, Director of Research and Development, Strategy and Portfolio Analytics at CSL, one of the organisations that have partnered with the university to take small teams of biotech students into their companies through the industry project.

'This is not simply an academic exercise. Bringing in the students gives us the opportunity to have a fresh pair of eyes, a fresh perspective, fresh energy, and perhaps even some knowledge and experience of the very latest thinking in biotech that's coming up through academia that we're not aware of.'

Students in the Master of Biotechnology come with a strong background in the life sciences or chemistry, but with a passion to take that knowledge and skills to industry.

'There are people working in business and commercialisation roles that are really drawing on their scientific knowledge,'

Paul Davies speaks with University of Melbourne Master of Biotechnology students at CSL. Image courtesy of Streamline Media

says Dr Krystal Evans, CEO of BioMelbourne Network, an industry-led membership organisation for the Victorian bioindustry.

The idea that if you study science, you become a scientist, is not always the case.

Vivian Gleeson completed his Master of Biotechnology at the University of Melbourne in 2016, and now works as a Business Development Officer at the Burnet Institute. He says the industry project was his first taste of how science can be a commercial entity.

'It also put me in a position to approach certain parties to start those conversations, to build confidence in myself to operate within this field, and has led me to where I am today,' says Gleeson.

If you are interested in becoming an industry partner, contact Fiona Simpson, Careers and Industry Consultant, Faculty of Science, University of Melbourne, at fiona.simpson@unimelb.edu.au.

A NEW APPROACH TO ALZHEIMER'S DISEASE

DR BILL KETELBEY, CEO, ACTINOGEN MEDICAL LTD

Thirty years ago, Alzheimer's disease (AD) was considered an uncommon disorder, attracting little attention from a medical fraternity busy tackling other pressing health problems such as cancer and cardiovascular disease.

In 2017, more than 50 million people worldwide are currently affected by AD, and the disease is poised to become the next global health crisis. Despite the dedication of many in this field, developing drugs for AD has proved particularly challenging. There are currently only four drugs to treat the disease, all of which provide limited symptomatic benefit – none prevent disease progression. Actinogen Medical, a Sydney biotechnology company, is taking on this challenge with its candidate drug Xanamem, using insights from 25 years of AD drug development.

A fundamental shift in the approach to AD research has helped shed light on a disease process that can start a decade or more before the onset of symptoms. AD drugs tested in the past may have failed because they were used too late in the disease to have much effect. Also, the ß-amyloid plaques, which for more than 30 years have been considered responsible for the neurodegeneration characteristic of AD, may in fact be a sign of the disease rather than the cause. This shift away from the amyloid hypothesis has opened the door to fresh approaches and the pursuit of new avenues of investigation.

One such avenue being pursued by Actinogen Medical is the association between chronically raised cortisol and the development of AD. Healthy, elderly individuals with high plasma cortisol levels were significantly more likely to develop AD than those with low cortisol levels, and those with concomitant ß-amyloid plaques were at even greater risk, studies showed.

Actinogen Medical is developing Xanamem, a centrally active drug designed to reduce brain cortisol through inhibiting the enzymatic activation of cortisol by 11ß-HSD1. In a mouse model of AD, Xanamem was effective in improving cognitive function and clearing amyloid plaques from the brain. Notably, improved cognitive function was observed after only four weeks of treatment, and was maintained for at least 41 weeks. While many drugs that showed early promise in animal models failed in human trials, these results, together with the evidence from the AIBL study and many others, support the hypothesis that reducing brain cortisol presents a very rational target for the treatment of this devastating disease.

Many drug candidates have been tested in AD, with very few successes, but while these failures have been frustrating and expensive, the Alzheimer's research community has gained valuable insights into drug research in AD through these failures. These insights have been instrumental in refining the design of Actinogen Medical's study for Xanamem in AD. XanADu (www.ClinicalTrials.gov: NCT02727699) is Actinogen Medical's Phase II safety and efficacy study of Xanamem in patients with mild Alzheimer's disease. XanADu is a double-blind, randomised, placebo-controlled study of 174 patients at 20 sites across Australia, the United Kingdom and the United States.

The XanADu patient cohort has mild Alzheimer's (MMSE 20-26), no longer responding to standard best care. While newly diagnosed patients are more likely to respond to medication, the downside is the difficulty in measuring a response to treatment in such a relatively 'well' patient. To address this, the trial includes ADCOMS[1] as a co-primary endpoint alongside ADASCog14.

XanADu is believed to be the largest global Alzheimer's trial ever run by an Australian biotechnology company. Patient recruitment and treatment commenced in 2017 and is on track to enrol the last patient in the fourth quarter of 2018, with top-line results expected in early 2019. If the results from XanADu demonstrate that Xanamem is effective in the treatment of mild AD, it will be one of the most meaningful global medical breakthroughs in this disease in many years.

1 Wang, J., Logovinsky, V., Hendrix, S. B., Stanworth, S. H., Perdomo, C., Xu, L., ... & Cummings, J. (2016). ADCOMS: a composite clinical outcome for prodromal Alzheimer's disease trials. J Neurol Neurosurg Psychiatry, 993-999.

Want to answer the world's wicked problems? You can.

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[†]QS World Rankings by Subject 2017

PROGRESSING THE PIPELINE

Therapeutic Innovation Australia (TIA) is an innovative not-for-profit company that supports access to specialised research facilities and expertise to accelerate the translation of medical discoveries from the lab to the clinic.

Established in 2008, TIA is delivering the Translating Health Discoveries project for the Australian Department of Education and Training's National Collaborative Research Infrastructure Strategy (NCRIS). TIA's core business is the support of critical operational staff at 13 publicly funded research entities, including universities, medical research institutes and the CSIRO, to enable access by researchers and industry. These facilities provide access to research capabilities in the areas of small-molecule discovery and development, biologics and cell-therapy development and production, preclinical testing, and clinical trial support.

In addition to providing support at these national facilities, TIA has developed infrastructure to help national translational research infrastructure build quality systems, and identify and attract new business. These tools include:

iQDOCs quality documents

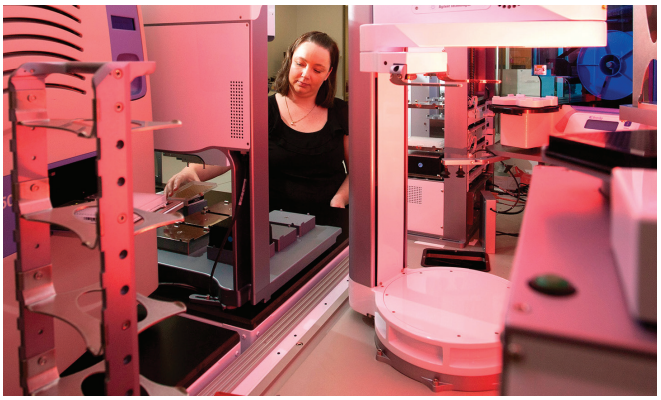
iQDOCs (www.iqdocs.org) is a world-first online repository of template documents related to the establishment and accreditation of laboratory-quality systems (for example ISO17025, Good Manufacturing Practice and Good Clinical Practice). These documents were sourced from industry professionals, and can be downloaded, edited and used to establish quality systems.

ATRAX – a snapshot of Australian medical research

ATRAX (Australian Translational Research Access) is a unique curated database of in-progress medical research projects. ATRAX aggregates public information to provide a constantly evolving picture of Australian translational research, and can help facilities to identify potential users and companies to find the right research partner.

It is clear, however, that Australia's translational research excellence extends far beyond the 13 TIA-supported facilities, and there is an unmet need to build connectivity between service providers whose capabilities span all stages of therapeutic development.

This is the goal of the Australian Therapeutic Pipeline.



The Australian Therapeutic Pipeline provides access to Australian translational research capability, including the national compound collection stored at Compounds Australia. Image source Griffith University

Introducing the Pipeline – building connectivity

Launched by TIA in 2014, the Pipeline leverages TIA's existing enabling infrastructure network, and is developing novel new mechanisms to:

- increase awareness of translational capabilities within the Pipeline membership
- develop an interactive web-based map of translational capability – the Pipeline Navigator
- provide an external showcase for Australia's excellent translational research capabilities
- support access by meritorious projects to Pipeline capabilities
- support industry access with a voucher-based researcher access scheme – the Pipeline Accelerator
- build a community of practice around translational research infrastructure to share important skills.

Where do you come in?

TIA is seeking public-funded research organisations with the capacity to offer quality translational research services to the wider community to join the Pipeline. We also welcome enquiries from research groups and commercial organisations seeking to connect with the appropriate translational research capability for their project development needs. To discuss how the Pipeline can help you, contact Dr Stuart Newman, CEO of Therapeutic Innovation Australia.

For more information on TIA, visit: www.therapeuticinnovation.com.au
For more on the Pipeline, visit: www.therapeuticpipeline.com
Mob: +61 (0)402 345 736
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AUSBIOTECH 2017 NATIONAL CONFERENCE

The annual AusBiotech conference creates a forum to reflect on the sector's achievements and exchange ideas to further advance the sector's standing, both nationally and globally.

AusBiotech is dedicated to consolidating this growth, and the 2017 conference will once again present issues critical to industry. Global biotech trends, breakthroughs, challenges and success stories will feature prominently on the program. Many of the articles in this edition of *Australasian BioTechnology* have been written by those presenting at the conference.

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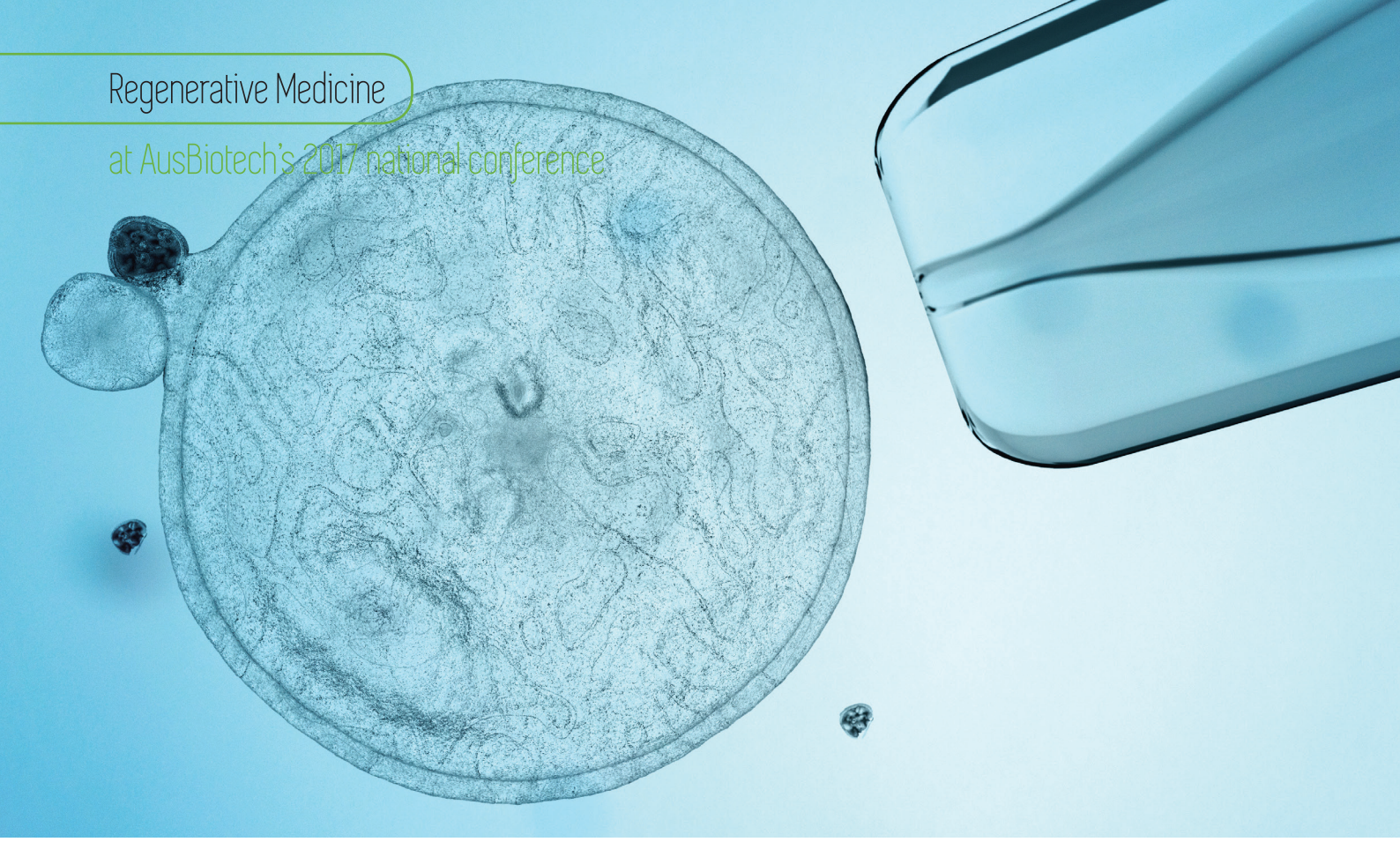

NEXT-GENERATION CELL-BASED THERAPIES

the potential of iPSCs

BY DR KILIAN KELLY, VICE PRESIDENT, PRODUCT DEVELOPMENT, CYNATA THERAPEUTICS LTD

Development of cell-based therapies has been gaining momentum, with more than 700 active clinical trials involving mesenchymal stem cells (MSCs) worldwide, the recent FDA approval of the first chimeric antigen receptor (CAR)-T cell therapy for a type of leukaemia (Kymriah™, Novartis), and exciting progress with other cell types for a number of previously unmet needs.

In order to successfully commercialise these therapies, however, a large-scale and consistent manufacturing process must first be established. While this is a necessity for any therapeutic product, it is a particular challenge for cell-based therapies, as the 'active substance' is typically derived from human-tissue donations, which are inherently variable and often not readily available for commercial use.

MSCs – multipotent adult cells, with important immunoregulatory and trophic functions – are a case in point. These versatile cells, which have attracted intense interest as the basis of therapeutic products for numerous conditions, are typically isolated from donated bone marrow or adipose tissue. While impressive clinical-trial results have been generated using donor-derived MSCs, there are significant limitations with this approach.

The fundamental problem is that very few MSCs can be recovered from a tissue donation, relative

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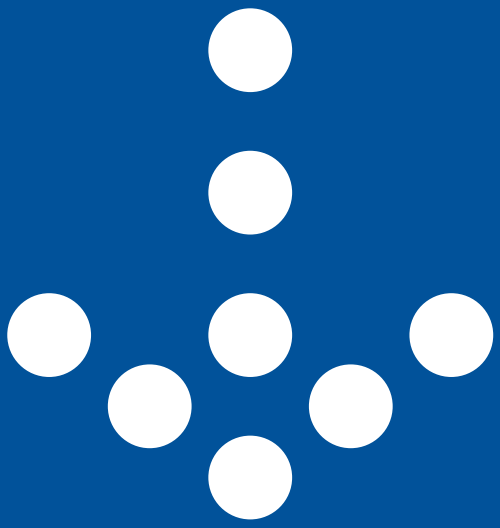
It takes a specialist to find a specialist



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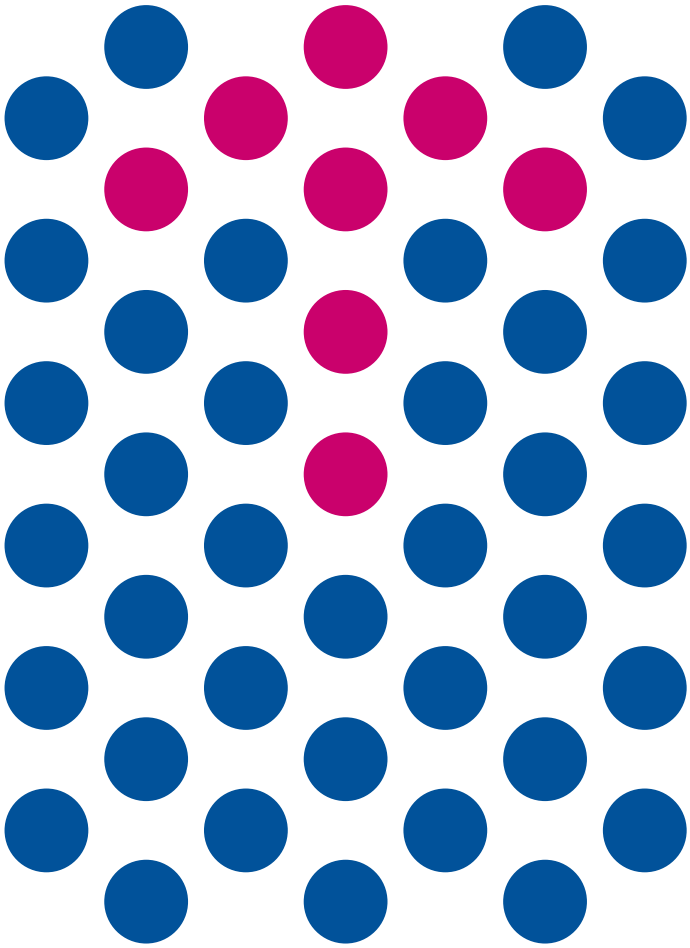

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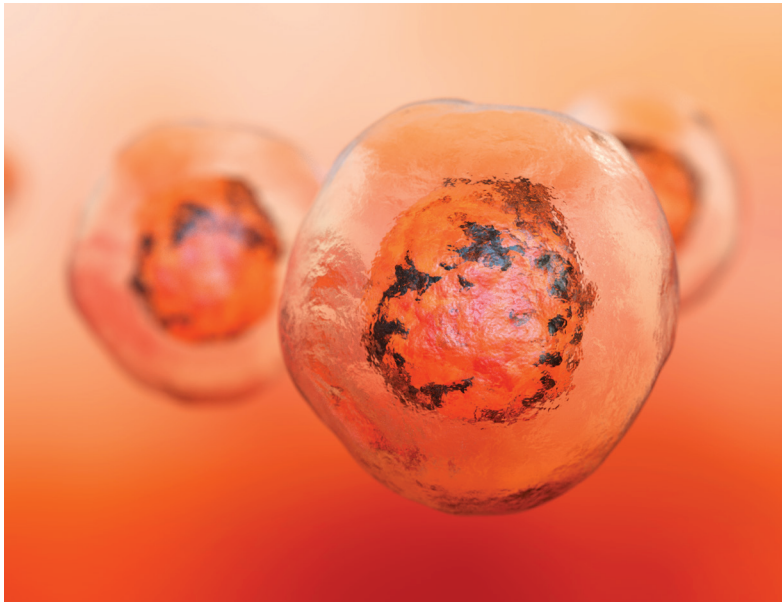
to the very large numbers of cells required for therapeutic use. This means that MSC populations must be extensively expanded in culture, but this is problematic as the functional properties of MSCs change during expansion. In fact, senescence and loss of potency have been reported at expansion levels sufficient to generate just a handful of clinical doses per donation.

As a result of the limited expansion potential of MSCs, reliance on a continuous supply of donors would be necessary to support a commercial manufacturing process. Aside from the cost and logistic challenges associated with this, it is well established that MSCs display a high degree of inter-donor variability, which has major clinical and regulatory implications.

Conversely, pluripotent stem cells (PSCs) have an effectively infinite capacity to reproduce without loss of their key characteristics, in addition to the ability to differentiate into any other type of cell in the body. There are two types of PSCs – embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs). Opposition to ESC research remains entrenched in some quarters, but this is not applicable to iPSCs, as they are produced by reprogramming cells obtained from adult donors. iPSC technology holds enormous promise for this field, as an iPSC bank created from a single blood or tissue donation has the potential to give rise to an effectively limitless number of cells.

Although the first-generation methods of iPSC production were truly groundbreaking – leading to the award of a Nobel Prize to Professor Shinya Yamanaka in 2012 – these methods were unsuitable for use in the manufacture of a therapeutic product, as they involved virus-mediated genetic modification, which is associated with risks such as insertional mutagenesis and persistence of reprogramming genes; however, non-integrating episomal reprogramming methods have since been developed. These methods use plasmids, which are short segments of DNA that do not integrate into the donated cells' DNA, and consequently avoid the risks associated with first-generation methods, thus enabling clinical use of iPSC-derived cells.

A number of companies are pursuing the use of iPSC-derived cells, including Cynata Therapeutics, BlueRock Therapeutics, Opsis Therapeutics, and Astellas Pharma (through its acquisition of Ocata Therapeutics). At Cynata, we are commercialising a proprietary manufacturing platform technology, Cymerus™, which



enables the production of iPSC-derived MSCs for therapeutic use. By harnessing the expansion potential of iPSCs, extensive expansion at the MSC stage can be avoided. Consequently, this technology facilitates the production of a virtually limitless number of minimally expanded MSCs from the same starting material, which avoids problems with senescence, loss of potency and donor-to-donor variability.

Positive data has been generated with Cymerus MSCs in preclinical models of critical limb ischemia (CLI), graft versus host disease (GvHD), asthma and myocardial infarction. Additionally, the first in-human clinical trial of Cymerus MSCs in patients with GvHD commenced earlier this year, and is continuing to enrol patients at a number of centres in the United Kingdom and Australia. This was the first clinical trial in the world involving systemic administration of iPSC-derived cells. Importantly, Cynata has entered into a strategic partnership with Fujifilm Corporation, which has an option to an exclusive, worldwide licence to market and sell Cynata's GvHD product.

Cynata also has ongoing programs investigating modification of the cells to release active molecules, such as cancer-killing toxins, and has recently filed patents concerning the application of Cymerus technology in immunotherapy treatments, including CAR-T and checkpoint inhibitor-based therapies.

The coming years can be expected to provide further evidence that iPSCs have the potential to solve the biggest challenge with cell-based therapies – consistent manufacture at a large scale.

Dr Kilian Kelly will be speaking at AusBiotech 2017.

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AUSTRALIAN COMPANIES AT FOREFRONT OF REGENERATIVE MEDICINE IN JAPAN

BY JOHN MARTIN, CEO, REGENEUS

In April 2013, Japanese Prime Minister Shinzo Abe said in a visionary speech: 'I will lead the efforts to carve out a new horizon for the latest medical technologies, including regenerative medicine and innovative drug development, through a streamlined system from research to practical application in which public and private sectors work together'.

Since early 2015, Japan has become the go-to market for regenerative medicine, with an accelerated product-approval pathway, and the leading market for international technology, clinical licensing collaborations and merger and acquisitions (M&A) deals. These attractive market conditions have drawn Australian companies in the regenerative medicine area to focus on Japan, often in preference to more traditional markets such as the United States and Europe. The early-adopting Australian companies have embraced the challenges of the Japanese market and are punching well above their weight.


John Martin

A key driver for this market change was the introduction in November 2014 of a new

regulatory framework to encourage the development of, and access to, regenerative medicine products, which include cell and gene therapies, and tissue-engineered products. The new laws allow for a regenerative medicine product that has cellular heterogeneity, proven safety, and probable efficacy to be granted conditional approval without the need for expensive and lengthy Phase III trials. This approval will allow the products to be sold on the market for up to seven years – potentially with a 70 per cent government reimbursement – while further efficacy data is being amassed.

Although these new laws are in many ways similar to the laws in Europe (for advanced therapy medicinal products) and now the United States (with the *21st Century Cures Act*), it created a clear fast track for cell, gene and tissue engineering products, without the limitation to only treat conditions that are considered life-threatening.

Japan, with its rapidly ageing population, has an obvious interest in accelerating the development of regenerative medicine products that have the potential to address the underlying causes of chronic disease. Its new policies have cleared the road of onerous regulation, attracting both local companies with capital, and foreign companies, to Japan. To give a view on the size and scope of regenerative medicine, Japan's Ministry of Economy, Trade and Industry (METI) has estimated that the regenerative medicine market will be a US$12.7-billion market within Japan, and US$120-billion market globally, by 2030, rising to US$25 billion in Japan and US$380 billion globally by 2050.

The Japanese market offers significant opportunities for Australian regenerative medicine companies, and Japanese companies are looking to Australia for collaborative research and development (R&D).

Japan's industry is actively engaged in this process, with the leading industry body Forum for Innovative Regenerative Medicine (FIRM) signing a memorandum of understanding with Austrade in 2015 to enhance collaboration between Japan and Australia. Australian companies have also been actively pursuing the Japanese market.

In April 2017, the Hon. Steven Ciobo MP, Minister for Trade, Tourism and Investments, led an Austrade business delegation to Japan, which showcased Australia's capabilities in a range of key sectors, including regenerative medicine. The Australian delegation included CEOs from AusBiotech, MTPConnect and regenerative medicine companies Mesoblast (ASX:MSB), Regeneus (ASX:RGS), Orthocell (ASX:OCC) and Cell Therapies.

AusBiotech has established an advisory group (RMAG) to foster stakeholder participation and help develop industry policy for this rapidly emerging sector, and also to assist with engagement with FIRM and the South Korean RM industry body. Regeneus has been focused on the Japanese market since the introduction of the new regulatory framework.

In December 2016, Regeneus partnered with Asahi Glass (TYO:5201), a leading Japanese manufacturer of biopharmaceuticals, in an exclusive manufacturing license for its Progenza stem-cell technology platform. As a part of the collaboration, Regeneus and AGC have also formed a joint venture, Regeneus Japan, to license out the clinical development and marketing rights for Progenza for all clinical indications for Japan. AGC paid US$5.5 million up front, with an additional US$11 million in specific milestones, one of which has already been paid.

Progenza is Regeneus's allogeneic mesenchymal stem-cell platform, which has the potential to treat a wide range of inflammatory indications. Progenza's initial focus is on knee osteoarthritis. Osteoarthritis is a major health challenge in Japan, which has an ageing population, and where access to, and acceptance of, joint replacement surgery for severe osteoarthritis is limited. Progenza has just passed Phase I in Australia, meeting primary endpoints of safety and tolerability. Progenza also showed statistically significant reduction of pain and promising signs of disease modification through the slowing and, in some cases, halting of the degradation of cartilage.

Other Australian companies that have also focused on Japan include Cynata Therapeutics (ASX:CYP), which signed an agreement with Fujifilm for its iPS cell-derived MSC technology. In January 2017, Fujifilm acquired a 10 per cent stake in Cynata, as well as several technology option agreements. Mesoblast, the world's largest pure play stem-cell company, has a collaboration in Japan with JCR Pharmaceuticals for its Temcell product for graft-versus-host disease. Temcell is one of the first allogeneic stem-cell products on the Japanese market.

Cell Therapies has partnered with PharmaBio of Japan in relation to the manufacture of regenerative medicine products in Australia and Japan.

We anticipate that Australian companies will continue to play a growing role in the development of the regenerative medicine market in Japan. We believe their future successes will help foster the growth and development of a robust Australian regenerative medicine industry.

STRATIFIED MEDICINE IS CHANGING THE GAME

Over the past two decades, the pharmaceutical industry has seen a decline in drug approvals awarded by the various drug agencies. Approaches that personalise or stratify medicines are a key component changing this productivity decline and identifying therapeutics for diseases with an unmet need. Such medicines are developed with a target patient group in mind, and for whom the therapeutic is either safer, with fewer adverse events, or more efficacious.

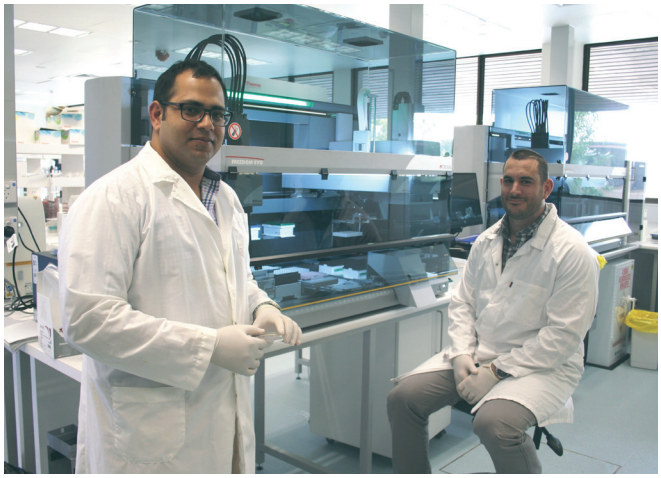
Stratifying patients requires the development of genomic, biochemical, clinical or other tools that differentiate patients into subgroups. The use of such tools to predict drug responses, such as efficacy and toxicity, is fundamental to achieving the success of drug registration. This is an area of research in which Murdoch University Health Sciences has developed a range of capabilities to improve patient care, as well as accelerate clinical trials and discover novel therapeutics. Three such examples are described in this article.

Metabolic phenotyping driving next-generation omics

Metabolic phenotyping provides a readout of the metabolic state of an organism and is the product of its genetic and environmental contributions. Through spectroscopic techniques, such as nuclear magnetic resonance spectroscopy and mass spectrometry, metabolic phenotyping enables scientists to examine the dynamic interactions between genes, environments, microbiomes, diets and lifestyles, and their impact on diseases. As one of the fastest-growing areas in life science research, metabolic phenotyping has become an essential tool for understanding biology, and fundamental to the greater global shift towards systems biology and post-genomics research.

Associate Professor Robert Trengove is leading the establishment of the nation's first metabolic phenotyping centre – the Australian National Phenome Centre (ANPC) – at Murdoch University.

As the only facility of its kind in the country, the ANPC was founded through a successful application to the Australian Research Council. ANPC's partners include all five Western Australian universities as well as the University of New South Wales, Telethon Kids Institute, the Harry Perkins Institute of Medical Research, the Western Australian Health Translation Network, the Western Australian Department of Health and Imperial College London.



Dr Sam Abraham (left) and Dr Mark O'Dea with one of the lab robots that will be used to test for antimicrobial resistance

The establishment of ANPC represents a watershed opportunity for metabolomics researchers to address the challenges associated with method harmonisation, throughput and turnaround, data sharing and interrogation.

As a partner of Imperial College London and the Nanyang Technology University (Singapore), ANPC will produce high-quality research outcomes by generating and leveraging harmonised data from integrated studies with its partners. Such consolidated efforts ensure that world-leading researchers are able to access data that is produced with the highest integrity, and solve global problems using a time-sensitive and economically efficient framework.

Through this quality framework, researchers will be able to produce robust datasets that allow for studies into variation in gene-environment interactions across global populations. This will lead to better-informed public health policies, new therapeutic measures and improved crop production, with more vigour.

Linking bioinformatics to molecular therapeutics

Murdoch University incorporates three interrelated research streams to support stratified medicine: firstly, comparing genetic differences that have implications for health and disease; secondly, designing and developing information systems to support research, clinical management and

The molecular therapeutics laboratory at Murdoch University

patient care; and thirdly, developing new therapies for human disease, with a focus on rare diseases.

To support this combined approach, collaborating teams are co-located in a purpose-built research facility that includes a Bioinformatics Research Laboratory (BRL). This has established expertise in experimental design and analysis, bioinformatics, comparative genomics, software development and high-performance computing. It also boasts a Molecular Therapy Laboratory that undertakes unique biomedical research to develop genetic therapies, and the Oligonucleotide Laboratory that builds novel nucleic acid drugs.

Led by Professor Matthew Bellgard, the BRL provides a unique scientific infrastructure and capability within Australia. The BRL develops and utilises innovative techniques and tools to drive its core research programs, as well as serving external clients.

Software developers and bio-informaticians offer a range of capabilities, including the development of computational tools; a vast range of data analysis and high-definition visualisation strategies; and the development of integrated internet-based information management systems. Registries developed by the BRL provide crucial data collection and management frameworks, enabling improved patient care and participation in clinical studies.

Led by Professors Sue Fletcher and Steve Wilton, the Molecular Therapy Laboratory undertakes design and development of antisense compounds to modify gene expression to ameliorate human disease. The researchers have expertise in antisense oligomer design and evaluation, synthesis of novel research antisense oligonucleotides, developing therapeutic strategies for genetic disorders, and assessing molecular outcomes in vitro and in vivo.

Antimicrobial resistance research

Disease surveillance complements stratifying medicine in the prediction of the spread of antimicrobial resistance. Established in 2017, the Antimicrobial Resistance and Infectious Diseases (AMRID) Research Laboratory – a $3.5-million One Health Initiative – is a research and antimicrobial resistance surveillance facility at the School of Veterinary and Life Sciences at Murdoch University. The laboratory has a suite of state-of-the-art molecular and non-molecular technologies. This includes next-generation whole-genome sequencing, DNA microarray, real-time polymerase chain reaction and mass spectrometry. By using robotic platforms, AMRID is able to perform large-scale screening of human and animal pathogens, including zoonotics, for the detection of antimicrobial virulence and resistance genes.

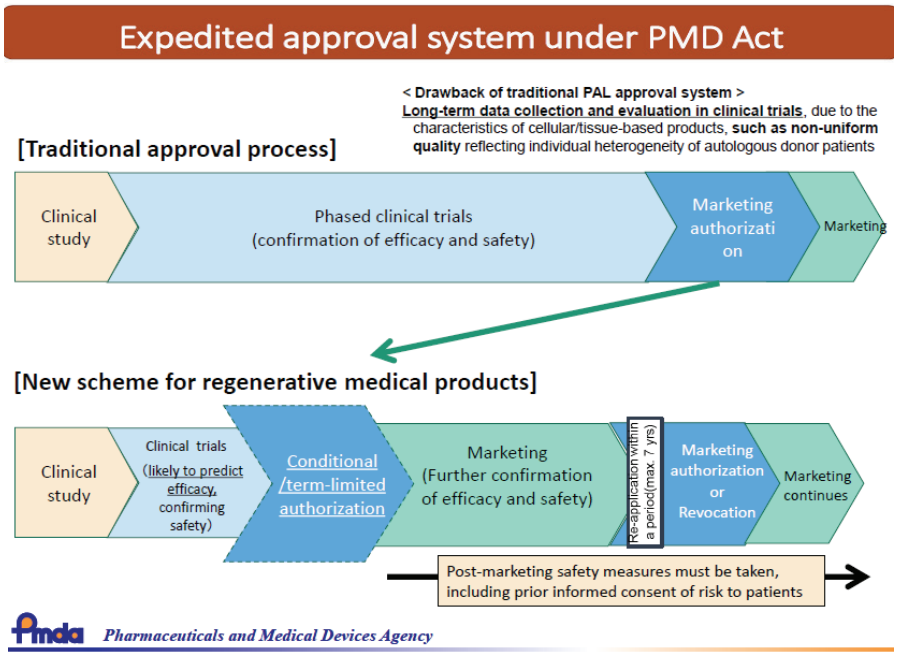
AMRID research focuses on the key emerging challenges at the human-animal-environment interface in Australia, and globally. This includes integrated management of animal health and zoonotic diseases in many developing countries, food safety risk assessment, antimicrobial resistance, and epidemiology of foodborne pathogens.

The Human Health area of AMRID, led by Professor Geoffrey Coombs, is the reference laboratory for Australia's national antimicrobial surveillance system, the Australian Group for Antimicrobial Resistance (AGAR), which involves 42 institutions located across the country. Visit www.antimicrobial-resistance.com for more information.

In Animal Health, AMRID has become one of the leading antimicrobial resistance laboratories for the Australian livestock industry, and is heavily involved in genomic characterisation of zoonotic pathogens and drug discovery for infectious disease in animals.

ASIAN REGENERATIVE MEDICINE OPPORTUNITIES AND PERSPECTIVES
JAPAN SPOTLIGHT

BY DR AKIHIKO IWAI, VICE DEPUTY CHAIRMAN OF FORUM FOR INNOVATIVE REGENERATIVE MEDICINE (FIRM), DIVISIONAL SENIOR VICE PRESIDENT OF CANDIDATE DISCOVERY SCIENCE LABS, DRUG DISCOVERY RESEARCH, ASTELLAS PHARMA INC.



The *Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act* (PMD Act). Conditional approval is employed considering the characteristics of regenerative medicine products. Pharmaceutical Affairs Law approval system.

Founded in 2011, Forum for Innovative Regenerative Medicine (FIRM) is a Japanese organisation of Japanese regenerative medicine (RM)–related industries, and currently consists of more than 200 companies.

Almost all the sectors related to RM business, including pharmaceutical companies; manufacturers of RM products; producers of medical equipment and devices; culture reagent companies; and finance, construction and transportation sectors, join FIRM to participate in active discussions across industries. Their collaboration has been realised.

In Japan, the *Pharmaceuticals, Medical Devices and Other Therapeutic Products Act* (Figure 1) and the *Act on the Safety of Regenerative Medicine* were promulgated in November 2014, and clinical trials and developments of Japanese RM products were promoted under the advanced, world-leading Japanese regulations. As a result of the law amendment, Thamescell of JCR Pharma was approved, and Terumo's HeartSeat® acquired conditional approval in Japan. In 2016, the SAKIGAKE Designation System, which is a Japanese system aiming to promptly provide the world's most advanced therapeutic drugs to the patient, was promulgated. Three RM products were designated in 2016, with three more designated in 2017. Using this system, Japanese public-private parties are developing and examining products for the benefit of patients.

In terms of legislation, new systems have also been established in the United States and the European Union. In the United States, Regenerative Medicine Advanced Therapy Designation (RMAT) was established following Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, and in the European Union, conditional marketing authorisation was conducted. Although they are still being implemented, the Japanese system is more useful because it better understands the characteristics of RM.

The pharmaceutical market report from 2013 says that North American RM market share will be 38 per cent of the global market, with Europe taking 24 per cent and Japan 12 per cent. Japan has the second-largest market in the world as a single country. In addition, the total market share of Asia, Oceania and Africa combined will be 30 per cent, which is almost as much as that of North America or Europe. Many countries in Asia, Oceania and Africa are expected to develop, so this market share should expand significantly in the future.

In Australia and Japan, there are companies and academies already collaborating on projects, and we anticipate that collaboration will increase in the future. We believe that Asia and Oceania can mutually cooperate to create excellent academia and bio-ventures, and to grow them into highly novel and distinguished products.

Dr Akihiko Iwai will be speaking at AusBiotech 2017.

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COOK MEDICAL AUSTRALIA CONTINUES TO EXPAND

The Australian operations for Cook Medical continue to grow as the company transforms its manufacturing processes and expands employment.

Cook Medical has been manufacturing medical devices in Australia since the late seventies, and over the years, has consistently experienced strong sales growth. In 2016, the company exported more than 92 per cent of its locally manufactured products, specialising in reproductive health and endovascular repair, at a value exceeding $100 million. This figure is particularly impressive as the total production output is also increasing.

Australia's success in global markets is often related to an innovation in product performance[1]. Cook Medical Australia has built a strong reputation for product innovation. Recent funding success will facilitate Cook Medical's continued expansion in the industry. Attracting $2.79 million in funding from the Australian Research Council (ARC), the Research Hub for Advanced Manufacturing of Medical Devices is endeavouring to make the production of devices, like the locally manufactured endovascular stent graft, better, faster and more efficient. Hub collaborators include the University of Queensland and other industry and university partners.

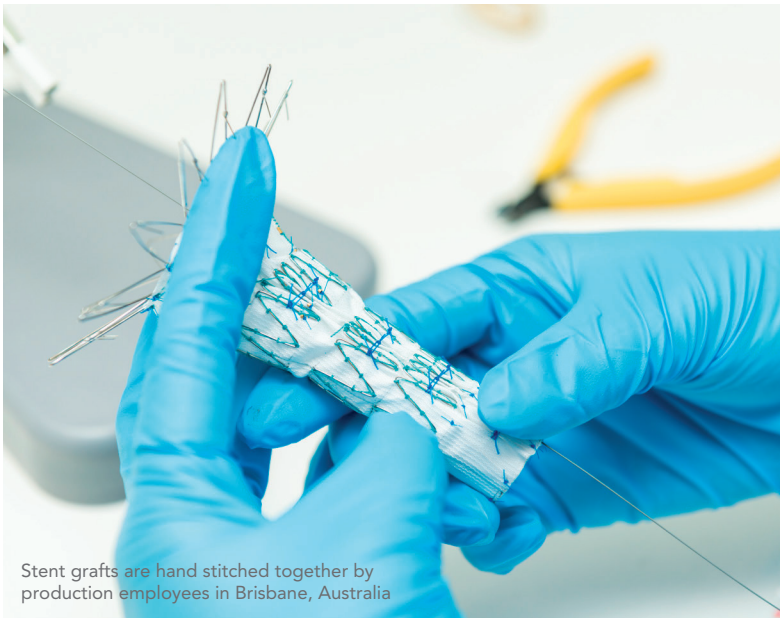
General Manager Dr Samih Nabulsi is confident of the hub objectives and benefits for introducing technologies and processes that support advanced manufacturing.

'We're looking at growth by building on the skills and expertise of the people we already have, optimising our processes and increasing production by offering a number of new opportunities.

'For us, it is about our ability to live by our mission and innovate so we can find more efficient ways to develop quality products and deliver these to our customers faster,' Dr Nabulsi says.

With the company's strong brand recognition and the increasing product demand, opportunities for Cook Medical continue to multiply – success that is then reinvested into the company and its people.

Investments in employee wellbeing and training has upskilled most of the local manufacturing staff and the company is actively recruiting for 60 people to launch a second shift towards the end of the year – challenging industry trends as employment rates in manufacturing decline[2].



Stent grafts are hand stitched together by production employees in Brisbane, Australia

With high production and resourcing costs, the future of Australian manufacturing will be dependent on the industry's flexibility to evolve. Cook Medical Australia has a proven track record, and recent efficiency improvement projects have increased manufacturing capacity in a number of areas.

Along with manufacturing success, Cook Medical's reach has extended to the innovation ecosystem. Earlier this year, the company launched the Asia-Pacific Commercialisation and Development Centre (ACDC) to assist businesses, entrepreneurs and researchers across the region to commercialise innovative medical products and health-related technologies.

Growth for Cook Medical Australia can be attributed to the company staying true to its grassroots beginnings, investing in its people, challenging industry trends and by leveraging opportunities to innovate.

The achievements over the last year reinforce Cook Medical's commitment to Australian research and development and creation of local advanced manufacturing jobs.

1 Advanced Manufacturing Growth Centre, Sector Competitiveness Plan, 2017

2 Australian Industry Report, 2016

Cook Medical Australia

Our mission is simple: We are dedicated to bold leadership in pioneering innovative medical solutions to enhance patient care worldwide.

Cook Medical Australia has over 500 employees including research engineers, laboratory staff, new technology associates and a commercialisation centre dedicated to finding innovative healthcare treatments and medical technologies to address some of the challenges facing healthcare systems.

Current initiatives include:

Asia-Pacific Commercialisation and Development Centre
To assist businesses, entrepreneurs and researchers from Asia-Pacific, to bring innovative medical products and health related technologies to market.

Asia-Pacific New Technologies Team
Formed to discover and evaluate new concepts and technologies from Asia-Pacific and to channel these into appropriate divisions within Cook Medical.

The ARC Research Hub for Advanced Manufacturing of Medical Devices
Aims to transform Australia's medical technology sector by developing cost competitive technologies for the rapid production of medical devices.

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MICROSAMPLING: CLINICAL TRIAL PANACEA OR PASSÉ?

BY ANNE COLLINS, GENERAL MANAGER: MICROSAMPLING, TRAJAN SCIENTIFIC AND MEDICAL

Blood, an information-rich source, is a major clinical tool in the determination of disease, the biochemical and physiological wellbeing of humans, the function of vital organs and the effectiveness of therapeutics.

The blood-testing market has an annual growth rate of 2.6 per cent, driven by common lifestyle diseases, ageing populations, personalised medicine, analytical advancements, and the desire for point-of-care or at-home testing.

These drivers have helped motivate innovation in the area of blood collection, with a focus on 'ease-of-use' devices that enable collection of accurate and precise micro-volumes of blood by non-healthcare professionals.

Advances in microfabrication have seen the emergence of devices that leverage microneedles to draw capillary blood. Seventh Sense's TAP device has recently been approved by the Food and Drug Administration (FDA) for testing of HbA1c, an analyte routinely employed for monitoring blood-sugar levels in diabetics.

There is also a wave of technologies that are leveraging the low sample volume, simple sampling, and convenient storage and transfer benefits of dried blood spot (DBS) technology, while addressing the challenges of sample volumetric accuracy, and precision and sample homogeneity on the collection matrix. Both Neoteryx's Mitra device and Spot On Sciences' HemaSpot leverage the absorption capacity of known size collection matrixes to get a known volume of the sample.

Trajan's hemaPEN leverages the volumetric accuracy of end-to-end capillary collection and sample transfer to a known size collection matrix, in a self-contained, automated system that maintains sample integrity and eliminates operator variation. This blood collection and storage device has the potential to be the most accurate and precise solution for microsampling once it is officially released into the market (beginning in early 2018).

While the clinical utility of DBS technology has been demonstrated for therapeutic drug monitoring and epidemiologic studies, it is still relatively new in the pharmaceutical clinical trial industry. The initial value may come in the ability to collect data that would otherwise be difficult to obtain, or when classical plasma sampling is not an option, such as in studies involving paediatric or elderly patient populations in developing countries, where facilities or phlebotomists are limited, or in post-approval monitoring.

Although most of the devices are intuitive and easy to use, new microsampling devices lend the technology to regulated bioanalysis.

Further, ambient temperature storage and shipping allows these DBS-based microsampling devices to provide increased logistical feasibility and, at the same time, decrease operational costs, with no specialised equipment required for (initial) sample processing. There is the potential for significant cost reduction for sample collection and transportation in large multi-centre trials. The analytical feasibility of implementing DBS microsampling technology that routinely provides 3–20 microlitre volume of blood, should consider:

- lower limit of quantification of the analyte of interest
- the stability of the analyte of interest
- homogeneity of the analyte in the sample
- requirement for volumetric accuracy
- inter-operator and inter-day volumetric variability.

Advances in the sensitivity of mass spectrometry and direct introduction of samples into this workflow further enable this traditional analytical laboratory technology to move into pathology.

With a huge drive from the clinical trial sector for 'patient-centric' solutions, the use of easy-to-use, non-centralised, needle-free blood sampling has been shown to increase trial recruitment, as well as adherence to trial regimes due to the ability to take additional data points.

It is likely that we will see further adoption of this technology and the adoption of microsampling into mainstream clinical practice.

JAPANESE INNOVATION AWAKES TO AUSTRALIAN CLINICAL TRIALS

BY COLIN LEE NOVICK AND ANDREW FLEURY, CJ PARTNERS INC.

When it comes to early-stage clinical development, Australia has long been able to hold a distinguished position of being simultaneously efficient, affordable and high quality.

Additionally, clinical dossiers generated through Australian clinical trials are routinely accepted by major regulatory agencies around the globe, resulting in an advantageous and user-friendly jurisdiction. Over the years, the Australian Government has worked to cultivate and maintain this position through such efforts as the continued implementation of the country's Clinical Trials Notification (CTN) scheme, and its research and development (R&D) Tax Incentive.

In addition to local Australian companies, firms from the United States – and, to a lesser extent, Europe – have been the major benefactors of Australia's early-stage clinical development advantages. Japanese companies, hailing from the world's second-largest single-country pharmaceutical market after the United States, have lagged behind their United States and European Union counterparts. This status quo, however, is being altered with an increasing number of cost- and quality-conscious Japanese biotechnology companies (referred to more commonly as 'bioventures' in Japan) taking advantage of the benefits available Down Under. OncoTherapy Science, ID Pharma, and AnGes are three influential and recent adopters of the Australian early-stage clinical path.

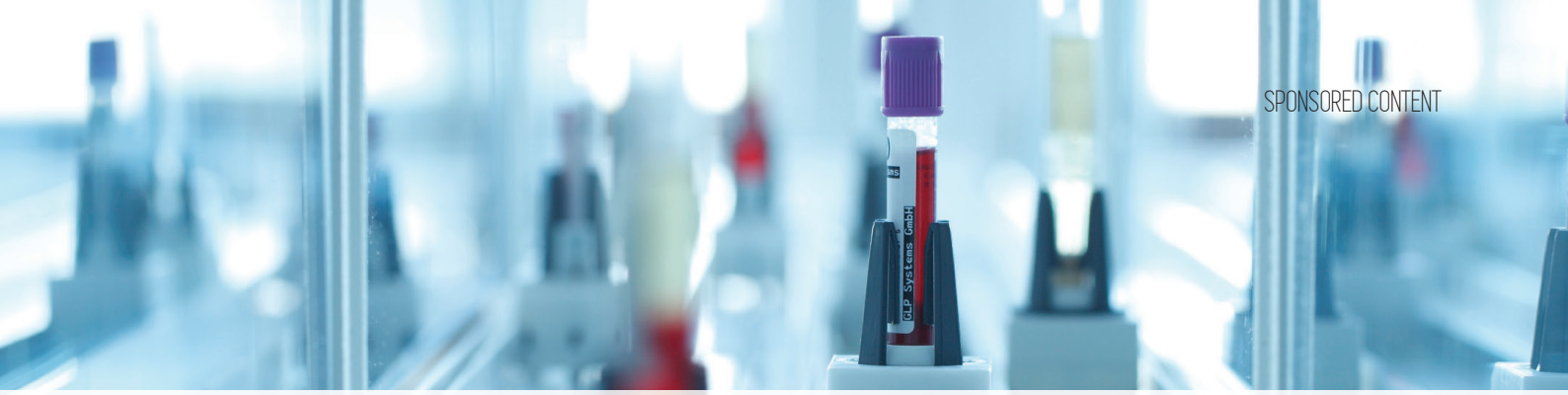
Founded in 2001 as a university-launched bioventure, OncoTherapy Science (OTS) conducts research and development of oncological drugs and therapies. Their technology is based on Dr Yusuke Nakamura's cancer-genomics research targeting oncogenes and proteins. The company announced in early January 2016 that they had received a green light from an Australian Human Research Ethics Committee (HREC) to commence a Phase I bioavailability study on their OTS167 (a MELK Inhibitor) investigational product (IP). Just over two months later in mid March 2016, the company announced completion, with 'favourable results', of the same study.

Another company taking advantage of the opportunities in Australia is ID Pharma. Established in 2003 as DNAVEC Corp., the successor company of a Japanese governmental research project that started in 1995, ID Pharma develops gene therapies and gene vaccines based on the firm's patented and proprietary Sendai virus vector technology. The company announced the commencement of a Phase I/IIa Australian trial in early May 2016 for its DVC1-0101 product for the treatment of critical limb ischemia. The company was acquired in 2013 by I'rom Group, the same firm to subsequently acquire Adelaide's CMAX Clinical Research from IDT Australia earlier this year.

Finally, we would be remiss not to mention AnGes. AnGes, established in 1999 by researchers from Osaka University, has been one of the most influential and trendsetting bioventures in Japan. So much so that its lead product, AMG0001, is on course to become Japan's first (and the world's sixth) approved gene therapy in the coming months. The company announced in late July 2017 that it is working towards a Phase I/II clinical trial in Australia for its AGMG0201 IP, a DNA vaccine for hypertension. Furthermore, this trial will take place at CMAX Clinical Research facilities, further intertwining the interests of Japan and Australia.

Traditionally, Japanese bioventures have faced the same problems that any non–United States biotechnology company is bound to face at some point: specifically, a lack of available capital. While some countries, including Australia, have opened their stock-exchange gates to the biotech community/industry, the listing requirements in Japan remain prohibitive for bioventures. Despite being the second-largest pharmaceutical market in the world, even a liberal count of listed bioventures in Japan comes to 25 companies; the contrast to the number of biotechs listed on the ASX is stark.

As Japanese firms are increasingly keen to tap into pharmaceutical markets outside of their home market, the speed/efficiency and cost benefits of the Australian CTN scheme make for a convincing strategic avenue for clinical development. We believe that more Japanese bioventures will make their way to Australia for early-stage clinical trials, with larger pharmaceutical companies to follow suit.



CHOOSING A CENTRALISED LABORATORY SERVICE MODEL FOR YOUR NEXT CLINICAL TRIAL

The biopharma industry has employed central laboratory services for more than 30 years in order to standardise pathology testing in clinical trials, and to speed up the drug approval process by providing clean, consistent and high-quality data.

The traditional central laboratory model for global clinical trials offers harmonised testing across strategically located regional laboratories. There are a number of well-established advantages to using a central laboratory service over local laboratory testing, including:

1. Harmonisation of pre-analytical, analytical and post-analytical processes:

- protocol-specific requirements are predefined in a clinical trials management system (CTMS)
- sites are supplied with trial-specific, visit-specific collection kits and request forms
- testing methods and platforms are maintained, including a single reference range used across all laboratories for the study duration
- prior to issuing reports, all data is cleaned in real-time, and a single, customisable data file is submitted as required to the sponsor and/or contract research organisation (CRO).

2. Decrease in the time it takes to bring a new drug to market.

3. Compliance with global and/or regional regulatory requirements.

4. A dedicated project manager is assigned to ensure the timely set-up and delivery of services.

Despite these advantages, there are occasions when using a local laboratory is more appropriate. Factors to take into consideration include your turnaround time requirements, such as acute care and Phase I studies, sample stability, and budget.

A potential problem with using local laboratories is the variation in laboratory values and the extent of data cleaning required, which can slow down the time to database lock and regulatory approval at the study's end. Today, central laboratories can offer alternative service models to accommodate those studies requiring local laboratory testing.

Central local laboratory model

In this model, a local laboratory performs safety testing, while other activities (study set-up, project management, logistics, reporting and data management) are centralised. This model provides the investigator with a quick turnaround on results while maintaining data quality and managing the budget. This model is well-suited to single-site studies.

Local laboratory, centralised data model

In this model, a sponsor may need to use the site's own laboratories. The local laboratory performs the analytical testing, and the central laboratory receives, cleans and merges multiple laboratory data into its database for transfer to the sponsor or CRO. This model is suited to multi-site studies in acute-care settings, providing effective data support.

Both of these hybrid local/central laboratory options have the advantage of offering quick turnaround times and clean, consistent data.

With the increasing complexity and expanding geographic reach of clinical trials, sponsors must weigh up their testing requirements, along with logistical and budgetary constraints, before deciding on the optimal laboratory service model. Fortunately, central laboratories today can offer an array of solutions to meet these requirements.

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VALUE-FOCUSED DRUG DEVELOPMENT STRATEGIES OF THE FUTURE

BY CRAIG RAYNER, PRESIDENT, D3 MEDICINE, A CERTARA COMPANY

Mounting healthcare and research and development (R&D) costs, high drug attrition rates leading to decreased numbers of new molecular entity approvals, and growing demands from regulators and payers indicate that a paradigm shift is needed to improve efficiency and productivity across the drug development continuum.

By thinking differently – Thinking Without Borders® – to tackle the impossible, we create new methods and approaches that can infuse the R&D ecosystem and add value. Unless an approach meaningfully impacts certainty, efficiency or cost, it does not add value.

Model-informed drug development (MIDD) is a quantitative and mechanistic 'in silico' modelling and simulation approach that is central to informing and creating value in drug-development programs (Figure 1). Rather than thinking of MIDD methods as being peripheral to drug development, when applied in a fit-for-purpose manner, MIDD improves certainty in decision-making, adds efficiency, may reduce cost to the drug-development process, and improves the ethical aspect of development by minimising unnecessary human or animal trials. Regulatory agencies, such as the US Food and Drug Administration (FDA), employ and encourage the use of in-silico tools in clinical trials to improve drug development and make approvals more efficient.[1] The FDA's Center for Drug Evaluation and Research (CDER) uses modelling and simulation to 'predict clinical outcomes, inform clinical trial designs, optimise dosing, predict product safety and evaluate potential adverse event mechanisms'.

MIDD tools focus on the drug (pharmacokinetics and pharmacodynamics, PKPD, population PK), the disease (quantitative systems pharmacology, QSP) and/or mechanistic details (physiologically based pharmacokinetics, PBPK), which, together with other complementary techniques, can be deployed across the development cycle. Another approach, Pharmacology to Payer (P2P), creates a framework that links relevant end points across adjacent disciplines to health economic value. With the increasing need to justify the pricing of medicines to society and payers, P2P aligns developers, regulators and payers earlier in the drug development program to enable accelerated access to affordable medicines.

Difficulty in accessing patient populations, scientific issues with bridging from healthy adult populations, and the operational and ethical issues in executing clinical trials are challenges encountered in development programs. The following are several examples of how MIDD has created value in accelerating the development of safe and effective therapeutics for pediatric populations and orphan diseases.

In the first example, a quantitative clinical pharmacology strategy was used to establish safe and effective dosing for the treatment of influenza in infants[2]. Existing data on children older than one year suggested a similar response to the anti-viral therapy oseltamivir; however, earlier toxicology findings heightened diligence impacting the move to infants. To overcome this challenge, a quantitative clinical-pharmacology adaptive trial design was developed where PK modelling from the first study informed the second study. Modelling and simulation was used to analyse the pooled PKPD data and account for design differences, including different formulations. Within six months of submission, oseltamivir was the first therapy approved by the FDA, and then later by the EMA, for the treatment of influenza in infants as young as two weeks old.

A novel MIDD approach was used to inform the design of a Human Challenge Model clinical trial resulting in accelerated development of a respiratory syncytial virus (RSV) therapeutic to pediatrics[3]. The translational medicine MIDD bridging program resulted in numerous benefits, including: predicting dose to yield therapeutic exposures in infants under two years old; shorter trial lengths; reduction in the number of patients needed; significant cost and time savings; high-quality science published in the *New England Journal of Medicine*; and data that enabled robust decision-making, including a US$1.75-billion transaction. Furthermore, the MIDD clinical strategy created a regulatory precedent for entry into RSV-infected infants early in a development program, and provided insights that will help guide future clinical trials.

Mechanistic approaches, such as PBPK, have been used to understand the mechanisms of how a drug is metabolised, so that the potential drug–drug interactions (DDI) across different patient populations could be understood and used to inform dose and regiment. PBPK models were used to gain a better understanding of Imbruvica®, an anti-therapeutic used for the treatment of rare diseases including mantle cell lymphoma and chronic lymphocytic leukemia[4]. PBPK was able to inform the Imbruvica label, provide guidance to clinicians, including 24 individual DDI scenarios removing the requirement to evaluate such DDIs in clinical trials, and provided a dose-optimisation strategy for individuals.

The final example of MIDD as it relates to health economic value is the development of a P2P influenza model to determine the cost utility of oseltamivir as the antiviral therapy used under various pandemic

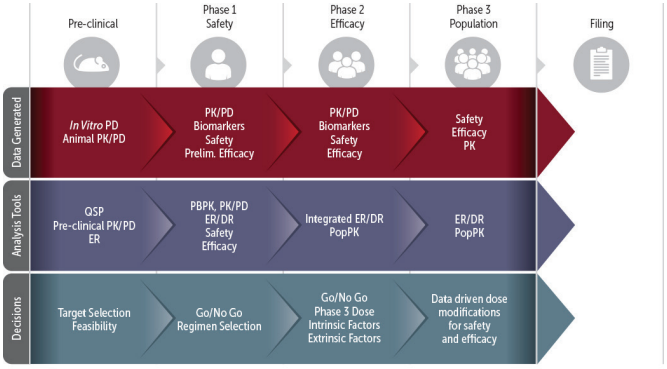

Fig 1. Model-informed Drug Development Methods

scenarios.[5] The proof of concept spanned and linked drug PKPD, epidemiological and health economic end points. The framework enabled all key stakeholders to use a common platform to simulate novel interventions that might impact society, and informed decision-making by all parties in 'what if' scenarios. Most importantly, the model facilitated transparent discussions on cost to society and cost to payers early in the development process, and on how a drug may be placed in the healthcare system.

When deployed in a fit-for-purpose manner, model-informed drug development methods play a key role in driving value in the drug-development process. MIDD approaches improve drug success rates by more accurately predicting efficacy and safety, and better characterising sources of drug response variability at early, less costly stages of development. Further, an MIDD framework can be valuable to create patient-centric alignment of key stakeholders throughout the drug-development process to ensure future development of safe, targeted, efficacious and affordable drugs that address unmet medical needs.

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Craig Rayner will be speaking at AusBiotech 2017.

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THE PROBLEM WITH BACTERIA

BY BYRON DARROCH, EXECUTIVE VP, NEXT SCIENCE PTY LIMITED

Bacteria exist in two essential forms: free-floating (planktonic) bacteria, which are the most virulent, familiar to researchers and easiest to kill; and anchored or sessile (biofilm) bacteria, which compromise 80 per cent of all bacteria, are the least understood and the most difficult to kill due to sophisticated protective mechanisms.

The world of medicine and research has found a way to deal easily with planktonic bacteria, through the use of antibiotics or disinfectants. The problem is bacteria that create biofilms, often in under an hour, forming a force field around themselves that protects them from eradication using traditional methods.

Biofilm bacteria account for nearly 80 per cent of global bacterial infections, and are extremely difficult to kill compared to planktonic (free-floating) bacteria. Biofilms pose a far-reaching threat to humans, animals and the environment. The continuing rise in antimicrobial resistance necessitates effective diagnosis and management of biofilm-associated infections. Collectively, infections contribute to significant morbidity, mortality and increased healthcare expenditure, and, up until now, we've had no effective way of managing biofilm-associated infections.

Example

Chronic sinusitis affects 30 million people in the United States and is the fifth most common disease treated with antibiotics, yet in more than 77 per cent of cases, biofilms can be found, and these have been proven resistant to antibiotics.

The big challenge is that sessile bacteria have created a sophisticated protective mechanism, like a force field, to protect themselves. When they come together and create these colonies, the bacteria secrete a slime-like substance called the extracellular polymeric substance (EPS), which is a physical structure that encapsulates and protects the bacteria.

Current treatments are either focused on planktonic bacteria, like antibiotics, and are therefore unable to deal with the physical EPS that the bacteria have created; or are highly toxic, oxidising and hazardous materials that break up the EPS, but do not fully remove it, allowing new bacteria to recolonise it quickly.

Byron Darroch

Next Science, a young Australian company, has been working for the last five years on solutions to the biofilm problem. Through a contrarian material science approach, Next Science has developed the Xbio™ Technology.

Xbio is a unique, unprecedented approach to eradicating both biofilm bacteria and planktonic bacteria with a proprietary, non-toxic technology that disrupts the biofilm's extracellular polymeric substance (EPS) matrix and makes the bacteria within the biofilm more vulnerable to attack by antimicrobials, antibiotics and the body's natural immune defences. Recent in vitro clinical studies have shown Next Science's products reduce the number of bacteria present and, regardless of setting, help to prevent the growth of further biofilm structures. This patented technology may help reduce the misuse of antibiotics and has shown no known evidence of bacterial resistance.

Next Science was founded on the belief that bacterial proliferations and infections should not be impossible to deal with. Rather, they are able to be prevented and treated effectively without the risk of resistance. Through a truly novel material-science approach, our team of scientists has developed a solution to the problem of bacterial biofilms that manages bacterial proliferations sustainably, gently and more effectively than all other known approaches. With three FDA-cleared products on the market, we're working with multiple partners to change the way we deal with bacterial infections.

For more information, you can visit our website at www.nextscience.com.

REIMAGINING THE FUTURE OF HEALTH CARE WITH 3D TECHNOLOGIES

It is becoming increasingly likely that 3D-printed anatomical models, guides and implants will be part of the future of patient treatment, and for more than just complex procedures.

But unlike the mass-produced medical device industry, the adoption of 3D printing needs a standardised system of measurement. The application of consistent and complete evidence-gathering methodologies across the industry could significantly foster the adoption of 3D printing in the healthcare sector.

Medical device developers and clinicians are often required to conduct clinical trials for their devices and procedures to ensure that they will perform safely and effectively across their patient population. Numerous medical professionals across the world have partnered with Materialise, using its 3D printing software and services to improve the efficiency and outcomes of these extensive and often costly trials that help bring innovations to market.

Enhanced patient screening and patient planning improve efficiency and outcomes of clinical trials

With Materialise's 3D imaging and printing solutions, surgeons have more tools now to analyse patient data for enrolment in clinical trials. Once patients have been selected, medical professionals can use 3D-printed, patient-specific anatomical models to develop surgical plans and workflows for the preparation and treatment of complex cases, resulting in a positive impact on patient care.

For medical device developers, 3D printing provides a more efficient process for prototypes and medical-device manufacturing, allowing developers to create trial-ready devices, either at the point of care or through Materialise's 3D printing services.

Materialise works very closely with hospitals and medical device companies to explore opportunities to assist in complex, innovative medical procedures. By working with them to leverage 3D printing for more effective and efficient

clinical trials, Materialise is helping them bring innovative devices and procedures to market and improve care for patients.

Working with a trusted partner

The use of 3D imaging to accurately screen patients, as well as 3D-printed anatomical models to plan for the procedure, will allow hospitals to have more tools to determine the patient's enrolment criteria for trials and future procedures. By implementing Materialise software, hospitals will be able to scale their 3D printing solutions, knowing they are working with a trusted partner in the medical device field.

Meeting the rigorous criteria of evidence-based medicine would not only accelerate the adoption of medical 3D printing, but it would also help to bring this technology to more patients who have no access to medical 3D printing.

Materialise, a leader in software solutions and 3D printing services in the medical and industrial markets, helps hospitals and medical device companies differentiate themselves as innovators and leaders by developing successful clinical trials.

To find out more, please visit www.materialise.com/en/medical. To discover how you can work with us, please email mimics@materialise.com.my.

TAKING ON THE TOUGHEST HEALTH CHALLENGES TOGETHER

Discovering ways to treat life-threatening diseases, or even ways to prevent them, is complex, all-consuming and continually evolving.

The same is true of AbbVie's approach to developing medicines that attack diseases like leukaemia, debilitating neurological conditions, and chronic viruses such as hepatitis C.

For more than 20 years, AbbVie has recognised that the best science comes from the best scientists. AbbVie knows that the introduction of any new medicine is a significant milestone for patients, and that it takes collaboration over many years to develop and deliver the latest breakthroughs in healthcare treatment.

'We proactively seek out research partners, healthcare and clinical experts, industry peers, patients and patient advocacy groups, so that we can leverage our own scientific expertise to take on health challenges,' says AbbVie Australia's General Manager, Kirsten O'Doherty.

One such partnership highlights their deep commitment to scientific discovery. Joining with the Walter Eliza Hall Institute (WEHI) in Melbourne, and biotechnology partner Genentech, AbbVie embarked on a decade-long journey to better understand apoptosis, the death of cells, which occurs as a normal and controlled part of an organism's growth or development.

Scientists from all three organisations worked together tirelessly, leading to the breakthrough discovery of B-cell lymphoma 2 (Bcl-2) apoptosis, which has led to a new anti-cancer agent that binds to the BCL2 gene and stops it from working so that the cancer cells' self-destruct process can go ahead. This breakthrough has been translated into approved treatments for blood cancer. Apoptosis has since become a major focus of research around the world, with relevance not just to cancer and autoimmune diseases but, possibly, also to heart attacks and stroke.

Reinforcing that commitment to nurturing great medical science in Australia, AbbVie is eager to capture new

opportunities to forge reseach and development (R&D) partnerships, and recently recruited an industry expert to search for opportunities that will help to deliver two important outcomes: production of innovative medicines; and to make a remarkable impact on patients' lives.

'It's important to put resources into the areas that matter most – funding innovative research is one of our most strategic priorities. That's why our research efforts are balanced with external collaborations across the highest levels of industry, academia and government, and we are committed to exploring opportunities that will lead to more medical breakthroughs in the future,' says O'Doherty.

AbbVie supports collaborative partnerships by leveraging insights and strengths in bench-to-bedside R&D. Combined with leadership in commercialisation and market access, AbbVie is dedicated to bringing medical discoveries to the bedside sooner.

'We are committed to combining the best talent, thinking and resources to foster innovation on behalf of people affected by disease,' says O'Doherty. 'We have stepped up our local commitment to R&D over the years because AbbVie recognises the high quality of Australian research, and the drive of local researchers to address unmet needs.'

To find out more about AbbVie and its commitment to scientific discovery, please go to www.abbvie.com.au or call Dr Laura Issa, AbbVie Business Development, on 0448 191 812.

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We are channelling our strengths to confront huge challenges in immunology, oncology, neuroscience and virology, building our pipeline to provide solutions in therapeutic areas served by our proven expertise.

To make new solutions available to patients, we team with our scientific peers, physicians, governments and advocacy groups.

When we work together, the result is a remarkable impact on patients' lives and the healthcare systems which serve them.

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INVENTING SUPPLY CHAINS FOR PRECISION MEDICINE

DR TIM OLDHAM, EXECUTIVE LEADER, TIJAN VENTURES

Cell and gene therapies, additive manufacturing, and 'smart' medical technologies are now delivering step changes in health outcomes. They also challenge traditional notions of 'make to stock, sell and forget' supply chains. Suppliers of 'precision medicine' products need to achieve just-in-time manufacturing and complete visibility of products throughout the supply chain, and take supply chain needs into account in product design.

'Make to stock, sell and forget' supply chains prevalent today

Traditional biopharmaceutical and medical technology supply chains (from raw materials to point of care) are based on large-scale, centralised manufacturing; one-way distribution models; and one payment per product. Each participant 'makes to stock', sourcing or making inventory to meet demand. They then 'sell and forget' by shipping product to the next participant and retaining little upstream or downstream transparency. New products are introduced as just another stock-keeping unit into a one-size-fits-all supply chain.

Precision medicine challenges traditional supply chain models

This model is insufficient to deliver precision medicine. Federal Drug Administration (FDA) approval of Novartis's CAR-T product Kymriah in August 2017 is the highest-profile approval to date of a wave of autologous cell and gene therapies that could represent a US$12-billion market by 2020. Kymriah is a living cell product manufactured by genetically reprogramming a patient's own white blood cells to seek an antigen expressed on the surface of leukaemic cells.

Kymriah challenges traditional supply-chain models in several ways. It is made individually for each patient. Production is triggered by physician prescription, making manufacturing slots both competitive and 'perishable'. Starting material varies significantly from patient to patient. The high cost of manufacturing and the resultant high product costs (US$475,000) are driving new pricing models (Novartis will not charge if the patient does not respond in the first 30 days) requiring real-time, continuous visibility and tracking of patient outcomes.

Scaling out the supply chain (there are no economies of scale) from fewer than 200 pre-approval treatments to thousands of patients per year is a fearsome challenge in distributed manufacturing, as Dendreon discovered when they went bankrupt launching Provenge (a dendritic cell vaccine for prostate cancer).

Oxford Performance Materials obtained the first FDA approval for a patient-specific-additive manufactured product in 2013 (a cranial implant). More than 85 such products are now approved, offering superior fit, reduced surgery time and customisation not possible with traditional machining. Forward and backward supply-chain interactions are necessary for securing high-quality CT images collected according to strict protocols, consultation with physicians to optimise design, quality control (presenting unique validation challenges when every lot is different) and point-of-care sterilisation.

'Smart' devices and cloud computing can provide real-time monitoring of disease, enabling real-time, remote physician intervention or algorithm-driven adjustment to treatment. Examples include glucose monitoring for diabetes and implantable defibrillators for heart arrhythmia. These devices must seamlessly and continuously connect to, and share data with, suppliers, patients and clinicians. They must be

functionally 'always on' and resilient to the constant evolution and proliferation of non-regulated mobile communication devices they may use. Customers and regulators also expect robust, up-to-date cybersecurity protection against threats such as the WannaCry ransomware attack that compromised many NHS hospitals and hacking risks that led former US Vice-President Dick Cheney to disable the wireless functionality on his implanted defibrillator and the FDA to 'recall' 500,000 pacemakers.

Network approaches to new product and supply chain design required

At least four trends will emerge in supply chains of the future.

1. Products will be designed for the supply chain and all its stakeholders. For example, the enormous research effort to convert autologous cell therapies to allogeneic models will continue, despite the biological and immunological complexity, and limited success to date. Cryopreservation of starting materials and product will be deployed where possible, despite cell losses. Limited clinical centres of excellence, pre-certified by suppliers, will be permitted to administer products: drugs will require in-servicing! Flexible pricing models will be deployed to both reserve production capacity and to permit pay for results reimbursement models.
2. Supply-chain participants will be transparently connected and share data in real time. This part of the 'product' for 'smart' devices, however, will also be essential for additive manufacturing and cellular therapy. All participants need visibility to available manufacturing capacity, and the location and status of products to optimise planning of both manufacture and patient care, and to enable 'release in transit'. Electronic batch records will become easy to deploy and modify. Big data and machine learning tools will become ubiquitous to both manage the supply chain and optimise product performance.
3. Distributed manufacturing networks will be integrated with clinical care. Patient-specific products demand multiple manufacturing locations as close to the point of care as possible. Automation, miniaturisation and remote telemetry will increase. Clinical sites will adapt procedures and infrastructure to accommodate new care pathways.

4. Just-in-time supply-chain approaches will be deployed from other industries. Many of these supply-chain challenges have been partially solved elsewhere. Airlines have demanded management and pricing tools to optimise perishable capacity (seats). Tuna can be delivered fresh from Australia to Tokyo within 24 hours. Data security for online payments is almost 'plug and play'. Online retailers deploy big-data analytics solutions to optimise products and forecast demand. Limited deployment in health care has occurred (chemotherapy compounding, organ transplantation and radiopharmaceuticals), but requires further customisation. Regulators must adapt validation, release and product definition criteria to accommodate infinitely variable products with short shelf lives and batch sizes of one.

To realise the full potential of precision medicine technologies, new supply chains focused on just-in-time manufacture and full information transparency must be invented. Suppliers, users, payers and regulators all need to change to adopt these models.

Dr Oldham is a non-executive director at Acrux Ltd and Respiri Ltd and a former CEO of Cell Therapies Pty Ltd. The views and opinions expressed here are entirely his own.

Dr Tim Oldham will be speaking at AusBiotech 2017.

AusBiotech 2017
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AMGEN BIOTECH EXPERIENCE LAUNCHES IN AUSTRALIA

With 75 per cent of the fastest growing occupations now requiring STEM skills, Amgen's new science program plans to give 5000 students hands-on biotech lab experience.

On 13 September 2017, The Amgen Foundation, in partnership with the University of Sydney, announced the launch of the Amgen Biotech Experience (ABE) in Australia as part of a $10.5-million investment in science education. The project will engage an expected 5000 students and 60 teachers in New South Wales over the next three years.

The three-week in-class initiative provides intensive professional development for teachers, as well as delivering teaching materials and research-grade equipment to classrooms to help educate students about the concepts and techniques scientists use to discover and develop medicines.

As year 12 students across New South Wales prepare for their upcoming biology exam, the University of Sydney's Dr Hannah Nicholas says the expansion of ABE into Australia through the University offered invaluable hands-on learning.

'Previously, biotechnology was an optional element of HSC Biology, but now that it is a core component, we are excited to support schools in this aspect of the curriculum. Through the ABE, students will gain an understanding of the medical applications of biotechnology, with a focus on insulin,' says Dr Nicholas, who is a Senior Lecturer in Molecular Biology and the University of Sydney's ABE Site Director.

'The Amgen Biotech Experience has already been well received by schools around New South Wales participating in the pilot and it's been amazing to see the students learning so much from this experience.'

International research indicates that 75 per cent of the fastest growing occupations now require science, technology, engineering and mathematics (STEM) skills and knowledge[1]. However, Australian students' results in mathematics and science have failed to keep pace, stagnating over the past 20 years[2].

The benefits of increased access to STEM education through this innovative program extend beyond the individual teachers and students participating. Research conducted

by PwC also indicates that shifting just one per cent of the workforce into STEM roles would add $57.4 billion to Australia's GDP.[3]

Dr Nicholas says that the program supports the goals described in the National STEM School Education Strategy. 'It helps increase student STEM ability, engagement and aspiration, as well as boosting teacher capacity and STEM teaching quality,' says Dr Nicholas.

The launch of the ABE in Australia follows nearly 30 years of the program supporting high school science teachers in the United States and Europe to implement real-world biotechnology labs in their classrooms, to help their students better understand science and how it influences their daily lives.

Jackie Randles, NSW Manager for Inspiring Australia (a government-funded program inspiring Australians to lead the world in science), says that STEM jobs were projected to grow at almost twice the rate of other occupations, so

Australian schools were looking for ways to help students develop the problem-solving skills they will need to succeed.

'Participation in the Amgen Biotech Experience will help students imagine what the future workforce will be like and develop the critical thinking skills that they will need to meet the technology and innovation challenges that are transforming Australia's economy,' says Randles.

Professor Judy Anderson, Director of the University of Sydney's STEM Teacher Enrichment Academy, says that it is important to continue to support Australian teachers by providing professional development opportunities, like those offered through the Amgen Biotech Experience.

'It is important to keep teachers engaged in, and inspired by, the curriculum they are teaching, as this is reflected in their students' enthusiasm as well. The teacher training offered by the Amgen Biotech Experience is comprehensive and provides teachers with the knowledge, skills, resources and support to make a real change in their classroom teaching of science,' says Professor Anderson.

Federal MP John Alexander, Member for Bennelong, echoed his support for the launch. 'I really commend Amgen for its commitment to innovative programs like the Amgen Biotech Experience that help inspire our next generation of leaders. Initiatives like these are crucial to help our children keep pace with the rest of the world when it comes to the STEM curriculum,' says Alexander.

My Linh Kha, Managing Director at Amgen Australia, welcomed the opportunity to partner with one of Australia's leading universities to offer the program.

'The Amgen Biotech Experience has already had a positive impact on science education around the globe. Our ultimate goal is to ignite students' interest in science and its career possibilities through hands-on learning techniques, in an effort to enhance Australia's future capabilities in scientific innovation,' says Kha. 'We are proud that this program addresses all five key areas of the Australian Government's National STEM School Education Strategy.'

Recently, the Amgen Foundation also announced ABE's expansion to Canada, France, Germany, Hong Kong, Italy, the Netherlands, Shanghai and Singapore, in addition to programs already underway in the United States, Puerto Rico, the United Kingdom and Ireland. Globally, ABE is expected to reach nearly 900,000 students by 2020 in 18 regions around the world.

The Amgen Foundation's past and current commitment to ABE now reaches more than $25 million, bringing the Foundation's total commitment to STEM education to more than $125 million globally.

To learn more about ABE, visit AmgenBiotechExperience.com. To learn more about the Amgen Foundation's other science education programs, visit AmgenInspires.com.

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COMPLEMENTARY MEDICINES FOR A GOOD BILL OF HEALTH

BY JUSTIN HOWDEN, HEAD OF GOVERNMENT RELATIONS, PUBLIC POLICY AND COMMUNITY DEVELOPMENT; AND SALI MIFTARI, PUBLIC POLICY ASSOCIATE, SWISSE WELLNESS

There is no denying that our country represents the international gold standard in health care. Australians live healthier lives, with the treatments that support this good bill of health accessible across the nation. Increased individual involvement in personal health and wellbeing has also been crucial to our healthy track record. Of course, no system is perfect, but this is a well functioning one.

It's easy to see why. Underlying concerns about preventable diseases and conditions have driven the fit, unwell and those somewhere in between to seek options that enhance their wellness. Many turn to exercise and some to better diets, with mixed success. Others desperately squander time and money on 'magic bullet' solutions, only to come out poorer and none the wiser.

And the rest – in fact, 75 per cent of the Australian public – turn to proven therapeutic goods that are regulated as if they were prescription medicines. Many readers will know of the rapid growth that Australia's $4.7-billion complementary-medicines industry has undergone over recent years and are quick to recognise a number of the mainstream brands in the industry.

Much of the trust in the sector comes off the back of significant investment in the scientific validation of complementary medicines. Notwithstanding the limited government funding available for complementary-medicine research (0.06 per cent of total National Health and Medical Research Council (NHMRC) funding allocations – a small figure considering the fact that 14 per cent of all therapeutic goods purchased are complementary medicines), the industry has made substantial investments in the research and development of scientifically verified

therapeutic goods that promote wellness and align with the broader pivot towards preventative health.

Changing consumer behaviour has driven this pivot towards preventative health care. Stronger consumer desire to take ownership of personal health highlights that a proportion of the nation's problems in the health system can be attributed to a lack of policy support for preventative health. Consumers have taken to complementary medicines, predominantly through private expenditure, to improve, protect and maintain their own health due to the system's undue focus on curing and treating illness after diagnosis.

Recent discussions concerning the role of complementary medicines in the preventative health space has been informed by the Review of Medicines and Medical Devices Regulation. Chaired by Professor Lloyd Sansom AO, the panel of eminent specialists recommended that Australia's therapeutic goods framework be updated to reflect modern-day best-practice standards.

As an industry leader, Swisse advocated for common-sense and overdue reforms to the regulatory framework governing complementary medicines. With this being the first root-and-branch review of the framework since its establishment in the late 1980s, the entire process was an opportunity to ensure the regulations reflected modern-day community attitudes to preventative health and responsible advertising of therapeutic claims.

In developing recommendations to the panel, the sector recognised that the supervision of the Therapeutic Goods Administration (TGA) as a best-in-class regulator for quality, safety and effectiveness was fundamental to the deep trust that consumers held in the complementary-medicines sector. Also important was the fact that the key difference between complementary medicines and other medicines was the low risk-profile.

Therefore, the challenge for the consumer, regulator and industry alike was not to discard the whole system and start from scratch, but rather identify improvements, efficiencies and better-practice solutions that closely aligned with the framework's remit to protect consumers. The reform process, while ongoing, will certainly benefit all three of the above stakeholders.

Take the rules surrounding the advertisement of complementary medicines and how issues of noncompliance were addressed; considering the fact that internet advertisements of complementary medicines were virtually unregulated, and that pre-approval of advertisements was delegated to two different authorities (often generating inconsistent reviews), it was clear that those arrangements were no longer of sufficient standards.

Sali Miftari

Justin Howden

The solution? In the context of cross-sector moves towards self-regulation, it made sense to transfer greater compliance responsibility to the sponsor. This would be balanced by a robust set of penalties and schedules, and a more accessible complaints resolution framework, enforced by the Advertising Standards Bureau, Australian Competition and Consumer Commission (ACCC), and the TGA. The Australian Consumer Law provides adequate legislative cover, with its effectiveness proven by the successful prosecution of a well-known over-the-counter medicine for negligent advertising.

In relation to intellectual property, the consensus view within the industry was to introduce a third intermediary category under the Australian Register of Therapeutic Goods. Falling between the existing listing and registration pathways, the new Aust-E pathway would provide three-year protection to allow for investment in science and innovation, and entry to the register at a cost that is proportionate to the consumer health risk posed by complementary medicines.

Consumers expect the highest standards from complementary medicine producers. This growing industry is committed to promoting the consumer's best interests and boosting the very high standards already in place. We also want to see a more sustainable, accessible and modern health system.

The numerous policy changes championed by the industry will ensure that we preserve – and, indeed, promote – the proud culture of consumer protection in Australia. Millions of Australians trust natural health products and should be applauded for taking greater control of their own health, with our country better off for it. Consumers know what is best for them, and the industry will continue to take its lead from them.

Justin Howden will be speaking at AusBiotech 2017.

AusBiotech | 2017
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MEDICINAL CANNABIS

The future of cancer treatment

BY DR STEWART WASHER, CO-FOUNDER AND DIRECTOR, ZELDA THERAPEUTICS

It's time for the medical community to start exploring other cancer treatment options.

Existing cancer treatment is centred on chemotherapy, a generally effective anti-cancer regime that can add years to the lives of cancer sufferers. The issue is that chemotherapy cannot target specific areas, so it also kills a lot of healthy cells. This results in a host of serious side effects, such as nausea, diarrhoea, and significant weight and hair loss. Other existing therapies, such as radiation therapy and immunotherapy, also have major side effects, and are currently very expensive.

But what if cancer patients had a cost-effective treatment with minimal side effects that worked well alongside chemotherapy? A treatment option derived from a plant so effective, so ancient and so enduring that it was used by ancient Egyptians to treat malignant diseases as long as 3000 years ago?

This plant is cannabis, and far from the stereotype of 'stoners' smoking it for recreational purposes, there is clinical evidence of it working as an effective treatment in a number of areas, such as controlling chronic pain and preventing nausea in chemotherapy patients.

Companies in several countries around the world, including the United States and Canada, have been using medicinal cannabis to treat people with insomnia, eczema and even cancer for more than five years.

Our researchers at Zelda Therapeutics have been involved in looking at cannabinoids, the phytochemicals from the cannabis plant and their effects on cancer cells. What is interesting is that the cannabinoids kill the cancer cells while leaving the healthy cells alive. This potentially means fewer side effects and more effective treatment for cancer.

There are a number of leading oncologists in the United States, such as Dr Noah Federman from the University of California, who have been using cannabis medicines with their cancer patients for several years. Dr Federman uses the cannabis medicine to control the terrible nausea associated with chemotherapy treatment, and he found that a number of his patients' cancers were shrinking or had stopped growing. While this is only anecdotal evidence, he was interested enough to join the medical advisory board of Zelda Therapeutics and work with us on advancing the study of the effects of medical cannabis on certain types of cancers.

Many people who are opposed to or doubtful of the use of cannabis as a medical treatment perhaps envision medicinal cannabis patients sitting around and smoking 'joints' all day. But most patients actually seek to avoid the psychoactivity that comes with tetrahydrocannabinol (THC) – the chemical

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inside cannabis responsible for most of cannabis's psychological effects. Getting high is an adverse side effect that clinicians in this field wish to avoid with medicinal cannabis.

> Cancer patients and their families are looking with great interest at the potential of medical cannabis. This applies not only to the treatment of the side effects of chemotherapy, but also as a potential treatment of the cancer itself

As it stands, medicinal cannabis may well disrupt the underlying machinery of cancer cells and prevent their reproduction, or target cancer cells for programmed death (called apoptosis). This would not only offer a new treatment for cancer patients, but also provide a treatment that works in synergy with existing treatment solutions.

Cancer patients and their families are looking with great interest at the potential of medical cannabis. This applies not only to the treatment of the side effects of chemotherapy, but also as a potential treatment of the cancer itself; however, to convince doctors that they should use this on their patients, the missing piece of the puzzle is clinical evidence obtained from well-controlled clinical trials. These should be designed so that they are fast and economical, enabling the industry to fast track cost-effective cannabis medicines to patients in need. This will clear the way for their use on cancer patients in Australia and other international markets.

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QUARTERLY ADVANCES TO FUEL AUSTRALIAN RESEARCH AND DEVELOPMENT SECTOR

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Radium Capital has launched a new service to assist with cash flow for companies conducting research and development (R&D) under the federal government's Tax Incentive program. Currently, some companies need to wait up to 18 months to receive their refund, whereas, under Radium's service, these funds can now be accessed quarterly.

Radium Capital is a specialist funding provider offering quarterly advances to companies on their expected annual R&D tax refund, and has launched the service with the support of an initial funding pool of $US100 million from a New York fund.

Radium has invested a great deal of time and money in systemising the application and approval process, which allows us to keep the costs of providing these advances to a minimum. Working with top-tier accounting firms, Radium requires only an estimate of the expected refund, along with limited company tax information, to process the application within 48 hours.

With no repayments for the duration of the advance and security being limited to the refund itself, it is a faster and simpler way to access your refund.

By receiving the advance quarterly, with no requirement for repayments until the government refund is received, Radium can reduce the amount of working capital needed to be raised by the company, allowing money to be poured back into R&D work programs.

Radium delivers a cost-effective private-sector solution of quarterly payments. This has come after changes to the R&D funding system to provide quarterly refunds were not implemented by the federal government.

Radium Capital co-founder and Chief Executive Officer, David Weir, says Radium has already been well received by early applicants, providing much-needed cash flow and cutting the amount of overall working capital required to fund R&D programs.

'We are solving a problem [that] the industry has been calling for and the government hasn't been prepared to deliver,' Weir says.

'We are seeing strong demand for our advances, particularly from the smaller companies that are delivering amazing bang-for-your-buck R&D solutions but are always stretched for cash [...] We are able to help these companies keep the momentum of their innovation going, and we are very proud to be playing that role.'

Radium only works with top-tier Australian accounting firms, which complete an assessment of the eligible expenditure on behalf of the company and provide a 'comfort letter' to Radium to commence the process.

Radium is processing applications, and advances are available now, through a seamless online platform, with approval granted within 48 hours of providing all the required information. The only security taken is a first charge over the expected refund.

Radium Capital is majority Australian-owned, and backed by an experienced Australian management team and board of directors that have built and operated online-lending platforms for the past four years.

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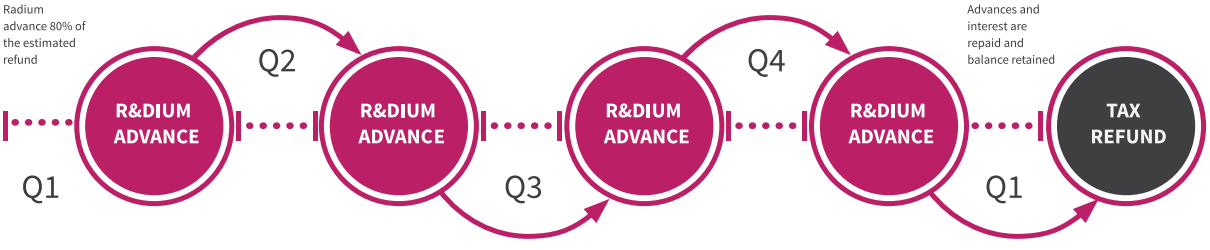

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INTEGRATING THE CLINICAL AND THE COMMERCIAL

BY JILL MCGUINN, VICE PRESIDENT, BIOTECHNOLOGY STRATEGY, INC RESEARCH/INVENTIV HEALTH

Biopharmaceutical companies must navigate a complex and fluid clinical development pathway. Commercial surprises come in the form of fast-changing payer landscapes, changes in standard of care and new forces impacting the valuation of a company portfolio.

In the past, a traditional contract research organisation (CRO) provided research and development (R&D) services. Separately, contract commercial organisations (CCOs), or standalone commercial solutions organisations (advertising, communications, consulting), provided commercialisation and life cycle management services. The separation of these services on the supply side mirrored the separation of these functions at biopharmaceuticals. As CEOs of biopharmaceutical companies are learning, cross-talk between the clinical and commercial organisations during product development has become a business necessity. It helps important medicines build in the necessary components for a robust and thorough approval to treat patients with high unmet needs.

Real-world evidence in development planning

Real-world evidence (RWE) can capture all the means to anticipate possible obstacles at the earliest opportunity, and generate the appropriate target product profile (TPP). It is important that, at the Phase II/III planning stages, there is a multi-stakeholder validated TPP and an integrated evidence plan that positions the product appropriately in the treatment paradigm 'at launch'. It is also crucial to identify the evidence gaps for not only the regulator, but also payers, patients and physicians, to remove impediments to reimbursement and maximise return on investment (ROI).

RWE is data derived from medical practice through sources such as insurance claims, patient registries and past clinical data. RWE could substitute for randomised controlled clinical trials in support of a regulatory decision.

Recently, a panel of Federal Drug Administration (FDA) and industry experts convened at the June 2017 Drug Information Association (DIA) conference to discuss this very topic. RWE based on Medicare data is being used in cardiovascular outcomes trials, with some trials costing significantly less than a typical post-marketing trial. RWE is also useful for drugs with breakthrough designation where the treatment effect is expected to be high. Here, RWE could substitute for confirmatory trials for drugs under accelerated approval.

Jill McGuinn

Industry is taking the lead on RWE and the prize for biopharmaceutical companies is reduced cost and complexity of clinical trials, and potentially the broadening of labels for approved drugs. But, as with any novel, fast-moving standard, biopharmaceutical companies need to be current on the appropriate methodologies and analytics and, most importantly, on the indications, trial designs and types of treatments for which RWE will be appropriate in early product-development planning.

Pros and cons of product strategies

Fully integrated biopharmaceutical solutions can support smaller companies in monetising their assets. Traditionally, small companies have faced the decision to proceed with funding support and/or partner their assets. What is the right strategy and when is the right time to implement it? The solutions are complex and attentive to rapidly changing funding trends, product development and pricing challenges, a competitive landscape, and regulatory and policy-rich environments.

Long-term planning during product development maximises opportunities and avoids pitfalls. A fully integrated biopharmaceutical solution could model all of the partnering scenarios to help a company understand and attain the best option to progress good science and medicines.

Jill McGuinn has more than 19 years of experience in the global pharmaceutical industry, specialising in various aspects of business development licensing and drug development.

BIOSIMILARS:

balancing access to affordable medicines with safety

BY KIM O'CONNELL, SUZY MADAR AND SARAH-JANE FRYDMAN, KING & WOOD MALLESONS

Biological medicines (biologics) are agents derived from a biological source. As a consequence, they are complex, and there is a high degree of variability between molecules of the same active substance.

Biosimilars are medicines that are closely related, pharmaceutically and therapeutically, to their reference biologic. They are not identical, nor bioequivalent, to the reference biologic as generic small-molecule drugs are bioequivalent to the innovator drug. Regulatory approval of a biosimilar involves comparability, but not bioequivalence or necessarily substitutability, with the reference product.

Australian regulatory position

In Australia, the regulatory drive in Australia towards substitution of biosimilars at pharmacy level is unique. In Australia, a sponsor of a generic product will be able to rely on safety and efficacy data relating to the originator product in order to obtain registration on the Australian Register of Therapeutic Goods (ARTG) if bioavailability studies demonstrate that the generic product is 'bioequivalent'. It is not possible, however, to demonstrate bioequivalence between a biosimilar and its reference product; it can only be 'similar' in the sense that there are no meaningful differences in terms of safety and efficacy.

In Australia, nine biosimilars have been registered on the ARTG. Two of these (infliximab and etanercept) can be substituted for the reference product by a pharmacist without any supervision by the prescribing doctor, and there is no limit on the number of times it may be substituted; a patient could receive multiple different versions of the biologic they have been prescribed. As far as the authors are aware, this position is unique to Australia.

Why is Australia unique?

The Australian regulatory position appears to reflect a strong push towards the timely uptake of biosimilar medicines. This is, of course, driven at least in part by the fact that six of the 10 most expensive PBS-listed medicines in 2015–16 were biologics, with a combined cost to the Australian Government of A$1.28 billion.[1]

Most recently, a Strategic Agreement between Medicines Australia and the Commonwealth (the Agreement) was released with the 2017–18 Budget in recognition of the potential cost benefits that biosimilars represent. The Agreement also foreshadows a move away from brand-name prescribing for both small-molecule and biologic drugs.

What is the concern?

The comparatively pro-substitution position for biologics in Australia, and the recent Agreement in particular, has attracted criticism from a range of groups, including the Australian Medical Association and the Australian Rheumatology Association, on the basis that there has been a lack of consultation with clinicians and consumers. The key concern for specialists appears to be that prescribers should retain control over whether a patient is dispensed the reference biologic or the biosimilar on a case-by-case basis. The primary concern, however, appears to be the safety of multiple switching where a patient may be switched between different versions of biologics with each script filled. Multiple switching between biosimilars may result in neutralising anti-drug bodies and a consequent loss of efficacy.

The Australian regulatory position relating to substitution of biosimilar medicines is unique. Not only is Australia the only jurisdiction in which a biosimilar may be substituted for the reference biologic by a pharmacist without prescriber supervision, it is also possible that a patient may be switched back and forward between different biologic products that are not 'bioequivalent'. Some vocal proponents of biosimilar uptake also suggest that because of inherent variance in biologic medicines, differences between batches of a reference biologic can trigger differences in immune responses.

We anticipate more regulatory activity in this area and plenty of public debate.

1 PBS Information Management Section: Pharmaceutical Policies Branch, Expenditure and Prescriptions Twelve Months to 30 June 2016, 2016 <https://www.pbs.gov.au/statistics/expenditure-prescriptions/2015-2016/expenditure-prescriptions-report-2015-16.pdf>.

POLICY'S ROLE IN BIOTECH INNOVATION

BY SUE MACLEMAN, MANAGING DIRECTOR AND CEO, MTPCONNECT

Australia is in an important time of growth and change, with innovation across all sectors at the forefront. The current acknowledgement of the importance of innovation, combined with the development and highly positive uptake of new technologies, means that we are entering an exciting period destined for strong growth, allowing us to make an incredible difference.

The medical technologies, biotechnology and pharmaceutical (MTP) sector is an increasingly important and growing sector globally. The Australian Government has seen the immense potential that we have for growth here in the Australian MTP sector. With the weight of the sector behind us, MTPConnect has been charged with making this change happen, to contribute to the sector realising its full potential.

MTPConnect, the Medical Technologies and Pharmaceuticals Growth Centre, was formed in November 2015 as part of the Australian Government Department of Industry, Innovation and Science's $250-million Industry Growth Centres Initiative to drive collaboration and innovation in Australia's MTP sector, and work with the policy frameworks in place that are supporting Australia's innovative capacity in the sector.

By addressing the key issue of information exchange, along with well-known barriers – including investment focus, skills, access to the global value chain, need for more collaboration, and the policy and regulatory impediments – that have limited the MTP sector's growth, MTPConnect is assisting our local industries to develop into global players, and take our research and development (R&D) output to the international market.

The government is supporting innovation by investing in enablers such as education, science and research,

and infrastructure; incentivising business investment; and removing regulatory obstacles such as restrictions around employee share ownership, and access to crowdsourced equity funding. Organisations, programs and strategies have been established to support and create a thriving environment for the Australian sector, with initiatives such as the Office of Innovation and Science Australia, the Biomedical Translation Fund, the Medical Research Future Fund, the CSIRO Innovation Fund, the National Collaborative Research Infrastructure Strategy, the Global Innovation Strategy, and the Accelerating Commercialisation program.

MTPConnect is playing its part through providing an independent voice, taking action, and funding projects that creatively address sector constraints and gaps, or help build capability on a national level. Our four-year $15.6-million Project Fund Program is bringing the sector together with collaborative projects that will have a true and lasting impact, boosting our capacity in areas of unmet need to strengthen the sector into the future.

One of these projects is BioFab3D@ACMD, a robotics and biomedical engineering centre. The centre is embedded within a hospital, bringing together researchers, clinicians, engineers and industry partners to work alongside each other, with a vision to build biological structures such as organs, bones, brain, muscle, nerves and glands.

Through embedding research into the clinical setting and clinical needs into the research environment, the rates of clinical breakthroughs such as the BioPen, which replaces and ultimately allows regrowth of bone, are set to increase and accelerate. Bringing together the group's scientists, clinicians and industry partners as a single, cohesive group at the point of care will enable immediacy in problem solving, give greater context to the research program and allow solutions brought by experts in the field to be enhanced by patients' real-world problems.

Another project, The Bridge Program, boasts a consortium of 14 companies, universities and industry associations aiming to transfer practical skills on pharmaceutical commercialisation through training and direct exposure to industry practitioners. At the PhD level, the IMNIS program aims to narrow the cultural gap that exists in Australia between business and academia. It is an award-winning mentoring initiative that connects PhD students with high-profile industry leaders, and has received funding via the MTPConnect Project Fund Program to facilitate national expansion.

Sue MacLeman, MTPConnect

We have also funded a clinical trial improvement initiative, based on the US model, with a vision for a whole-of-sector approach to improve the quality, efficiency and impact of clinical trials. Australia is a world-class clinical research destination that attracts a significant level of clinical trial activity, and we are working with the sector to strengthen Australia as an attractive clinical trial research destination. Our recent in-depth analysis of Australian clinical trial activity demonstrates the significance of the local industry on the world stage; up to 1360 new clinical trials were started in Australia in 2015, and Australia ranks 10th in the world for clinical trials.

Our independent voice in the sector has allowed us to take important action on a number of issues that have presented threats to the sector's ability to continue ongoing positive growth in Australia, ensuring that we have competitive, globally relevant and attractive regulatory and policy frameworks in place. We participated in the Productivity Commission's public inquiry into Australia's IP system, raising issues, and providing views and feedback from the sector to influence the recent well-received government response. We advised the government's response to the Expert Review of Medicines and Medical Devices Regulation, identifying key sector issues and consulting with the sector. We listened to, and advocated for, the sector on the R&D tax incentive, and the review of 457 visas.

Supportive policy has an invaluable role to play in ensuring Australia's success on a global scale and we will continue to advocate for the sector. We congratulate the government for supporting positive change for a fruitful environment, and we are excited to work with all of you to take advantage of the exciting opportunities coming our way.

For more information on the Australian biotechnology landscape, visit MPTConnect.org.au.

MELBOURNE: AUSTRALIA'S LEADING BIOTECHNOLOGY CITY

A conversation with Andrew Wear, Director Medical Technologies and Pharmaceuticals, Victorian Government.

Why do international companies choose Melbourne as their Australian business base?

As one of the world's leading life sciences clusters, Melbourne is a highly sought-after destination by global companies. We have a low-risk, high-quality and competitive business environment with a rich legacy of commercial success, advanced manufacturing expertise, key research and development (R&D) infrastructure, and a talented and skilled workforce.

Global companies are increasingly outsourcing early phase clinical trials to Melbourne, and there are three key reasons:

- Cost-efficiency: Australia offers attractive R&D tax incentives, including cash rebates. A cost comparison study revealed that Australia is 28 per cent cheaper than the United States before tax incentives, and 60 per cent cheaper after tax incentives.
- Speed: the clinical trial process allows flexibility without compromising quality, avoiding duplication, and saving time and money.
- Quality: Melbourne has a network of quality universities, independent medical research institutes, clinical trial networks, biobanks and contract research organisations.

With one of the most rigorous patent protection systems in the world, scientific research conducted in Australia ranks the highest in the Asia-Pacific for productivity and impact. Data can be used to support international regulatory applications, including in the United States and Europe.

Companies also have access to the Australian Government's R&D tax incentive, providing 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.

Importantly, Melbourne is also a great place to live and work, and is recognised as the world's most livable and the nation's fastest-growing city.

Melbourne is a leader in a number of key clinical and research areas. What are these?

Andrew Wear

Melbourne is one of only three cities in the world with two or more universities in the global top 30 Biomedicine Rankings[1], and in 2017, Monash University was ranked second in the world for pharmacy and pharmacology behind Harvard University[1]. Our researchers annually win more than 40 per cent of Australia's competitive medical research funding.

Melbourne's researchers, institutions and companies are improving health outcomes for people around the world, with new drugs and clinical trials in the areas of infectious diseases, cancer, regenerative medicine, respiratory disease, neuroscience, and medical technologies and device development. In the therapeutic areas of oncology and infection and immunity, Victoria has 42 companies with a combined total of more than 100 preclinical and clinical assets in development to prevent, treat and diagnose unmet clinical needs.

These discoveries and transformations in patient care and new technology development have cemented Melbourne's reputation as one of the world's best biotechnology R&D locations.

Tell us about some of Melbourne's homegrown success stories

CSL in Melbourne has grown to become one of the world's largest biotherapeutics companies, employing more than 10,000 employees in 27 countries. This year, CSL also committed to doubling its R&D presence at the University of Melbourne.

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

emergency pain relief, marketed as Penthrox®. Developed through MDI's collaboration with the CSIRO, the company has improved the delivery of the active constituent methoxyflurane and reduced its manufacturing cost. As a result, MDI has significantly increased its market value and export performance, with the green whistle now used around the world.

We are also home to Starpharma, the world-leading developer of dendrimer products, for pharmaceutical, life sciences and other applications. Starpharma's underlying technology is a type of synthetic nanoscale polymer that is highly regular in size and structure, and is well-suited to pharmaceutical and medical uses. The company is developing a number of products including its VivaGel® portfolio and DEP® drug delivery technology.

The development of the breakthrough cancer therapy venetoclax (Venclexta®) is the result of a successful research collaboration between the Walter and Eliza Hall Institute (WEHI), and companies Genentech and AbbVie. The Institute recently announced a landmark US$325-million deal for the partial sale of the rights for Venetoclax, the outcome of 30 years of research.

What do you think the role of government is in supporting and growing Melbourne's biotechnology sector?

Victoria's biotechnology sector has had intensive bipartisan support from the state government for more than two decades. This has made Melbourne Australia's leading biotechnology location.

It is our role as a government to identify gaps and take action to reduce risk so that companies can grow and thrive. The Victorian Government is providing this key support to industry and manufacturing with the delivery of its Medical Technologies and Pharmaceuticals Sector Strategy, supported by the Future Industries Fund.

Victoria's pharmaceutical capabilities are boosted by government-funded initiatives BioCurate and the Medicines Manufacturing Innovation Centre, to accelerate the development and commercialisation of new medicines. A number of Victorian medical technology and pharmaceutical manufacturers, such as MDI, IDT Australia, Baxter Laboratories and dorsaVI, have also received support to grow their businesses.

We have a strong focus on connecting our businesses and researchers with the world's best. The Victorian Government's network of 20 international offices is identifying opportunities for international businesses and institutions to partner with Melbourne-based organisations.

We are supporting Melbourne start-ups and entrepreneurs through LaunchVic, investing $60 million in the state's innovation ecosystem to give Melbourne start-ups the support they need to thrive. We are also growing entrepreneurship through support for Australia's largest medtech start-up competition, STC Australia's Medtech's Got Talent.

In Melbourne's health innovation system, you can translate your idea or discovery into a market-ready product or treatment.

For more information, visit tradeandinvestment.vic.gov.au, or contact Andrew Wear:
Email: andrew.wear@ecodev.vic.gov.au
Telephone: 03 9651 8041.

1 QS World University Rankings 2017

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BY JOANNA HILL, 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)
AtCor Medical Holdings Limited	ACG	Developr and international marketer of blood pressure at the heart device SphygmoCor	9-Nov-05	7.5	0.03	0.11	0.03	-2	-1	1	
Alchemia Limited	ACL	Drug discovery and development Fondaparinux, antithrombotic; oncology compounds FAK pathway	23-Dec-03	2.6	0.01	0.02	0.01	0	-5	1	
Acrux Limited	ACR	Transdermal drug delivery platform technology	29-Sep-04	30.8	0.19	0.38	0.18	0	-123	22	
Actinogen Ltd	ACW	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders including Alzheimer's	16-Oct-07	32.3	0.05	0.09	0.04	-1	-10	1	
Anteo Diagnostics Limited	ADO	Multi-component coatings for solid phase of immunoassays for biomarker development	7-Apr-00	20.7	0.02	0.06	0.01	-1	-2	1	
Adherium Ltd	ADR	Digital technologies – monitoring medication use in chronic respiratory conditions	26-Aug-15	15.5	0.09	0.40	0.09	-8	0	13	
Agenix Limited	AGX	ThromboView clot imaging diagnostics	2-Sep-92	4.2	0.02	0.05	0.01	-2	-1	0	
Admedus Ltd	AHZ	Tissue engineering regenerative medicine and vaccine development for herpes and HPV	24-Mar-04	67.5	0.26	0.55	0.22	-5	-5	7	
Analytica Limited	ALT	eHealth devices. PericCoach System for stress urinary incontienence	25-Oct-00	12.7	0.01	0.01	0.00	0	-4	1	
Allegra Orthopaedics Ltd	AMT	Prosthetic implants tools	5-Dec-07	13.2	0.16	0.05	0.02	1	-6	5	0
Antisense Therapeitics ltd	ANP	Antisense Pharmaceuticals. (Psoriasis, MS)	20-Dec-01	6.7	0.04	0.04	0.01	-2	2	1	
Antara Lifesiences Ltd	ANR	Natural, plant-based therapeutics for gastrointestinal diseases	16-Oct-14	68.7	1.39	1.42	0.72	-3	-40	24	
Avita Medical Ltd	AVH	Tissue-culture, regenerative products for the treatment of wounds, scars and skin defects	11-Aug-93	39.1	0.06	0.15	0.06	-2	-4	1	
Avexa Limited	AVX	R & D drugs for treatment of infectious diseases. HIVintergrase program and antibiotic-resistant bacterial infections.	29-Sep-04	10.2	0.03	2.63	0.75	-1	8	1	
AirXpanders Ltd	AXP	Aeroform tissue expander for breast reconstruction	29-Sep-04	221.5	0.77	2.63	0.75	-38	8	16	
Biotron Limited	BIT	Antiviral drug developer, HIV and HCV	24-Jan-01	7.1	0.02	0.06	0.02	-1	-2	0	
Benitec Limited	BLT	Gene silencing technology	17-Feb-97	25.6	0.13	0.28	0.09	-3	-4	10	
Botanix Pharmaceuticals Ltd	BOT	Development and commercialisation of therapeutics for bone and joint disease	24-Jan-85	18.9	0.05	0.08	0.03	-1	0	1	
Bionomics Limited	BNO	Small molecule product developer in areas of cancer, anxiety, epilepsy and multiple sclerosis	21-Dec-99	22.8	0.48	0.51	0.27	-1	-34	7	0
Brain Resource Limited	BRC	Provider of International Database for Human Brain Function	28-Aug-01	10.9	0.07	0.15	0.05	-6	-1	-4	
Bioxyne Ltd	BXN	Developer of treatments for respiratory diseases	14-Dec-00	11.7	0.02	0.03	0.01	0	-7	1	
Cellmid Limited	CDY	Midkine – novel cancer therapeutic and diagnostic target and anti-midkine antibodies with hybridoma cell lines and nucleotides	9-Dec-05	26.8	0.03	0.04	0.02	0	-6	0	

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)
Cogstate Ltd	CGS	Diagnostic and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's)	13-Feb-04	119.4	1.05	1.39	0.79	-1	0	9	
Clover Corporation Limited	CLV	Refines and supplies natural oOils	30-Nov-99	64.4	0.39	0.69	0.39	1	0	17	0.75
Cochlear Ltd	COH	Manufacturer and marketer of implants for impaired hearing	4-Dec-95	9,118.0	158.50	161.14	112.51	390	41	355	270
CSL Limited	CSL	Supplies blood products and vaccines	8-Jun-94	59,388.1	131.25	145.00	91.62	382	34	605	175.302
Cryosite Limited	CTE	Collection, processing and long-term storage of blood stem cells	9-May-02	6.1	0.13	0.20	0.13	0	27	6	0.5
Clinuvel Pharmaceuticals Limited	CUV	Developer of treatment for UV-related skin disorders. Lead drug CUV1647 in Phase III clinical trial for the treatment of polymorphous light eruption (PLE)	13-Feb-01	324.6	6.80	9.19	5.67	15	46	53	
Cyclopharm Limited	CYC	Manufacturer and distributor of radiopharmaceuticals, molecular imaging. Lead product: Technegas (lung ventilation imaging drug)	18-Jan-07	49.8	0.73	1.24	0.72	-2	-47	22	0.996
Cynata Therapeutics	CYP	Large-scale production of mesenchymal stem cells	20-Dec-07	63.0	0.70	0.81	0.37	-6	-12	1	
Dorsavi Ltd	DVL	Motion analysis device technologies for clinical, elite sports and OHS	11-Dec-13	46.1	0.28	0.60	0.25	-2	0	6	
Dimerix Ltd	DXB	Oraline' device for occupational and law enforcement multidrug tesing, and Dimeris Phase II chronic kidney disease and diabetic retinopathy	4-Feb-93	16.5	0.01	0.01	0.00	0	-4	0	
Ebos Group Ltd	EBO	Distributor of healthcare products	6-Dec-13	2,506.6	16.50	18.05	15.42	84	0	-58	51.382
Ellex Medical Lasers Ltd	ELX	Production of ophthalmic instruments for treatment of impaired vision	12-Sep-94	115.1	0.95	1.62	0.89	-1	0	29	0
Factor Therapeutics Ltd	FTT	Developer of biomedical technology in wound healing, tissue regeneration, cell culture; VitoGro platform technology enhancing cell growth and migration	19-Mar-04	43.8	0.06	0.08	0.05	-1	-8	1	
Genera Biosystems Limited	GBI	Advanced molecular diagnostic tests	11-Jun-08	16.1	0.16	0.31	0.12	-3	-5	-6	
Gi Dynamics, Inc	GID	EndoBarrier: endoscopically delivered treatement for obese type two diabetes	7-Sep-11	27.1	0.05	0.09	0.02	-254	0	17	
Genetic Technologies Limited	GTG	Genomics. Genetic technology – non-coding DNA	30-Jul-87	14.6	0.01	0.02	0.01	0	-2	0	
IDT Australia Ltd	IDT	Manufacturer of pharaceuticals and clinical trial management services	24-Sep-93	20.6	0.08	0.24	0.07	0	-27	12	
Innate Imunotherapeutics Ltd	ILL	Immunomodulator microparticle technology	23-Dec-13	8.3	0.04	1.83	0.03	-3	-1	3	
Immuron Ltd	IMC	Oral immunotherapy treatments	30-Apr-99	22.8	0.18	0.70	0.16	-6	-3	5	
Imugene	IMU	Immuno-oncology biopharma, gastric and breast cancer immunotherapies	2-Dec-93	35.5	0.02	0.02	0.01	0	-13	0	0
Impedimed Limited	IPD	Diagnostic devices: lymph oedema, muscle wasting and metabolic disorders	24-Oct-07	270.3	0.72	1.74	0.54	-7	-10	15	
ITL Limited	ITD	Innovative medical devices, blood collection and related markets	29-Oct-03	37.8	0.39	0.66	0.18	4	0	12	
Invion Ltd	IVX	Clinical-stage developer for inlammatory respiratory diseases and high blood pressure	15-Feb-10	2.9	0.00	0.01	0.00	0	0	0	
LBT Innovations Limited	LBT	Automated preparation and streaking of microbiological specimens. MicroStreak – automated routine agar plate processing	31-Jul-06	45.4	0.32	1.09	0.16	0	-67	6	
Living Cell Technologies Limited	LCT	Developer of live cell products for treatment of neurological and metabolic disorders	1-Sep-04	77.1	0.14	0.15	0.07	-1	-18	1	
Lifehealthcare Group	LHC	Critical care medical devices and implatable devices	5-Dec-13	107.0	2.40	2.56	1.83	17	14	0	13.75
MedTech Global Ltd	MDG	Healthcare software solutions, clinical management, EMR capability and consultancy services	13-Aug-87	4.7	0.05	0.15	0.05	-2	-2	1	
MediBio	MEB	Diagnostic tests for depression and other mental health disorders	29-Jan-01	56.6	0.38	0.53	0.26	-7	-5	3	

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)
Medigard Limited	MGZ	Medical safety devices. Lead products: retractable hypodermic syringes; blood collection device; IV cannula/catheter introducer device	5-Feb-04	2.3	0.03	0.03	0.01	0	-28	-1	
Medical Australia Limited	MLA	Distributor of medical devices, IV system, blood banking lab. collection of human and animal biologics	20-Dec-04	11.2	0.08	0.08	0.05	0	27	4	
Mach7 Tech Ltd	M7T	Imaging IT solutions, 3D printing and holographic projection provider	30-Nov-05	18.3	0.16	0.55	0.11	-16	-1	0	
Mesoblast Limited	MSB	Commercialisation of adult stem cell technology with specific application in the regeneration of bone and cartilage	16-Dec-04	636.0	1.38	3.41	1.06	-25	-5	13	0
Monash IVF Group	MVF	Reproductive, obstetric, gynaecological services, diagnostic and genetic testing	26-Jun-14	341.3	1.45	2.55	1.45	13	12	-39	8.8
Medical Developments International Limited	MVP	Medical and veterinary equipment. Lead analgesic agents (pre-hospital and emergency). Penthrox Inhaler.	15-Dec-03	283.1	4.80	5.58	4.12	3	155	-4	4
Mayne Pharma Ltd	MYX	Branded and generic pharma products, oral drug delivery systems and complex oral dose forms	29-Jun-07	1,134.1	0.74	2.07	0.64	6	12	5	
Nanosonics Limited	NAN	Disinfection and sterilisation technology, decontamination products to prevent spread of infections	17-May-07	789.0	2.65	3.60	2.15	9	30	24	
Neuren Pharmaceuticals Limited	NEU	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders	3-Feb-05	127.2	0.06	0.09	0.04	0	0	0	
Novogen Limited	NRT	Patents around ATM technology in cancer therapeutics	1-Sep-94	19.3	0.04	0.11	0.04	-2	0	2	0
Memphasys Ltd	MEM	Cell and protein separation systems	14-May-07	2.1	0.00	0.01	0.00	0	0	1	
OBJ Limited	OBJ	Magnetic micro-array drug delivery technologies	29-May-00	77.6	0.04	0.09	0.04	0	-14	0	0
Orthocell Ltd	OCC	Regenerative cellular soft tissue therapies for restoration of tendon, cartilage injuries	12-Aug-14	24.9	0.35	0.54	0.28	-4	-8	3	
Opthea Ltd	OPT	Biologics drugs for opthalmic diseases	18-Apr-91	156.4	0.19	0.28	0.07	-4	-30	27	
Oncosil Medical Ltd	OSL	Medical radiation treatments, OncoSil silicon and phosphorus beta emitter to be used as brachytherapy	15-Aug-05	44.8	0.09	0.14	0.08	-1	-6	2	
Osprey Med Inc	OSP	AVERT™ Plus System, to reduce dye (contrast) usage in coronary and peripheral angiographic procedures, preventing induced nephropathy (CIN). Limb Recovery™ System, percutaneous technology to deliver targeted doses of antibiotics to the lower limb in patients with diabetes.	2-May-12	142.5	0.42	0.51	0.33	-10	-4	0	
Pharmaaust Ltd	PAA	Drug developer of synthetic compounds for treatment of human and canine cancers	2-Oct-01	9.6	0.06	0.09	0.05	-1	-6	2	
Patrys Limited	PAB	Developer of natural human antibody-based therapies including cancer	13-Jul-07	15.6	0.02	0.02	0.00	0		0	
Probiotec Limited	PBP	Distributor of prescription and OTC pharmaceuticals	14-Nov-06	27.0	0.51	0.58	0.37	4	12	0	2
Prana Biotechnology Limited	PBT	Commercialising research into age-related neuro-degenerative diseases including Alzheimer's, Crutzfeldt-Jacobs, MND and Parkinson's. Lead compound PBT in Phase II clinical trials	28-Mar-00	29.9	0.06	0.12	0.04	-1	-4	4	0
PolyNovo Ltd	PNV	PolyNovo biomaterials tissue engineering and metabolic pharma	26-Nov-98	161.3	0.29	0.35	0.17	-1	0	2	
Phosphagenics Limited	POH	Vital health science. D & C patented phosphorylation technologies, nutraceuticals, dietary supplements, Vit E phosphate complex.	11-Aug-93	24.0	0.02	0.04	0.01	-1	0	0	0
Prima Biomed Ltd	PRR	Fund biotechnology research (inc. cancer immunotherapy, rheumatoid arthritis, vaccine technology preventing parasitic diseases in animals)	23-Jun-88	49.5	0.02	0.04	0.02	0	0	0	0
Prescient Therapeutics Ltd	PTX	Immunotherapeutic products for chronic infectious diseases and Co-X-Gene thechnology for cancer treatment	2-Jan-92	11.0	0.05	0.15	0.05	-1	0	4	

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AusBiotech

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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)
pSivida Corp.	PVA	Sustained-release micro-insert drug and biologics controlled delivery products	12-Jun-08	9.5	1.60	4.75	1.33	-86	-2	0	
Pharmaxis Ltd	PXS	R & D and commercialisation treatment for autoimmune and chronic respiratory diseases (inc. MS, cystic fibrosis, rheumatoid arthritis)	10-Nov-03	89.5	0.28	0.32	0.23	-6	-5	1	
Phylogica Limited	PYC	Discovery and development novel peptide therapeutics for treatment of asthma, stroke and diabetes	30-Mar-05	93.3	0.04	0.05	0.01	0	-44	0	
ResApp Health Ltd	RAP	Developer of smartphone medical app for respiratory diseases	12-Jan-05	51.4	0.08	0.55	0.06	-2	0	1	
Regeneus Ltd	RGS	Developer of adipose-derived cells with regenerative capacity for cell therapies	19-Sep-13	25.1	0.12	0.19	0.11	2	8	0	
Reproductive Health Science	RHS	Developer of chromosomal abnormality embroy testing in IVF cycles	5-Mar-87	10.3	0.12	0.30	0.05	-2	-5	2	
Resonance Health Ltd	RHT	MRI and tools for diagnosis and monitoring of liver diseases FerriScan and HepaFat	2-Jan-92	8.9	0.02	0.04	0.02	0	-26	0	
Resmed Inc	RMD	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing	25-Nov-99	14,118.0	9.93	10.43	7.15	44	23	0	12.271
Rhinomed Limited	RNO	BreatheAssist technology nasal device for sport, sleep and drug delivery	21-Sep-07	18.3	0.20	0.29	0.13	-7	-3	2	
RSH Respiri Ltd	RSH	Mobile health aplications for respiratory disorders	14-Jul-00	14.7	0.03	0.07	0.02	-1	-6	0	
Reva Medical, Inc	RVA	Bioresorbable stent products, drug-eluting coronary scaffolding treatment for cardiovascular diseases	23-Dec-10	3,03.1	0.74	1.32	0.65	132	1	-31	
Sonic Healthcare Limited	SHL	Diagnostic, pathology and radiology services	30-Apr-87	8,785.3	20.92	24.58	19.72	103	20	347	77
SciGen Limited	SIE	Development marketing sales pharmaceuticals (including Sci-B-Vac Hepatitis B vaccine)	15-Nov-02	3.4	0.07	0.07	0.01	1	13	15	
Somnomed Ltd	SOM	Specialises in products for sleep apnoea. Lead product SomnoMed mandibular advancement splint (MAS)	27-Aug-04	205.4	3.55	4.08	2.84	-6	-57	36	
Starpharma Holdings Limited	SPL	Global R & D funding for biotechnology. Commercialisation of dendrimer nanodrugs (including treatment of STD)	28-Sep-00	398.6	1.08	1.15	0.59	2	48	17	
Sirtex Medical Limited	SRX	R & D novel technology for cancer treatment (radioactive particles SIR-Spheres for liver cancer treatment)	24-Aug-00	853.9	14.80	32.16	10.45	-46	-33	244	30
Suda Ltd	SUD	Drug delivery OroMist, oro mucosal administration for off-patent drugs	24-Jan-02	25.6	0.02	0.03	0.02	0	-19	0	
Simavita Ltd	SVA	Wireless sensor technology solution for assessment of urinary incontinence in the elderly	22-Feb-14	7.1	0.02	0.09	0.02	-3	-1	1	
TBG Diagnosticas Ltd	TDL	Molecular diagnostics	22-Dec-95	29.4	0.26	0.30	0.14	-5	-3	9	
Universal Biosensors Inc.	UBI	Specialist medical in-vitro diagnostic tests for point-of-care; blood test C-reactive protein test	13-Dec-06	65.9	0.38	0.48	0.27	3	12	9	
Uscom Limited	UCM	Develop, supply and operate medical equipment – Ultrasonic Cardiac Output Monitor	10-Dec-03	19.7	0.18	0.29	0.15	-2	-11	0	
Viralytics Limited	VLA	Anti-cancer virotherapy technology using naturally occurring Coxsackievirus and Echovirus. Lead product: CAVATAK	15-Oct-86	214.2	0.89	1.35	0.78	-5	-17	16	
Virtus Health Ltd	VRT	Assisted reproductive services, diagnostics and day hospitals	11-Jun-13	434.9	5.41	8.09	4.94	35	15	-178	25
Vita Life Sciences Limited	VLS	Development and distribution of 'over the counter' medicines, complementary, alternative, dietary supplements and health foods	23-Aug-07	54.4	1.00	1.62	0.98	5	18	40	3.75

Data current at 15 September 2017. 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.

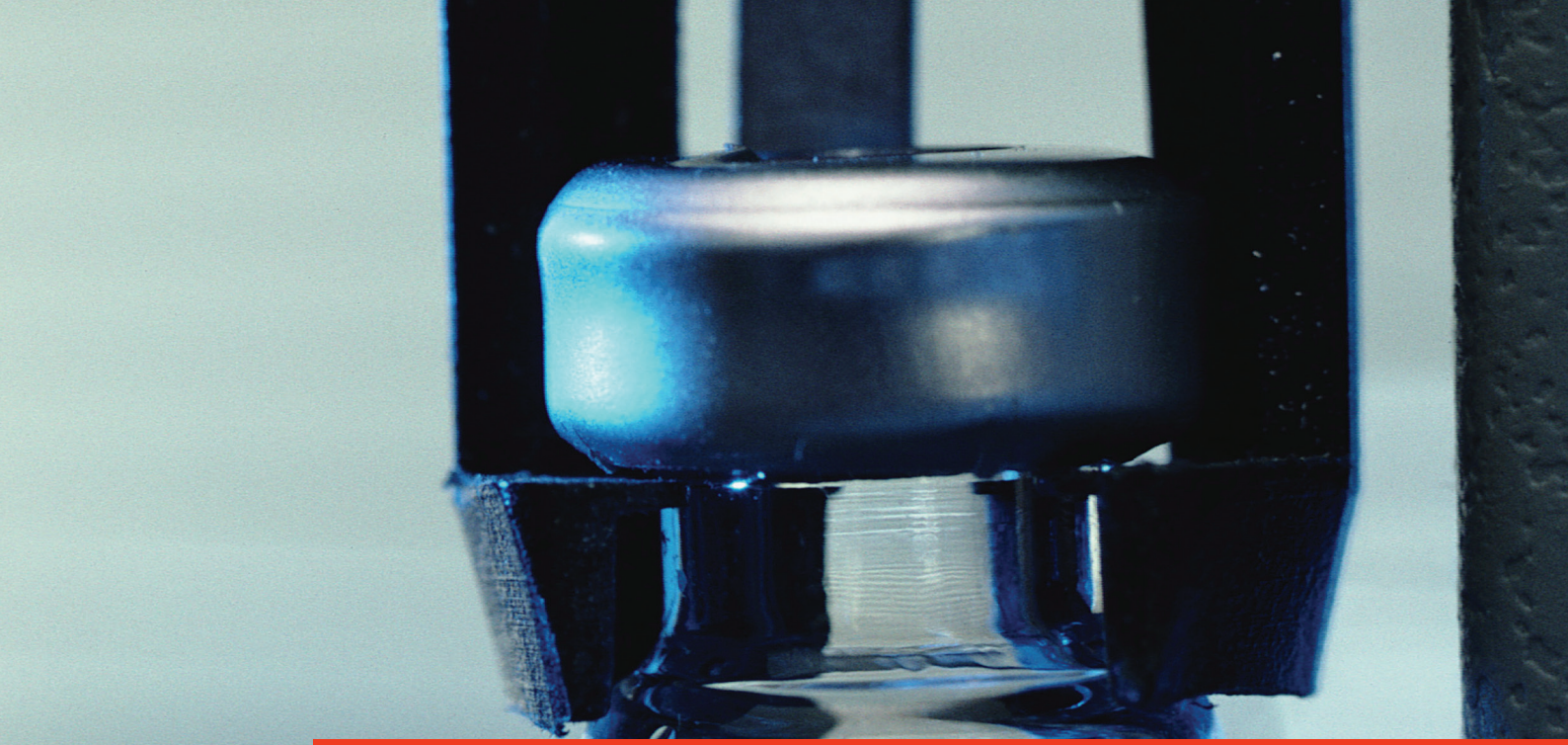
This quarter's top ASX healthcare sector performers

ASX CODE	Company Name	Last Price	Quarter Return %
PAB	Patrys Limited	$0.02	104
MGZ	Medigard Limited	$0.03	102
PNV	Polynovo Limited	$0.30	44
SPL	Starpharma Holdings	$1.08	38
POH	Phosphagenics Ltd.	$0.02	38
MLA	Medical Aus Limited	$0.08	35
ANR	Anatara Ls Ltd	$1.38	30
M7T	Mach7 Tech Limited	$0.14	29
LBT	LBT Innovations	$0.32	27
BRC	Brain Resource Ltd	$0.07	26
DXB	Dimerix Ltd	$0.01	25
ANP	Antisense Therapeut.	$0.04	24
BXN	Bioxyne Ltd	$0.02	23
PBP	Probiotec Limited	$0.52	23
LCT	Living Cell Tech.	$0.13	21
BNO	Bionomics Limited	$0.48	17
IPD	Impedimed Limited	$0.71	17
SRX	Sirtex Medical	$14.79	17
SIE	SciGen Limited	$0.07	17

This year's top ASX healthcare sector performers

ASX CODE	Company Name	Lasts Price	Year Return %
OIL	Optiscan Imaging	$0.08	110
PAB	Patrys Limited	$0.02	105
PYC	Phylogica Limited	$0.04	101
GID	Gi Dynamics, Inc	$0.05	90
ITD	ITL Limited	$0.39	77
IMU	Imugene Limited	$0.02	58
LBT	LBT Innovations	$0.32	58
BNO	Bionomics Limited	$0.48	56
MLA	Medical Aus Limited	$0.08	54
SPL	Starpharma Holdings	$1.08	48
BXN	Bioxyne Ltd	$0.02	45
CYP	Cynata Therapeutics	$0.70	41
LCT	Living Cell Tech.	$0.14	41
PHG	Pulse Health Limited	$0.47	39
UBI	Universal Biosensors	$0.38	29
BOT	Botanix Pharma Ltd	$0.05	28
CSL	CSL Limited	$131.25	26
FTT	Factor Theraptcs Ltd	$0.06	21
AMT	Allegra Orthopaedics	$0.16	20
PBP	Probiotec Limited	$0.51	19
OSP	Osprey Med Inc	$0.42	19
LHC	Lifehealthcare Grp	$2.40	18
CGS	Cogstate Ltd	$1.05	18

Data current at 15 September 2017. 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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Clintec is an award-winning full service CRO and functional service provider (FSP) expert in global clinical research, with operations in more than 80 developed and emerging countries. Clintec works with the world's best clinical experts in diverse geographical locations to deliver a unique mix of technical, operational and scientific expertise from Phase I–IV. Its 'focused, flexible, forward' approach enables it to provide precision tailored solutions for clients and deliver global trial excellence.

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Edison

Edison is an investment research and advisory company with offices in North America, Europe, the Middle East and the Asia-Pacific. The heart of Edison is its world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, research is widely read by international investors, advisors and stakeholders. Edison advisors leverages a core research platform to provide differentiated services, including investor relations and strategic consulting.

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Genome.One

Genome.One is a pioneering health information company providing genetic answers to life's biggest health questions through clinical whole-genome sequencing and analysis. It aims to enhance the lives of patients, families and communities by enabling the future of precision health care. Its portfolio of services and tools includes efficient analytical platforms for large-cohort sequencing; flexible diagnostic and prognostic genetic-testing solutions; sophisticated applications that intelligently capture clinical data; and highly accessible software interfaces.

Dr Andrew Stone, Head, Cohort Sequencing and Analytics
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Health Industries South Australia

This South Australian Government agency is a single contact point for health and life sciences companies investing in Adelaide. Staffed by business professionals, the agency understands what companies need and provides advice on grants and regulations; help accessing land; and introductions to the local life sciences community, from education and research through to venture capital and industry. Health Industries South Australia supports companies every step of the way as they establish and grow in Adelaide.

T: +61 8 8463 6191 E: healthindustries@sa.gov.au W: healthindustries.sa.gov.au

Numedico Technologies

Numedico Technologies is an Australian-based wholesaler of the ClickZip™ Needle Retractable Safety Syringe, the highest-quality manual retractable needle injectable delivery system in the Asia-Western Pacific region. Its mission is to provide access to truly functional, practical and safe medical devices. The ClickZip™ Needle Retractable Safety Syringe is a new and globally patented Swiss technology active, high-quality needle with a retraction mechanism, thus preventing needlestick injury and syringe reuse. It is ideal and safe for many applications, including large-scale immunisation programs, hospitals and medical clinic applications.

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PRAXIS Australia

PRAXIS Australia is fast becoming Australia's leading provider of education and training for the Australian human research ethics and research sectors. A not-for-profit company, PRAXIS's mission is to enhance the understanding and practice of research for the benefit of the broader community. With 1600 students enrolled in its training since its launch in late 2015, its pivotal models – HREC Essentials and Research Essentials – are innovative, affordable options, with 78 modules of online content that can be used to create tailor-made solutions for students and staff. GCP training models are Transcelerate-accredited and include online, workshop and 'Train the Trainer' models.

E: info@praxisaustralia.com.au | T: 08 8122 4576 | W: www.praxisaustralia.com.au

Prescient Therapeutics Limited

Prescient Therapeutics (ASX: PTX) is a clinical-stage oncology company developing a portfolio of novel compounds to treat a range of cancers that have become resistant to frontline chemotherapy. The company's two novel drug candidates, PTX-200 and PTX-100, are targeted therapies that address specific mutations that drive cancer and contribute to treatment resistance. Both drugs emanate from prestigious US institutions and are in clinical development in the United States.

Steven Yatomi-Clarke, CEO and Managing Director
T: +61 417 601 440 | E: steven@ptxtherapeutics.com | W: ptxtherapeutics.com

Prota Therapeutics

Prota Therapeutics is a private company developing novel probiotic oral immunotherapy to treat a range of food allergies, particularly life-threatening peanut allergies. Studies by Professor Mimi Tang at the Murdoch Childrens Research Institute support the probiotic acting as a bacterial adjuvant, reprogramming the immune response to allergens to switch off or reduce the severity of the potentially deadly immune reaction, which could lead to a long-lasting ability to tolerate peanuts.

Dr. Suzanne Lipe, CEO
E: suzanne.lipe

Therapeutic Innovation Australia

Therapeutic Innovation Australia (TIA) is the lead agent for the NCRIS 'Translating Health Discoveries' project. We support access to research facilities that can accelerate translation of discoveries from the lab to the clinic. Our members provide a wide range of quality translational services in the fields of biologics, cell therapies, small molecules, preclinical testing and clinical trials. TIA works to encourage quality accreditation in Australian research labs through its www.iqdocs.org resource.

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