

Australasian BioTechnology

Special edition:
**Investment and
funding**

Crowdsourced funding regime on its way

Medical cannabis: the investment market

Keys to attracting capital in China

Agtech and foodtech: an expanding
investment sector





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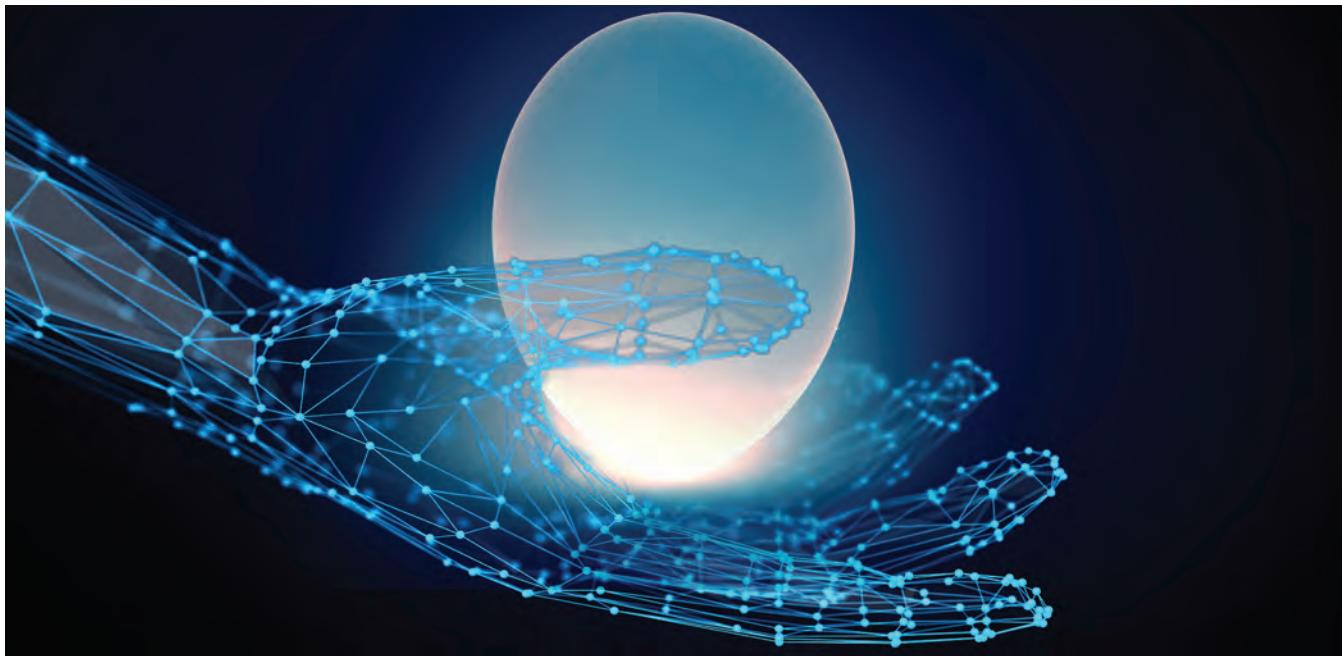
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NURTURING LIFE SCIENCES INVESTMENT TO STRENGTHEN A SECTOR OF OPPORTUNITY

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

This edition of *Australasian BioTechnology* is dedicated to an important pillar of AusBiotech's mission and strategic plan: investment in the Australian life sciences industry.

AusBiotech, as the leading organisation for the life sciences industry, seeks to foster a growing, strong and profitable life sciences industry in Australia. It is well documented that access to capital is a key challenge for emerging life sciences companies, as innovation in our sector can take up to 15 years to reach the market. AusBiotech is committed to helping companies overcome the 'valley of death' by facilitating investment in the Australian life sciences, and providing a strong investor platform that attracts investment and partnership opportunities.

AusBiotech has successfully launched its Global Investment Program, with funding from the MTPConnect Project Fund Program. This initiative aims to deliver the Guide to Life Science Investing; the development and delivery of the Roadmap to Preparing for a Successful IPO; and Pitching to Investors workshops; as well as



Julie Phillips



Glenn Cross

upscaling and enhancing AusBiotech's current global investment event series. With these tactics, AusBiotech is strengthening its position as Australia's primary facilitator of investment partnerships and consolidating effective government relationships in the life sciences.

AusBiotech was proud to announce that the past year was the strongest on record for the Australian life sciences, according to positive data from the 2017 Biotechnology Industry Position Survey. The majority of respondents described the past year as 'excellent' or 'good', and the sector raised more than \$1.3 billion in capital in 2016. We are working so that the sector's growth and success will continue in years to come.

AusBiotech remains concerned about proposed changes to the research and development (R&D) tax incentive, Australia's flagship innovation program. The incentive currently provides tax offsets for eligible research and development activity, offers increased access for international companies, and is consistently referenced as a key reason to invest in, and partner with, the Australian life sciences sector. According to the Department of Industry, Innovation and Science, more than 1250 companies registered around 3500 projects conducting life sciences research activities from 2014–15, contributing a total \$1.56 billion in R&D expenditure.

Despite the clear value of this program to the life sciences sector and its role in strengthening Australia's position globally, it has been constantly threatened by tweaks and reviews. While we were relieved to see that the 2017 May Federal Budget left the vital program intact, we expect the government to respond to the Finkel, Ferris and Fraser 2016 review of the R&D tax incentive later this year. AusBiotech will continue to advocate on behalf of its members and the broader life sciences industry to preserve the program that returns capital to innovative, value-adding Australian companies.

Australian life sciences companies have attracted more than \$2 billion in deal flow over the last 18 months, which is bolstering confidence and showing that success is not theoretical

AusBiotech will continue to advocate on behalf of its members and the broader life sciences industry to preserve the program that returns capital to innovative, value-adding Australian companies

In addition to nurturing positive policy for the life sciences sector, the first half of 2017 has been a busy period for AusBiotech. We delivered the Asian Investment Series in three key locations this year; co-organised the Australia National Pavilion with Austrade at BioKorea; co-presented AusMedtech 2017 for the first time with the International Conference on Mechanics in Medicine and Biology (ICMMB) 2017; and led the Australian delegation to the 2017 BIO International Convention in San Diego.

The Asian Investment Series drew almost 400 delegates to Singapore, Hong Kong and Shanghai to hear 21 Australian biotechnology and medical technology companies present their investment proposition. The event, made possible by the MTPConnect's Project Fund Program and held as part of AusBiotech's Global Investment Program, demonstrated strong investor interest in the life sciences. To complement these events, AusBiotech is also establishing a comprehensive database of key Asia-based investors. AusBiotech will hold the Asian Investment Series once again in 2018, and we will hold our flagship investment event, Australian Biotech Invest, in Melbourne on October 24.

Austrade Korea, in collaboration with AusBiotech, co-organised the Australian Pavilion at BioKorea, Asia's premier event for the global biotech industry. The Australian delegation included 10 biotechnology companies, which represented regenerative medicine, clinical trials and pharmaceutical sectors. This mission aimed to capitalise on the already strong foundations that exist between Australia and Korea, established through memorandums of understanding (MoUs) signed with the Korea Health Industry Development Institute (KHIDI) and Korea's Global Stem Cell & Regenerative Medicine Acceleration Center (GSRAC). Both KHIDI and GSRAC are finalising plans to attend AusBiotech 2017 in Adelaide to participate in the



Iverson Health Innovation Research Institute Launch Event attendees Aleksandar Subic, Deputy Vice-Chancellor (Research & Development); Sue MacLeman, CEO & Managing Director, MTPConnect; Stephen Tomisich, CEO & Director, Trajan Scientific and Medical; Gavin Lambert, Director, Iverson Health Innovation Research Institute; Amelia Iverson, daughter of the late Professor Iverson; Prof Linda Kristjanson, Vice-Chancellor, Swinburne University; Lynne Iverson, wife of the late Professor Iverson; and Glenn Cross, CEO, AusBiotech. The Institute honours the memory of the late Professor Don Iverson, who was the inaugural Executive Dean of the Swinburne University Faculty of Health, Arts and Design.

conference's regenerative medicine stream, along with Japan's Forum for Innovative Regenerative Medicine (FIRM).

AusMedtech 2017 & ICMMB 2017 attracted 400 delegates to Melbourne to explore the latest insights and research trends in medical devices and diagnostics. It was a privilege to have Richard Bolt, Secretary to the Department of Economic Development, Jobs, Transport and Resources, Victoria; and Yosry Morsi, Chair of ICMMB, to open the event. Conference sessions focused on challenges for medtech CEOs, provided an update on the Biomedical Translation Fund (BTF) and explored the future of digital health. Policymakers and other key stakeholders of the medtech sector reported that co-presenting AusMedtech with ICMMB provided a valuable opportunity to connect directly with researchers and discover new technologies as they emerged. All in all, AusMedtech 2017 and ICMMB 2017 signified an important step for strengthening connections between industry and academia.

In late June, AusBiotech led the Australian delegation to the 2017 BIO International Convention, which included more than 40 exhibitors in the Australian Pavilion. At BIO, AusBiotech signed an MoU with Biocom, the largest and most experienced advocate

for California's life sciences sector, to allow greater collaboration. Lorraine Chiroiu, Deputy CEO of AusBiotech, delivered the Global Innovation Hubs presentation on behalf of Australia. This was complemented by subsequent presentations by the Victorian and Queensland governments.

AusBiotech once again held its hallmark event, the Australian Wine Tasting event, gathering delegates from all corners of the exhibition hall and the globe to meet at the Australian Pavilion. Our mission to BIO was a definite success, and we look forward to leading Australian life sciences companies to this important annual global event for our sector in years to come.

As we head into the second half of the year, we encourage the life sciences community to support AusBiotech, Australia's largest industry network, in strengthening our sector. I invite you to continue your support of the organisation that works on your behalf by renewing your membership now for the 2017/18 financial year. Your support enables AusBiotech to continue to address key issues relevant to our industry, and provide platforms for growth and investment, as well as networking and educational opportunities for our members. We welcome you to get in touch with us to find out more by emailing admin@ausbiotech.org, or visiting ausbiotech.org.

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

Published by: Executive Media ABN 30 007 224 204
430 William Street, Melbourne VIC 3000 | Tel: (03) 9274 4200 | Fax: (03) 9329 5295
Email: media@executivemedia.com.au | Web: www.executivemedia.com.au

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Editor: Eden Cox
Graphic Designer: Robert Smith
All stock images from iStock.com

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INDUSTRY NEWS

Nominations open for 2017 AusBiotech and Johnson & Johnson Industry Excellence Awards

The 2017 AusBiotech and Johnson & Johnson Industry Excellence Awards are fast approaching, with entries now open to recognise the highest-achieving companies in the Australian life sciences sector.

The awards were established to recognise world-class discoveries made by Australian researchers working in the biotechnology and medical technology sectors, including researchers who have successfully translated their discoveries into clinical practices, and companies that are leading the way in the development of new treatments, devices and reliable diagnostics.

The awards that will be presented in Adelaide at AusBiotech this October include the Industry Leadership Award; Australian Company of the Year Award; and the Australian Emerging Company of the Year Award. Nominations are open to individuals and companies headquartered in Australia, and all nominations must outline why the nominees should receive the award in a statement no longer than 400 words. The closing date for nominations is 29 September 2017, with details about how to apply available on the AusBiotech conference website.

Glenn Cross, Chief Executive Officer of AusBiotech, has praised the awards, saying, 'The AusBiotech and Johnson & Johnson Industry Excellence Awards represent leading success stories in the Australian life sciences [sector]. The companies and individuals recognised by these awards have made a valuable contribution to the sector, driven by a passion for innovation and technical excellence in the life sciences'.

Support service launched for SMEs to improve understanding of TGA regulations

SME Assist, a new service for understanding Australia's regulations surrounding therapeutic goods, was launched in June by the Honourable Greg Hunt MP, Minister for Health. The service is designed to assist research and development groups working on new medicines and medical devices, as well as small to medium-sized enterprises, in understanding and keeping track of their regulatory and legal obligations.

SME Assist provides targeted regulation information that will help researchers to identify if their product is classified as a therapeutic good, and how it will be classified more specifically under the Therapeutic Goods Administration (TGA) regulation. This will allow researchers to understand not only when they are obligated to engage with the TGA, but it will also provide additional guidance in the form of information about importing, supply and manufacturing responsibilities, and information about applications for products to be assessed for marketing within Australia.

The service will also provide education and training through various webinars, presentations and face-to-face workshops, which will keep researchers and small to medium-sized enterprises up to date with regulations. The first workshop will be held in August, with topics such as sponsor obligations and manufacturing requirements on the agenda.

Currently, the five key areas of support that are offered by SME Assist include SME Assist Entry Point; education and training; decision trees and other decision-making tools; triage and improving phone and email support; and data capture. The service is set to evolve over time, in order to keep up with changes and industry requirements. 

The Vision

Novartis wanted to bring their three divisions - *Alcon*, *Novartis Pharmaceuticals* and *Sandoz* - together in Australia with a view of driving innovation and collaboration, within and across each division, and for their healthcare partners. They wanted to provide a campus-style building that not only reflected its mission as a company, but that created an ideal working environment.

Designed with the principles of activity-based working in mind, the office offers a variety of work settings enabling all associates across all levels of the company, to choose how they would like to work every day. Spaces include collaborative desks for teams to work together, a range of focus spaces for individual tasks and sit to stand desks to help with the physical health of employees.

HDR worked closely with Novartis to bring these ideas to life.

Creating Social Fabric through Architecture

The building form is an enabler for the potential of cultural uplift that is best typified by the use of the central atrium that rises through the building. As the curved timber-clad stairs wind from floor to floor, overlooking the atrium, people meet, conversations start, projects leap forward. There is a sociability and interaction generated in the atrium that met the client's brief thoroughly, whilst also creating a highly innovative environment to work in.

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AUSMEDTECH 2017 & ICMMB 2017

AusMedtech, Australia's premier medical technology conference, was co-presented for the first time with the International Conference on Mechanics in Medicine and Biology (ICMMB) from 24–25 May 2017 in Melbourne. The conference brought together

more than 400 key stakeholders of the Australian and international medical devices and diagnostics sector to explore the future of digital health, discuss challenges for medtech CEOs and receive an update on the Biomedical Translation Fund (BTF). 





1. Qiao Watkins,
QuintilesIMS

2. Cook Conference Dinner

3. Filming at AusMedtech
2017 with Bronwyn Le Grice,
Director, Fidere and Special
Advisor, BioScience Managers

4. Professor Peter Choong, Sir
Hugh Devine Chair of Surgery,
University of Melbourne
Director of Orthopaedics, St.
Vincent's Hospital, Melbourne

5. Warren Bingham, VP Asia
Pacific, Clinical Genomics;
and Lis Boyce, Partner,
DibbsBarker

6. Professor Yosry Morsi,
ICMMB Chair and Swinburne
University



The Adelaide Convention Centre is set in the heart of the City's Riverbank precinct, adjacent to BioMed City (pictured far right)

A NEW DIRECTION FOR ADELAIDE CONVENTION CENTRE

Adelaide Convention Centre (ACC), Australia's first purpose-built convention centre, will soon be reborn as Australia's newest, with the venue just weeks away from opening the doors of its new East Building – the final stage in a \$400-million expansion.

Set in the heart of the city, with expansive views of the River Torrens and surrounding Riverbank precinct, the Centre's central location is a bold reminder of the importance of conferences and events to the city, particularly in attracting thought leaders to help drive investment in South Australia's transitioning economy to high-tech industries, including defence, medical research and biotechnology.

An extension of BioMed City

The Centre sits adjacent to Adelaide's growing BioMed City, the largest in the Southern Hemisphere. The team at the ACC has worked to form a strong alliance with the precinct to support conference organisers and add value to their programs.

Adelaide Convention Centre Chief Executive Alec Gilbert says the development of BioMed City is proving a key drawcard in attracting more health and medical conferences to Adelaide.

'The Centre is working with conference organisers to help delegates connect with local thought leaders, innovative industry and research bodies, and academics, to conduct site tours, share ideas and gain access to key speakers,' says Gilbert. 'This approach is about enriching the conference experience for delegates both within the Centre and the city itself.'

The ultimate in flexibility

For conference organisers, the completion of the ACC's new East Building enables the facility to not only host much bigger events across the seamlessly integrated three buildings, but also host a number of smaller conferences and events simultaneously. The high degree of flexibility built into the expanded Centre's design and operations provides conference and event organisers with greater options.

Gilbert adds, 'The new East Building is the final stage in creating Australia's most flexible convention centre – a multi-purpose, state-of-the-art facility with plenary capacity of up to 3500 seats.'

New technologies are the hallmark of the \$400-million expansion, which will set a new benchmark in convention centre design and functionality. The delegate experience at the Centre is also more personal than many other convention centres, and being part of a relatively compact and highly accessible city makes the delegate experience more relaxed and enjoyable.'

Proud partners

The Adelaide Convention Centre is proud to partner with AusBiotech – a relationship it is keen to develop, particularly given Adelaide's strengths in the biomedical, technological and agricultural spaces. As evidence of Adelaide's emergence as a popular destination for such industries, the Centre will play host to the AusAg & Foodtech Summit, 29–30 August, and the annual AusBiotech Australia's Life Sciences Conference, 25–27 October. 

Additional information on the Adelaide Convention Centre can be found at www.adelaidecc.com.au.



A NEW DIRECTION



A proud partner of AusBiotech, the Adelaide Convention Centre is delighted to welcome delegates to the AusAg & Foodtech Summit, 29 – 30 August, and the annual AusBiotech Australia's Life Sciences Conference, 25 – 27 October.

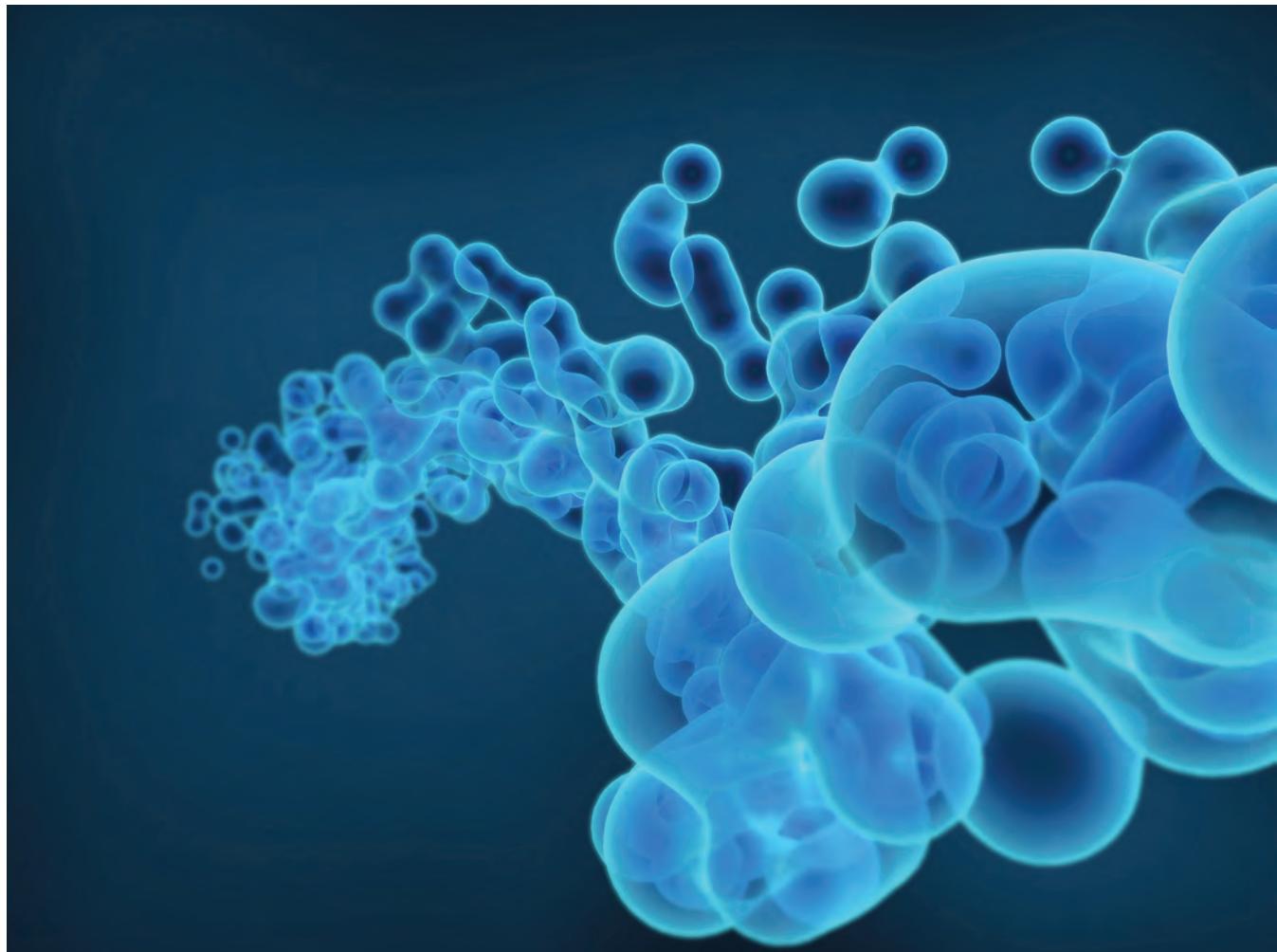
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Australia's Life Sciences Conference

At the heart of Adelaide's new medical, entertainment and cultural precincts, the Adelaide Convention Centre is one of the world's most modern, flexible and technologically-advanced conference facilities. In recent years, the City has emerged as a hub for biomedical, technological and agricultural industries, making it an ideal destination to connect with thought leaders in these fields. In August, the Centre celebrates the completion of its \$400 million redevelopment with the launch of its new East Building: a multi-purpose, state-of-the-art facility with plenary capacity of up to 3,500 seats.

For enquiries, please contact:
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ATTRACTING INVESTORS TO REALISE AUSTRALIAN LIFE SCIENCES' FULL POTENTIAL

The opportunity to invest in, and partner with, the Australian life sciences sector is stronger than ever, but greater investor participation is essential if we are to realise the full potential of cutting-edge life sciences technologies.

Innovation in Australian biotechnology has been ranked among the global top five for the third consecutive year, and industry research and development (R&D) spend is estimated at \$630 million per year. The flourishing sector is an important

contributor to the Australian economy, generating approximately \$4.4 billion in gross economic value-add and employing more than 48,000 people in medical technology, biotechnology and pharmaceutical companies.

AusBiotech's 2017 Biotechnology Industry Position Survey revealed the strongest year on record, with 72 per cent of respondents describing the past year as an 'excellent' or 'good' year.

Investment in the life sciences is evident and increasing, with the sector raising \$1.384 billion in capital in 2016, and with government programs, such as the Biomedical Translation Fund (BTF), stimulating private sector investment.

Yet, the sector needs to boost investment and funding opportunities to preserve its strong position, develop revolutionary life science technologies, and solve critical problems in health and agriculture. While retail investors and institutional players have the potential to provide valuable sources of capital, the sector's complex nature and lack of digestible information deters investors from funding life science technologies.

Australian life sciences achievements might be well known – with the cervical cancer vaccine and the Cochlear implant among the most notable – but detailed information such as terminology, time lines and regulatory frameworks are not. The challenge for capital-seeking life sciences companies is to convey their messages to investors, especially to those embarking on their first life sciences venture. By addressing communication challenges, these efforts will attract funding into the sector to increase stability and productivity, and strengthen confidence among key stakeholders. This is anticipated to generate a self-perpetuating growth cycle, demonstrating that Australian life science small and medium-sized enterprises (SMEs) are a viable investment opportunity for Australian and overseas investors.

The new AusBiotech Global Investment Program will employ a three-pronged approach to advance the quantity and quality of investment in the sector. The first component will provide private and institutional investors with information about the unique ecosystem of the life sciences sector via the publication of the 'Guide to Life Sciences Investing', and the implementation of corresponding workshops and events.

Investment in the life sciences is evident and increasing, with the sector raising \$1.384 billion in capital in 2016, and with government programs, such as the Biomedical Translation Fund (BTF), stimulating private sector investment

The program's second component will provide companies and researchers with training to attract investors through the provision of training and resource materials in the Pitching to Investors, and the Roadmap to a Successful IPO (for life sciences companies) workshops, and corresponding workshops. This will provide life sciences companies with a strategic investment strategy, insight into different funding options and opportunities to advance pitching skills.

The final component of the program will increase life sciences companies' access to global markets by upscaling AusBiotech's current Global Investment Series, the only event series striving to connect Australian life sciences companies with Asian investors. While AusBiotech has previously held investment events in Australia, Singapore and Hong Kong, the program has already supported the organisation of Australia-China Biotech Invest, held in Shanghai this year, and it will support the series' expansion to the United States and Europe.

Considered together, the three intersecting components of this program will give Australian life sciences companies a competitive advantage in attracting investment. Start-ups, SMEs and innovators with commercial-ready technology will have access to skills and insight to connect with prospective investors and bridge the notorious 'valley of death'. Specialised information regarding the life sciences sector will be readily available for prospective investors, reducing barriers to entry. This will reduce the gap between industry and investors to enable life sciences technology development, assist the preparation of products and services to market, and advance the Australian life sciences industry's economic position. These outcomes will have enormous spillover benefits for Australia, making a valuable contribution to the national economy, and improving the overall health and wellbeing of its citizens. ☺

BROKER MEETS BIOTECH

Broker Meets Biotech, run by Ausbiotech, offers listed and initial public offering (IPO)-ready companies the opportunity to present their investment case to a captive audience of brokers, investors and high-net-worth individuals. Over the past three years, audiences of up to 150 brokers and investors have attended events across Adelaide, Brisbane, Sydney and Perth to hear presentations from biotech companies across a range of industries and stages of growth. Broker Meets Biotech events are invitation only, guaranteeing that at least 75 per cent of the audience are brokers, financial advisers, investors or high-net-worth individuals.



Scott Power

To find out more about the investment landscape for Australian life sciences companies, *Australasian BioTechnology* spoke with Scott Power, Senior Analyst at Morgans Financial Limited, and supporter of Broker Meets Biotech.

What are the main things that make biotechnology companies attractive to investors, both local and international?

The main attraction of investing in the life sciences is the opportunity for high-risk return on investment; however, the long lead times to clinical success or product approval and ultimate commercialisation means there is a limited domestic and international investor audience. Also, the complex nature of many discoveries and clinical trials restrict the appeal for investors.

What business models do investors look for, and why?

The preferred business models are those that have clearly stated milestones that lead to a value creation event within three to five years. Regardless of whether it is a diagnostic, drug developer or medical device company, investors need to know the path to commercialisation or to licensing to a larger pharmaceutical or device company. All too often, Australian life sciences companies require additional funding, which can often be diluting to investors. The closer a company is to revenue generation (either product sales or licensing revenue) the more attractive it becomes to investors.

Examples of companies that have clearly stated milestones and a possible exit strategy for investors include: Neuren Pharmaceuticals (NEU) with its Fragile X Phase 2 trial now looking for a partnering opportunity; Innate Immunotherapeutics (IIL), which

is awaiting its Phase 2b results ahead of partnering or sale; Nanosonics (NAN), which is building a profitable high-level disinfection company that has expanded across a number of major regions in the world; and Volpara Health Technologies (VHT), a digital health company that has developed quality assurance measurers used at breast imaging centres and is transitioning to a SaaS revenue model.

Do you see any patterns currently emerging in the investor market?

The life sciences sector is cyclical and investor interest will wax and wane. Also, interest will be generated within sub-sectors; in the medical cannabis space, changes to regulation have created opportunities and a number of companies have benefitted from renewed interest. In late 2016, there was interest in the tele-medicine sector and a number of companies saw their market capitalisations increase significantly. We always recommend that clients approach the sector with caution, and suggest holding a core position and a position that can be traded around key milestones.

How is the Australian biotechnology IPO market looking at the moment?

The current sentiment in the life sciences sector in Australia is weak. A number of mandates have been lost by small-cap fund managers, which has reduced the appetite for more speculative investments.

What is your prediction for the biotechnology IPO market in Australia in the near future?

The second half of the year is typically a stronger period, particularly leading into Christmas. We are confident that the momentum will return to the sector in 2017, as many companies are maturing with revenue and profits in sight. ☺

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CROWDSOURCED FUNDING REGIME ON ITS WAY



BY SIMONE COLLIGNON, SENIOR ASSOCIATE, DIBBSBARKER

For early-stage or start-up life sciences companies, the path to commercialisation is often characterised by a near-constant pursuit of cash. Traditionally, funds have come from a mixture of angel, seed and sophisticated investors, as well as research grants and bank debt. However, with the federal government's crowdsourced equity funding legislation coming into effect from 29 September 2017, there will soon be another option available to some early-stage companies to bridge the funding gap.

What is crowdsourced equity funding?

Crowdsourced equity funding (CSEF) is a take on traditional 'reward' crowdfunding, which involves a fledgling business offering funders the opportunity to pledge cash in return for some sort of reward (most often a sample of the company's product, or sometimes just the 'warm, fuzzy' feeling that comes from supporting a business idea). CSEF is an extension of this model, allowing companies to seek investment from a broad group of investors whose reward is a direct equity stake in the company.

The new CSEF regime is a key part of the government's National Innovation and Science Agenda¹, which promotes CSEF as a means of removing some of the barriers that start-ups traditionally face when trying to raise capital. It is intended to serve as both a complement and a source of competition to more traditional forms of funding² by allowing eligible companies to tap directly into the retail equity market.

CSEF is an exciting development in Australia's fundraising landscape. For those in the life sciences space, CSEF may:

- Offer an alternative source of capital that can be used to 'top up' funds typically raised from other sources, including seed investors and mainstream forms of finance, such as bank debt. This may ease the pressure to go public 'too early' via an initial public offering (IPO) – a criticism sometimes levelled at companies in the life sciences space.
- Depending on a company's key product or technology, allow them to appeal directly to investors who may be looking for more from

¹ Australian Government National Innovation and Science Agenda, accessible at www.innovation.gov.au/page/access-crowd-sourced-equity-funding

² Federal Treasurer Scott Morrison, Second Reading of the Bill on 24 November 2016. The full reading is available at www.parlinfo.aph.gov.au/parlInfo/search/search.w3p.

Who is eligible for CSEF?	Initially, the regime will only be open to small, unlisted public companies – those with less than \$25 million in both consolidated gross assets and annual revenue.
How much can you raise and from whom?	Up to \$5 million in any 12-month period from 'retail' investors, who can invest up to \$10,000 per company in any 12-month period.
How is a CSEF offer made?	Companies must engage a CSEF platform holding the prescribed form of Australian Financial Services Licence. There are a number of crowdfunding platforms already operating in Australia (targeting sophisticated investors). These typically charge a flat fee to host a crowdfunding offer as well as a percentage of total funds raised.
What are the disclosure requirements?	Biotechnology start-ups have traditionally been limited to making offers to sophisticated investors or small-scale offers to retail investors, which are exempt from the onerous disclosure requirements under the Corporations Act 2001. While a CSEF offer document must still be prepared, it is expected that the level of disclosure will be far less onerous than under a traditional offer document.
What about private companies?	Given that proprietary companies make up around 99 per cent of company structures in Australia, the exclusion of private companies from the CSEF regime has attracted strong criticism. ¹ The government has responded by releasing draft legislation as part of its 2017–18 budget package that will, if passed, extend the CSEF regime to private companies. That legislation was open for public comment until 6 June 2017. Realistically, it will be some time before private companies will be able to avail themselves of CSEF.
What about converting to a public company?	The CSEF regime provides temporary relief to newly converted or incorporated public companies from certain reporting and corporate governance requirements, provided that they complete a CSEF offer within 12 months of incorporation/conversion. This temporarily removes one of the big disincentives and costs associated with operating as a public company and is intended to encourage entities to convert to take advantage of the CSEF regime. However, with the proposed extension of CSEF to private companies, the government proposes to remove these concessions for companies that convert or are incorporated as public companies after commencement of the private company CSEF legislation. Consequently, private companies keen to access CSEF as soon as possible will need to decide whether to convert to a public company to access the regime in September, or hold out for the promise of a private company CSEF regime.

their investment than mere financial return – that is, a whole new market of smaller-scale 'angel' investors. People whose lives have been touched by cancer, dementia or other devastating diseases may be more inclined to invest in companies that focus on treating those afflictions, and be more accepting of the fact that their investment is both long-term and inherently risky.

- Reduce the competitive disadvantage faced by local biotechnology start-ups compared to their counterparts in countries like the United Kingdom, the United States and New Zealand, which have had CSEF regimes in place for some time now.

That said, going down a CSEF path may not be the right choice for every start-up or early-stage company. Companies considering CSEF must decide whether or not it aligns with their business objectives, and consider the effect it may have on their ability to raise funds from other traditional sources.

How will Australia's CSEF fundraising regime operate?

Until the CSEF regulations and guidance notes from the Australian Securities and Investments Commission (ASIC) are published, exactly how the regime will operate in practice is unknown. The table above summarises what we know so far.

Key considerations for life sciences companies
For early-stage or start-up life sciences companies,

the impending arrival of the CSEF regime presents an exciting opportunity for alternative funding during a key phase in their life cycle, when costs are high and revenue streams are low or non-existent. On the downside, the long-term effects of having a large number of shareholders may raise challenges for future fundraising rounds, whether via further capital raisings or venture capital investment. Balancing the interests and demands of various classes of investors, including a potentially large number of CSEF investors, is not necessarily an easy or desirable position to be in.

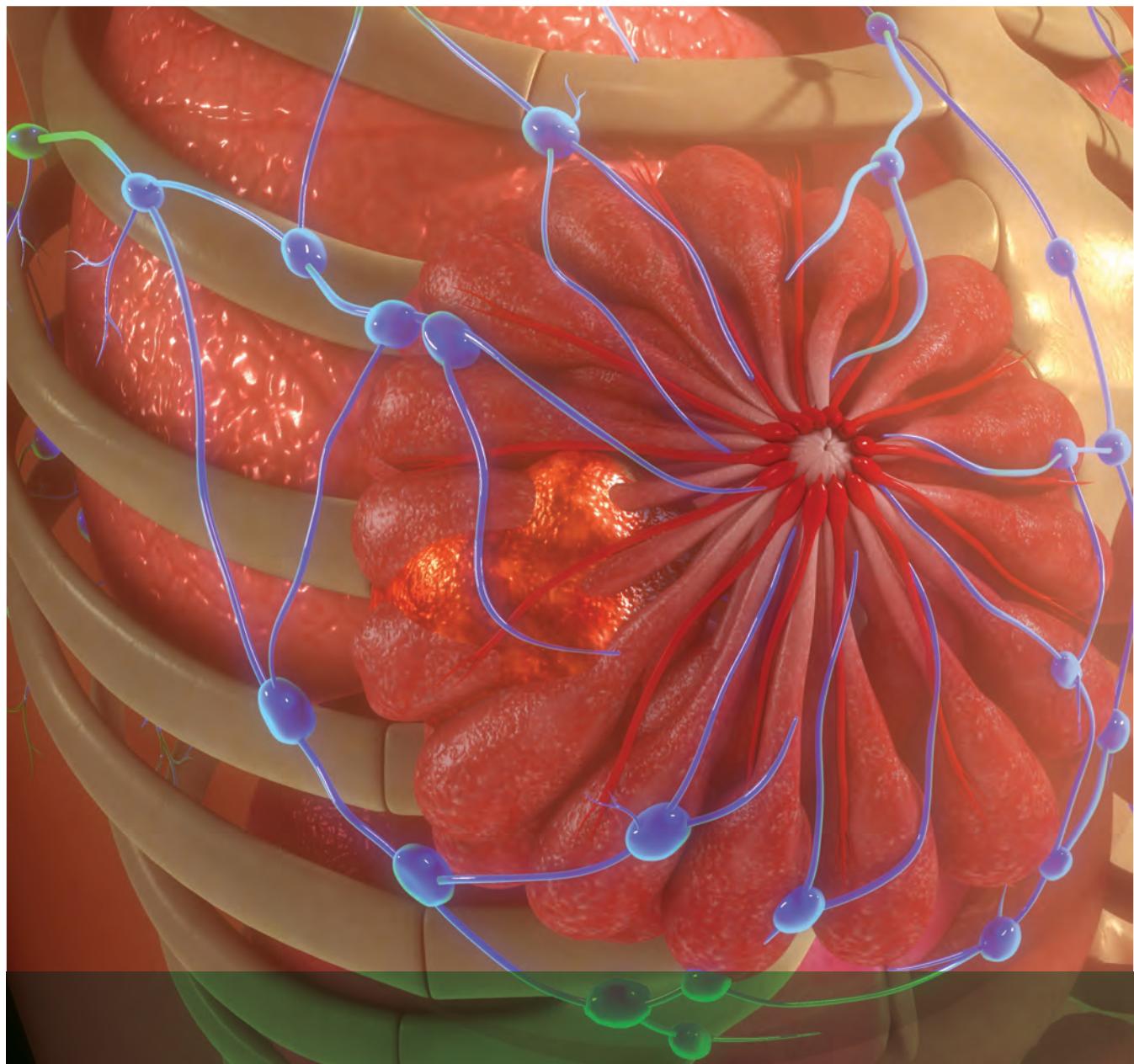
Nevertheless, for biotechnology companies considering CSEF as a viable funding option, now is the time to consider what measures they will need to take to ensure that they are ready once the CSEF framework is up and running later this year. ☺



Simone Collignon

This article contains general commentary only. It is not legal advice and must not be relied upon as such. Readers should obtain specific advice relating to their particular circumstances.

¹ 'Slow-clap for ScoMo's dodo; equity crowdfunding legislation that is already extinct', www.afr.com/technology/slow-clap-for-scomos-dodo-equity-crowdfunding-legislation-that-is-already-extinct-20170217-gufkiih.



INTERNATIONAL COLLABORATION ON CANCER TREATMENT

Imagion Biosystems Limited, an Australian medical device company with a US-based research and development operation, has just listed on the Australian Securities Exchange (ASX: IBX). The company's focus is on the development of new medical imaging products to find and eliminate cancer and other human diseases. The company is planning to do its first clinical studies here in Australia before commercially launching its medical device and undertaking global expansion.

CEO Robert Proulx, who has more than 25 years of experience in bringing life science and medical device products through development and commercialisation, says, 'We looked at listing in other jurisdictions such as Singapore, Canada and, of course, the NASDAQ, but we found the Australian stock exchange offered all the regulatory oversight of the United States, with an investor base becoming more familiar with technology companies, and without the expense of the United States.' He adds, 'Australia's friendly treatment of research and development expense through tax credits and the more favourable regulatory environment in Australia, compared to the US Food and Drug Administration (FDA), made Australia an attractive opportunity for our company.'

Most cancers are asymptomatic, growing unnoticed and undetected until the tumour has grown large enough to cause identifiable symptoms. Many of today's medical imaging methods are not sensitive enough to detect cancer in the early stages, where it would be best treated and patient survival would be improved. Additionally, they most often do not specifically differentiate malignant from benign tumours. This results in missed cancers, exploratory surgeries or biopsies, and potentially improper or unnecessary treatment, with needless patient anxiety. While newer blood-based testing, such as detection of circulating tumour cells or nucleic acids, may provide earlier identification of the presence of cancer, such blood-based testing will necessitate a complementary technology to locate and stage the disease.

The company's proprietary technologies and methods employ magnetic nanoparticles targeted towards cells associated with cancer and other diseases, and provide the ability to detect these cells using highly sensitive magnetic sensors. The technology is expected to be more sensitive than current imaging methods, as evidenced by the company's pre-clinical

research publications. Pre-clinical research projects have focused on the staging of HER2 breast cancer, the early detection and diagnosis of ovarian cancer, and the detection and diagnosis of prostate cancer.



Robert Proulx

Breast cancer is the second-leading cause of cancer-related deaths in women and the second most common cancer diagnosed in women, with approximately 20 per cent of primary tumor breast cancers being identified as HER2-positive. Following diagnosis of the primary tumour, cancer staging is usually undertaken prior to treatment and often includes assessment of lymph nodal involvement and metastases. The current method of detecting whether there is cancer metastasis in the sentinel lymph node is by extracting the node and having a pathologist examine it – a Sentinel Lymph Node Biopsy (SLNB). These procedures put the patient at risk and often result in post-operative side effects due to the removal of the lymph nodes. Additionally, a significant number of HER2-positive primary tumours have not spread to the lymph nodes, which means patients with no metastases have had surgical removal of the nodes unnecessarily. Replacing the SLNB with a non-invasive tumour-specific in-vivo detection test will eliminate unneeded surgeries, improve patient lives and reduce overall healthcare costs.

Through collaborations with the University of New Mexico and the MD Anderson Cancer Center, Imagion Biosystems Limited has been developing a HER2-positive Breast Cancer test as an alternative to SLNB as its first commercial product. Following the IPO, the company aims to leverage the highly reputable Australian cancer research and treatment institutes as well. The company's business development manager, who is based in Australia, has started to establish dialogue with the likes of the University of Sydney, Monash University, the Peter MacCallum Cancer Centre, the Victorian Comprehensive Cancer Centre and the Monash Comprehensive Cancer Consortium in the hopes of establishing formal collaborations. The company expects to undertake its first in-human trials for its lead HER2 breast cancer test within the next 18 months, and is looking to see if it can be done in Australia. ☺

REMOVING THE AIR LOCK IN THE PIPELINE OF INNOVATION

BY PROFESSOR FRANK GANNON, DIRECTOR AND CEO, QIMR BERGHOFER MEDICAL RESEARCH INSTITUTE



Australia is excellent at medical and healthcare research. We rank as one of the best in the world for the quality of research we publish in peer-reviewed journals. We have, however, unfortunately fallen behind when it comes to converting the knowledge we generate into practical outcomes that will benefit the community. It is as if there is an air lock in the pipeline; there is an abundance of oil in the tank, but a blockage in the connecting pipe means that the flame is only flickering instead of burning strongly.

This 'Australian paradox' is frustrating to those who fund research and who expect that the work being done in our busy laboratories will produce jobs, economic growth, and health benefits for the community. It should be acknowledged that there are indirect benefits to this knowledge-based 'discovery' research we are so good at. For example, QIMR Berghofer was ranked in the top 10 institutions in the world for generating publications that were cited by others in patents. We did not know that our cutting-edge research defined new commercial prospects for others.

A number of attempts are being made to address the Australian paradox. For example, the language used in government strategies, and changes to the way in which infrastructure funding is allocated to universities, are two attempts to bring about change. But these measures alone will not lead to a change in practice unless there is also a shift in culture and certain practices within the research sector. As Nilofer Merchant wrote in the *Harvard Business Review*, culture will always trump strategy.

Medical research institutes (MRIs), such as QIMR Berghofer, exist solely to improve the community's health through scientific research. Knowing that this is our very reason for being, MRIs often declare that we 'translate research' and move research 'from bench to bedside'; however, these pithy statements are oversimplified. The reality is that even the most inspired and promising medical research isn't automatically translated into a new therapy or diagnostic tool. MRIs have to take deliberate steps to make this happen, and there are a number of traps we can fall into that impede the translation of research.

The first trap we have identified seems obvious: to translate research, you need to have something to translate. The research performed has to do more than just provide an understanding of a disease; there must be the potential for a definable, new treatment or diagnosis to be developed. This is the first pitfall for Australia's medical research. Most of this country's high-quality research simply provides new insights into some very specific aspect of human biology. The extrapolated message is that this is relevant because it shows what can potentially go wrong, resulting in disease. But usually, the follow-up research does

not pursue that path. That is left to 'others'. The product of this research tends to be knowledge, as represented by publications, rather than a new treatment or diagnostic test. It follows that we are producing high-quality research that too often has low consequences for the community. When this is the norm, it is difficult to change. The question of getting investment for the great new insight rarely arises, as the focus is on getting even more detailed insights that will lead to another well-received publication. The first trap is therefore staying stuck in the discovery stage of research. Getting investment at that stage has been difficult since the demise of the de' Medicis.

Sometimes, researchers are willing to move from new knowledge to a useful product. This is where the second trap can become evident. The individual who had the brilliance to make the discovery may not have the persistence to translate it. Usually, when a scientist establishes a potentially useful insight, the required experiments have not yet been converted into a robust, industry-standard proof of reproducibility. Many pre-clinical experiments are needed to provide confidence that the treatment can be delivered, and to attract the interest of business. The scientist who is expert at expanding the limits of knowledge is not always motivated to engage in the more repetitive work needed to add robustness to the brilliant discovery. This mismatch can give rise to a confusing situation and conversation for a prospective investor.

Even if the scientist is willing to put resources into confirming and consolidating the initial discovery, a third and related trap is that funding for the continuing research is competitive, and not always compatible with research translation. Today in Australia, most funding comes from the National Health and Medical Research Council (NHMRC) and to secure this funding, scientists have to publish papers. Securing funding means a scientist can retain their staff and perform the next series of discovery studies, which will allow them to publish more great papers and boost their reputation. Their salaries also depend on this funding, which is obtained through a highly competitive process.

The decisions on grant applications are made by other scientists, and hence, individuals with the same mindset. This means that submitting papers to journals inevitably takes precedence in the laboratory

‘ We recognise that today, individual projects are generally too early and risky for an investor, but we believe there is opportunity for investment in a portfolio of projects. When we demonstrate that we have a pipeline that is flowing freely, we expect that this portfolio of opportunities will attract external interest ’

over other translational work. Only papers published in the last five years are considered as part of grant applications, so it is hard to get off the treadmill that leads to funding success. And the demands on the researcher do not stop with publications; there is the international keynote talk that has to be prepared because this is a measure of leadership. And then the reviewer of a scientist’s paper or grant application asks for more experiments to be done to satisfy a query. And so the scientist’s focus moves away from translating their earlier discovery and onto the research group’s ‘core business’, as defined by the criteria of funding bodies.

Funding has recently become available from the Medical Research Future Fund and it appears that the goal is to move research into the clinic. This will hopefully change the dynamic. The NHMRC has also recently announced changes to its funding programs, but there does not appear to have been a change in philosophy. And with the same total funding available and the same number of applicants, one can anticipate that scientists will continue to prioritise publishing quality papers in order to meet the funders’ criteria and to build their international reputations.

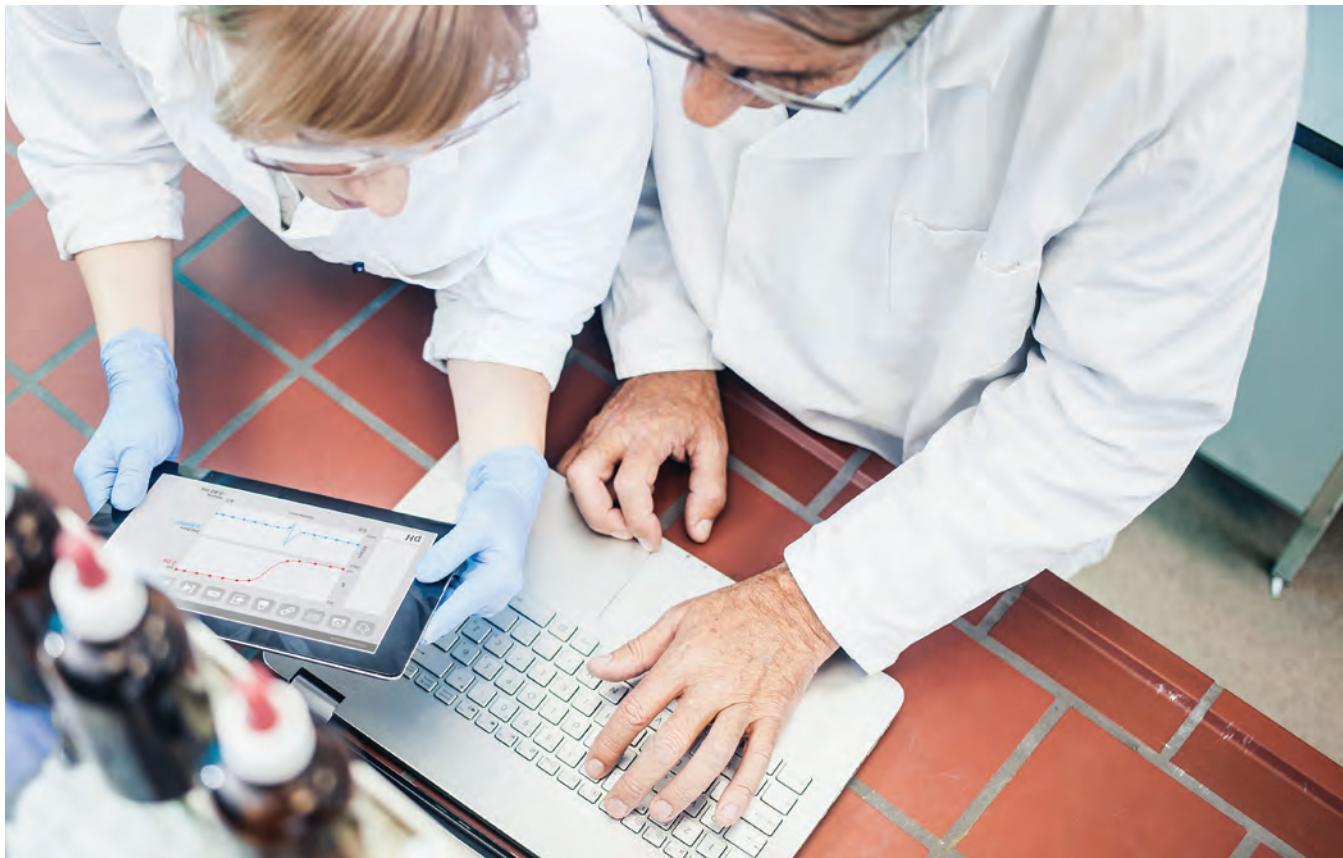
Being aware of these traps – excessive focus on discovery research, a culture that does not champion the conversion of discovery to product, and a system that rewards knowledge generation above translation – we at QIMR Berghofer have undertaken a serious assessment of our activities and have changed our processes accordingly. To avoid the first trap, we assessed whether we had the right balance between discovery research and its translation in our labs. We defined the steps involved in research and plotted our activities on a grid. We found that 50 per cent of our research was in disease-related discovery. Forty-seven per cent was at various steps from identifying

a new target for a treatment or diagnosis, to getting a new drug to work on the target, and then moving into clinical translation. An almost invisible amount was disinterested basic research. We believe that this is a good balance, with most of our laboratories conducting a mixture of discovery research and moving their findings closer to, or into, the clinic.

In response to the second trap, of thinking that research findings can be moved effortlessly into the clinic, we have come up with a new mantra of B2B2B, which stands for ‘bench to business to bedside’. The ‘business’ in the middle can be a biotech or major pharmaceutical company. To get research to the point where the input of business is needed, we encourage scientists to identify early concepts or results that could one day become the basis for a new treatment or cure. We refer to this as a ‘good meal for a good idea’ because we provide a small voucher for each valid disclosure. These disclosures, and our own assessment of current research projects, provide us with a list of targets that are at an early stage but show promise. We recognise that today, individual projects are generally too early and risky for an investor, but we believe there is opportunity for investment in a portfolio of projects. When we demonstrate that we have a pipeline that is flowing freely, we expect that this portfolio of opportunities will attract external interest.

To address the related issue of more work being needed at the stage beyond the initial discovery of a new target, we have established a proof of concept fund to ensure that a critical experiment that will allow a discovery to be patented can be performed. It is essential to exercise careful judgement here, as the discovery must have some real commercial promise. This is not the place to support a broad project; a measurable outcome to a defined experimental approach is essential. To ensure that our judgement is astute, we have partnered with industry (CSL) to select the right projects and to monitor the outcomes.

To combat the third trap, of scientists’ priorities being diverted away from translating research, we have established a new entity that we call the SEEDBox®, where SEED stands for Scientific Exploitation and Entrepreneurial Development. The SEEDBox® consists of a different team working in a more biotech environment and managed by someone with



industry experience. This team works in-house with access to special equipment and assays, and works in close collaboration with the 'mother laboratory'. It is resourced to ensure that the process of translation progresses and that the research is scientifically robust. There is a time limit on projects that enter the SEEDBox® and again, we engage with experts with an industry background to ensure that our selection has a realistic chance of success.

We anticipate that the SEEDBox® will add significant value to our research projects and bring returns on the investment. The first projects are now in the SEEDBox® and we will monitor their success closely. It is too early to know if it will attract investment either to the portfolio or to individual projects. The SEEDBox® has been established at a time when federal and state plans are promoting more commercialisation, but we have not been able to find the correct funding mechanism to support the SEEDBox®, due to different eligibility requirements. Sometimes, it is because we are not a company, sometimes it is because the collective entities in the SEEDBox® do not have a single focus, and in some cases it is because we receive state funding as a statutory body.

By introducing and supporting these initiatives we have learnt much about the investments that need to be made and the structures that need to be

implemented to change our culture and the balance of our research teams' priorities. Some researchers become enthusiastic and see a career in industry or developing their own discoveries in a biotech start-up as an attractive alternative to the uncertain world of academia. We have decided to make this decision easier for those staff by establishing an Entrepreneurial Leave of Absence scheme. Under the scheme, a researcher can take a leave of absence for up to two years to work in the biotechnology sector. The scientist retains entitlements for that period and can return to the institute if the outside world is less attractive than was anticipated.

Talking about translation and innovation is easy, but doing it right – really translating or developing research that has substance, value and potential impact – requires more than that. Just as there are 'valleys of death' once a company is formed around a product, there are also traps to be avoided to move research from the bench to the bedside. We believe that an integrated series of measures is required within the organisation to avoid these traps and we have put in place actions to address them. Others have introduced, or could introduce, variations on our approach. There is a new level of commitment and understanding about what needs to change. Time will tell if we are successful.



MEDICAL CANNABIS

The current and future investment market

BY DR STEWART WASHER, EXECUTIVE DIRECTOR, ZELDA THERAPEUTICS LTD; CONSULTANT, AUSCANN LTD; CHAIRMAN, ORTHOCCELL LTD; AND DIRECTOR, CYNATA LTD

The medical cannabis industry has flourished over the last five years, as we see governments across the globe legalise its use in response to consumer demand and growing scientific evidence that cannabis is an effective treatment for a range of conditions.

Some of these conditions include chronic pain, post-traumatic stress disorder (PTSD), sleep disorders, anxiety, epilepsy, nerve pain, chemotherapy-induced nausea, Tourette syndrome and glaucoma.

Earlier this year, the peak international authority on medicine, the National Academy of Sciences and Medicine, reviewed some 100,000 studies on pre-clinical and clinical trial data around medical cannabis, and determined that there was sound evidence that cannabis works as a medicine in a number of these diseases, including for the treatment of chronic pain, multiple sclerosis (MS) spasticity and chemotherapy-induced nausea.

The market for prescription medicines is huge, with Americans spending an estimated \$40 billion on prescription medications in 2016 to treat these conditions; expenditure is forecast to grow to more than \$44 billion by 2019. In Australia, there are more than three million people suffering from chronic pain, and we have a real problem with the amount of opiates

being prescribed. Cannabis medicines have been used successfully for around five years in Canada to treat chronic pain, and the overall usage of opiates has been dramatically reduced.

Cannabis is a unique plant that contains over 100 different phytocannabinoids, which include the well-known psychotropic tetrahydrocannabinol (THC) and its dance partner, cannabidiol (CBD). These plant-derived cannabinoids bind natural receptors in the body called the endocannabinoid system that are present on the nervous system and also throughout the immune system. This is why we see a wide range of therapeutic effects, from pain control to anti-inflammatory activity, with different ratios of key cannabinoids.

The oldest known written record of medical cannabis use comes from the Chinese Emperor Shen Nung in 2727 BC, and the ancient Greeks and Romans were also familiar with the use of cannabis as a medicine. Unfortunately, the United States declared the war on drugs, with cannabis highly taxed, and then prohibited. A 1930s campaign by the US Federal Bureau of Narcotics portrayed marijuana as a powerful, addictive substance that would lead to narcotics addiction. The Controlled Substances Act (CSA) of 1970 classified marijuana, along with heroin and LSD, as a 'Schedule I' drug, meaning that it had the relatively highest abuse potential and no accepted medical use.

Today, the US recreational and medicinal cannabis market is valued at US\$3.5 billion, with approximately 65 per cent of the market attributed to patients using medical cannabis for chronic pain (IBISWorld, 2016).

The fact is that cannabis THC is a very safe drug and has been widely used by people for centuries; it is only now that the science is catching up. Pre-clinical studies show that animals can tolerate doses of up to 1000 milligrams per kilogram. This would be equivalent to a 70-kilogram person swallowing 70 grams of the drug – about 5000 times more than is required to produce a high. Despite the widespread illicit use of cannabis, there are no instances of people dying from an overdose. So, with this in mind, let's look at the potential future for cannabis as a medicine in Australia.

Many companies that have sprung up in the medicinal cannabis space are engaged in a range of activities, from growing the plants, right through to prescribing medicines for patients.

In Australia, medicinal cannabis was legalised in November 2016. Imports of medicinal cannabis have been approved to treat patients immediately until a local industry can be developed. The first Australian licences to grow medicinal cannabis and produce local medicines are being granted now.

I am proud to be involved in two Australian companies that are fast emerging as global leaders in their field. AusCann is involved in the production of high-quality clinical-grade medical cannabis medicines, and Zelda Therapeutics is building on the learnings from the experiences in the United States and Chile, where medical cannabis has been used to treat patients for a number of years. We have seen the anecdotal evidence that certain medical cannabis formulations work against a number of disease targets. This is the basis of our clinical trials to validate these cannabis medicines for widespread medical use.

AusCann Ltd (ASX: AC8) is an Australian company that has been licensed to grow medicinal cannabis in Australia and Chile, and it is focused on treating patients for chronic and neuropathic pain. There are more than three million patients in Australia that suffer from these conditions. AusCann has a partnership with Canopy Growth Corporation in Canada, the largest producer of medicinal cannabis in North America, with a valuation of more than A\$1.2 billion. Canopy is



also the major shareholder of AusCann. AusCann has expanded its operations into Chile, where it holds the only licence to grow medicinal cannabis. The Chilean Government is a leader in Latin America, with a high-quality regulatory body and health ministry.

While cannabis has been clinically validated in a number of key disease areas such as neuropathic pain, there are other opportunities where there is a good deal of anecdotal patient evidence, but a lack of high-quality clinical trial data. Areas here include insomnia, childhood epilepsy, Crohn's disease and inflammatory skin conditions.

Zelda Therapeutics Ltd (ASX: ZLD) is focused on clinical trials of specific medicinal cannabis formulations that were developed in California and Chile. The company will soon commence a clinical trial in Australia for insomnia and are getting ready to perform several clinical trials, in Chile, in autism, insomnia and eczema.

Another very interesting area for cannabis is cancer. Currently, medicinal cannabis is being used in Canada and the United States to control the side effects of cancer treatment, such as chemotherapy-induced nausea; however, there is emerging preclinical data that demonstrates the potential use of cannabis formulations to slow or stop the growth of cancer. Zelda has achieved some positive pre-clinical results with THC-rich cannabis formulations against several human breast cancer lines, including hard-to-treat triple negative cancer cell lines.

So, the future looks brighter for patients that suffer from these conditions as cannabis-based medicines become available for them. Companies in the cannabis medical space have large opportunities in front of them if they can navigate the strict legal and regulatory environment. ☀



THE OPPORTUNITY IN CHINA'S HEALTHCARE MARKET

BY ROB SCOTT, DIRECTOR, CHINA BLUESKY PARTNERS

'In the coming five years, China is expected to import \$8 trillion of goods [...] and make \$750 billion of outbound investment [...] Innovation will continue to feature prominently on our growth agenda,' says Chinese President Xi Jinping.

China is now the world's second-largest economy and Australia's most important trading partner; however, it seems that the recognition of China's importance to Australia as a key healthcare market is still a work in progress.

Ever since the 12th Five Year Plan (in 2010), health care has been a top agenda item for Chinese policymakers, with China's Central Government striving to address both inequality and domestic consumption via healthcare policy reforms. Rapid economic development, adoption of a Western diet and pollution have created a host of social and environmental health challenges for China. These include an increasing prevalence of diabetes (already 100 million) and hypertension (400 million), in addition to the three million cancer deaths annually.

China's GPs see more than 100 patients a day at an average consultation time of two minutes. So, despite growing sixfold over the past decade to more

than \$400 billion total healthcare spending, China's overburdened health system simply cannot meet the nation's health needs.

China's 200-million-strong middle class has become significantly more conscious about the importance of health, food safety and medical services. Rising wage levels has led to an increasing ability of this sector to pay for insurance, as well as Western drugs, diagnostics and medical devices, all of which are still perceived as superior to local product offerings.

Big Pharma and leading device companies like Medtronic have created billion-dollar businesses from servicing the Chinese market. The Chinese Government is pushing the health sector toward greater collaboration with international partners, with many Chinese pharma and medical device companies now actively seeking to in-license or acquire Australian health innovations, and apply these to address China's growing health concerns.

This trend is highlighted by the \$3 billion in cross-border acquisitions that have been made by Chinese firms in the Australian healthcare sector in the past 12–18 months, including Genisys Care (\$1.3 billion – China Resource Pharma), Ansell (\$600 million – CITIC) and Healthe Care (Luye Medical – \$700 million).

These join a host of smaller Chinese investments, licensing deals and partnering ventures with Australian biotechnology and medical research companies over the same period: Prima Biomed (Wuxi AppTec), QIMR (Beijing Genomics), University of South Australia (Yabao Pharma), SUDA (Eddingpharm) and Oventus (Zhuhai Medical).

Yet, very few Australian life sciences companies seek to enter this market, or even engage at all with Chinese counterparts.

So, what is holding Australia back?

Perhaps it is the belief that China is still the 'Wild West', where intellectual property is not respected; or that regulatory approval takes an inordinately long time, if it is ever achieved; or that the process of finding and assessing the 'right' partner is simply too difficult. Others cite barriers of distance, language and differences in doing business.

What many companies often fail to consider, however, is the rapid change that has occurred over the past decade. These changes have made China the largest patent-filing nation since 2015. Moreover, enforcement has dramatically improved in recent years, with win-rates for Western companies seeking protection under China's special IP courts now above 85 per cent.

The China Food and Drug Administration (CFDA) regulations have also been undergoing a complete revamp in recent years. Many rapid access mechanisms (Green Channels) now exist and are expanding for oncology, infectious disease and other areas of urgent need. CFDA has also introduced reforms over the past year for both Phase 3 and Phase 1 trial approvals, significantly contracting the waiting and approval regulatory times for both phases. In addition, CFDA has recently relaxed IVD legislation, enabling more than 100 types of tests already in use in other markets to enter the Chinese market with minimal regulatory requirements.

Many of these changes were discussed during the AusBiotech Australia-China Biotech Invest Forum held in Shanghai in March 2017. A dozen Australian biotechnology and medtech companies presented

at the event and met with senior representatives from around 150 dedicated healthcare venture capital funds, and the Chinese pharma and device sector.



Rob Scott

As the Australian participants discovered, Chinese venture capitalists (VCs) have a higher appetite for risk and significantly larger investments than their Australian counterparts. To encourage more local healthcare innovation, many VCs have teamed up with local companies to fund in-licensing and thereby increase VC funding flowing into early-stage companies entering China. The key criteria to being invested in China? To be relevant to, and engaged in, the China market.

The Australia-China Biotech Invest Forum marks the latest of a long list of initiatives undertaken by the association to help its members to better understand and gain the benefits of engaging with one of the largest and fastest-growing healthcare markets globally. Government at both the federal and state levels are also increasing their support for greater development of the China market.

In addition, there is also an established on-the-ground network of proven professionals from Australia and other markets, as well as trusted local service providers, who can offer sound advice on areas such as intellectual property protection, CFDA regulatory requirements, partner selection and venture capital funding here.

The Chinese have a proverb that states 'A good opportunity is seldom presented, and is easily lost'.

Australian life sciences companies have such an opportunity now to become part of China's phenomenal healthcare market growth story. Hopefully, we will not lose the opportunity to do so. ☺

BlueSky Partners, a Shanghai-based business advisory firm, has been assisting Australian life sciences companies to better understand and engage with the Chinese market since 2012. The firm is the co-organiser (with AusBiotech) of the Australia-China Biotech Invest Forum.

KEYS TO ATTRACTING CAPITAL IN CHINA

BY TOM ELLIS, INVESTMENT DIRECTOR, MAI CAPITAL

As an investment house with strong connections in China, we are often approached by, or are referred to, Australian biotechnology companies for potential investment. Much of what we have seen of late is really exciting, and gives us a lot of faith in the Australian biotechnology sector going forward.

The enormous opportunity that China represents for companies in this industry is no secret, and accordingly there is an increasing number of companies that wish to expand into China or attract Chinese capital.

Being firmly planted within this space, we have seen some common themes in how companies think about China, and the kinds of choices that biotechnology companies make before seeking a China expansion that can affect their attractiveness to Chinese investors.

Plans for a China expansion

The first point to consider is actually having China in mind as an initial market for expansion, not an eventual one. Often, companies will look to the United States

as the big market for initial international expansion, as it is a familiar market with a similar culture. This thought process usually comes from looking at those in the past who have had success through a US expansion, but in today's business world, China offers just as much commercial opportunity. This kind of thinking is not unique to biotechnology; we see companies from all sectors looking to expand to the familiar US market.

Wanting to expand into China is more than just saying it; China is a difficult country to successfully expand into, and doing so requires careful planning, combined with significant effort. Telling investors you want to expand into China just to convince them to fund the company can lead to many headaches down the road.

Even if you don't have plans to expand into China and you just want to attract Chinese capital, note that many Chinese investors want to invest in upcoming technologies that will help China. Having a plan to expand into China will help to align the company with these investors, and it is also where investors can add the most value to the company, often having significant contacts within China.



Tom Ellis

Protected technology/IP

When any investor looks to Australia for potential investments, often a key thing they look for is defensible technology that is significantly better than what is currently on the market, as these kinds of innovations are what the next successful companies become, operating around the initial valuable piece of technology.

This is quite fitting for biotechnology companies, as the technology and intellectual property (IP) are the core assets of the company.

Business or research

Investors need to understand that there is a real difference between investing in, a business with a clear vision and strategy that has commercial applicability, and funding research that may or may not lead to a breakthrough product; the former is favourable to investors.

Only using funds for research means that all the investor's capital is now depending on the success of one event, such as a clinical trial.

Going public versus staying private

Sometimes, we will be approached by a business that we feel is very promising, but we ultimately can't invest for one reason: the company is already publicly listed. This not only falls outside of our investment mandate, but it sits outside the mandate of the entire venture capital industry, which is the main funding source for early-stage high-growth companies.

Most early-stage private active investors prefer to invest in private companies, and use the public markets as more of an exit mechanism to gain liquidity, rather than a place to invest in directly. When you invest in a private company, the capital provided goes straight into the company's balance sheet to be used on company operations, which adds tangible value to the company.

Private investors (including Chinese investors) taking moderate to large stakes in early-stage companies

like to have some level of operational control over the companies in which they invest. Private companies make this easier; compliance requirements are lower, and less information is required to be publicly disclosed.

It's understandable that public markets are sometimes more effective to raise capital for many young biotechnology companies that lack key milestones that many private investors look for before investment, but once the capital from the IPO round has run out, it makes raising additional capital to fund operations all the more difficult for companies that are still very much considered early-stage investments.

Going from being a private company to a public one will always be there as an option for companies, but going from a public company to a private one is a less conventional process that simply makes the company a more illiquid investment.

When raising capital, companies should take a long-term view and consider what is best for the company, rather than focus on the short-term and take the easiest source of capital available.

All of this is not to suggest that Chinese capital will only flow to private companies with patented technology expanding to China; there is plenty of Chinese capital available that is simply looking for attractive investment returns. If you do attract some Chinese investors to your company, you should look at your investors as more than just capital, particularly at earlier stages. Having an open dialogue with investors, and being approachable and open to feedback, is critical to curating good investor relations.

When your company is small and your human resources are limited, the right investor can be a strong partner that creates opportunities that would otherwise not have been found. ☺



Brigitte Smith

THE NEUROVANCE TRANSACTION

BY BRIGITTE SMITH, MANAGING DIRECTOR, GBS VENTURE PARTNERS

The March 2017 acquisition of Neurovance by Otsuka represents a stand-out success for GBS Venture Partners as another major pharmaceutical company acquisition of one of its portfolio companies. With an up-front payment that delivers more than double invested capital, and a further 20 times invested capital in development and sales milestones, Neurovance is a fund maker for GBS and its investors.

The Neurovance transaction follows other successful acquisition exits for GBS and its investors – including Peplin, Chemgenex, Spinifex and Hatchtech – as well as ASX-listed initial public offerings (IPOs) – including Pharmaxis, AirXpanders and Cogstate – and NASDAQ IPOs, including Viveve Inc.

The Australian story

Neurovance is a great example of the strategy of bringing early-stage drug development candidates to Australia for early clinical development. Neurovance

was attracted to Australia because of its excellent early-stage clinical trial facilities and favourable regulatory environment, enhanced by the research and development (R&D) tax credit program. Neurovance completed human pharmacology studies including Single Ascending Dose and Multiple Ascending Dose studies on sustained release formulations required to make the drug suitable for the market in Australia, and later further tested extended release formulations of its molecules in Australia.

A little background

GBS invested in Euthymics Bioscience, a company based on molecules with simultaneous activity against serotonin, dopamine and norepinephrine for CNS disorders in May 2010. The Euthymics board determined that potential investors in, and acquirers of, Euthymics, which was initially focused on depression, were likely different from those for Neurovance, and Neurovance was spun out in December 2011.

Neurovance focused a subset of the parent's molecules on attention deficit hyperactivity disorder (ADHD). Hypothesis-driven proprietary research at Neurovance discovered and developed centanafadine (CTN), a triple reuptake inhibitor that represents a novel approach to help adults and children with ADHD. Neurovance was funded by a venture capital syndicate including GBS Venture Partners, Novartis Venture Fund, Venture Investors, Tekla Capital Management and State of Wisconsin Investment Board (SWIB). Two Phase 2 clinical trials in adults, including a Phase 2b trial, were completed by Neurovance for centanafadine, setting the stage for the start of Phase 3 trials in ADHD.

Centanafadine is a non-stimulant drug candidate that, in its development to date, has shown it may achieve comparable efficacy to stimulant drugs with a potentially lower risk of abuse.

Neurovance first completed pharmacological studies in Australia, followed by a single-arm efficacy study in patients, then an abuse liability study, and finally a placebo controlled 2b study. Armed with excellent data, the company had the ability to continue on to Phase 3 studies independently, or work with a partner.

About ADHD

ADHD is a CNS disorder marked by a persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. Some people with ADHD only have problems with one of the behaviours, while others have symptoms of both inattention and hyperactivity-impulsivity. Most children with ADHD have the combined type. ADHD symptoms often appear in childhood, and can continue through adolescence and into adulthood. Symptoms of ADHD can be mistaken for emotional or disciplinary problems or missed entirely in quiet, well-behaved children, leading to a delay in diagnosis. Adults with undiagnosed ADHD may have a history of problems at work, difficult or failed relationships, or poor academic performance.

Scientists are not sure what causes ADHD. Like many disorders, a number of factors can contribute to ADHD, such as genes, exposure to cigarette smoking, alcohol use, drug use or environmental toxins during pregnancy, low birth weight, or brain injuries. ADHD is more common in males than females. Other conditions, such as learning disabilities, anxiety disorder, conduct disorder, depression and substance abuse, are common in people with ADHD.

The lifetime prevalence of ADHD in adolescents aged 13 to 18 in the United States is nine per cent, and of those, 1.8 per cent are classified as 'severe'. In the United States, in adults aged 18 and older, the lifetime prevalence is 8.1 per cent, with the average age of onset being seven. The 12-month prevalence in US adults is 4.1 per cent, with 41.3 per cent of those being classified as 'severe.' The global market size for ADHD therapies was US\$11.2 billion in financial year 2016.

The deal

On 3 March 2017, Otsuka announced that it would acquire Neurovance. Under the terms of the agreement, Otsuka America, Inc (OAI), a subsidiary of OPC, is to provide an estimated US\$100 million in up-front payments at closing, up to \$150 million in additional payments contingent on achievement of development and approval milestones, and future additional payments contingent on achievement of sales milestones. GBS's A\$9-million investment in Neurovance from an A\$122.5-million fund has the potential to return the entire fund, and then some. 

WAITE LEADS THE WAY IN AGRICULTURAL RESEARCH

The University of Adelaide has a 130-year history of world-leading research into food, wine and agriculture, particularly at the Waite campus, which sits on 54 hectares of land bequeathed by pastoralist Peter Waite to the University of Adelaide in 1922.

The Waite is a collocated partnership of 15 complementary organisations and centres, including the CSIRO, Australian Wine Research Institute (AWRI), and the South Australian Research and Development Institute (SARDI). It is known internationally for research underpinning the breeding of crops – including cereals, legumes, almonds and native plants – the management of soils, diseases and weeds in food production, viticulture and wine production, and dryland farming systems agronomy.

With more than \$270 million worth of unique research infrastructure, more than 1500 staff and students, and annual research expenditure of more than \$120 million, the Waite Research Precinct is the largest concentration of agricultural research and education expertise in the Southern Hemisphere. The world-class research at the Waite is diverse and takes a value-chain approach.

Plant breeding

In collaboration with industry, plant-breeding programs at Waite have produced more than half of the commercially grown grain varieties in southern Australia, including varieties with improved baking characteristics for bread products, and wheat varieties for better pasta.

Molecular genetics work at the Waite has been translated into breeding technologies that are widely applied in public and private cereal crop improvement programs around the world. A recent example is the identification of two key genes that make a wild wheat variety more salt tolerant, which, when crossed into modern cereal varieties, achieve a 25 per cent increase in durum-wheat grain yield in saline soils, and have now been distributed to more than 18 countries.

The Australian Research Council Research Hub for Wheat in a Hot and Dry Climate brings together wheat researchers and Australia's three major wheat breeding companies to exploit global diversity for wheat and advanced genomic technologies for faster development of heat- and drought-tolerant varieties that make better use of nitrogen fertiliser.

Grapes and wine

With four of the leading Australian grape and wine research agencies in partnership as the Wine Innovation Cluster (WIC), nearly 70 per cent of Australia's grape and wine research capability is located at the Waite. Collectively, the WIC partners cover the entire grape and wine research, development and extension spectrum and the WIC is continuously exploring opportunities for collaborative research projects.

Waite research is improving vineyard management through the use of remote sensing technologies for identification of water and nutrient stress, and through the development of innovative digital tools for assessment of the severity and incidence of powdery mildew, or to help uncover the link between canopy size, yield and grape and wine quality. Collaborative projects with industry are investigating how the environment, and stressors such as parasites, disease and drought, influence vine performance and productivity.

Agriculture

Waite research on sustainable agricultural systems focuses on crop production and agronomy and is particularly relevant to dryland agricultural systems in Australia and overseas. International partnerships include research on biofortification, agroforestry and extension.

World-leading soil scientists work directly with industry and grower groups to investigate how soils respond to different nutrient levels, the impact of different soil-moisture regimes on plant growth, and how fertilisers can be formulated to increase nutrient levels in food crops while minimising residues. The Fertiliser Technology Research Centre team designs new fertiliser coatings that improve product storage and prevent caking and product breakdown.

Scientists from the ARC Centre of Excellence in Plant Cell Walls here at Waite are also exploring a range of potential sources of biofuel. They have discovered that a variety of sorghum growing wild in Australia has the potential to yield more than 10,000 litres of bioethanol per hectare per year.

In collaboration with the horticultural sector, Waite research is helping farmers and growers design and implement native plantings to support bees and other insect populations needed to pollinate their crops and orchards.



Food

Sensory research is a strength of the Waite, investigating not only consumer wine preferences but also other food products.

One current research project involves studying consumer perceptions and attitudes towards a range of edible insects, looking at ways of overcoming barriers to insect consumption in Australia and enhancing consumer acceptance.

Other work is investigating the traditional practices of Australian Aboriginal people in producing fermented beverages and foods. The study will improve understanding of the use of native plants and their cultural context, and it may also reveal the involvement of novel organisms unique to Australia.

Waite researchers are also partnering with local beverage companies to explore ways to use waste pulp from cider production to make spirits.

The FOODplus Research Centre at Waite works at the intersection of agriculture, food and human health – for example, developing low glycaemic index (GI) breakfast foods from a high-amylose wheat developed at the Waite campus, and studying the relationships between nutrition in pregnancy and infant development. Potatoes with less 'bad' starch, food with natural additives to boost the immune system, or baby's milk formula that more closely matches breast milk are some of the potential benefits being explored by the Adelaide Glycomics laboratory.

Innovation, facilities and capability

The Waite Research Precinct is also an important service provider to the local, national and international agricultural sector. These services include crop breeding, high-throughput phenotyping capabilities at the Plant Accelerator®, Adelaide Microscopy, seed services and genebank, soil diagnostics, wine chemistry and winemaking services, DNA sequencing and genomics services, and glycomics.

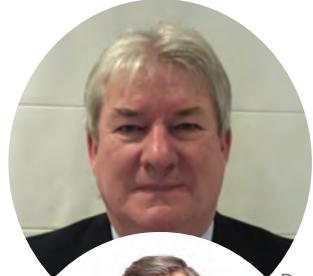
Waite research delivers outcomes of direct significance to both the Australian and global agricultural, food and wine industries. It also delivers real on-farm impacts through new varieties that perform better under Australian conditions; real industry benefits through innovative opportunities in production; and real consumer benefits through healthier food and better wine products. 

www.thewaite.org



AGTECH AND FOODTECH: AN EXPANDING INVESTMENT SECTOR

BY PROFESSOR PAUL WOOD FTSE, CHAIR AUSAG & FOODTECH ADVISORY COMMITTEE, AUSBIOTECH; AND DAVID HUDSON, MANAGING DIRECTOR, SGA SOLUTIONS PTY LTD



David Hudson



Prof. Paul Wood

The value of the agriculture sector to the Australian economy is in excess of \$60 billion, with the bulk of products – such as meat, dairy, wool and wheat – going to export markets. With the enormous challenge of global food security, it is estimated that food production will need to be increased by more than 70 per cent to meet the needs of the predicted 9.7 billion global population by 2050.

At the same time, there are significant constraints regarding the availability of new land for farming, the utilisation of water resources, and the need to manage greenhouse gas emissions, all of which are affecting the agriculture industry's ability to meet this challenge.

In 2016, investment in the global agtech market was US\$3.2 billion, with more than 670 unique investors (AgFunder, 'AgTech Investing Report – 2016'). In Australia, the federal government provides approximately \$300 million in annual funding for research in agriculture via the 15 rural development corporations (RDCs), direct support to universities, the CSIRO and the CRC program. While it is dependent on seasonal conditions, the RDCs generate a further matching \$300 million in funding through levies on production, which is used for research and development, as well as extension programs.

To date, the major private sector investments in Australian agriculture have been directed by the major banks and superannuation funds towards the acquisition of farms and rural businesses, and have shown little interest in the technology side. At the same time, investment in the commercialisation of agricultural technology innovations, especially emanating from the co-funding by the Australian Government and producers in public sector research, has been constrained by a lack of awareness and knowledge within the Australian investment sector of the value-generation opportunities that exist. Yet, a report on agtech in Australia, commissioned by StartupAUS in 2016, predicted that agriculture would become Australia's next \$100-billion industry by 2030.

In addition to the lack of awareness of the investment opportunities in the agricultural technology sector, the politically motivated moratoriums on the release of genetically modified (GM) crops has also acted to

limit development of the sector. So far, only two GM crops have been approved for growing by Australian farmers: cotton and canola. Each has generated significant economic, social and environmental benefits for supply chain stakeholders ranging from the technology developers through to farmers, and onto the broader community.

There are a wide range of agricultural technology innovations that are being developed in Australia that present unique investment opportunities because of their domestic and global application. For example, a number of Australia's research precincts are global leaders in the application of agricultural biotechnology, and the use of new breeding technologies in plant and animal production, especially where agricultural production is limited by abiotic and/or biotic stress.

Australian researchers are also leading global developments in the adaptation and application of wireless sensors, drones, robotics, predictive analytics, novel farming systems and GPS-based systems, all of which will enhance farm management and agricultural production. Food Innovation Australia Ltd (FIAL), one of the federal government's six Industry Growth Centres, is focused on helping companies in the food-manufacturing sector to access new markets and increase productivity and competitiveness. It estimates that there are more than 178,000 agriculture and food businesses in Australia, which are employing 520,000 people.

In recognition of this potential, there have been a limited number of innovative programs established in 2016, which are aimed at increasing the level of awareness in opportunities for investment in the Australian agricultural technology sector. The National Farmers' Federation (NFF) recently joined with Findex to establish SproutX, an agtech innovation hub to assist grassroots ideas to get off the ground. More than 100 people have completed the six-week accelerator program run by SproutX. Rabobank is one



There have been a limited number of innovative programs established in 2016, which are aimed at increasing the level of awareness in opportunities for investment in the Australian agricultural technology sector

making monoclonal antibodies for the management of pain in pets, which recently announced an offer of \$110 million from Zoetis and The Yield, a company focused on the use of the Internet of Things (IoT) technology, and which has raised \$6.5 million in funding from Bosch, KPMG and AgFunder.

AusBiotech, through its AusAg & Foodtech Committee, is becoming increasingly aware of the need to facilitate and create linkages between the Australian agricultural technology sector and the domestic and/or global investment sector. In recognition of this role, the AusBiotech Agtech & Foodtech Committee is organising an AusAg and Foodtech Summit in Adelaide (29–30 August). The aim of the summit is to bring together representatives from the domestic and global investment community with major agricultural technology customers, researchers and start-up companies.

The objective is to leverage AusBiotech's long history of running successful investor-focused events in the pharma and medtech sectors, and expand this into the agricultural technology sector. There are already a number of investment funds and investors dedicated to agtech from the United States, New Zealand, Singapore and Australia who have committed to attending the summit, and who will be actively looking for investment opportunities in Australian agricultural technology innovations. ☺

of the few exceptions in the private investment sector. It has recognised this opportunity with its Farm2Fork Summit and its 2016 FoodBytes! event in Sydney. The event allowed 50 foodtech and agtech start-ups to showcase their products and technologies.

Some recent examples of successful companies in the agricultural technology sector include Observant, which is a world leader in providing in-field hardware and cloud-based applications for precision farm water management with their remote sensor technology, and which has been acquired by Jain Irrigation. Another example is Nexvet, a Melbourne-based company



Welcome to Adelaide for the AusAg & Foodtech Summit 2017

Our Food Innovations Team



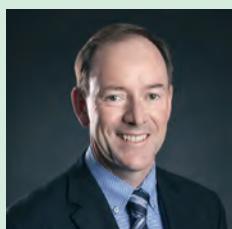
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START-UP COMPANIES TARGET AGRIBUSINESS WITH CUTTING-EDGE TECHNOLOGY

South Australia's long-held reputation for agricultural innovation is continuing under the guidance of newly formed government agency TechInSA, which is supporting early commercialisation for high-tech businesses, including foodtech and agritech companies.

Two new South Australian companies are taking 21st-century communications technology to the farm gate in the tradition of 19th-century innovators the Smith brothers – Richard Bowyer and Clarence Herbert – whose stump-jump plough solved the problem of preparing mallee scrub for cultivation, and John Ridley, whose grain stripper was the world's first mechanised harvester.

Driven by the need to increase productivity in a sector predicted to become Australia's next \$100-billion industry by 2030, Myriota and Safe Ag Systems have each received South Australian Early Commercialisation Fund (SAECF) grants from TechInSA to roll out trials.

Start-up company Myriota, (www.myriota.com) spun out of the University of South Australia's Institute of Telecommunications Research, has global markets in its sights with ambitions to keep remote agricultural assets and operations connected via nanosatellite and small-packet data communications.

Business Development Manager Tom Rayner says a \$300,000 SAECF grant has allowed Myriota to recently launch national trials, including a farm trial in New South Wales's Armidale region, that will see transmitters attached to water tanks for remote monitoring.

The technology, which also has applications for miners, and environmental and defence agencies, allows cheap remote machine-to-machine connectivity.

'The long-term vision is to be the connectivity data provider of choice for small amounts of data in remote areas,' says Rayner.



Myriota's low-cost satellite transmitter

'Most of the intellectual property of the company is in the waveforms and the algorithms of the receiver software that enable us to have huge populations of terminals communicate over small bandwidths, decode that data, and send it to the right person.'

'With agritech, for example, the technology can monitor water tank levels, link with weather stations or track livestock through smart cattle tags,' says Rayner.

'We've got quite a few large-scale commercial trial deployments happening now. We have a livestock water tank monitoring trial run in conjunction with the Australian Livestock Spatial Innovation Program, some marine science deployments, as well as some large listed corporate entities looking to track and monitor various assets at a low cost.'

Rayner says the technology uses the satellites of its Canadian shareholder, exactEarth, with short messages transmitted in very large numbers using tiny

slivers of radio bandwidth (kilohertz) and with very little power (milliwatts).

Those messages are sent to low-orbit nanosatellites and are then received by land-based satellite stations, where they are processed using cloud-based software.

Safe Ag Systems (www.safeagsystems.com), which has technology at its heart, has a firm farming base, with Co-Founder and Chief Executive Katy Landt from a fifth-generation grain-producing family in South Australia's premium Yorke Peninsula region.

A 'near miss' with machinery on the family farm operated by her brother and father was the catalyst for creating an online software system to mitigate farmers' risk when it comes to workplace hazards and safety compliance. The noble goal is to reduce the 'staggering' workplace death rate in agriculture in Australia, which employs three per cent of workers, but suffers 24 per cent of workplace deaths.

'It's a risky environment to work in; stats show that untrained use of machinery and an ageing population are the two main contributors (to workplace injury on farms)', says Landt.

'Developing the program with the insight of five generations of farming has helped us to build a product that people are going to use.'

The Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES) estimates that only one per cent of farmers have safe work systems in place, despite legal obligations being in place for the sector in Australia since 2012.

The company researched well-established safe work systems in the mining and construction sectors, but nothing complemented the varied practices of farming, often done by people working alone.

'A farmer could move from chemical use to working at heights within a couple of hours. Average safe work methods just don't fit. You'd be forever stopping and starting to fill out the paperwork,' says Landt.

Safe Ag Systems' SAECF grant of almost \$500,000 will allow the company to further develop and market a work health and safety system without the technical jargon, which doubles as a daily work tool.

The current program provides custom inductions, policies and emergency response plans, easily viewed and activated at the touch of a button. Farm owners can equip themselves and their workers with safety instructions specific to a machine, task or tool, and to perform an inspection out on the farm.

SafeAg Systems is now using a variety of channels, including grower groups, government bodies and advocates on the ground, to raise awareness of the technology within farming communities.

'With client numbers increasing daily, the grant will give us the ability to support, as well as further develop, the program to include productivity gains,' says Landt.

'Global food demand is forecast to increase 70 per cent by 2050; we need to think differently and embrace technology to improve productivity. Our key goal is to position Safe Ag Systems as the industry leader in safety culture change within agriculture by giving the community the tools it needs to get there,' she says.

TechInSA Industry Development Director Dr Judy Halliday says Myriota and Safe Ag Systems are prime examples of the breadth of innovation and people breaking into the agribusiness sector.

The agency, which launched the SAECF grants in November 2016, will assist with funds and expertise to develop these high-tech companies, where private sector funds are scarce.

'This early-stage, high-risk stuff is very difficult for the private sector to fund. I think that's not just in South Australia – I think it's everywhere,' says Dr Halliday.

'This program is unique to South Australia, and it is part of a longer-term strategy to develop a whole generation of new businesses in a variety of industry sectors.'

'Businesses that are high tech, and that can use new technology to develop high-value, high-tech jobs, are very important in driving economic development. We're talking about businesses that are 50–200 people eventually. They're the sorts of businesses that are powerhouses and contribute to the economy broadly.'

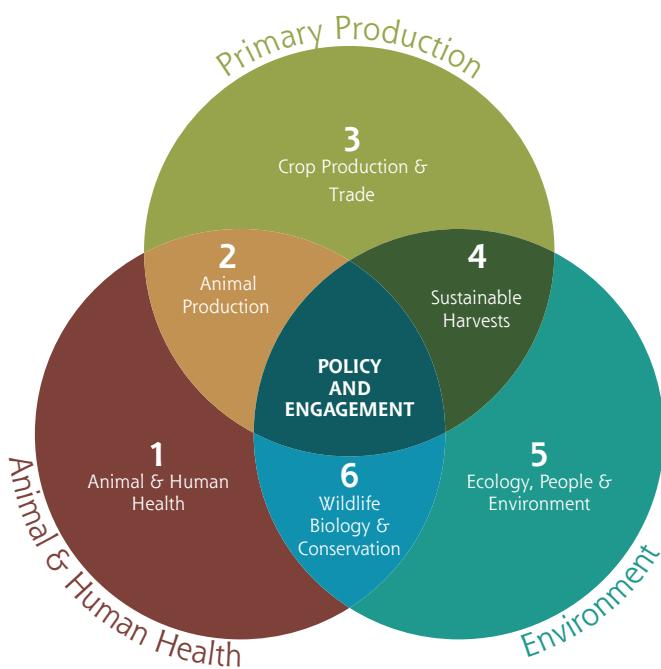
TechInSA (www.techinsa.com.au)

WA'S AGRICULTURAL BIOTECHNOLOGY CENTRE



The driving force behind agricultural biotechnology in Western Australia

BY MICHAEL JONES, PROFESSOR OF AGRICULTURAL BIOTECHNOLOGY AND DIRECTOR OF THE WA STATE AGRICULTURAL BIOTECHNOLOGY CENTRE



Research in the School of Veterinary & Life Sciences

Western Australia: the driver of agricultural exports of the nation

Western Australia is Australia's major grain producer and exporter. Cropping industries export \$4 billion a year, led by cereals (\$3.1 billion), pulses, pastures and oilseeds (\$900 million) and horticultural crops (\$142 million). This is backed up by the beef, sheep, dairy and pork industries (\$1.8 billion), plus poultry and eggs (\$200 million).

Murdoch University and the Western Australian State Agricultural Biotechnology Centre (SABC) provide the focus in Western Australia for molecular and biotechnology support for the major crops, wheat and barley, and underpins research and development for vegetable crops like potatoes, which is undertaken by Potato Research Western Australia. The SABC also supports a range of veterinary research projects.

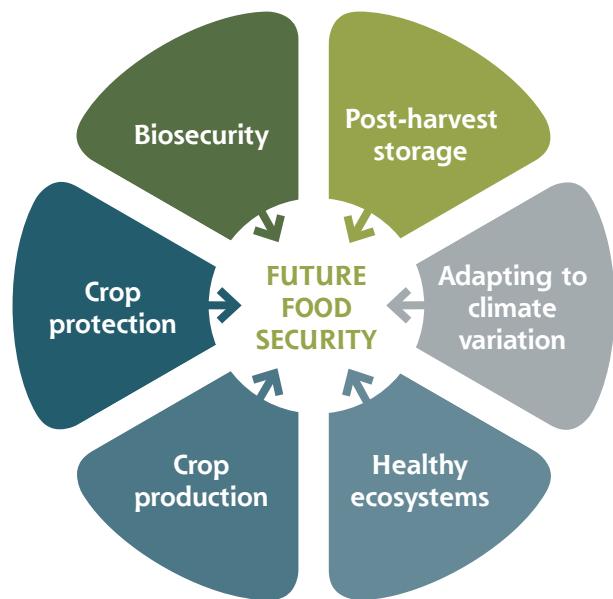
With the only veterinary degree and teaching hospital in Western Australia, Murdoch University is the major provider of research and research training in all aspects of veterinary studies.

Strategic focus on agricultural R&D, the interactions of primary production with the environment, and animal and human health

Murdoch is a leader in future food security, with integrated programs spanning genomics, bioinformatics, transgenic technologies and genome editing, marker-assisted breeding, crop protection, biosecurity, post-harvest storage, climate adaptation and healthy ecosystems.

Future food security focus at Murdoch University and the State Agricultural Biotechnology Centre

The research activities that underpin future food security are coordinated by the University Agriculture Institute, and include:



- crop production and biodiversity via the Centre for Crop Innovation (CCI)
- animal production, health and welfare
- animal and human health
- wildlife biology and conservation
- ecology, people and environment.

Many of the platform technologies of the Agriculture Institute are provided by the SABC, which operates as a 'research hotel'. These include advanced equipment and facilities to support the research and development of a wide range of university research groups, state government researchers and start-up companies, including:

- Wheat Quality Australia
- Western Barley Genetics Alliance
- Plant Biotechnology Research
- Rhizobium Studies
- Soil metagenomics
- Potato Research WA
- CRCs: Plant Biosecurity, High Performance Soils, Pork, Sheep
- Vector and waterborne pathogens
- Centre for Production Animal Research
- Many international centres and links.

Companies at the SABC:

Edstar Genetics, Orthocell, Nemgenix, ProteoWA, AusCann, Animetics 



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AUSTRALIA'S MEDICAL RESEARCH FUTURE

BY HANS VERHEUL, DIRECTOR, ADVISORY LIFE SCIENCES, AND GEORGIA KING-SIEM, RESEARCH AND DEVELOPMENT POLICY LEAD, KPMG

Australia is renowned for quality medical research and development (R&D), having produced many medical world firsts. With more than 4000 research programs partly funded by the National Health and Medical Research Council (NHMRC) in 2017 alone,¹ Australia remains a world leader in research; however, we still face many obstacles when it comes to translating research into commercial outcomes.

The quality and effectiveness of Australian medical R&D is exceptionally high; Australia produces more research per million dollars spent than most other countries², and it produces world-leading innovations, including the first electronic heart pacemaker in 1926, in-vitro fertilisation, the implanted bionic ear, and the cervical cancer vaccine (Gardasil), to name a few.

Despite this, Australia lags behind other countries when it comes to translating research into commercial outcomes³. For medical research, there are two main reasons for this:

1. a disconnect between researchers and business
2. a lack of capital and cash flow.

Researcher/business disconnect

Australia has numerous independent research institutions (a distinctive feature of the Australian research landscape). This independence provides diversity and a depth of research capability that can't be underestimated when one considers that 70

¹ National Health and Medical Research Council (NHMRC) Research Management Database as at 1 March 2017, see <https://www.nhmrc.gov.au/grants-funding/research-funding-statistics-and-data> (last accessed May 2017)

² World Bank, 2016, World Bank Indicators, see <http://data.worldbank.org/indicator> (last accessed May 2017)

³ Australia ranks 19th on the Global Innovation Index, but only 73rd when it comes to translating research into commercial outcomes. See Cornell University, INSEAD, and WIPO (2016): The Global Innovation Index 2016: Winning with Global Innovation, Ithaca, Fontainebleau, and Geneva.

per cent of all drugs entering the market originate outside of pharmaceutical organisations⁴; however, on the downside, this same independence and diversity makes the Australian research landscape hard to map and difficult to engage with efficiently – there is no common platform or unifying framework to facilitate or promote connections between researchers and business⁵. For those overseas, Australia is often overlooked in favour of other, more connected jurisdictions.

To illustrate, the Australian pharmaceutical and medical device landscape is dominated by affiliates of multinationals, generally focused on sales and marketing rather than having any interest in collaborating with Australian researchers or institutions. This is not always the case – for example, Johnson & Johnson actively seeks to collaborate with Australian researchers and institutions, but such instances are the exceptions and not the norm; not yet, anyway. Solving this problem requires action from all three stakeholders: researchers, business and government. Before looking for solutions, let's discuss the other major problem: the lack of capital and cash flow.

Lack of capital and cash flow

The vast majority – 90 per cent – of pharmaceutical research fails during development: either failing to deliver results or having serious side effects. In a small capital market such as Australia, lower cost and faster ventures attract investors over the high-cost, high-risk stakes of medical research. Furthermore, many local investors lack relevant medical knowledge, which can lead to poor investments and an aversion to investing in medical research in the future.

⁴ ATLAS Report 2016

⁵ T Cutler, Venturous Australia, Review of the National Innovation System, 2008; Productivity Commission, Public Support for Science and Innovation, 2007; ATSE, Strengthening Links Between Industry and Public Sector Research Organisations, 2011.

For more knowledgeable investors (including multinationals), navigating Australia's research landscape remains difficult, and international investment (whether inbound or outbound) becomes incredibly complex with the cacophony of constantly changing tax incentives and anti-avoidance measures such as patent boxes, R&D tax incentives, income tax holidays, capital gains tax relief, transfer pricing and base erosion profit shifting (BEPS). As a result, international investors tend to favour jurisdictions known for stability or with particular research credentials. In that respect, Australia should attract more than it does, but concern over the longevity of the R&D Tax Incentive, coupled with generous tax incentives in other jurisdictions, have had an impact.

A second and equally critical issue is the patent life of an innovation. Patent protection commences when the patent is granted, which happens long after millions of dollars have been sunk into R&D, but often long before the innovation is ready for market. Any interruptions to cash flow – especially after a patent has been granted, but before market – will effectively foreshorten the exclusivity period in which an investor can recoup the investment, and grow revenue. Given that patent lives are unlikely to change, this problem needs to be resolved through improved access to capital and cash flow, especially at the embryonic stage between patent grant and market entry.

What can Australia do?

As previously noted, these problems cannot be solved by one group alone. Researchers, business and government must work together to solve these problems, and we must do it quickly. If we don't, we will continue to slide down the innovation index, and our world-leading researchers and investors (whether Australian or not) will look to more attractive destinations.

What can researchers and institutions do?

They can play a larger role in identifying opportunities to translate their research into commercial outcomes. Institutions (or groups of institutions) need to offer programs that deliver business needs training to researchers so that they can translate research into a business case. Institutions can also help researchers to identify businesses that may be interested, therapeutically, in their research, and create forums in

which researchers and businesses can connect.

To address this, education is key. AusBiotech, supported by MTPConnect, is producing two guides – one for the research community and one for the investment community – that will both focus on closing the gap between these two groups. Furthermore, several state governments are exploring the establishment of medical precincts that will support research, and also offer a range of services to facilitate stronger translation opportunities.

What can business do?

Business must evolve and embrace change or risk extinction. Knowledge and diversification is key in a rapidly evolving environment. Businesses that understand Australia's research landscape can identify potential investments and collaborations, giving them a competitive advantage. Business should make use of existing and emerging resources (research networks, government programs, and even business networks) to bridge the researcher/business disconnect and fund research that will profit them, the researchers and ultimately our economy.

What can government do?

The creation of government-sponsored medical research funds like the Biomedical Translation Fund (BMF) has helped to address the lack of capital and cash flow, but more needs to be done. Government has a vital role to play in connecting researchers and business; it can help to create a common framework or platform, and it can leverage our world-leading research to attract researchers and more capital from both national and international businesses. This will have a snowball effect, attracting researchers to Australia, driving more medical research, attracting more funding for more researchers, and so on.

Finally, judicious use of tax incentives, such as the R&D Tax Incentive or the collaboration premium (as recommended in the recent R&D Review Report), help to offset the cost of R&D, and incentivise business to engage with researchers and research institutions.

Ultimately, we are all in this together. Beyond education, creating stronger ties between the business community and research institutions, while preserving the integrity of their independence, will greatly enhance the translation and commercialisation of Australia's medical innovations. ☺



BUILDING AN INVESTIBLE HEALTHCARE COMPANY

A founder's perspective

BY PROFESSOR MALCOLM HORNE, CO-FOUNDER AND CHIEF SCIENTIFIC OFFICER, GLOBAL KINETICS CORPORATION

As healthcare systems around the world struggle with caring for ageing populations and managing the costs of the growing epidemic of chronic disease, the opportunities for innovative, technology-based solutions to bridge the gap are stronger than ever.

Whether it's to avoid time in hospital, allow earlier intervention, or enable remote monitoring of patients, technology can and does play a key role. Digital health technology, in particular, is stepping up to the mark in many areas by improving our ability to

monitor, measure and record symptoms, medication compliance and patient outcomes.

Having moved beyond the first wave of simple wellness devices, successful companies in the digital health sector have been able to demonstrate more than promise. They've combined the power of advanced analytics, the convenience of patient-friendly interfaces and the weight of clinical evidence to support their value proposition to clinicians, payers and, importantly, to investors.

Despite the appeal and potential of digital health innovations, there are no shortcuts to success. It is

readily accepted that many digital healthcare start-ups won't survive, often losing steam before reaching Series A funding. And it appears that experience in healthcare does count when it comes to attracting investors, with Rock Health reporting in mid 2016 that the companies taking out the top six largest deals were founded, on average, 10 years ago.¹

For start-ups, once issues of technical feasibility, safety and patent protection are satisfied, investors will assess the technology on its ability to make a real difference in patients' lives and address the mounting cost pressures on health systems.

The two key questions investors will ask of any new health technology are:

1. Will it lead to better health outcomes for patients?
2. Will it provide a more cost-effective way of delivering care, reducing the burden on our health systems?

As innovators, if we're able to answer 'yes' to both of these questions, then it's likely that the new technology, by making health care both more effective and efficient, will be attractive to investors. But this is easier said than done.

Health care presents unique business challenges, with more regulations than most industries and a complex ecosystem of decision-makers to satisfy.

Just having a novel solution to a problem is not enough; you have to understand who will use it, who will pay for it and who you may need to partner with to make it all happen. Investors will be looking for scalable business models built on the priorities of users, payers and channel partners that control the money flow.

Demonstrating efficacy is also paramount. In health care, clinical validation and proof of utility builds credibility and trust – elements critical to driving adoption of technologies where neither the users nor the decision-makers are technologists. Delivering this evidence takes time, but it is a cornerstone requirement for the success of any serious health technology.

Efficiency, the other key variable, allows funding to be spread across a greater number of patients, or even better, avoids the need for care by earlier intervention,

improved compliance and, ultimately, prevention. Demonstrating efficiency, like efficacy, can also take time, but it is a key ingredient in the business case for early adopters.

Diabetes is one chronic illness where technology has shown potential to benefit patients, and has captured the interest of technology innovators and investors.

Digital technology is empowering people with diabetes to make more effective decisions regarding dosage, nutrition and diet by helping them to calculate, adjust, estimate and track relevant indicators.

ASX-listed company MedAdvisor has been able to show improvement to medication adherence via its technology platform that alerts patients to take their medication and see the doctor for new scripts, and it connects to the pharmacy to enable scripts to be filled on time.

With poor medication adherence widely recognised as a common and preventable cost to health care, the MedAdvisor medication system has leveraged the high uptake of mobile devices to deliver value at a very low per-patient cost.

Another very challenging illness is Parkinson's disease. Difficult to diagnose and with no cure, Parkinson's affects approximately 64,000 people in Australia. A high proportion of patients suffer disabling, uncontrolled symptoms that can lead to unplanned and expensive hospitalisation. It's a difficult condition to manage, but one where technology can play an important role.

Until recently, Parkinson's disease symptoms could not be objectively measured. Clinicians relied on observation, clinical assessment and patient recall during a short office consultation to assess the frequency, severity and duration of symptoms. Problems with this model of care are compounded by the fluctuating nature of the disease, which makes it difficult for patients to tell their clinician exactly when and what symptoms they are experiencing.

The Parkinson's KinetiGraph™ system (PKG™) is providing a solution to this. Developed by Global Kinetics Corporation (coincidentally, founded 10 years ago), the PKG system includes a patient-friendly, wrist-worn device that records symptoms continuously over seven days as people go about their daily lives. The



data generated is then analysed in the cloud using proprietary algorithms to produce a detailed report for clinicians, providing an accurate, representative view of the person's Parkinson's symptoms.

Demonstrating efficacy and efficiency is a priority

Similar to those suffering from diabetes, Parkinson's patients use more healthcare resources when their symptoms become uncontrolled. Using the PKG, clinicians can more accurately identify patients with uncontrolled symptoms, leading to better-targeted therapy and symptom control. The interim results of a 2016 study² even suggested that the PKG could help to identify patients whose symptoms were not controlled, yet would have otherwise gone 'under the radar' of clinicians. Patients also have better compliance with medication routine through the medication reminders features, and they are more able to engage with clinicians to explain their symptomatology at consultation.

The remote monitoring capability of the PKG also opens the door to home care and telehealth opportunities for people living in remote areas who otherwise do not receive adequate care, or who have to travel long distances to see a clinician. This opportunity is currently being demonstrated in a trial with Air Liquide's home healthcare division in France.

We live in an age of personal fitness trackers and wearable technology, but if we want to encourage continued investor support and uptake of medical technology by payers and health systems, the

economic benefit generated must be measurable. On the Parkinson's frontier, the case is clear: research has shown that the cost of care for patients who have uncontrolled Parkinson's symptoms is more than double^{3,4} the cost for those whose symptoms are controlled. By adding the PKG to a patient's therapy treatment, patients with uncontrolled symptoms saw significant improvements in their Parkinson's symptom scores⁵.

Ultimately, prevention is better than cure, and medical technology also has an important role to play here. The PKG is currently being used in two clinical studies looking to identify the early warning signs of Parkinson's disease, with the hope that treatments that delay or avoid the onset of the illness will be developed faster.

Today and in the future, for innovations in medical technology to be supported by investors and be successful in the market – whether they're classified as digital health, mobile, wearable or remote monitoring – they need to make a fundamental difference to patients' lives and allow our health systems to be sustainable and accessible. ☺

1 www.rockhealth.com/reports/2016-ytd-digital-health-funding-10-things-you-should-know/.

2 Farzenehfar P, Braybrook M, Kotschet K, Horne M, 'Objective Measurement in Clinical Care of Patients with Parkinson's disease', IMDS, (2016).

3 Dodel R, Eur J Neurol, 2011;6 (Suppl.1); 13-6.

4 Suh D-C, Pawha R, Mallya U (2012) 'Treatment pattern and associated costs with Parkinson's disease levodopa induced dyskinesia'. *Journal of the Neurological Sciences*, 319, 24:31.

5 Horne M, *Value in Health*, (2016) 18 (7), A685.

DIGITAL HEALTH: THE KEY LEGAL ISSUES IN 2017

BY YARMELA PAVLOVIC, PARTNER, FDA MEDICAL DEVICES PRACTICE GROUP; AND ADRIANA TIBBITTS, SENIOR ASSOCIATE, CORPORATE PRACTICE GROUP, HOGAN LOVELLS

Technology is rapidly changing the way the healthcare industry operates, opening doors to untapped business opportunity.

With these changes comes a dramatic shift in the competitive and regulatory landscape. These changes require companies entering the digital health space to think strategically about investment and funding options, and plan for regulatory and legal issues.

The digital health space includes a wide diversity of products, from simple health and wellness mobile applications, to wearable medical sensors, to digital therapeutics. The broad range of potential applications for digital health technologies has created interest among a variety of stakeholders, including life sciences companies, government agencies, investors and the patient community. Investors are closely watching the digital health space, and there has been a significant increase in funding for companies developing these tools over the past few years.

According to a report issued by StartUp Health, more than \$8 billion was invested globally in more than 500 digital health companies in 2016, with more than 200 new investors entering the funding ecosystem in 2016; the total number of unique investors that year was almost 900.

In addition to traditional venture capital firms and angel investors, Fortune 500 companies and private equity funds have become active investors. This trend has continued this year; industry sources estimate that more than \$1.47 billion worth of deals were signed in the first quarter of 2017. While more than two-thirds of these investments have been early stage (seed series or Series A stages), later-stage investments have been on the rise, as has the number of large deals, with almost 25 per cent of the funding invested in digital health companies in 2016 concentrated in five deals.

In addition to traditional financing models, stakeholders looking to develop and commercialise digital health technologies, whether as a complement to existing products or as a new line of business, are turning to non-traditional partners and business models in

order to accelerate the development of digital health technologies. For example, the sector has seen an increase in the number of partnerships between traditional life sciences companies and high-tech players, start-ups and academic institutions. These partnerships provide partners with the opportunity to leverage expertise that would not ordinarily be available to each of them individually.

While the opportunities created by these partnerships are exciting, they do present some potential challenges, such as the introduction of non-traditional life sciences companies to the highly regulated pharmaceutical and medical device environment. One way to address these potential issues is through the creation of an independent company to market and sell the digital technologies developed under the partnership. This model has been leveraged in several recent high-profile partnerships. Alternatively, if the partnership is between a large company and a smaller start-up, the partners may decide to keep the smaller company's operation separate, rather than completing a traditional acquisition. These and other similar corporate structuring issues are playing a notable role in the way that the digital health industry is evolving.

At the same time, as investment in the digital health sector continues to evolve, stakeholders in the industry – including investors, entrepreneurs and acquirers – must navigate a number of unique legal and regulatory issues on the road to product launch and commercialisation. The specifics and regulatory approach vary from jurisdiction to jurisdiction; but in general, the following issues warrant consideration:

- **Medical device regulation:** many digital health tools and products are regulated around the globe according to the local medical device regulations. For example, in the United States, the Food and Drug Administration (FDA) regulates any digital health products that meet the definition of a 'medical device' in the *Federal Food, Drug and Cosmetic Act*, according to a risk-based regulatory framework. Many such products require

clearance or approval by the FDA before they can be launched commercially. In addition, when the product is intended to be used in conjunction with another therapeutic product – such as a drug or biologic – additional regulatory considerations are raised. Similar regulatory frameworks exist in other countries.

- **Reimbursement:** some digital health tools are marketed under a self-pay business model in which the consumer is expected to pay for the technology. Other products enter the market through agreements with employers, healthcare institutions, or third-party payers. In the United States, the most traditional model of payment involves reimbursement by a patchwork of public and private payers. This is also true in European countries, where reimbursement is managed on a country-by-country basis. Thus, even where digital health tools do not require or are able to quickly obtain marketing authorisation, companies must still navigate varying reimbursement frameworks throughout the world.
- **Advertisement considerations:** various jurisdictions impose regulatory requirements on the advertisement of medically oriented products. For example, in the European Union, each member state issues its own regulations governing the advertisement of medical devices. In addition, if the digital health product mentions the use of a pharmaceutical, the content of the product may also be regulated, as the advertising of prescription medicinal products to the general public is prohibited and advertising of non-prescription medicinal products is highly controlled. Similar issues are presented in other jurisdictions, such as in the United States, where advertisements for medical devices are governed by the FDA, and advertisements for consumer products are overseen by the Federal Trade Commission (FTC).
- **Healthcare compliance:** in many jurisdictions, interactions between the life sciences industry, and healthcare providers and practitioners are closely regulated by the government. For example, in the United States, where products are paid for by the government through Medicare or Medicaid, arrangements that are common in non-healthcare industries may be prohibited as kickbacks, and can be subject to civil and criminal penalties. Arrangements involving physicians may also be subject to the federal Stark Law, which restricts physicians from making referrals for certain services

where the physician would benefit financially. Similar concepts are at play in other countries.

- **Privacy and cybersecurity:** digital health tools frequently collect and store data, including sensitive medical and personal information. These activities give rise to varying regulatory requirements around the world. In the United States, the most relevant to the digital health environment are the FTC consumer protection laws and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). States also have consumer protection and privacy laws. In addition, cybersecurity has become an issue of increasing interest to numerous governmental entities. Recent high-profile reports of medical device cybersecurity vulnerabilities have exponentially heightened concern related to digital health cybersecurity, and related regulatory regimes are fast evolving.
- **Intellectual property:** protection of intellectual property rights is critical to effectively develop and commercialise new digital health products. These efforts should begin early in a product development.
- **Other regulatory considerations:** due to the intersection of multiple novel technologies, products in the digital health space can potentially raise a number of other regulatory issues, such as regulation of communications technologies, consumer safety regulation, and oversight of the practice of medicine. These issues must be considered on a product-by-product basis.

In short, the digital health industry brings important opportunities for healthcare innovation, as well as business growth. To effectively leverage the opportunities present, companies must think strategically about a range of issues, from funding and corporate structure, to local government regulation. For a copy of Hogan Lovells's complete 'Digital Health Issues Guide', please visit bit.ly/2k7RvVX.



Yarmela Pavlovic



Adriana Tibbitts



THE JOURNEY FROM START-UP TO SCALE-UP

BY GARTH SUTHERLAND, CEO, ADHERIUM

When I was young, I never thought that having asthma was a positive thing. I only knew about the repeated hospital stays or the sports days and school I missed; however, the journey of Adherium from a very humble start-up company in New Zealand to our position now, a lot of that success came about because of our deep knowledge of what it means to live with asthma and other respiratory diseases.

While these chronic conditions cannot yet be cured, they can be effectively managed, enabling people to enjoy a life free from the limitations familiar to the estimated 300 million people diagnosed with asthma globally¹.

Knowing firsthand that people struggle to adhere to their prescribed medications drove us to develop Smartinhaler™. The need to engage patients in their own health care and improve outcomes, with the ultimate aim of transforming the management of chronic health conditions, is at the heart of Adherium.

We focus on bringing scientific rigour to our digital health solutions to improve adherence to respiratory inhalers. Patients are reminded when they need to take their medication, and doctors and patients alike can



Garth Sutherland

automatically keep track, via cloud-based records, of medication adherence. It sounds easy, but achieving this became a highly technical challenge involving regulators and clinical testing. The sheer number of different Smartinhaler™ devices we had to engineer was a challenge, not to mention the need to continually innovate and stay ahead of the market.

I don't mean to minimise the challenges of growing from a start-up – there have been many, and each one has been a significant hurdle for Adherium – but having a clear idea of purpose and mission, and never losing it, has been one of the keys for us.

We have always wanted to empower people with chronic conditions to live the lives they want, to reduce unnecessary hospitalisation and suffering, and to also meet important secondary aims, such as reducing costs for the health system and the strain on hospitals, doctors and insurers.

Initially, Adherium was making a very small number of Smartinhalers™ for use in clinical trials. They were effectively custom-manufactured units and they did a good job of keeping track of medication doses, which is essential information when you are running a clinical trial of a blockbuster drug. We were getting terrific feedback about our devices, but it was obvious that we needed to get our technology into the broad market.

To get there would require a lot more capital and some supportive shareholders who could help us, not just with money, but with the right connections to international players and advice about clearing regulatory hurdles.

Finally, we needed to strike a deal with a major pharmaceutical player, that could ensure that our products were distributed internationally, and provide us with the impetus for a share market listing so that we had the validation, the ability to raise capital as needed, and the financial discipline and regulation to enable our partners to deal with us on an equal footing.

In the end, we achieved all of those goals, but each one brought with it a unique set of issues, ranging from ensuring that we had enough intellectual property (IP) protection of our products in the major markets we were targeting, right through to making the design of each device as intuitive and user-friendly as possible so that people would enjoy using the inhalers, and get the correct dose every time.

Fortunately, we were able to find the right investors very early – when we were a tiny private company and well before we listed on the Australian share market. Most of those investors who shared our vision have stuck with us

all the way through to today, and some have been crucial in helping us on the commercialisation path.

While Adherium has made incredible progress since our early days, we have big ambitions for the future, and there's still a long way to go. The journey from start-up to scale-up is both challenging and exciting, but for Adherium, it is still very much a work in progress.

Continuing innovation is key to beating the competition

Having a strong focus is essential for growing a company, but you also need to keep an eye on the competition. When Adherium's very first Smartinhaler™ devices were being built more than 15 years ago, we were the pioneers on the cutting edge of a very new field. Today, as we knew it would, competition has risen to meet the challenge of reducing the avoidable healthcare costs of respiratory disease, which equal \$34 billion a year in the United States alone.

For us, the challenge will always be to remain at the forefront of developing world-class digital health technologies and robustly proving that our products produce exceptional results. Smartinhaler™ is currently the most clinically proven solution for respiratory medication adherence in the world. Recent published results demonstrated a fivefold reduction in hospitalisations for children with asthma, due to better adherence. In another clinical study, our Smartinhaler™ showed that 3.4 times more patients achieved 80 per cent or more adherence to their medication compared to 2.5 times for a competitor.

SmartinhalerLive™, our cloud-based data platform, already has more than 25 million device logs from more than five million data uploads, and it is growing at 243 per cent per year, but we can see these figures being totally dwarfed in the future. This brings with it the chance to use predictive algorithms as an early warning system for patients and caregivers.

The other way we are remaining ahead of the competition is building the largest suite of products compared to our competitors and securing regulatory approval, which is current in the United States, United Kingdom, China, Canada and Australia. Our intellectual property is now protected by 10 patent families and more than 70 design registrations.

Our 10-year commercial product development and supply agreement with AstraZeneca, which began at the start of 2015, is also a vital part of our strategy to remain market leaders. These are all valuable things, but the bottom line is that you need to be continually innovating if you want to remain competitive; there is no chance to rest on your laurels. ☺

INDEX

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	Developer and international marketer of blood pressure at the heart device SphygmoCor	9-Nov-05	10.3	0.04	0.15	0.04	-2	-2	1	
Alchemia Limited	ACL	Drug discovery and development: Fondaparinux, antithrombotic, oncology compounds FAK pathway	23-Dec-03	2.3	0.01	0.02	0.01	0	-8	1	
Acrux Limited	ACR	Transdermal drug delivery platform technology	29-Sep-04	37.5	0.23	0.84	0.22	6	4	19	
Actinogen Ltd	ACW	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders including Alzheimer's	16-Oct-07	37.2	0.06	0.09	0.04	-1	-9	1	
Anteo Diagnostics Limited	ADO	Multi-component coatings for solid phase of immunoassays for biomarker development	7-Apr-00	19.3	0.02	0.07	0.02	0	-3	3	
Adherium Ltd	ADR	Digital technologies – monitoring medication use in chronic respiratory conditions	26-Aug-15	17.7	0.13	0.52	0.13	-6	0	18	
Agenix Limited	AGX	ThromboView clot imaging diagnostics	2-Sep-92	3.6	0.03	0.05	0.01	-2	-1	1	
Admedus Ltd	AHZ	Tissue engineering regenerative medicine and vaccine development for Herpes and HPV	24-Mar-04	67.5	0.27	0.55	0.26	-8	-3	9	
Analytica Limited	ALT	eHealth devices. PericCoach System for stress urinary incontinence	25-Oct-00	14.0	0.01	0.01	0.01	0	-2	0	
Allegra Orthopaedics Ltd	AMT	Prosthetic implants tools	5-Dec-07	13.2	0.16	0.05	0.02	-1	-6	4	0
Antisense Therapeutics Ltd	ANP	Antisense Pharmaceuticals. (Psoriasis, MS)	20-Dec-01	5.8	0.03	0.04	0.01	-1	2	2	
Antara Lifesciences Ltd	ANR	Natural, plant-based therapeutics for gastrointestinal diseases	16-Oct-14	50.2	1.02	1.37	0.72	0	221	27	
Novita Healthcare Ltd	NHL	(formerly Avexa) Monitec cognition and attention difficulties in early childhood	23-Sep-04	5.1	0.03	0.04	0.02	1	2	1	
AirXpanders Ltd	AXP	Aeroform tissue expander for breast reconstruction	29-Sep-04	192.5	0.67	2.63	0.75	-36	8	12	
Biotron Limited	BIT	Antiviral drug developer, HIV and HCV	24-Jan-01	6.9	0.02	0.07	0.02	-1	-3	0	
Benitec Limited	BLT	Gene-silencing technology	17-Feb-97	26.7	0.12	0.28	0.09	-8	-2	11	
Bone Medical Limited	BNE	Development and commercialisation of therapeutics for bone and joint disease	24-Jan-85	16.2	0.04	0.08	0.03	-1	-4	0	
Bionomics Limited	BNO	Small molecule product developer in areas of cancer anxiety, epilepsy and multiple sclerosis	21-Dec-99	185.4	0.38	0.50	0.23	-5	-8	5	0
Brain Resource Limited	BRC	Provider International Database for Human Brain Function	28-Aug-01	9.1	0.06	0.18	0.05	-7	-1	-5	
Bioxyne Ltd	BXN	Developer of treatments for respiratory diseases	14-Dec-00	9.1	0.02	0.02	0.01	0	-12	0	
Cellmid Limited	CDY	Midkine – novel cancer therapeutic and diagnostic target, and anti-midkine antibodies with hybridoma cell lines and nucleotides.	9-Dec-05	27.9	0.03	0.04	0.02	0	-7	0	
Cogstate Ltd	CGS	Diagnostic and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's)	13-Feb-04	129.6	1.14	1.39	0.60	1	127	11	

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)
Clover Corporation Limited	CLV	Refines and supplies natural oils	30-Nov-99	74.3	0.44	0.69	0.36	1	0	17	0.75
Cochlear Ltd	COH	Manufacturer and marketer of implants for impaired hearing	4-Dec-95	9,161.8	158.64	161.14	112.51	360	44	480	250
CSL Limited	CSL	Supply blood products and vaccines	8-Jun-94	65,048.2	142.72	143.41	91.62	394	36	593	172.441
Cryosite Limited	CTE	Collection, processing and long-term storage of blood stem cells	9-May-02	7.5	0.16	0.25	0.16	1	22	6	1
Clinuvel Pharmaceuticals Limited	CUV	Developer of treatment for UV-related skin disorders. Lead drug: CUV1647 in Phase 3 clinical trial for the treatment of polymorphous light eruption (PLE)	13-Feb-01	307.4	6.44	9.19	4.10	-1	-460	43	
Cyclopharm Limited	CYC	Manufacturer and distributor of radiopharmaceuticals and molecular imaging. Lead product: Technegas (lung ventilation imaging drug)	18-Jan-07	49.8	0.84	1.45	0.72	1	59	18	0.991
Cynata Therapeutics	CYP	Large-scale production of mesenchymal stem cells	20-Dec-07	56.7	0.65	0.81	0.26	-5	-13	5	
Dorsavi Ltd	DVL	Motion analysis device technologies for clinical, elite sports and OHS	11-Dec-13	48.5	0.29	0.60	0.26	-2	0	6	
Dimerix Ltd	DXB	OraLine device for occupational and law enforcement multidrug testing and Dimerix Phase 2 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	2,491.4	17.00	19.10	14.88	84	0	38	51.501
Ellex Medical Lasers Ltd	ELX	Production of ophthalmic instruments for treatment of impaired vision	12-Sep-94	131.4	1.11	1.62	0.90	3	0	31	0
Factor Therapeutics Ltd	FTT	Developer of biomedical technology wound healing, tissue regeneration, cell culture; VitoGro platform technology enhancing cell growth and migration	19-Mar-04	46.0	0.06	0.08	0.03	-0	-89	2	
Genera Biosystems Limited	GBI	Advanced molecular diagnostic tests	11-Jun-08	13.1	0.15	0.31	0.12	-3	-5	-5	
Gi Dynamics, Inc	GID	EndoBarrier: endoscopically delivered treatment for obese type 2 diabetes	7-Sep-11	37.6	0.07	0.09	0.02	-189	0	1	
Genetic Technologies Limited	GTG	Genomics, genetic technology – non-coding DNA	30-Jul-87	19.5	0.01	0.02	0.01	0	-2	1	
IDT Australia Ltd	IDT	Manufacturer of pharmaceuticals and clinical trial management services	24-Sep-93	22.3	0.09	0.27	0.08	5	2	15	
Imagion Biosystems Ltd	IBX	Biotech and nanotech imaging systems. MagSense tech for cancer detection	24-Sep-93	22.3	0.09	0.27	0.08	0	2	0	
Innate Immunotherapeutics Ltd	ILL	Immunomodulator microparticle technology	23-Dec-13	144.4	0.64	1.83	0.28	-3	-19	3	
Immonuron Ltd	IMC	Oral immunotherapy treatments	30-Apr-99	41.0	0.27	0.70	0.22	-6	-4	3	
Imugene	IMU	Immuno-oncology biopharma, gastric and breast cancer immunotherapies	2-Dec-93	33.1	0.01	0.02	0.01	0	-6	0	0
Impedimed Limited	IPD	Diagnostic devices: lymph oedema, muscle wasting, metabolic disorders	24-Oct-07	296.4	0.76	1.82	0.54	-8	-10	19	
ITL Limited	ITD	Innovative medical devices, blood collection and related markets	29-Oct-03	48.9	0.48	0.66	0.16	1	0	10	
Invion Ltd	IVX	Clinical-stage developer for inflammatory respiratory diseases and high blood pressure	15-Feb-10	4.4	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	34.3	0.23	1.09	0.15	-1	-36	5	
Living Cell Technologies Limited	LCT	Developer of live cell products for treatment of neurological and metabolic disorders	1-Sep-04	59.9	0.11	0.15	0.06	-1	-14	2	
Lifehealthcare Group	LHC	Critical care medical devices and implantable devices	5-Dec-13	97.2	2.25	2.56	1.60	17	13	40	13.75
MedTech Global Ltd	MDG	Healthcare software solutions, clinical management, EMR capability, 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	48.3	0.36	0.53	0.25	-10	-3	5	

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	.8	0.01	0.04	0.01	0	-5	-1	
Medical Australia Limited	MLA	Distributor of medical devices, IV system, blood banking lab, collection of human and animal biologics	20-Dec-04	8.3	0.06	0.07	0.04	1	9	2	
Mach7 Tech Ltd	M7T	Imaging IT solutions, 3D printing and holographic projection provider	30-Nov-05	14.2	0.20	0.55	0.11	-38	-1	5	
Mesoblast Limited	MSB	Commercialisation of adult stem cell technology with specific application in the regeneration of bone and cartilage	16-Dec-04	898.7	1.99	3.44	1.01	5	38	-7	0
Monash IVF Group	MVF	Reproductive, obstetric, gynaecological services; diagnostic and genetic testing	26-Jun-14	414.3	1.76	2.55	1.52	13	14	-40	8.8
Medical Developments International Limited	MVP	Medical and veterinary equipment. Lead analgesic agents (pre-hospital and emergency). Penthrox Inhaler.	15-Dec-03	309.6	5.27	6.44	4.12	3	176	0	4
Mayne Pharma Ltd	MYX	Branded and generic pharma products, oral drug delivery systems, complex oral dose forms	29-Jun-07	1,708.6	1.15	2.11	0.99	7	15	5	
Nanasonics Limited	NAN	Disinfection and sterilisation technology, decontamination products to prevent spread of infections	17-May-07	771.1	2.57	3.60	2.06	9	30	27	
Neuren Pharmaceuticals Limited	NEU	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders	3-Feb-05	118.3	0.07	0.09	0.04	-1	0	0	
Novogen Limited	NRT	Patents around ATM technology in cancer therapeutics	1-Sep-94	23.7	0.05	0.12	0.04	-3	0	2	0
NuSep Ltd	NSP	Cell and protein separation systems	14-May-07	.7	0.00	0.01	0.00	0	0	0	
OBJ Limited	OBJ	Magnetic micro-array drug delivery technologies	29-May-00	87.0	0.05	0.11	0.05	0	-17	0	0
Orthocell Ltd	OCC	Regenerative cellular soft tissue therapies for restoration of tendon and cartilage injuries	12-Aug-14	24.9	0.35	0.54	0.28	-5	-8	0	
Ophea Ltd	OPT	Biologics drugs for ophthalmic diseases	18-Apr-91	156.4	0.19	0.28	0.07	-5	-30	9	
Oncosil Medical Ltd	OSL	Medical radiation treatments, OncoSil silicon and phosphorus beta emitter to be used as brachytherapy	15-Aug-05	45.3	0.10	0.18	0.08	-1	-7	3	
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	103.1	0.39	0.51	0.20	-9	-4	12	
Pharmaust Ltd	PAA	Drug developer of synthetic compounds for treatment of human and canine cancers	2-Oct-01	9.9	0.07	0.10	0.05	0	650	3	
Patrys Limited	PAB	Developer of natural human antibody based therapies, including cancer	13-Jul-07	4.5	0.01	0.01	0.01	0		0	
Probiotec Limited	PBP	Distributor of prescription and OTC pharmaceuticals	14-Nov-06	20.6	0.42	0.58	0.37	2	18	46	2
Prana Biotechnology Limited	PBT	Commercialising research into age-related neuro-degenerative diseases including Alzheimer's, Crutzfeldt-Jacobs, MND, Parkinson's. Lead compound PBT in Phase 2 clinical trials	28-Mar-00	26.7	0.05	0.15	0.04	-2	-3	5	0
PolyNovo Ltd	PNV	PolyNovo Biomaterials tissue engineering and metabolic pharma	26-Nov-98	118.2	0.20	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	20.2	0.02	0.04	0.01	-1	0	1	0
Prima Biomed Ltd	PRR	Fund Biotechnology Research (inc. cancer immunotherapy, rheumatoid arthritis, vaccine technology preventing parasitic diseases in animals)	23-Jun-88	60.3	0.03	0.05	0.03	0	0	1	0
Prescient Therapeutics Ltd	PTX	Immunotherapeutic products for chronic infectious diseases & Co-X-Gene thechnology for cancer treatemnt	2-Jan-92	11.6	0.06	0.15	0.05	-2	0	5	

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	14.4	2.55	5.25	2.10	-86	-3	0	
Pharmaxis Ltd	PXS	R & D and commercialisation treatment for autoimmune, chronic respiratory diseases (including MS, cystic fibrosis, rheumatoid arthritis)	10-Nov-03	79.8	0.25	0.34	0.23	-5	-5	3	
Phylogica Limited	PYC	Discovery and development of novel peptide therapeutics for treatment of asthma, stroke and diabetes	30-Mar-05	89.0	0.04	0.05	0.01	0	-23	0	
ResApp Health Ltd	RAP	Developer of smartphone medical app for respiratory diseases	12-Jan-05	184.9	0.30	0.55	0.24	-1	0	2	
Regeneus Ltd	RGS	Developer of adipose-derived cells with regenerative capacity for cell therapies	19-Sep-13	27.2	0.13	0.19	0.11	2	8	4	
Reproductive Health Science	RHS	Developer of chromosomal abnormality embryo testing in IVF cycles	5-Mar-87	14.8	0.17	0.30	0.05	-3	-6	2	
Resonance Health Ltd	RHT	MRI and tools for diagnosis and monitoring of liver diseases: FerriScan and HepaFat	2-Jan-92	11.7	0.03	0.04	0.02	-0	-31	1	
Resmed Inc	RMD	Developer, manufacturer, distributor. Medical equipment for diagnosis and management of sleep disordered breathing	25-Nov-99	14,575.4	10.33	10.43	7.15	32	32	0	12.194
Rhinomed Limited	RNO	BreatheAssist technology nasal device for sport, sleep and drug delivery	21-Sep-07	19.7	0.18	0.29	0.13	-6	-3	2	
RSH Respiri Ltd	RSH	Mobile health applications for respiratory disorders	14-Jul-00	18.6	0.04	0.08	0.03	-1	-5	1	
Reva Medical, Inc	RVA	Bioresorbable stent products, drug-eluting coronary scaffolding treatment for cardiovascular diseases	23-Dec-10	356.1	0.83	1.35	0.80	-18	-5	-29	
Sonic Healthcare Limited	SHL	Diagnostic, pathology and radiology services	30-Apr-87	10,094.2	24.26	24.36	19.72	111	22	-349	75
SciGen Limited	SIE	Development, marketing, sales. Pharmaceuticals (including Sci-B-Vac Hepatitis B vaccine)	15-Nov-02	3.7	0.07	0.07	0.01	1	14	-16	
Somnomed Ltd	SOM	Specialises in products for sleep apnoea. Lead product SomnoMed mandibular advancement splint (MAS)	27-Aug-04	174.8	3.04	4.08	2.85	-2	-192	40	
Starpharma Holdings Limited	SPL	Global R & D funding for biotechnology. Commercialisation dendrimer nanodrugs (including treatment for STDs)	28-Sep-00	273.1	0.71	0.88	0.59	-6	-12	9	
Sirtex Medical Limited	SRX	R & D novel technology for cancer treatment (radioactive particles SIR-Spheres for liver cancer treatment)	24-Aug-00	783.5	13.54	35.05	10.45	84	16	177	30
Suda Ltd	SUD	Drug delivery OroMist, oro mucosal administration for off-patent drugs	24-Jan-02	20.7	0.02	0.03	0.02	0	-14	0	
Simavita Ltd	SVA	Wireless sensor technology solution for assessment of urinary incontinence in the elderly	22-Feb-14	10.8	0.03	0.09	0.03	-6	-1	2	
TBG Diagnostics Ltd	TDL	Molecular diagnostics	22-Dec-95	34.8	0.26	0.30	0.14	-7	-3	10	
Universal Biosensors Inc.	UBI	Specialist medical in vitro diagnostic tests for point-of-care; blood test C-reactive protein test	13-Dec-06	72.1	0.41	0.48	0.26	1	57	8	
Uscom Limited	UCM	Develop, supply, operate medical equipment – Ultrasonic Cardiac Output Monitor	10-Dec-03	22.4	0.21	0.35	0.19	-2	-11	3	
Unilife Corporation	UNS	Injectable drug delivery, prefilled automatic needle retraction syringes, wearable autoinjectors, ocular delivery systems	26-Jun-86	1.8	0.01	0.09	0.00	-739	0	17	
Viralytics Limited	VLA	Anti-cancer virotherapy technology using naturally occurring Coxsackievirus and Echoavirus. Lead product CAVATAK	15-Oct-86	226.2	0.94	1.35	0.85	-4	-23	18	
Virtus Health Ltd	VRT	Assisted reproductive services, diagnostics, day hospitals	11-Jun-13	436.5	5.40	8.37	4.94	37	15	-186	28
Vita Life Sciences Limited	VSC	Development and distribution of 'over the counter' medicines, complementary, alternative, dietary supplements, health foods	23-Aug-07	53.9	1.02	1.62	0.98	6	17	41	3.75

Data current at 26 June 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 %
SIE	SciGen Limited	\$0.07	95
DXB	Dimerix Ltd	\$0.01	41
OIL	Optiscan Imaging	\$0.10	31
PYC	Phylogica Limited	\$0.04	27
BXN	Bioxyne Ltd	\$0.02	25
PAA	Pharmaust Limited	\$0.06	19
MLA	Medical Aus Limited	\$0.07	17
PVA	pSivida Corp	\$2.55	17
COH	Cochlear Limited	\$157.89	15
OSL	Oncosil Medical	\$0.09	15
RHT	Resonance Health	\$0.02	13
CGS	Cogstate Ltd	\$1.15	13
CSL	CSL Limited	\$140.01	13
POH	Phosphagenics Ltd.	\$0.02	12
BNO	Bionomics Limited	\$0.40	11
SHL	Sonic Healthcare	\$24.24	10
RHC	Ramsay Health Care	\$74.66	9
RMD	ResMed Inc.	\$10.13	8

This year's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Year Return %
SIE	SciGen Limited	\$0.07	195
OIL	Optiscan Imaging	\$0.09	155
PYC	Phylogica Limited	\$0.04	117
ITD	ITL Limited	\$0.51	99
CYP	Cynata Therapeutics	\$0.59	75
OSP	Osprey Med Inc	\$0.39	65
MSB	Mesoblast Limited	\$1.99	65
FTT	Factor Therapcts Ltd	\$0.06	65
BOT	Botanix Pharma Ltd	\$0.04	61
OPT	Opthea Limited	\$0.76	50
IMU	Imugene Limited	\$0.01	49
MLA	Medical Aus Limited	\$0.07	46
CGS	Cogstate Ltd	\$1.13	37
LCT	Living Cell Tech.	\$0.11	36
CUV	Clinuvel Pharmaceut.	\$6.36	36
BLT	Benitec Biopharma	\$0.13	35
RHT	Resonance Health	\$0.02	34
BNO	Bionomics Limited	\$0.40	34

Data current at 28 June 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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NEW AUSBIOTECH MEMBERS

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FivePhusion, a private Australian oncology company, owns worldwide rights to Deflexifol, a widely patented formulation of 5-Fluorouracil and Leucovorin with Cyclodextrin, designed to increase efficacy and reduce toxicity. Our Phase 1 trial demonstrated markedly reduced toxicity, the ability to deliver 25 per cent higher doses and provided evidence of increased efficacy. Deflexifol can replace 5-FU/LV in all current 5-FU/LV CRC regimens. Deflexifol is suitable for a Section 505(b)(2) NDA. FivePhusion seeks to out-licence or partner to commercialise Deflexifol.

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OneVentures

OneVentures is a venture capital firm with \$320 million under management, investing in life sciences products, including needle-free vaccine delivery, allergy treatment and colorectal cancer diagnostics. OneVentures Healthcare Fund III launched in December 2016 and is licensed under the Commonwealth Government's Biomedical Translation Fund (BTF) program. Emerging technology investments include companies in sectors such as telecommunications, information technology and new media. OneVentures' first funds were raised in 2010. It is based in Sydney, with offices in Brisbane and Melbourne.

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Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals was listed on the ASX in August 2015. Paradigm's work is focused on repurposing pentosan polysulphate sodium (PPS) for the treatment of inflammatory disease, including orthopaedic conditions, respiratory conditions, heart failure and the debilitating arthritis associated with arthritogenic alphaviruses. By developing therapeutics that are able to modulate the unchecked propagation of inflammation, without causing undesirable side effects, we aim to improve the lives of patients whose needs are not met by available therapeutics.

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Rhinomed

Rhinomed Limited (ASX: RNO) is a Melbourne-based technology firm with a focus on nasal, respiratory and breathing management technologies. The company is developing and commercialising applications of its technology portfolio in the sport, sleep, cough, cold, allergy and drug delivery markets. The company has two products in market (Turbine for sports and exercise, and Mute for snoring and better sleep), and it has recently completed a pilot Phase 1 clinical trial of its new INPEAP technology, targeting mild to moderate sleep apnea.

Michael Johnson, CEO

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Sonic Clinical Trials

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Zelda Therapeutics

Zelda Therapeutics Limited (Zelda) is an Australian-based biopharmaceutical company that has global access to human data collected over several years related to medicinal cannabis treatments in a number of key disease areas. Zelda is building on this knowledge and bringing together international leaders in the field to develop cannabis-based medicines for specific disease targets. Zelda has embarked on pre-clinical cancer research targeting brain, pancreatic and breast cancers, and human clinical trials in insomnia, autism and eczema indications.

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AUSBIOTECH CORPORATE MEMBERS

Organisation	Australian Regenerative Medicine Institute	Celestino Pty Limited	Department of Science, Information Technology and Innovation (QLD)
360biolabs Pty Ltd	Avatar Brokers Pty Limited	Cell Therapies Pty Ltd	Department of State Development (QLD)
3M Australia Pty Ltd	Baker IDI Heart and Diabetes Institute	Cellmid Limited	DibbsBarker
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Adherium Limited	BIASSEX P/L	Clarity Pharmaceuticals	Elastagen Pty Ltd
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Anteo Diagnostics	Biotech Daily	CSL Behring	FB Rice
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Atomo Diagnostics Pty Limited	Bioxyne Limited	Cynata Therapeutics	Forbes Meisner Pty Ltd
AusCann Group Holdings Ltd	Blueprint Life Science Group	D3 Medicine: A Certara company	FPA Patent Attorneys
Australia China Business Council (ACBC) – Victoria	Bosch Australia Pty Ltd	Datapharm Australia Pty Ltd	Franke Hyland
Australia HM Pharmachine Pty Ltd	Brandon Capital Partners	Davies Collison Cave	French Embassy, Trade Commission - Business France
Australian Agricultural Company Limited (AACo)	Brandwood Biomedical Pty Ltd	Deakin Research Commercial	Australia & New Zealand
Australian National Fabrication Facility (ANFF)	Bristol-Myers Squibb (Australia) Pty Ltd	DEK Technologies	Frost & Sullivan (Australia) Pty Ltd
Australian National University (ANU)	Brooker Consulting	Deloitte Touche Tohmatsu	Fusidium Pty Ltd
Australian Nuclear Science and Technology Organisation (ANSTO)	BTG Australasia P/L	DendroCyte BioTech Pty Ltd	Gadens Lawyers, Brisbane
Australian Proteome Analysis Facility (APAF)	Burnet Institute	Dennemeyer & Associates	Garvan Institute of Medical Research
Australian Red Cross Blood Service (ARCBS)	Business Events Sydney	Australia Pty Ltd	GBS Venture Partners Pty Ltd
	Calimmune Australia	Department for International Trade - British Consulate General	Genetic Signatures
	Cancer Trials Australia	Department of Economic Development, Jobs, Transport and Resources	Genome.One
	CareerLounge Pty Ltd		
	Cedrus Investments HK Ltd		

Global Kinetics Corporation Pty Ltd	Science and Engineering	Paradigm BioPharmaceuticals Ltd	Southern Star Research Pty Ltd
Global Orthopaedic Technology	Madderns Patent & Trade Mark Attorneys	Paranta Biosciences Limited	SpeeDx Pty Ltd
GO Resources Pty Ltd	MasterControl Inc.	Patheon Biologics Pty Ltd	St Vincent's Hospital Melbourne
Gold Coast Health & Knowledge Precinct	McCloud Consulting Group	Patrys Ltd	Starpharma Holdings Limited
Golja Haines & Friend	Meat and Livestock Australia Ltd	Peter MacCallum Cancer Centre	Suda Limited
Grant Thornton Australia Limited	MedAdvisor Ltd	Pfizer Australia	Swinburne University of Technology
Grey Innovation	Medibio Ltd	Pharmaxis Ltd	Swisse Wellness Pty Ltd
Griffith Hack	Medlab Clinical Ltd	PharmOut Pty Ltd	SydPath
Griffith University	Medtronic Australasia Pty Ltd	Phillips Ormonde Fitzpatrick	Sypharma Pty Ltd
HDR Rice Daubney	Melbourne Convention Bureau (MCB)	Phosphagenics Limited	Tasmanian Alkaloids
Heidrick & Struggles Australia Pty Ltd	Melbourne School of Engineering	Phylogica Ltd	TechInSA
Hogan Lovells US LLP	Merck Sharp & Dohme	Planet Innovation Pty Ltd	Telethon Kids Institute
Holman Webb Lawyers	Mesoblast Limited	Plunkett Consulting Pty Ltd	TetraQ
Houlihan ² Patent & Trade Mark Attorneys	Minomic International Limited	PolyNovo Limited	Teva Pharmaceuticals Australia Pty Ltd
Hudson Institute of Medical Research	Mobius Medical Pty Ltd	Prana Biotechnology Ltd	TGR Biosciences Pty Ltd
Hydrix Pty Ltd	Molecule 2 Medicine Limited	PRAXIS Australia Ltd	The University of Newcastle, Newcastle Innovation Division
ide	Monash Innovation	PresSura Neuro	The University of Queensland
IDT Australia Ltd	Monsanto Australia Ltd.	Pricewaterhouse Coopers	The University of Western Australia
Ikaria Australia (now part of Mallinckrodt Pharmaceuticals)	Morgans Financial Limited	Prime Accounting and Business Advisory Pty Ltd	The Walter & Eliza Hall Institute of Medical Research
Imagon Biosystems	MTPConnect Ltd (MedTech and Pharma Growth Centre)	Pronto Software Limited	THEMA Consulting Pty Ltd
Immuron Limited	Murdoch Childrens Research Institute	Protagonist Pty Ltd	Trajan Scientific and Medical
Imugene Ltd	Murdoch University	Proteomics International Laboratories Limited	Translational Research Institute Australia
INC Research Australia Pty Limited	Nanosonics Limited	Provectus Biopharmaceuticals, Inc.	TruScreen Pty Ltd
Innate Immunotherapeutics Limited	National Association of Testing Authorities Australia	pSivida Corp	UniQuest Pty Ltd
Innovfusion Pte Ltd	National Measurement Institute	QBiotics Limited	Universal Biosensors Pty Ltd
Institute for Glycomics	National Trauma Research Institute, Alfred Health and Monash University	QIMR Berghofer Medical Research Institute	University of Adelaide
Inter-K Peptide Therapeutics (Inter-K Pty Ltd)	Neuren Pharmaceuticals Limited	InstituteQ-Pharm Pty Limited	University of South Australia
Intertek Pharmaceutical Services	Neuroscience Trials Australia	Queensland Alliance for Agriculture & Food Innovation (QAAFI)	University of Sydney, Engineering and Information Technologies
iPug Pty Ltd	Neurosciences Victoria Ltd	Queensland University of Technology	University of the Sunshine Coast
IQ3 Corp Ltd	NeuroScientific	QuintilesIMS	University of Wollongong
IQnovate Life Science Organisation	Biopharmaceuticals Pty Ltd	qutbluebox Pty Ltd	UNSW - School of Biotechnology and Biomolecular Sciences
IOX Ltd	Newline Australia Insurance Pty Ltd	R&D Capital Partners Pty Ltd	UNSW Innovations
JCT Healthcare Pty Ltd	Norton Rose Fulbright Australia	Race Oncology Ltd	Vectus Biosystems Limited
Johnson & Johnson Innovation	Novartis Pharmaceuticals Australia Pty Ltd	Regeneus Ltd	Venture Valuation
Johnson Matthey (Aust) Ltd	Novogen Limited	ResApp Health Limited	Viralytics Ltd
Kain Lawyers	Novotech	Research Australia Limited	Volpara Solutions Limited
Kenelec Scientific Pty Ltd	NSW Stem Cell Network	Research, Innovation & Commercialisation (RIC), University of Melbourne	Vudbenk Life Science Australia Pty Ltd
King & Wood Mallesons	Nucleus Network	REVOX Sterilization Solutions	WA Department of Commerce
Kingspan Insulated Panels Australia	NZBIO	Rhinomed Limited	WA Health Translation Network (WAHTN)
KPMG	OccuRx Pty Ltd	RSM Australia	Wartermark Patent & Trade Mark Att.
Laboratory Analysers Australia	OFX	Russell Kennedy Pty Ltd	WE Buchan
LBT Innovations Ltd	Omniblend Innovation Pty Ltd	Sayco Pty Ltd	Wellspect HealthCare
Liberty Medical Pty Ltd (Hollister/ Dansac)	Omnigon Pty Ltd	SeerPharma Pty Ltd	West Pharmaceutical Services
Linear Clinical Research Ltd	On Q Recruitment	Sementis Limited	World Courier (Australia) Pty Ltd
Logan Office of Economic Development	OncoRes Medical Pty Ltd	Seqirus Australia - a CSL Company	Wrays
Luina Bio Pty Ltd	Oncosil Medical Ltd	Shimadzu Scientific Instruments (Oceania) Pty Ltd	Zelda Therapeutics Pty Ltd
M. H. Carnegie & Co.	OneVentures Pty Ltd	Shire Australia Pty Ltd	
Macquarie University - Faculty of	Ophea Limited	Sienna Cancer Diagnostics Ltd	
	Orthocell	SMR Technologies	
	Osprey Medical	Sonic Clinical Trials Pty Ltd	



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