August 2018 | Volume 28 | Number 2

Australasian BioTechnology

The journal of AusBiotech

Regenerative Medicine

PLUS

Agtech

Patents

PRINT POST APPROVED 100022288

QT9 Australasia

Specialists in end to end business management tools for any industry

QMS

Conforms to ISO13485, TGA & FDA Standards

Key Modules

- Document Control
- CAPA
- Product Development
- Change Control
- Training

ERP

Key Modules

- Sales
- Purchasing
- MRP
- Forecasting
- Capacity Planning
- Accounting
- Batch Management

Cloud or Local Server solutions available

Contact Us now for a Demo or 30 Day Free Trial

sales@qt9software.com.au

www.qt9software.com.au

CHAIR REPORT

BY JULIE PHILLIPS, CHAIR, AUSBIOTECH

Change of leadership at AusBiotech

After 13 years of service and two years leading the organisation, Glenn Cross retired from his role as Chief Executive Officer of AusBiotech in July this year.

Lorraine Chiroiu (MBA, GAICD) took over as Chief Executive Officer from early July. Well-known to members, and previous Deputy Chief Executive Officer of AusBiotech, Chiroiu will lead the organisation through its next phase of growth and evolution.

Chiroiu's dedication to the life sciences sector has seen her passionately pursue public policy changes that have impacted the sector at state and federal levels. Since joining AusBiotech almost a decade ago, she has advocated positive outcomes across regulation, tax incentives, patent protection, and medical research and commercialisation.

Prior to joining AusBiotech, Chiroiu held corporate and public affairs roles for a multinational biopharmaceutical company, the Pharmacy Guild of Australia, the University of Melbourne and a health consumer organisation. Chiroiu was selected for the role of Chief Executive Officer following an external recruitment process.

Julie Phillips

Farewell to Glenn Cross

Glenn Cross has spent most of his career in the life sciences sector, significantly contributing to its growth in Australia. His three decades in the industry are underscored by a range of roles and career highlights – from founding DePuy Synthes Australia (now a Johnson & Johnson company), to leading Vision Systems Instrumentation, as well as his role as Chief Operating Officer and then Chief Executive Officer of AusBiotech.

While we farewell Cross from his role as Chief Executive Officer, we are pleased to note that he will remain connected to the organisation and the sector, taking on a part-time role with AusEvents™, where he will be leading its business development program.

On behalf of the Board and the sector, we thank Cross for his leadership and commitment to expanding the life sciences sector in Australia, and wish him a rewarding and prosperous future in his new role and all future endeavours.

CHIEF EXECUTIVE OFFICER REPORT

BY LORRAINE CHIROIU, CEO, AUSBIOTECH

I feel truly privileged to have the opportunity to lead AusBiotech into its next phase of growth. Together we can support the expansion and prosperity of the Australian life sciences industry, a significant economic and social contributor with a proud history that is well positioned to build on its success for many years to come. I thank the Board and acknowledge Cross for his contribution to AusBiotech. When I think about our industry, as innovators, we have the perseverance, commitment and passion required to drive the development process – the development process that changes lives. I look forward to continuing to work with all of you.

Lorraine Chiroiu

Record numbers highlight the success of the Biotechnology Innovation Organization International Convention

The 2018 Biotechnology Innovation Organization International Convention (BIO) took place in June in Boston, one of the largest biotech hubs in the world. BIO is the largest annual gathering of the global biotechnology and life sciences sector. The Australian sector was

well represented once again at the convention, with the 350 Australian representatives making up one of the single largest delegations, led by AusBiotech in partnership with MTP Connect.

Innovation and supporting the international growth of the sector were major focuses of the convention. In this context, Australia's role as a global leader was clear, delivering research projects with attractive long-term investment opportunities.

The presence of Australian political leaders at the convention further supported our position on the international stage and is testament to the ongoing recognition of the sector's contribution to the Australian economy.

Federal Health Minister Greg Hunt took part in a 'Fireside Chat' titled 'Australia: Island of Research and Innovation', as part of a focus on emerging opportunities in global markets. Meanwhile, Queensland Premier Annastacia Palaszczuk's presence was specifically in support of the 'Discover Queensland innovation – a biotechnology showcase' event at the convention.

The convention covered myriad topics, from biofuels and renewable chemicals, genome editing, and infectious diseases and vaccines, to digital health, business development and finance, and regulatory innovation.

The convention even set a Guinness World Record this year for the Largest Business Partnering Event.

Life sciences sector gains reprieve on research and development tax

AusBiotech has long advocated, on behalf of members, the investment into Australia's world-class biotechnology research to support continued growth in the sector. The commercialisation of research to deliver world-class technologies has, to date, been buoyed by the research and development (R&D) tax incentive (RDTI). This is supported by the fact that Australia has experienced a five per cent annual growth in clinical trials since the RDTI program began.

AusBiotech was therefore firm in its opposition of plans floated ahead of the May Federal Budget of a proposed cap to the RDTI, which would jeopardise the viability of the sector and stifle developments in commercial products. The Federal Budget ultimately revealed a comprehensive plan for 'better targeting the research and development tax incentive'. This specifically included announcements such as:

- clinical trials exempted from a $4-million cap for the refundable component
- no lifetime cap for the refunds
- a coupling of the incentive to each company's tax rate
- a graduating reward premium for higher intensity and an increased cap for larger companies.

AusBiotech is pleased that the government recognises the critical role R&D expenditure plays in the development of world-class technologies, and in fostering the growth of a leading and innovative Australian biotech sector.

An ongoing commitment from the government is necessary to foster a strong Australian medical technology, pharmaceutical (MTP) and life sciences R&D sector; it also supports job creation and long-term investment in projects, and attracts clinical trials in the sector. At the time of going to print, the draft legislation was under consultation.

Upcoming AusAg & Foodtech Summit

This September, the AusAg & Foodtech Summit 2018 will be held at Rydges on Swanston, Melbourne. The Summit brings together delegates from the entire ecosystem of agtech and foodtech, with the sole purpose of advancing commercialisation opportunities in the sector that, ultimately, turn science into business.

The cross-section of delegates present at the Summit will allow relationships to be fostered across every stage of the sector's value chain. The Summit will prove an invaluable event for:

- investors, and agtech and foodtech investment experts
- industry enablers, including incubators, accelerators, service providers and government representatives
- technology creators, such as researchers, developers and academics
- customer and user groups seeking access to innovation in agriculture and food science.

Keynote speakers and their topics of note include:

- Sarah Nolet, Chief Executive Officer, AgThentic: 'The Australian Agrifood Tech Advantage'
- Professor German Spangenberg, Deputy Secretary, Agriculture Research for Agriculture Victoria: 'Medical cannabis and government regulation'

- Dr Christine Pitt, CEO, Food Futures Company: 'Role of RDCs in the AgTech and FoodTech Ecosystem'
- Radek Sali, Chairman, Light Warrior: 'People, principles and passion come before profit'
- Robert Poole, National Lead Partner, Agribusiness, Management Consulting, KPMG: 'Advancements in Australian AgriTech – Towards 2030'
- Dr Joanna McMillan, Adjunct Senior Research Fellow, La Trobe University: 'Food influences on the gut microbiome'

To read the full program and register for the Summit, visit www.agfoodtech.com.au.

Survey confirms life sciences sector booming and more buoyant than ever

AusBiotech, supported by Grant Thornton, has released the eighth annual Biotechnology Industry Survey – which this year revealed a renewed sense of optimism and strong potential for the industry to play a larger role in Australia's economy.

Key findings from the report:

- Biotech is booming – 87 per cent of businesses surveyed expect to grow in 2018.
- Life sciences sector employs more than 232,000 people across 1654 organisations – the equivalent size of the labour force in the information media and telecommunications sector or the mining sector.
- About 84 per cent are SMEs (employing less than 100 people), which represents 733 of the companies within the industry sector.
- A huge A$1.073 billion was raised by Australian biotech companies in 2017 – the second largest amount this decade.
- Skills and talent attraction looks to be a significant issue in the future.
- Business sentiment across the industry is the strongest on record. The survey shows another jump, to 77 per cent, in the number of companies reporting that last year (2017) was an 'excellent' or 'good' year. The vast majority (87 per cent) expect their business to grow in 2018; a significant jump on last year's result and no respondent expected their business to contract.
- A record 37 per cent believe the Australian operating environment remains conducive to growing a biotechnology business, adding to the 47 per cent that felt the environment was neutral.
- The employment outlook for 2018 has strengthened to the highest on record, with 73 per cent of companies indicating an intention to hire, up from 64 per cent in 2017.
- The magnitude of the Australian life sciences sector (232,213 people employed) across 1654 organisations represents 1.86 per cent of the labour force and is comparable to the information media and telecommunications sector that represents approximately 1.73 per cent (215,000 people) and the mining sector, which accounts for 1.74 per cent (or 216,500 people).
- The life sciences sector is a significant economic driver for Australia.

Globally, Australia has a well-deserved reputation for quality, innovation and expertise in the life sciences sector. Once dominated by human therapeutics companies, the mix has evolved to include the larger and fast-growing medical technology (devices and diagnostics), and digital health sectors, as well as the steadily emerging agriculture and food technology sector.

With respect to industry credentials, there are currently about 140 ASX-listed life sciences companies, with a market capitalisation of more than A$50 billion.

A convergence of industry maturity, deal flow, regulatory advances, increased capital and development programs makes this the most buoyant the sector has been in almost a decade at AusBiotech. The survey data agrees. The opportunity is ours to further build this industry towards its potential as a driver of our economy and quality of life.

There was a return to capital raising among Australian biotech companies in 2017, with a huge A$1.073 billion raised by 31 December 2017, the second largest amount this decade (second only to A$1.153 billion, which was raised in 2015). Nearly half the respondents indicated they actively sought funds in 2017, which compared favourably to the 43 per cent that confirmed a focus on capital raising in 2016.

Funds flowed in through the Medical Research Future Fund and the A$500-million Biomedical Translation Fund (BTF). The R&D tax incentive scheme continues to facilitate investment in biotechnology, though it is underpinned by feelings of uncertainty as companies grapple with potential caps to tax refunds and policy changes.

In addition, we saw 10 biotech companies listed on the ASX in 2017, joining the 130-plus existing listed life sciences firms.

AUSBIOTECH BOARD

Julie Phillips
Chair
AusBiotech Ltd
CEO and Executive Director
BioDiem Ltd

Lorraine Chiroiu
Chief Executive Officer
AusBiotech Ltd

Michelle Burke
Principal and Managing Director
Indigo Advisory

Barry Thomas
Director
Cook Medical Asia Pacific
Vice President
Cook Incorpated

Lawrence Gozlan
Chief Executive Officer
Scientia Capital

Dr Megan Baldwin
Managing Director and CEO
Opthea Limited

Dr Andrea Douglas
Vice President, R&D Strategy and External Affairs
CSL Limited

Serg Duchini
Partner, Chief Strategy Officer, National Leader R&D and Government Incentives & Co. Director,
Deloitte Touche Tohmatsu

Prof Jan Tennent
CEO
Biomedical Research
Victoria

AusBiotech staff list

Chief Executive Officer	Lorraine Chiroiu
Member Services Manager	Tanya Daw
Executive Assistant	Jo Beamsley
National Event Operations Manager	Hayley Laing
Events Manager	Jenny Delaforce
Financial Controller	Crystal Tan
Website & Data Administrator	Harshini Bellana
National Projects Coordinator	Dr Claretta DSouza
State Membership Liaison Officer	Stephanie Cruzat
Events Manager	Vincent Portier
Events Manager	Johnny Ni
Business Development Manager AusEvents™	Glenn Cross

AusBiotech 2018

31 October – 2 November 2018 Brisbane Convention and Exhibition Centre, Southbank www.ausbiotechnc.org #AusBiotech

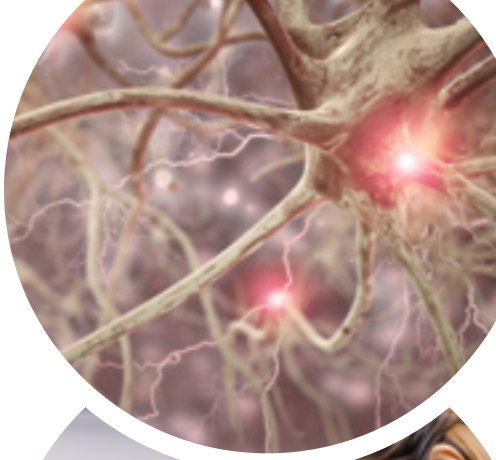
Australia's premier life sciences conference returns to Brisbane

proudly sponsored by the

Queensland Government's Advance Queensland initiative

ADVANCE QUEENSLAND | Queensland Government

CONTENTS



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

AusBiotech: Level 4, 627 Chapel Street, South Yarra VIC 3141
Tel: 03 9828 1400 | Email: admin@ausbiotech.org | Web: www.ausbiotech.org

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

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

INC Research and inVentiv Health have become Syneos Health™, the only fully integrated biopharmaceutical solutions organization with a unique approach. At Syneos Health, all the disciplines involved in bringing new therapies to market, from clinical to commercial, work together with a singular goal — greatly increasing the likelihood of customer success. We call our business model Biopharmaceutical Acceleration. You can call it the future.

Syneos™ Health

ENGINEERING AT THE CENTRE OF NEW MEDICAL RESEARCH HUB

A new Australian Research Council (ARC) Research Hub will focus on research partnerships that will deliver new advances for the rapid production of medical devices to improve the health of Australians and grow the medical devices industry.

The Research Hub will develop new advanced materials, optimise designs and identify improvements in the processes involved in the manufacturing of medical devices, and train the next generation of industry-ready researchers.

With researchers based at Cook Medical Australia, Bosch Australia Manufacturing Solutions are working to develop the engineering to enhance advanced manufacturing technology and capabilities.

'As engineering and manufacturing partner, Bosch is excited to bring our expertise to this project,' says John Croft, General Business Development Manager of Bosch Australia's Manufacturing Solutions.

'This project allows us to work together on the design for manufacture. It gives us a unique opportunity to work simultaneously on a value stream map, ensuring optimum manufacturing processes and then, in turn, specification of line and equipment for manufacture. It's a win-win for next-generation manufacturing,' says Croft.

General Manager of Cook Medical Australia, Dr Samih Nabulsi, believes that the Research Hub will make a significant contribution to the medical device industry in Australia and has the potential to increase export opportunities for the intellectual property derived from manufacturing process improvements.

'Research and industry partnerships are key to increasing the translation of new technology in the medical device industry and growing workforce capability,' says Nabulsi.

'Our primary goal with this partnership is to improve patient health outcomes, while identifying process efficiencies and advances in the materials and technologies involved with manufacturing medical devices,' he says.

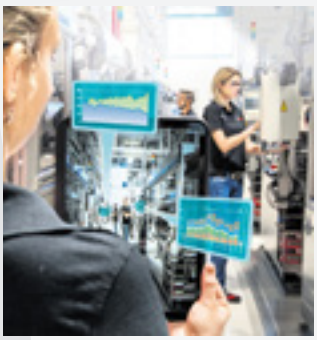
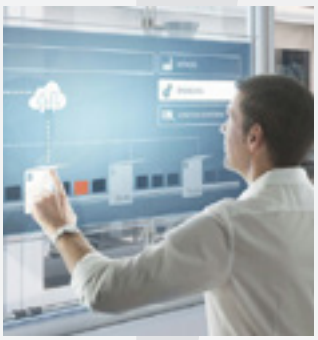
A number of research projects are already underway across lean manufacturing, design and materials, adaptive automation systems, digitisation, metallic biomaterials, ergonomics and collaborative robotics. The model includes embedding and integrating the research teams into industry facilities, some of which are already achieving positive results for improving productivity and pre-manufacturing processes.

Bosch Australia was recently honoured with the Manufacturer of the Year award by the Victorian Government. Bosch Australia Manufacturing Solutions is an externally oriented technology division focused on improving efficiency, reliability and quality in production processes. It has already supplied millions of dollars' worth of production equipment and technology to a variety of manufacturing companies.

BOSCH
Invented for life

Bosch Australia Manufacturing Solutions

Leading User Leading Provider

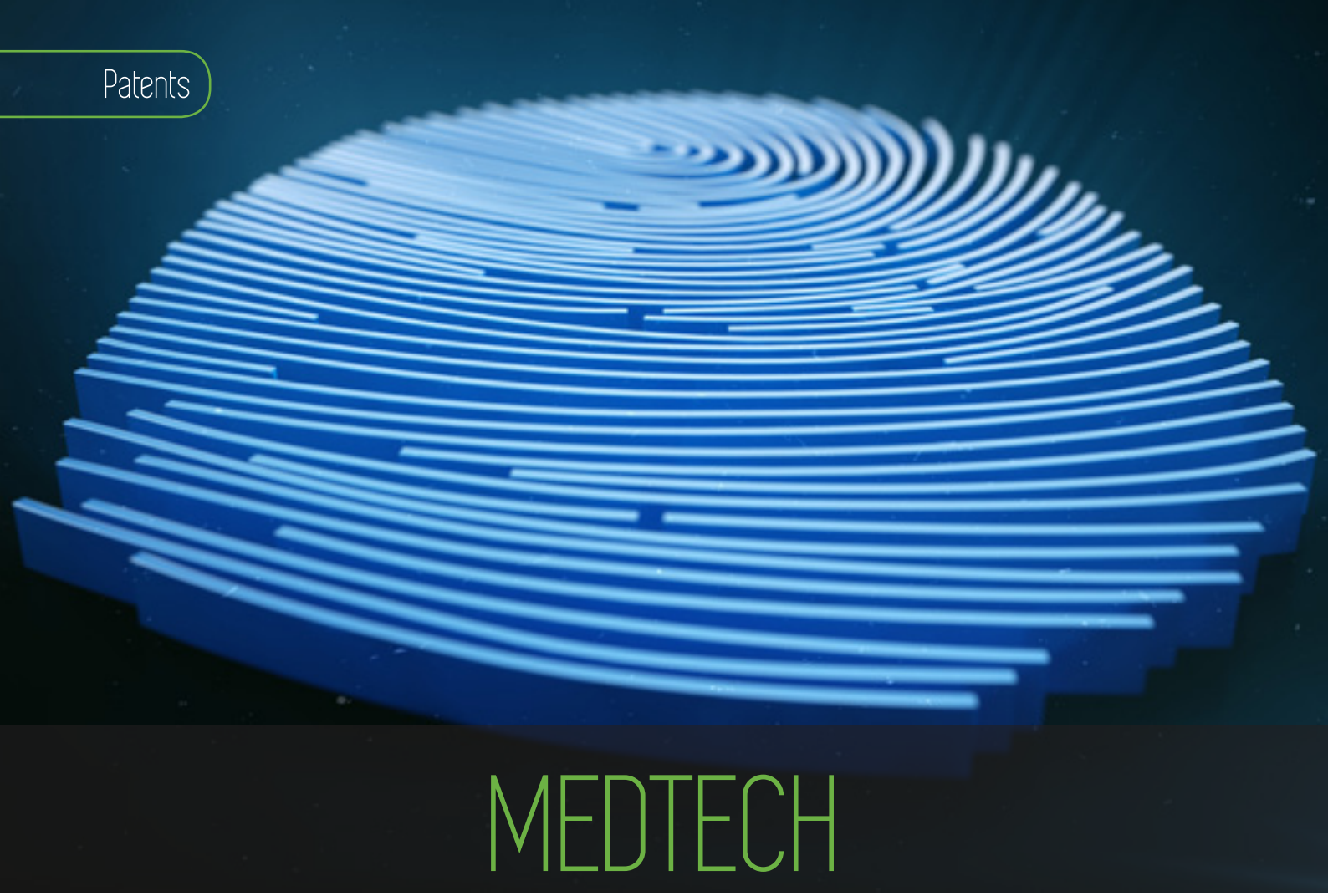




I4.0 describes the networked Manufacturing of the future.

- The real opportunity Bosch can offer you is to provide it's experiences from which you can take advantage from.
- Open standards are essential to integrating equipment and software of various suppliers into connected concepts.
- Real-time analysis of relevant manufacturing and logistics data.

Contact us for your path in the i4.0 journey

M (61) (0) 434 185 329
T (03) 9541 5086
E john.croft@au.bosch.com
W bosch-manufacturingsolutions.com.au



MEDTECH

a safe harbour in US diagnostic method patent practice?

BY DANIELLE BURNS, SENIOR ASSOCIATE; AND PRUE COWIN, ASSOCIATE, FB RICE

Personalised medicine is a move away from a traditional one-size-fits-all approach to a customised approach to medical treatment, in which appropriate therapies are selected based on a patient's genetic profile or other molecular and/or cellular analysis.

Diagnostic testing is often employed to diagnose disease, monitor disease progression, and assess the risk of disease recurrence, as well as determine a patient's susceptibility to developing a disease. In addition to tailoring medical treatment to an individual's needs, personalised medicine allows preventative or therapeutic interventions to be concentrated on those who will benefit the most, reducing or eliminating side effects (and expense) for those who will not.

Patent protection

While we have seen a significant increase in patent filings in the medtech sector in recent years[1], the ability to protect diagnostic tests has been brought into question in the United States. The US Supreme Court has repeatedly denied patent eligibility of diagnostic methods on the basis that they define laws of nature/natural phenomena. Medical device and diagnostic patent owners need to understand the law to optimise strategies to protect their investment.

Mayo and Alice in the United States

Patent-eligible subject matter in the United States includes four statutory categories defined in title 35, section 101 of the US code as, 'any new and useful process, machine, manufacture, or any new and

1 http://www.wipo.int/pressroom/en/articles/2017/article_0002.html

Danielle Burns

Prue Cowin

useful improvement thereof'. Laws of nature, natural phenomena, and abstract ideas are considered to be implicit exceptions to the patent-eligible subject matter under section 101.

The patentability of diagnostic methods was first considered in the US Supreme Court's decision in *Mayo Collaborative v. Prometheus Labs*[2]. The court held that a method of optimising a therapy based on the relationship between concentrations of certain metabolites in a patient's blood, and the likelihood that a particular drug dosage would be either ineffective or cause harm, was not patentable.

The methods at issue recited 'administering' a drug to a subject, 'determining' the level of a metabolite, and clauses that correlated specific levels of the metabolite with a need to increase or decrease the drug amount.

In its decision, the Supreme Court held that the claimed methods were not patent-eligible because they recited laws of nature – the claimed correlation depended only on the natural process of drug metabolism. Based on the facts, the court found that the remaining steps, when taken alone or in combination, added nothing significant to the natural law.

The Supreme Court in *Alice Corp v. CLS Bank*[3] spelt out Mayo's determination of patent eligibility as a two-part test in determining that patent claims directed to a scheme for using a third party to mitigate settlement risk were drawn to a patent-ineligible abstract idea. Under the Alice test, one must first determine whether the claims are directed to a patent-ineligible concept (i.e. law of nature, natural phenomena, or abstract idea) and, if so, then determine if there is an 'inventive concept' – does the claim include an element, or a combination of elements, that is sufficient to ensure that the claim amounts to 'significantly more' than a claim to the ineligible concept itself?

Sequenom

Diagnostic method claims have fared poorly since Mayo and Alice[4]. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*[4], the Federal Circuit Court applied the two-step framework set out in Mayo and Alice to determine that claims to detecting cell-free foetal DNA in maternal blood or serum were directed to natural phenomenon. The court held that the additional claimed elements (amplifying and detecting steps) did not amount to significantly more than the ineligible concept, as these steps were routine and conventional. This is despite an acknowledgement that the discovery that cell-free foetal DNA is present in maternal plasma or serum (that was previously discarded as medical waste) and subsequent implementation of a method for detecting a small fraction of cell-free foetal DNA represented a 'positive and valuable contribution to science'. The test derived from the discovery allows non-invasive prenatal diagnostic screening using a simple blood test, removing the risk of miscarriage associated with invasive prenatal testing procedures. The Federal Circuit Court denied Sequenom's petition for re-hearing *en banc* and the US Supreme Court denied Sequenom's petition for review.

Relevant to constructing patent claims to diagnostics, the Federal Circuit held, in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited*[5], that claims to a method of treating a patient with schizophrenia with iloperidone, where the dosage is based on the results of a genotypic assay, are patent eligible. As in Mayo, the claims correlate an individual's ability to metabolise the drug with the proper dosage for that individual; however, Mayo was distinguished as merely claiming the natural relationship. In contrast, Vanda claims an application of that relationship, requiring a treating doctor to administer one of two dosages depending on the results of the genetic assay. Interestingly, where the District Court found the claims eligible at step two of the Mayo/Alice analytical framework, the Federal Circuit found them eligible at step one.

2 Mayo Collaborative v. Prometheus Labs, 132 S. Ct. 1289 (2012)
3 Alice Corp v. CLS Bank 134 S. Ct 2347 (2014)
4 See, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015), Genetic Techs. Ltd v. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016), Cleveland Clinic Found v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017)
5 Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, Nos. 2016-2707, 2016-2708 (Fed. Cir. Apr. 13, 2018)

The patentability of methods of diagnosis in Australia

Unlike in the United States, there is no recent Australian decision that impacts negatively on the patentability of diagnostic claims. It is unlikely that the precedent set in the US Sequenom case will be applied in the counterpart Australian case (set for hearing in August 2018).

In particular, it is unlikely that the Australian courts will adopt the two-step approach to patentability set out in Alice. In contrast to the position in the United States, Australian law does not have a 'laws of nature' exception to patentability.

Instead, the Federal Court is likely to ask what the 'substance of the invention' is and then determine whether the invention falls within the existing concept of patentable subject matter. If it does, the court's determination of patentability will likely be based on whether the claimed invention is a method that has been made by human intervention, and whether it has economic utility. If the court determines that the invention involves a significant new application or extension of the patentable subject matter concept, then they may look to additional factors: potential negative effects on innovation; the potential chilling effect on activities beyond the scope of the patent; consistency with the purposes of the *Patents Act 1990;* the doctrinal coherence of patent law; international factors; and whether such a decision on patentability should be left for the Federal Parliament to determine.

Critical to the Australian case will be the determination of the 'substance' of the claims – where the patentability is assessed on its substance, not its form. Although unlikely, there is arguably scope for the Australian courts to import a two-part test as set out in Alice if the substance of the invention is considered to be directed to information.

Advances in the medtech sector

The exclusion of patentability to diagnostic methods in the United States may be circumvented by drafting medical device and diagnostic claims, such that they qualify as a process, a machine, an article of manufacture, or a composition of matter, as opposed to describing a law of nature. For example, a diagnostic claim could include a targeted therapeutic step, require an imaging step, or be tied to a device. As an example, granted US patents that cover the Food and Drug Administration (FDA)–approved wearable continuous glucose-monitoring system, Dexcom® G5 (which comprises a small sensor that measures glucose levels just underneath the skin and transmits this data wirelessly to a compatible smart device), include multiple claim formats that cover various aspects of the device, as well as the sensor system for measuring glucose levels.

We expect that patent filings in the medtech sector will continue to grow, and will respond to the limitations exacted by Mayo and Alice, by focusing on targeted therapeutics, rapidly shrinking wearables, imaging tools, biosensors, and trackers that can be used for patient-specific diagnosis, monitoring and treatment.

www.fbrice.com.au

TAILORED LIFE SCIENCES & CLINICAL TRIALS SOLUTIONS

Newline Group's experienced underwriters have been consistently providing the Life Sciences sector with broad coverage, competitive pricing, significant capacity and excellent security.

We are a recognised market leader in Life Sciences and Clinical Trials' insurance and recently launched a revolutionary global Clinical Trials product, which can provide clients with vital local policies and certification in over 90 countries on a "just in time" basis.

We Specialise:

Key Industry Segments:

Active Ingredient Manufacturing
Alternative and Complementary Medicines
Biological Engineering
Biotechnology Research and Development
Clinical Trials and Contract Research Companies
Contract Manufacturing
Cosmetics
Nutraceuticals
Medical Equipment and Machinery Manufacturers and Distributors
Medical and Surgical Devices (including invasive)
Pharmaceutical Manufacturers, Contract Manufacturers and Distributors
University Research and Development
Veterinary Medicines

We Understand:

Key Coverages Can Include:

Advancement of Defence Costs
Emergency Defence Costs
Public Relations' Expenses
Compensation for Court Attendance
Joint Venture Liability
Continuous Cover
Run Off Cover
Extended Reporting Periods
Principals' Indemnity
Vendors' Liability
No Fault Compensation for Clinical Trials
Legal Liability for Clinical Trials
Products Financial Loss
Product Contamination
Government Mandated Recall
Barcode Coverage
Manufacturers' Errors and Omissions
Reputational Injury Cover
Advertising Liability
Inquiry Costs
Loss of Documents
Broad Insured Definition

We Deliver:

Key Products:

Public and Products' Liability Wording
Clinical Research Wording
Clinical Trials Wording -- Single and Master Trial Policies
Locally Admitted Clinical Trials Policies
University Combined Liability Wording
Biotechnology and Life Sciences Wording
Pharmaceutical Wording
Biotechnology and Medical Malpractice Wording
Professional Indemnity Wording
Directors' and Officers' Wording

CONTACT US

Craig Rowsell
Underwriting Manager – Liability
T: +61 3 9999 1908
M: +61 428 998 229
E: crowsell@newlinegroup.com.au

Kevin Khaw
Underwriter – Liability
T: +61 3 9999 1906
M: +61 400 722 522
E: kkhaw@newlinegroup.com.au

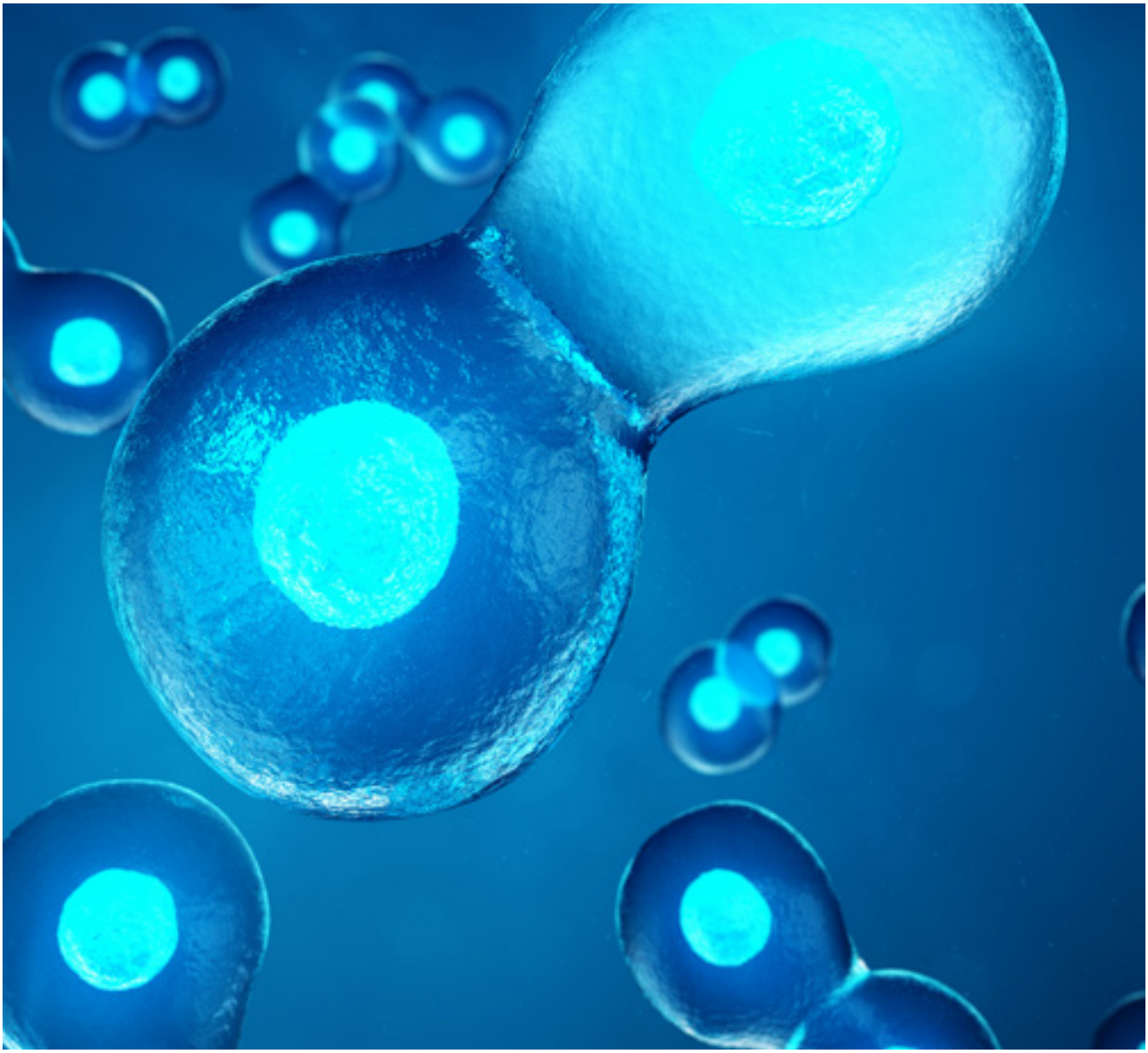
Will Clarke
Underwriter – Liability
T: +61 3 9912 4021
M: +61 477 222 534
E: wclarke@newlinegroup.com.au

Newline Australia Insurance Pty Ltd
ABN 81 118 089 651
Level 11, 535 Bourke Street, Melbourne VIC 3000
PO Box 16208, Collins St West, VIC 8007
Telephone: 03 9999 1901
www.newlinegroup.com.au

Access to Newline Australia Insurance Pty Ltd is available through your professional insurance intermediary.

TRENDS IN STEM CELL THERAPY

BY ERIC QIAO, KNOWLEDGE EXCHANGE DIVISION OF ENTERPRISE, UNIVERSITY OF NEW SOUTH WALES, SYDNEY



History of stem cell regenerative medicine

Tissue regeneration is one of the hallmarks that differentiate living organisms from machines. Stem cell therapy and regenerative medicine has a long history in applied medicine. The first successful bone marrow transplant was performed in 1956 by Dr Edward Donnall Thomas. This milestone was recognised by the award of a Nobel Prize in Physiology or Medicine in 1990. Tissue grafting and organ transplantation can also be considered forms of regenerative medicine if performed between tissue-compatible donors and recipients.

Past challenges and recent advancements

Despite the long success of bone marrow and organ transplantation, the discovery of innovative stem cell therapies tumbled in the past decade. Some obstacles include ethical concerns of cloning human tissue and undertaking research employing human embryonic stem cells obtained from abortions, as well as the scientific fuzziness of defining hierarchies of stemness and characterising various stem cell populations.

Arguably, regulatory uncertainty is one of the challenges that has created longstanding tension among unmet market need, innovative stem cell biotech companies and regulatory authorities. According to a report published by Paul Knoepfler in 2016, there were more than 570 clinics in the United States offering unapproved stem cell therapies[1]. In recognising both the chaos and enormous therapeutic potential of stem cell technology, Dr Scott Gottlieb, Food and Drug Administration (FDA) Commissioner, issued a number of statements in 2017[2] and announced the release of four guidance documents[3]. The guidelines clarify the FDA's interpretation of when cell- and tissue-based products would be exempt or regulated, its definition of 'minimal manipulation' and 'homologous use', as well as eligibility criteria for receiving a regenerative medicine advanced therapy designation.

Although cell therapy has been a much discussed topic, regulatory agencies of major markets only approved a handful of stem cell treatments beyond the use of umbilical cord blood stem progenitor cells. In contrast to the conservativeness of the FDA and the European Medicines Agency (EMA), the Japanese Government relaxed pharmaceutical affairs law, allowing fast-tracked stem cell therapy. Under the new *Pharmaceuticals and Medical Devices Act,* a stem cell product could be conditionally approved if it is proven to be safe. The therapeutic developer has up to seven years to gather a sufficient amount of evidence demonstrating the efficacy of their product[4]. This legislation relaxation invigorates the field of regenerative medicine, and Japan has become the paradise of clinical trials involving innovative stem cell technology.

Technologies in first- and second-generation stem cell therapy

Based on the underlying technology, popular stem cell therapies on the market and in development can be clustered into two generations. Early-generation technology isolates stem progenitor cells from donor tissue (for example, cord blood, umbilical cord, bone marrow and adipose tissue). It expands extensively in culture before being transplanted into a recipient to treat a spectrum of diseases, including neuro-spinal disorders, cardiovascular diseases, liver cirrhosis and inflammatory conditions. Despite perceived safeness, cultured stem cells have limited regenerative capacity in vivo. Although the mechanism of action has not been fully understood, this treatment seems to help patients tame their uncontrolled inflammatory response. The pioneering companies that are applying this first-generation stem cell therapy includee TiGenix and Mesoblast, both of which receive decent market valuation (more than US$500 million). In light of European market approval and the FDA registration trial, Takeda offered a US$630-million takeover of TiGenix in January this year. This shows the market welcomes an unconventional, effective stem cell therapy.

The discovery of induced pluripotent stem cells (iPSC) by Professor Shinya Yamanaka revolutionises this field and breeds the second-generation stem cell therapy. Compared with the first generation, iPSC is best known for its regenerative potential and

1 Turner L, Knoepfler P. *Selling stem cells in the USA: Assessing the direct-to-consumer industry*. Cell Stem Cell 2016: 19(2);154–157.
2 Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's comprehensive new policy approach to facilitating the development of innovative regenerative medicine products to improve human health, 16 November 2017, FDA News Release.
3 FDA announces comprehensive regenerative medicine policy framework, 16 November 2017, FDA News Release.
4 Konomi K., Tobita M., Kimura K., Sato D., New Japanese Initiatives on Stem Cell Therapeis, Cell Stem Cell 2015: 16(4); 350-352.

could theoretically differentiate all the cell types that constitute a human body; however, the clinical development of iPSC is hampered by two key risk factors: inherited tumourigenicity of pluripotent cells and the necessity of genetic manipulation during cell reprogramming. To overcome the first limitation, researchers would have to (at least partially) differentiate iPSC toward a selected lineage prior to transplant.

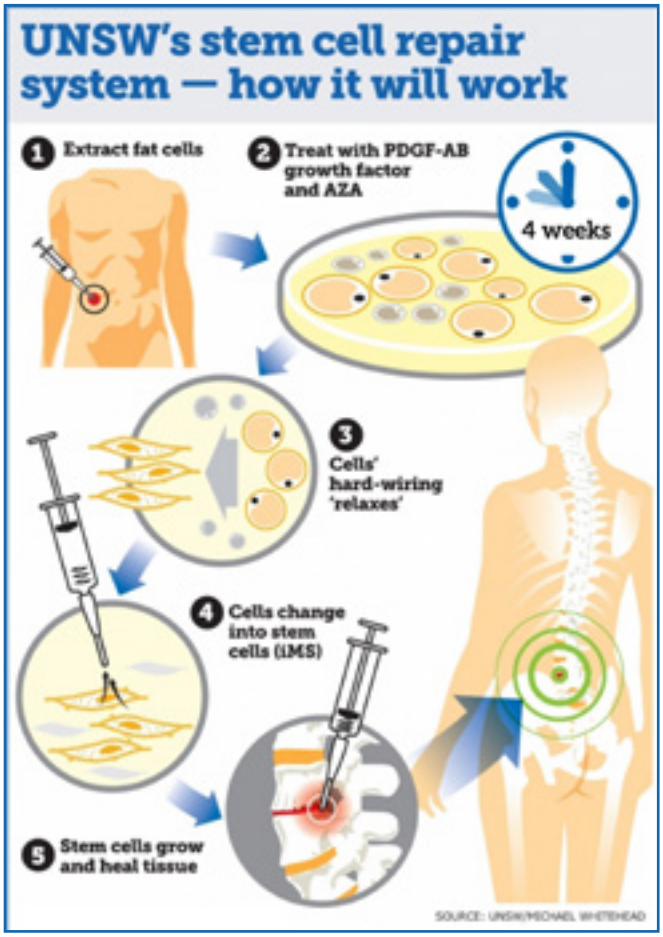
To mitigate the second risk factor, scientists have invented a virus-free and integration-free episomal vector-based reprogramming or chemical induction pluripotency[5], replacing the original viral transduction. Although reducing the key risks, these mitigation strategies also lead to downstream complications relating to genome instability associated with prolonged tissue culture, complex manufacturing process (combining reprogramming with subsequent differentiation), increased production costs, as well as ultra-low reprogramming efficiency (1/10-4-10-6). All of these are obstacles in front of developers of an iPSC-based therapy. RIKEN, Takeda (T-CiRA), Fujifilm and Cynata are leading companies adopting the second-generation stem cell technology.

The third generation, ims cells

To bypass those obstacles in the development of an iPSC-based cell therapy, Professor John Pimanda and Dr Vashe Chandrakanthan, at the University of New South Wales, invented a game-changing method, which enables vector-free reprogramming. This method employs only an approved small-molecule compound (5-azacitidine) and a well-studied growth factor (platelet-derived growth factor AB (PDGF-AB)) to convert fully differentiated cells (for example, human adipose cells) into multipotent stem cells. These reprogrammed cells were termed induced multipotent stem (ims) cells, a third-generation stem cell technology.

Evidence compiled from a wide range of animal studies has shown that ims cells are non-tumourigenic and, in contrast to cultured mesenchymal stem cells, have the capacity to regenerate tissues in multiple rodent spinal fusion and lateral muscle injury models in a context-dependent manner. Compared with iPSC, ims reprogramming only requires a transient treatment

5 Cao S., Yu S. et.al., Chromatin Accessibility Dynamic during Chemical Induction of Pluripotency, Cell Stem Cell 2018: 22(4); 529-542.



of cells with two clinically approved ingredients before transplantation, and the reprogramming process could be automated in fully closed, GMP-certified equipment. Furthermore, the reprogramming cocktail has been optimised to allow a much higher reprogramming efficiency (four per cent) using human specimens. As such, ims cells have significant scope for application in tissue regeneration.

To facilitate clinical translation of this technology, Pimanda and Chandrakanthan have teamed up with Associate Professor Ralph Mobbs, a neurosurgeon from the Prince of Wales Hospital who is a leader in spinal disc surgery in Sydney. Patents covering the ims reprogramming method have been granted, with broad claims in the United States and Australia. The team recently won a second prize in the Second Innovation and Entrepreneurship International Competition in Shenzhen, China. The team is also in the process of establishing a start-up, and is actively looking for commercial partners to sponsor an early-phase open-label pilot study to evaluate the safety and efficacy of ims cells in treating degenerative disc disease – a disease affecting one third of Americans aged over 50.

AusBiotech

Business Solutions Program

AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AVATAR

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

CHUBB

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

FROST & SULLIVAN

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

Biotech Daily

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

OFX

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

BIOTECH GATE
GLOBAL DATABASE

Biotechgate is the global lead-sourcing database for the biotech, pharma and medtech industries. Biotechgate is pleased to extend AusBiotech members a special 15 per cent discount on a subscription to the database.

biotechPrimer

BioTech Primer is pleased to extend AusBiotech members a special 10 per cent discount on course registration fees for BioTech Primer 'online' courses.

ausbiotech.org/business_solutions

THE DECISION EVERY CEO SHOULD MAKE

Implementing a paperless quality management system (QMS) will reduce risk and optimise resources, improving business performance and results.

Most companies are still relying on time-consuming and resource-dependent quality management processes, which are inefficient and can increase risk.

A quality management system (QMS) is an essential tool for any business wanting to improve. From ensuring product traceability and compliance, to meeting regulatory requirements, the success of your business can depend upon getting this decision right.

'By systemising your quality management, you can free up your resources,' says Director Grant Swanepoel from QT9 Software Australasia. 'Implementing the change to an eQMS [electronic quality management system] will significantly reduce the time spent doing quality control, allowing you to focus on other important tasks in your business, to help grow your business.' Whether you are a small business or a multinational enterprise, a QMS is essential in today's fast-changing business environment.

When Dane Brescacin, Technical Manager at Lovell Surgical Solutions, was brought on board to assist with the company's transition from TGA to BSI (ISO13485), he saw an opportunity to streamline operations by implementing a paperless QMS.

'The business was heading for a period of considerable growth and expanding over multiple sites, so the change was significant. I needed to write new procedures tailored to 13485 anyway, so it made sense to streamline the whole quality assurance process at the same time.'

Within just a few months, the product portfolio tripled and output rose twofold. The company could not have sustained a level of control through this period of growth if they had not implemented an eQMS.

Additionally, because QT9 offers integration between their QMS and ERP systems, Lovell Surgical Solutions was easily able to manage and maintain their high-quality standards while their production volumes were increasing.

'The system offers automated document control, total traceability, and remote login for approvals and reviews – this freed up so much time. So the return on investment

was noticeable within a short period, as our performance improved and production increased dramatically.'

For Ewen Laird, owner of Device Synergies, QT9's concurrent licensing model and the fact that it is a cloud-based system made it both an affordable and practical choice. It is also scalable, so you get every module but only pay for the number of licences you need. 'If you are building a company from the ground up, then QT9 is the solution for you. As it is cloud based, it was much simpler to get up and running,' says Laird. Another deciding factor for Laird was the fact that, although QT9 is a global company, there is local support available from QT9 Software Australasia.

'I've had the experience before of waiting a day for support from overseas. But with Chris and Grant based in Melbourne, they're just a phone call or email away, so any issues or queries can usually be resolved by the same day.'

QT9 QMS is a cost-effective and flexible quality management solution suitable for businesses of all sizes. Brought to you by QT9 Software Australasia, QT9 QMS combines the power of global reach with local presence. Make the right decision for your business today. Call or email us at sales@qt9software.com.au to arrange an obligation-free demonstration, or sign up for a 30-day free trial of the whole system (this includes local support). For more information, visit www.qt9software.com.au.

QT9 Australasia

Specialists in end to end business management tools for any industry

QMS

Conforms to ISO13485, TGA & FDA Standards

Key Modules

- Document Control
- CAPA
- Product Development
- Change Control
- Training

ERP

Key Modules

- Sales
- Purchasing
- MRP
- Forecasting
- Capacity Planning
- Accounting
- Batch Management

Cloud or Local Server solutions available

Contact Us now for a Demo or 30 Day Free Trial

sales@qt9software.com.au

www.qt9software.com.au

REGENERATIVE MEDICINE:

a new hope in dementia treatment?

BY DR NIAMH O'REILLY, CLINICAL RESEARCH CORPORATION

Recent advances in regenerative medicine research have led to the emergence of stem cell therapies as a potential therapeutic option for the treatment of Alzheimer's and other forms of dementia.

Unlike existing treatments for dementia that only slow the progression of the illness, stem cell therapy potentially holds the key to reversing symptoms and providing an eventual cure for the disease. Investment in research and development is therefore essential to establish the risk-benefit profile of this therapy in time to treat an ageing population that is currently at risk of developing dementia.

Dementia is a progressive neurodegenerative disorder affecting around 50 million people worldwide, with a new case occurring somewhere in the world every three seconds. It represents an estimated global cost burden of US$818 billion, and is recognised as one of the most significant health and social care challenges of the 21st century[1,2]. In 2018, around 425,416 Australians are living with dementia, while the yearly cost of caring for people with dementia is A$15 billion[3]. Without significant advances in the treatment of dementia, the cost to the Australian healthcare system could reach more than A$36 billion by 2056[3].

Dementia is characterised by multiple symptoms, including amnesia, cognitive impairment, disorientation, behavioural disturbance and loss of daily function[2]. The biggest risk factor for dementia is age, and with the world's population ageing rapidly, the burden is set to increase[2]. There are many different dementia types affecting the brain, the most common being Alzheimer's disease[4].

Pathogenesis of Alzheimer's disease

There is no cure or treatment to effectively target the underlying causes of Alzheimer's disease. The majority of cases are late onset and sporadic, driven by the interaction of complex genetic and environmental factors, with age being the predominant risk factor[2].

Neurodegeneration in Alzheimer's disease is linked to accumulation of two types of misfolded proteins: amyloid beta (Aβ) and tau (τ) proteins. Aggregation of Aβ protein fragments results in formation of amyloid plaques in the brain, while changes in the structure of τ protein leads to diminished structural support in neurons.

The progression of Alzheimer's disease also involves an inflammatory response to the presence of amyloid plaques. Immune cells cannot remove the plaques while inflammation in the brain tissue remains switched on, resulting in unchecked neurodegenerative damage[2].

The majority of treatments for Alzheimer's currently under clinical investigation have a disease-modifying mode of action, rather than targeting symptoms

alone[5]; however, clinical studies face challenges such as regulatory hurdles, slow trial recruitment and lack of validated biomarkers[6]. Indeed, the Food and Drug Administration (FDA) has not approved a new drug for the treatment of Alzheimer's disease since 2003[5].

Regenerative properties of stem cells

Stem cells can be derived from multiple sources, including embryonic cells, umbilical cord blood and various adult tissues (adipose tissue, skin and bone marrow). They have the potential to regenerate damaged tissue, reduce inflammation and promote healing. Stem cell therapies are prepared by extracting stem cells from a donor or the patient's own tissue. Cells are sometimes genetically modified and then incubated to increase their number before administering them to the patient.

Researchers discovered the presence of endogenous neural stem cells, consequently disproving the long-held theory that the adult brain was not capable of regenerating new neurons[7]. These endogenous neural stem cells are capable of migrating and integrating into injured regions of the brain[8]. One theoretical approach to treat neurodegeneration in dementia is to augment the function of endogenous stem cells, thereby promoting protection of remaining tissue and generation of new neurons. Longstanding research assessing the potential for newly generated neurons to integrate efficiently into brain tissue and to effect neurological improvements is ongoing[2,8].

Research progress

There are multiple active clinical studies investigating the potential to use stem cells to treat Alzheimer's disease, the majority of which use mesenchymal stem cells (MSCs)[9]. MSCs can be obtained from various sources, such as umbilical cord blood, adipose tissue and bone marrow. There are multiple advantages to using MSCs: they can be administered intravenously, exhibit blood-brain barrier penetration, have low tumorigenicity and do not elicit a strong immune response[10].

Transplantation of MSCs into rodents can reportedly inhibit Aβ- and τ-related cell death, reduce Aβ plaque formation, and stimulate neurogenesis, thereby successfully treating Alzheimer's disease in pre-clinical studies[2]. While the neuroprotective effects and reduced cognitive decline reported in animal studies are yet to be demonstrated in humans, the successful demonstration of safety and efficacy in animal models has supported the approval of several human trials using stem cells[2].

Multiple Phase I and II clinical studies to investigate the potential of MSCs from various sources are underway in Korea, China and the United States[2,11]. An open-label Phase I clinical trial has been completed to evaluate the safety and tolerability of intracranially injected MSCs derived from umbilical cord blood. While no patients showed serious adverse effects, the procedure did not slow cognitive decline over 24 months of follow up[11,12].

Future investigations may involve a multimodal approach to treatment using a combination of pharmacological therapies, augmentation of endogenous stem cells and administration of exogenous stem cells to achieve regeneration of neurons, and reverse the symptoms of dementia. The outlook is optimistic; stem cell therapies do have the potential to be used in the treatment of Alzheimer's disease and other forms of dementia.

References:

1. Huges J. 'This is one of the biggest global health crises of the 21st Century' [Internet]. World Economic Forum. 2017. Available from: https://www.weforum.org/agenda/2017/09/dementia-trillion-dollar-global-crisis/.

2. Duncan T, Valenzuela M. 'Alzheimer's disease, dementia, and stem cell therapy'. Stem Cell Res Ther. 2017;8(1):111.

3. Dementia Statistics [Internet]. Dementia Australia. 2018. Available from: https://www.dementia.org.au/statistics.

4. What is Dementia? [Internet]. Dementia Australia. 2018. Available from: https://www.dementia.org.au/about-dementia/what-is-dementia.

5. Cummings J, Lee G, Ritter A, Zhong K. 'Alzheimer's disease drug development pipeline: 2018'. Alzheimer's Dement Transl Res Clin Interv. 201AD;4(May):1–18.

6. Alzheimer's Drug Discovery Foundation. 'Closing in on a cure: 2017 Alzheimer's clinical trials report'. Alzheimer's Drug Discov Found. 2017.

7. TAKAGI Y. 'History of Neural Stem Cell Research and Its Clinical Application'. Neurol Med Chir (Tokyo). 2016;56(3):110–24.

8. Tang J. 'How close is the stem cell cure to the Alzheimer's disease future and beyond?' Neural Regen Res. 2012.

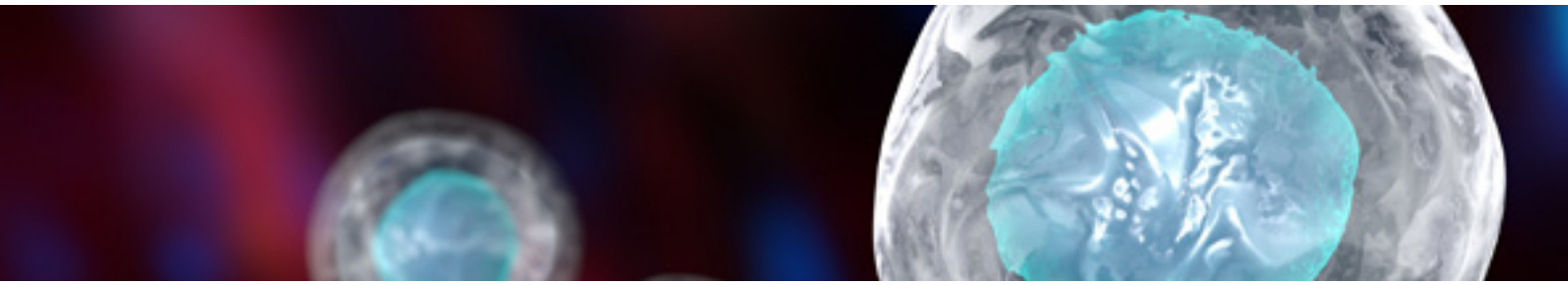
9. Clinical trials for Alzheimer's disease using stem cells [Internet]. 2018. Available from: https://www.clinicaltrials.gov/ct2/results?cond=Alzheimer%27s+Disease&term=stem+cell&cntry=&state=&city=&dist=&Search=Search.

10. Kwak K, Lee S, Yang J, Park Y. Review Article 'Current Perspectives regarding Stem Cell-Based Therapy for Alzheimer's Disease'. 2018.

11. Kang JM, Yeon BK, Cho S-J, Suh Y-H. 'Stem Cell Therapy for Alzheimer's Disease: A Review of Recent Clinical Trials'. J Alzheimer's Dis. 2016;54(3):879–89.

12. Shukla AA, Hubbard B, Tressel T, Guhan S, Low D.' Downstream processing of monoclonal antibodies - application of platform approaches'. J Chromatogr B Analyt Technol Biomed Life Sci. 2007 Mar 15;848(1):28–39.

MESOBLAST LEADING THE WAY TO COMMERCIALISATION



BY DR SILVIU ITESCU, CHIEF EXECUTIVE OFFICER, MESOBLAST

Following strong results from its Phase III acute graft versus host disease trial, Mesoblast's objective is to be first to market in the United States with a Food and Drug Administration (FDA)–approved allogeneic mesenchymal lineage cell product.

Mesoblast's leading portfolio of cellular medicines is based on its disruptive cellular technology platform, proprietary manufacturing processes, and multiple Phase III assets.

The company's Phase III trials are evaluating Mesoblast's product candidates for the treatment of steroid refractory acute graft versus host disease (aGVHD), chronic heart failure and chronic lower back pain due to degenerative disc disease.

Two allogeneic products using Mesoblast's patented mesenchymal stem cell technology have been approved in Japan and Europe, with both licensees the first to receive full regulatory approval for an allogeneic cellular medicine in these major markets.

Mesoblast's goal is for MSC-100-IV (remestemcel-L) to be the first commercially manufactured allogeneic stem cell product in the United States.

Disruptive technology platform

Mesoblast is developing immuno-selected, culture-expanded cellular medicines based on mesenchymal precursor cells (MPCs) and their progeny, mesenchymal stem cells (MSCs). Rare mesenchymal lineage cells (approximately 1:100,000 of bone marrow cells) are found around blood vessels and are central to their maintenance, repair and regeneration. Preclinical studies have shown that these cells respond to signals associated with tissue damage, secreting mediators that promote tissue repair and modulate immune responses.

Mesoblast's immuno-selection process provides a homogeneous population of MPCs, which are at the apex of its mesenchymal lineage hierarchy, with receptors that appear to respond to activating inflammation and damaged-tissue signals. This enables targeting of multiple pathways that may result in therapeutic benefits in a number of complex and intractable diseases.

A key feature of Mesoblast's mesenchymal lineage cells is that they are allogeneic and immune-tolerant. They are administered without the need for donor–recipient matching or recipient immune suppression,

and therefore are often referred to as off-the-shelf medicines.

Extensive intellectual property estate provides substantial competitive advantage

Mesoblast's intellectual property (IP) portfolio encompasses approximately 800 patents or patent applications across 69 patent families, which the company believes will provide substantial competitive advantages for the commercial development of its cell-based therapies in major markets, including the United States, Europe, Japan and China.

The strength of Mesoblast's IP portfolio has been demonstrated by Mesoblast's licensure of certain patent rights to TiGenix and its acquirer Takeda, enabling the launch of its adipose stem cell-derived MSC product, Alofisel®, for the local treatment of perianal fistulae, a complication of Crohn's disease. Alofisel was the first allogeneic stem cell therapy to receive central marketing authorisation approval in Europe.

Manufacturing capabilities

Mesoblast's cellular technology platform enables allogeneic 'off the shelf' product candidates with batch-to-batch consistency and reproducibility. The inherent technical properties of Mesoblast's mesenchymal lineage cells allow for scalable culture expansion for purposes of producing anticipated commercial quantities. Proprietary media formulations, advances in development of 3D bioreactor technology and automation are intended to deliver step changes in yield and cost of goods sold (COGS) reductions.

An alliance with the Lonza Group has been established to ensure long-term commercial manufacturing requirements.

The path to commercialisation

Mesoblast's licensee, JCR Pharmaceuticals Co. Ltd., was the first cellular medicine to receive full regulatory approval for commercial use in Japan with its treatment for aGVHD, TEMCELL® HS Inj[1].

In America, there are no Food and Drug Administration (FDA)–approved treatments for steroid-refractory aGVHD. This is a devastating disease associated with significant morbidity, and is a leading cause of mortality following an allogeneic bone marrow transplant. Mesoblast's Phase III trial of remestemcel-L in 55 children with steroid-refractory aGVHD (89 per cent suffering from the most severe form, grade C/D disease) successfully met the primary endpoint of Day 28, and improved overall response rate and associated survival benefit at Day 100. Based on interactions with the FDA, Mesoblast believes that successful results from the completed Phase III trial, together with Day 180 safety follow-up, survival and quality-of-life parameters in these patients, may provide sufficient clinical evidence to support a US regulatory filing.

Dr Silviu Itescu

Mesoblast is evaluating its mesenchymal precursor cell product, MPC-150-IM, in a Phase III trial in moderate to advanced chronic heart failure. This events-based study is targeted to complete enrolment of up to 600 patients in 2018. The National Institutes of Health (NIH) is also sponsoring a Phase II-b study of MPC-150-IM in patients with end-stage heart failure who have a left ventricular assist device (LVAD). The use of MPC-150-IM in this indication has been granted an FDA Regenerative Medicine Advanced Therapy Designation, which aims to expedite the development of regenerative medicine therapies for the treatment of serious and life-threatening diseases. Mesoblast hopes that the results of the NIH-sponsored Phase II-b trial could potentially support a regulatory filing for MPC-150-IM in this patient population.

Mesoblast's third product candidate in Phase III clinical development, MPC-06-ID, is being investigated for treatment of chronic lower back pain due to degenerative disc disease in patients who have failed conservative therapies. Enrolment of 404 patients has been completed across 38 sites in the United States and Australia. Previously, Phase II results in 100 patients showed that a single intra-discal injection of MPC-06-ID alleviated pain and improved function for up to three years in patients whose symptoms were not adequately treated with standard of care therapies.

This robust pipeline of late-stage cellular medicines for serious and life-threatening conditions, recognition by the FDA of their importance, a burgeoning portfolio of earlier-stage therapy candidates and a very comprehensive IP portfolio puts Mesoblast in a very strong position going forward.

1 TEMCELL® HS Inj. is a registered trademark of JCR Pharmaceuticals Co. Ltd.

THE AUSTRALIAN STEM CELL PATENT LANDSCAPE

BY BRYAN LEAW (PHD), TRAINEE ATTORNEY, WATERMARK INTELLECTUAL PROPERTY

Stem cells have been a particularly shiny beacon in regenerative medicine due to the ever-growing observations of their therapeutic benefits in the laboratory.

Stem cells are undifferentiated cells with unlimited potential to regenerate cells lost as a result of disease, and thus restore normal function. More recently, studies have shown stem cells to have reparative properties, homing in on sites of injury and stimulating tissue repair. These remarkable discoveries beg the question – how can they be protected, and to what extent, by intellectual property rights?

What stem cells are patentable?

Stem cells are patentable in Australia as long as they meet the requirements laid out in the *Patents Act 1990 (Cth)* as interpreted by the courts. According to the most recent guidance, a patentable invention requires (among others):

- an intervention by a technologist so that biological materials claimed are removed from their natural state
- a demonstrable use.

The exception is where embryonic stem cells are involved, as section 18(2) of the *Patents Act* specifically excludes 'human beings and the biological processes for their generation' from patentability. This stance contrasts with other major intellectual property destinations:

- The United States: arguably the most liberal, it only disbars patent claims 'directed to or encompassing a human organism'.[1] Three key patents are held by the Wisconsin Alumni Research Foundation for human embryonic stem cell use.
- Europe: stem cell patents are only granted if the biological materials are accurately described and have industrial application. Previously, stricter laws completely banned stem cell patents, but this ban was overturned in 2014[2].
- The United Kingdom: 'Use of embryos for commercial purposes is not patentable', nor are totipotent cells that 'have the potential to develop into an entire human'[3]. In the United Kingdom, a distinction between totipotent and multipotent cells has been made. This is an important distinction for stem cell clinical trials, as some meet the multipotency criteria (ability to differentiate into multiple cell types) but not totipotency (ability to differentiate into an entire organism). In Australia, claims for stem cells isolated from their natural environment and cultured into cell lines for use in therapeutic application are typically allowed. This extends to products created by the cells: synthetic genetic DNA sequences, proteins expressed by a gene, or isolated DNA coding for a gene sequence[4].

In its guidelines, IP Australia makes clear that human embryos, totipotent human cells and processes involving the creation of embryos are not patentable[5]. This is because section 50(1) provision of the *Patents Act* empowers the Commissioner to reject patents that are 'contrary to law'[6]. The relevant statutes relating to stem cell patents are the *Research Involving Human Embryos Act 2002 (Cth)* and *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*, which both include a provision that it is unlawful to create a human embryo except for the purposes of assisted reproductive technology.

1 United States Public Law No 188–199, s 634.

2 Case C-364/13, *International Stem Cell Corporation v. Comptroller General of Patents, Designs & Trademarks* [2014] EU:C:2014:2451.

3 United Kingdom Patent Office, 'Inventions Involving Human Embryonic Stem Cells', Practice Notice, April 2003, <www.patent.gov.uk/patent/notices/index>.

4 IP Australia, Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms, <www.ipaustralia.gov.au/pdfs/patents/ specific/biotech.pdf> at 16 June 2004.

5 Section 2.9.3.5.1 Stem Cells, IP Australia, Manual of Practice and Procedure (7 June 2018) <http://manuals.ipaustralia.gov.au/patents/Patent_Examiners_Manual.htm>.

6 The relevant statutes relating to stem cell patents are the *Research Involving Human Embryos Act 2002 (Cth)* and *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*, which include a provision that it is unlawful to create a human embryo except for the purposes of assisted reproductive technology.

Despite this, Australia is considered one of the more liberal jurisdictions worldwide in protection of embryonic stem cell research. This is reflected in a recent patent office decision, which found that a blastocyst produced by parthenogenesis (unfertilised activation) does not have the potential to develop into a human being and hence the claimed methods defined as patent-eligible matter[7]. This is a step forward for the law surrounding the field of regenerative medicine in Australia, which is rapidly advancing into clinical trials.

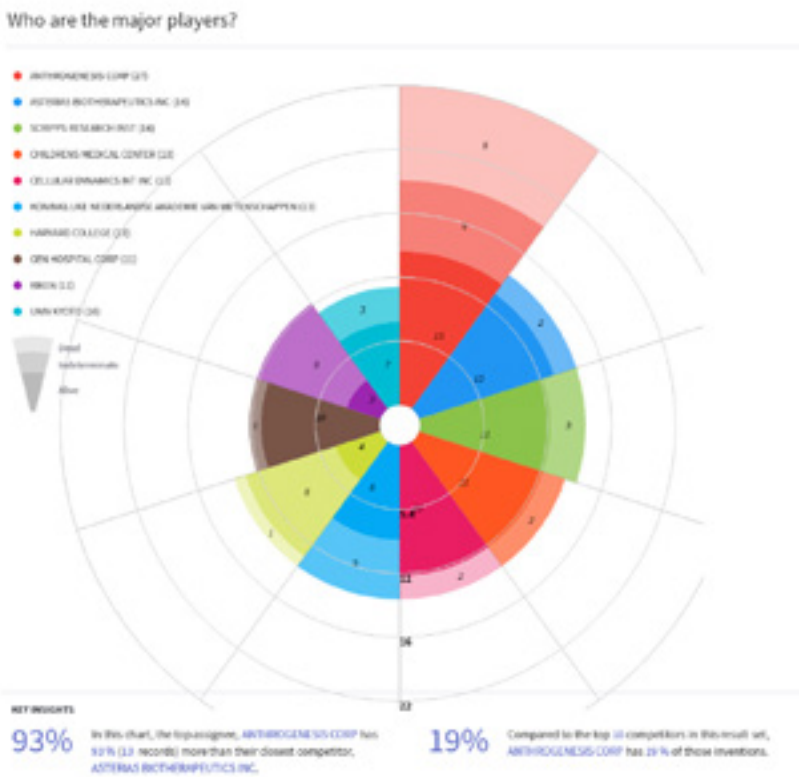


Figure 1 | Analysis of stem cell patent holders in Australia. Source: Derwent Innovation Analytics

State of research and patents in Australia

Translational research leading to clinical trials has mainly utilised multipotent adult stem cells in alignment with global stem cell research trends. The Australian Clinical Trials website (www.australianclinicaltrials.gov.au) reveals that there are 15 clinical trials actively recruiting patients in Australia citing stem cell therapies. The clinical trials are evenly split between Phase I (dose escalation) and Phase II/III (safety and efficacy). These cells serve several therapeutic functions:

- self-renewal: these cells are multipotent and can replenish missing cells
- therapeutic cargo: these cells can release proteins and other factors that can reduce injury
- modulatory: these cells can interact with host cells to stimulate recovery.

Australian researchers play a critical role in stem cell research at a global level. Scientist members of Stem Cells Australia were cumulatively granted A$30 million from 2011–2017, and published more than 700 research articles. In the last five years, 613 stem cell–related patents have been submitted to IP Australia, with 334 granted to date (55 per cent). The majority of the patents protect the stem cell types listed above that are currently in clinical trials. This makes sense, as these cells are closest to market and hence have clear, attributed commercial value. Interestingly, American assignees hold 52 per cent of granted stem cell patents – the leading assignee Anthrogenesis Corp is a US biotech company harvesting placental stem cells from tissues discarded after deliveries (Figure 1).

Stem cell patents bring with them unique challenges. A patent typically lasts up to 20 years, but the design, registration and completion of a clinical trial that meets the strict regulatory and ethical requirements for stem cell therapy could take 10 to 15 years. That US entities are more protective of their intellectual property might be a reflection of the innovation landscape in the United States, and a greater willingness (and more available capital) to do so. This is also reflected in the continued investment of US entities in securing intellectual property. Professor Alta Charo, a leading authority on law and bioethics, puts it quite simply; 'With no patent, there is no return [on investment]'.

Stem cell therapy will likely be the leading form of regenerative medicine moving forward. Increasing numbers of registered clinical trials reflect the growing belief in the observed therapeutic and reparative properties of stem cells, in both in vitro and in vivo models of disease. Australian researchers occupy the upper echelon of stem cell research, but currently US assignees hold the vast majority of Australian stem cell patents. The biological patent landscape is becoming increasingly dynamic and contested. Therefore, the strategic use of patents will be important, not only for commercialisation and bringing new products to market, but also to generate new channels for funding and perpetuating stem cell research.

7 International Stem Cell Corporation [2016] APO 52 (16 August 2016).

BIOTECH AND THE CLOUD

Are you getting left behind?

Exigence, a local Australian success story, is driving innovative information technology (IT) for biotech and life sciences with Amazon Cloud Solutions.

Exigence has partnered with Amazon Web Services (AWS) to bring biotech-specific cloud-based solutions to the healthcare and life sciences sectors. These are aimed at simplifying infrastructure, enhancing security and providing immediate return on investment. The cloud can be used cheaply and effectively to:

- create secure and compliant collaboration platforms for managing the information life cycle
- build your disaster recovery system or offsite backup at a fraction of the cost
- upgrade your legacy infrastructure using the cloud without large capital expenditure investments, while retaining compliance with FDA 21 CFR Part 11, SOX and other regulatory bodies
- store/mine large datasets and convert to knowledge using business intelligence, artificial intelligence and machine learning, without investing in expensive hardware
- centralise your infrastructure to solve the latency and accessibility issues across geographic regions
- build highly scalable computer systems, supporting your 'Good Laboratory, Clinical and Manufacturing Practices' (GxP)

Exigence recently completed the following projects with AusBiotech members:

Client: MTPConnect
Our solution: An industry-first, totally innovative design utilising the AWS public cloud, while also ensuring that complete encryption of all information and systems was commissioned. The design was in line with government data sovereignty and Australian Signals Directorate (ASD) guidelines. The infrastructure was complemented by a 'workstations as a service' solution, which ensured that the entire ecosystem was cloud hosted.

Client: Starpharma
Our role: Strategic IT adviser and managed services partner for complete range of IT infrastructure services.
Our solution: Infrastructure capacity planning, sizing and solution cost modelling, and managing security services with reporting to the executive team. Exigence designed and deployed scalable virtualised IT infrastructure utilising government-approved AWS cloud for backup, business continuity and disaster recovery.

Client: Hume Rural Health Alliance (incorporating 17 health centres and hospitals)
Our solution: Exigence designed cloud-hosting solutions for a centralised patient administration system. We successfully reviewed and outlined available public cloud solutions, with cost comparisons against on-premises, hybrid and various cloud-optimised solutions demonstrating multimillion-dollar savings.

Reduce time to insights

The Exigence and AWS cloud offers the perfect place to experiment. With no large up-front capital expenses, you can resource projects instantly or augment your existing data modelling for computationally demanding workloads. The cloud facilitates collaboration between partners, contract research organisations, manufacturers, universities, authorities and supply chains within 190 countries.

Data storage and lakes

Data output from clinical trials, genomic analysis, and research and development can be large and complex. With Exigence, you have access to secure, durable and highly scalable cloud storage, and only pay for the storage used.

Risk assessment and management

With the Notifiable Data Breach scheme, Exigence has developed industry-specific risk assessments, which allow insight into an organisation's security posture and data vulnerabilities, offering a remediation plan developed under ASD guidelines, and incident response, policies and procedures.

Disaster recovery – business continuity

Clients replicate their business data and systems to our secure cloud and can confidently recover this data within minutes of a disaster being declared. We've automated and simplified this process – eliminating large, up-front capital expenses and providing peace of mind.

IT compliance

Translating many compliance and risk-management requirements into IT systems to meet regulatory standards is complex. Bridging the gap requires expertise of IT systems and regulatory compliance standards, such as 21 CFR Part 11. We apply standards and recommendations by APRA, HIPAA, FDA, TGA, EHR and more.

Benefit now, accelerate scientific discovery, enable operational efficiency, simplify global collaboration and return greater shareholder value.

Call Iby Boztepe, Director of Professional Services, Exigence, for a free consultation on 03 9568 5437 or email ibyb@exigence.com.au. AusBiotech members receive a discount for services from Exigence.

EXIGENCE

WHEN MEDIOCRITY IS INTOLERABLE
SUCCESS IS INEVITABLE

Exigence brings proven experience in managing IT for clients within the Healthcare, Biotech and Life Sciences industries for over 19 years.

MANAGED SECURITY

- Data Loss Prevention
- Security policies
- Firewall and intrusion protection
- Anti-Virus and Anti-Spam
- Sandboxing protection
- Staff security awareness training

MANAGED SERVICES PROGRAM

- Remote support
- Remote monitoring
- System maintenance
- Server management
- Helpdesk – support queries and personal interaction with your staff

MANAGED CLOUD SERVICES

- Disaster Recovery as a Service
- Cloud migration
- IT Infrastructure as a Service
- Collaboration Services [Email, Video and Tele-Conferencing, File Sharing]
- Virtual Workstation
- Backup & Storage

03 9568 5437
WWW.EXIGENCE.COM.AU

SUPER-HIGH OLEIC SAFFLOWER OIL A GAME CHANGER

The Office of Gene Technology Regulator (OGTR), responsible for administering the *Gene Technology Act 2000*, announced in July that a super-high oleic (SHO) safflower, propriety of GO Resources, has been approved for commercial cultivation.

This major milestone achievement brings the introduction of GO Resources' game-changing super high oleic safflower oil (SHOSO) for the oleochemical industry one step closer.

This is a major advancement, both commercially and environmentally, as this raw material is meeting the increasing demand from consumers, producers and governments for bio-derived feedstocks for industrial applications, with a focus on the biolubricant, biochemical and biomaterial industries.

SHO safflower will be the world's first plant-based source of oleic oil at greater than 90 per cent purity (directly on extraction from the seed). SHOSO represents an exciting step in the development of plant-sourced alternatives to petroleum-based raw materials and other traditional sources of oleic oils used in petrochemicals in industrial products ranging from fuels and lubricants, to specialty chemicals and plastics.

Michael Kleinig

The purity of the oleic acid, and the corresponding very low levels of other fatty acids, provide significant functionality advantages when compared to current bio-based oils (such as palm, high oleic (HO) canola, HO soybean and HO sunflower oils).

The oil combines purity with functionality, stability, biodegradability and renewability. Compared to other bio-based oils, GO Resources' SHOSO provides superior thermal properties and functionality, which make it ideal for use in industrial applications. SHOSO also performs as well as, or better than, synthetic oils derived from fossil reserves.

Oleic oils have many uses, particularly as a raw material for bio-based feedstocks used in multiple industrial products, including lubricants, solvents, cosmetics, plastic additives, resins and polymers, biofuels, coatings, and paints and inks. The advantage of SHOSO is that its more than 90 per cent purity is expected to facilitate the production of these bio-based feedstocks at a reduced cost.

SHO safflower was developed at the Commonwealth Scientific and Industrial Research Organisation (CSIRO), through the CSIRO and Grains Research and Development Corporation (GRDC) Crop Biofactories Initiative. GO Resources has the exclusive worldwide licence to commercialise this technology.

GO Resources' Managing Director, Michael Kleinig, comments, 'The GO management team has achieved a major milestone by gaining regulatory approval for this pioneering technology in a relatively short period. This is only the fourth crop in Australia to achieve this type of approval from the Office of the Gene Technology Regulator.

'Oleic acid at more than 90 per cent purity (when extracted from the seed) is a first. This level of oleic acid is currently the highest of any commercially available plant-derived oil worldwide. When coupled with greatly reduced levels of the less-desired saturated and polyunsaturated vegetable fats, this source of oleic oil is ideally positioned to replace oleic oil sourced at much lower levels of purity from palm, tallow and other oilseeds. Further, it is from a naturally occurring and replaceable source.'

GO Resources' Head of Research and Development, David Hudson, says that the focus for the balance of 2018 will be into continued research on farming systems and market development activities, including the supply of samples of its SHOSO for evaluation by potential end-use customers in the Australian and global industrial and oleochemical industries.

'Safflower is a hardy and adaptable crop that can be grown successfully in both dryland cereal crop rotations and in irrigated cotton and rice rotations, where it delivers both agronomic and yield benefits to farmers,' says CSIRO's Dr Craig Wood.

Wood says that safflower is an ideal crop for Australian conditions as it flourishes in warm conditions from southern Australia through to central Queensland and Western Australia.

According to GRDC's General Manager Business Development, Ron Osmond, safflower crops now provide farmers with an additional profitable crop alternative.

GO Resources remains on track with its commercialisation plans, with production planned initially for south-west Victoria through to northern New South Wales this year.

This milestone brings GO Resources one step closer to moving out of the start-up phase, and towards becoming a company with increasing local and international reach. GO Resources is currently seeking funding that will complete the commercialisation of SHOSO, with its 2018 market development crops already in the ground in some regions. A much larger widespread commercial release is still on schedule for our 2019 winter.

GO Resources is also well advanced in bringing its second-generation 'elite' safflower variety to market through the use of sophisticated accelerated plant-breeding techniques. This variety is expected to have significantly higher oil content, as well being higher yielding. This elite variety is expected to be released in 2021.

GO Resources has already expanded its cropping regions into northern Australia, as well as investigating northern hemisphere regions such as the United States and Canada.

For more information, visit www.go-resources.com.au.

NEW AGRITECH HUB IN CANBERRA LINKS INDUSTRY WITH RESEARCH

Australia's newest and smartest agritech hub, the Centre for Entrepreneurial Agritechnology (CEAT) is set to transform the way agritech is developed and used in Australia.

The new hub will be a one-stop shop for agritech, providing entrepreneurs and farmers with access to the latest discoveries, academics with the potential to translate their research, and students with opportunities for industry placements.

Located in the National Agricultural and Environmental Sciences Precinct in Canberra, the CEAT is a unique collaboration between Australian National University (ANU), Commonwealth Science and Industrial Research Organisation (CSIRO), agricultural peak bodies and the Australian Capital Territory Government.

Its strategic location in Canberra provides direct access to key government departments, including the Australian Centre for International Agriculture Research, and the Department of Foreign Affairs and Trade.

A one-stop hub for agritech

The CEAT will be a one-stop hub for agritech, supporting basic research, translation and product development. Entrepreneurs will be able to source the latest research and technological innovations, while farmers will no longer have to search the country for researchers to solve their problems.

'We have innovative plant science research at ANU sitting alongside the world's best agricultural plant-breeding research at CSIRO – it's a nexus that hasn't occurred anywhere in this country and is rare elsewhere in the world,' says Professor Mick Cardew-Hall, Pro Vice-Chancellor (Innovation), ANU.

The CEAT is unique because of the breadth and depth of research it covers, which ranges from genetics and molecular structures to whole organisms and their place in the ecosystem.

'Understanding ecosystems will enable us to overcome barriers to sustainable farming,' says Professor Saul Cunningham, Director, Fenner School of Environment and Society, ANU.

Plant science event in Canberra. Image © Derek Collinge

'I'm excited that better technology such as drones and on-ground sensors will provide opportunities for farmers to be productive and profitable, and also meet sustainability goals,' says Cunningham.

The CEAT will provide access to cutting-edge facilities such as the Australian Plant Phenomics Facility, which offers state-of-the-art phenotyping tools and growth chambers not seen elsewhere in the world, as well as omic platforms through the Joint Mass Spectrometry Facility.

The ability to analyse large data sets – a critical bottleneck in digital agriculture – is catered for by the National Computational Infrastructure, which houses the largest supercomputer in the Southern Hemisphere, as well as the Computational Biology and Bioinformatics unit at ANU. Coding and engineering advice is available from the ANU College of Computing and Engineering Science.

The co-location of plant and agricultural research at ANU and CSIRO, combined with access to research facilities, is a powerful resource and creates incredible opportunities for collaboration.

Opportunities for entrepreneurs

'The agritech space is very rapidly changing – it's one of the most disrupted areas globally,' says Dr Jen Taylor, Research Scientist with CSIRO Plant Industry.

Phenomobile. Image © CSIRO/APPF

The CEAT aims to harness this space by fostering interactions between researchers and industry.

'Companies will get immediate access to the results and innovation that is coming from academic research,' says Professor Robert Furbank, Director of the ARC Centre for Excellence of Translational Photosynthesis and Leader of the Furbank Lab at the ANU Research School of Biology.

This will provide industry partners with a huge competitive advantage.

'There is a rich store of expertise and intellectual property within ANU that has great commercial potential. We are looking for partnerships with investors or companies that can help translate our research into something that will have economic benefit,' says Cardew-Hall.

These partnerships will be supported by the large number of entrepreneurial resources in Canberra, including CSIRO's ON program, Canberra Innovation Network, GRIFFIN Accelerator, CICADA Innovations, ANU Innovation and ANU Connect Ventures.

Researchers see their work translated

At the CEAT, researchers get opportunities and support to translate their research.

'Previously it was an almost accidental process for discoveries to be taken through to the product stage,' says Furbank.

Now there is a structure that links research ideas with end users, collaborators and funding.

'The exciting part about [the] CEAT is it's an opportunity for fundamental researchers like myself to have direct access to people with more entrepreneurial thought,' says Dr Megan McDonald, a Grains Research and Development Corporation–funded postdoctoral scientist at the ANU Research School of Biology.

Increasingly, researchers are also being asked by funding bodies and by government about their impact on society. So working on research that gets translated 'is a big draw for fundamental researchers,' says McDonald.

Students work with industry on real-world projects

A feature of the CEAT is internships and company placements for students and researchers, which provides opportunities to work with industry, consider new career paths and establish networks.

'Networks are extremely important for getting a job or moving around in the field,' says McDonald.

Students will also have the opportunity to work on real-world projects to help farmers to produce food efficiently, or improve the sustainability of crop production.

'The breadth of experience students will get will be unparalleled,' says Dr Robert Sharwood, Senior Lecturer at the ANU Research School of Biology.

'There is no better time to be involved in agritech,' Sharwood adds.

To find out more about the Centre's research partnerships, co-location, translational opportunities and industry placements, contact us at ceat@anu.edu.au.

LINKING AGTECH TO THE NEW-WORLD CONSUMER

BY ROBERT POOLE, AGRIBUSINESS NATIONAL LEAD; AND EMMA WHEELER, MANAGER, AGRIFOOD MANAGEMENT CONSULTING, KPMG

The ability to feed the global population will be challenged with the addition of approximately one-third more people by 2050, and with increasing consumption per person. Not only will the challenge be providing enough food, but providing food with nutritional adequacy to alleviate malnourishment and other human health risks. For example, global malnutrition increased from 777 million people impacted in 2015, to 815 million in 2016.

The speed at which new systems and technologies emerge and are adopted will underpin the food and fibre sector's capacity to meet the world's future nutritional demand.

The challenges relating to the doubling of agricultural output from Australia are outlined in 'Talking 2030' – a report written by KPMG in conjunction with the National Farmers' Federation (NFF) and many guest authors.

Our changing view of the food we consume

Consumers with rising disposable incomes are increasing their focus on how they can understand more about the food they eat – commonly referred to as food provenance. This includes the food's nutritional constituents, expectations on producers to be ethical and sustainable, and advancing product traceability and safety. A combination of current and emerging technologies (such as mobile phones, the cloud, sensors, blockchain, robotics, Internet of Things, augmented reality and satellite) can enable improved data capture, and subsequently result in a more seamless and gratifying connection with the consumer.

From the farm to the consumer, the traditional and linear value chain is being disrupted by a web that is constructed around the consumer. Infrastructure to support access to fresh food will supercharge the supply chain for Australia. Emerging technology has facilitated the emergence of direct pathways within the web, acting as a direct connection to any participant within the web. Processes are increasingly becoming simplified and there is a question around the role the middlemen will play; products can now flow directly to consumers through online digital channels.

This addresses cost efficiency, and health and safety issues, and decreases resources needed (that is, taking trucks off the road who transport goods from farms to distributors, then to consumers). A reduction in the number of parties in a chain means more value could potentially be captured by fewer players, including

primary producers. To gain the benefit, all those involved should understand their own position, and how they fit into the web and interact with others. This will facilitate maximum contribution and deliver high-value products.

Technology not only provides many different channels to the consumer, it creates an environment in which products can be designed based on an understanding of the consumer and their expectations. Technology will assist in personalising the consumer's experience to ensure that this is achieved.

As consumers will constantly seek information about the product they are after, information and education on products is crucial. Uncertainty around the sustainability, efficacy, safety or quality of one product in comparison to another will make the buying decision easier. Producers are up for scrutiny as health becomes the focus of communities globally.

Products are no longer purely products; leveraging technology, they can be tailored to meet nutritional requirements specific to the buyer. This creates an interesting opportunity for the merging of pharmaceuticals and nutraceuticals with food. Industries are integrating as the gap between nutrition and medicine is closed, moving towards a preventative healthcare system that includes food and nutrition as a solution.

Functional, high-health foods are entering the market to facilitate this transition from curative to preventative health care. Food organisations have an opportunity to strategically pivot to nutritional businesses, providing scientifically enhanced functional foods. In January 2018, Nestlé did just this and sold its confectionary arm to Ferrero, investing heavily in innovative products where it sees market growth, including nutritional products.

Traditional protein options have changed in line with consumer preferences. Cellular agriculture is slowly permeating into mainstream markets and will provide cheaper or at least new options for nutrition that are likely to have a smaller environmental footprint.

The challenge to get fresh, nutritious food to the consumer is increasing with urbanisation. The solution is establishing farming practices in urban areas. Closed-loop, vertical farms on the top of high-rise buildings, supermarkets, offices and central city gardens are popping up. Modular Farms Co, an Australian company, is a complete indoor vertical-farming system that is capable of producing fresh, healthy plants virtually anywhere in the world, in any climate. They have custom-designed their infrastructure based on an urban farm, with the ability to scale as needed, and can add modules for multiple purposes.

Robert Poole

Emma Wheeler

How does agtech and the food supply chain support this new consumer need?

The use of technology in food and fibre production is partly about customisation of more broadly applied science. For example, in digital technologies, agriculture provides unique challenges due to the outdoor environment, low connectivity, lack of capital, the large number of small businesses and variable conditions (such as soil and weather). The role of developers is often to customise the technology and ensure that it connects to direct commercial problems or opportunities.

In the digital space, there is a clear role of local organisations to customise application by providing baseline data about things such as soil and climate, and integrated support in areas such as agronomy and finance. It is also important that digital systems link to retail and food processing supply chains, and the requirements of commercial companies and regulators. In some cases, the requirements will flow through to export destinations and customers. For example, the concept of borderless fresh food precincts designed to link with airfreight has emerged (see KPMG's 'Think Big Think Fresh' 2016 report). In other cases, new science is directly applied to food production, such as new breeding technologies.

In this example, technology can create a tension between higher productivity, or improved environmental and nutritional outcomes, and consumer needs. This tension has been clear in the challenges faced in the commercialisation of some genetically modified plants and animals. The emergence of a new set of plant-breeding techniques is exciting, but the food industry must ensure that the regulatory and commercial foundations are in place to allow adoption in a manner that is founded in science, and is well understood by the new-world consumer.

KPMG will be speaking at AusAg & Foodtech Summit 2018.

LANDMARK WINTER GRAIN SEASON CASE STUDY

BY ANASTASIA VOLKOVA, CHIEF EXECUTIVE OFFICER AND FOUNDER, FLUROSAT

A leading agribusiness innovator has teamed up with an innovative start-up to create accurate and actionable grain-crop nutrition maps.

Landmark is Australia's leading agribusiness company, servicing more than 100,000 clients from their national network of around 400 locations. Having been a part of rural Australia for 150 years, Landmark is widely recognised for its vision of growing value through a world of innovation in practical applications.

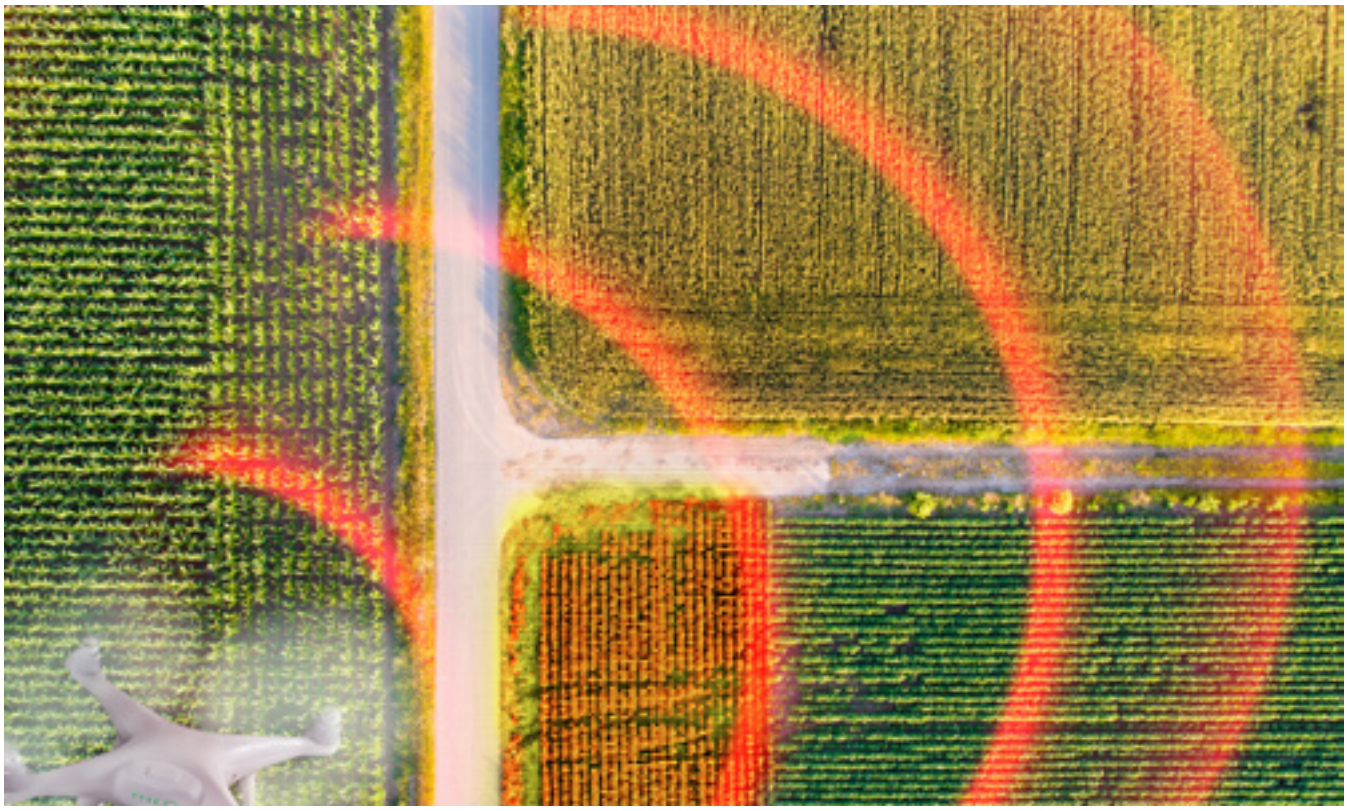
Recognising both the innovation and practical application of FluroSat, Landmark partnered with the company to trial the FluroSat platform's analysis of grain-crop nutrient and moisture content at key growth stages across 24 of their customers' fields in the Jamestown region in South Australia. The relationship between the resulting yield and nitrogen content at an early key growth stage (tillering – Z20–Z29) was also validated by regressing harvester spatial data from a selection of the fields against the nitrogen maps produced by FluroSat.

Key findings:

- high correlation between remote sensing data analysis and tissue sampling
- mapping nitrogen, phosphorus, potassium and other nutrients for the entire field, not just for a few scattered sampling points
- nutrient content grouped in zones, allowing for precise and efficient applications
- strong correlation between nitrogen content, mapped at key growth stages and the resulting yields.

FluroSat is a crop health monitoring start-up that allows agronomists and growers to proactively improve yield performance and efficiency. Agronomists use FluroSat's remote sensing data in maps and graphs of their paddocks to target and optimise nutrition, irrigation, disease and pest strategies. With a unique multilayered data approach that combines multispectral and hyperspectral imagery calibrated with in-crop ground-truthing, FluroSat provides a comprehensive yet detailed analysis and decision-support tool for precision agriculture.

A unique feature of the FluroSat platform, FluroViewer, is its multilayer data approach that combines multispectral and hyperspectral imagery acquired by satellite, aircraft and unmanned aerial vehicles. This means that data can be acquired ad hoc by aircraft or by drone during cloudy weather. The FluroSat platform then calibrates the analysis results with satellite imagery to create regularly updated maps throughout the season.



For this case study, satellite multispectral and radar data, along with drone multispectral data, was collected across the season. This data was calibrated with in-crop ground-truthing by conducting tissue sampling at the time the data was captured. The results are then correlated against the reflectance values generated by the FluroSat platform's analysis.

The Landmark team was highly encouraged by resulting high correlation between FluroSat and the ground-truthing provided by the tissue sampling. The nitrogen, phosphorus, potassium, zinc and iron content detected at the tillering stage all had an R2 coefficient ratio of 0.51 or higher.

According to Steve Richmond, agronomist at Landmark, 'Being able to map nutrient levels across a paddock allows identification of specific areas of deficiency, adequacy and toxicity within a paddock, which leads to zonal management of nutrition. This gives far more useful information than the traditional method of tissue sampling for nutrients, which is generally a bulked sample from multiple areas of a paddock'.

A key component of the FluroSat platform is its ability to generate management zones within each field by grouping areas with similar nutrient values detected. The number of zones and the algorithm used to create each zone is highly configurable. The zones can be exported as shapefiles to a wide range of farm management applications.

Being able to sort, classify and compare data from different algorithms is important to Richmond, '[It] allows for real and subtle differences in paddocks to be identified and managed if required. In a recent practical example, a normalised difference vegetation index photo showed no significant differences in biomass across a paddock, whereas a canopy chlorophyll content index (CCCI) image on the same day clearly identified a change in a liquid fertiliser treatment applied at sowing'.

In addition to multispectral data, FluroSat has successfully applied its analysis to hyperspectral data, allowing earlier and more accurate detection of nutrients, as well as other common stressors like water, pests and disease. Hyperspectral sensors provide a much finer resolution than multispectral; by dividing the data into more bands it is possible to detect even the slightest changes in reflection.

Other data sources, such as satellite radar and thermal imaging, are also used by FluroSat to generate accurate wet biomass and plant-water content maps, strongly correlated with yield data at R2 coefficient ratios in excess of 0.70. By combining these multiple data sources of the same crop, FluroSat delivers a uniquely comprehensive crop analysis that is a game-changing decision-support tool for the agriculture industry.

Anastasia Volkova will be speaking at AusAg & Foodtech Summit 2018.

CROWDFUNDING ASSISTS AGTECH WITH CRUCIAL CHALLENGE

BY JILL STOREY, CEO, READYFUNDGO; AND DIRECTOR, AGCROWD

Global food security is recognised as one of the most crucial challenges of our generation. Today, it is estimated that around 815 million people are malnourished and an additional two billion lack food security as a result of varying degrees of poverty.

By 2050, the Earth's population is expected to reach over nine billion. Food supply needs to increase by 60 per cent to meet global demand. This will only be achieved using the best science and technology, with agtech playing a critical role.

Australia's opportunity

Australia has the opportunity to play a significant role in meeting

Jill Storey

this global challenge. The Australian agtech sector is predicted to reach $100 billion by 2030; however, it is widely recognised that it will take more than the constant call to further innovate in science, particularly in agtech, to achieve this.

On the global stage, Australia is recognised as a world-class agricultural research hub for new ideas and collaborative research, but it will take several core ecosystem components to work together to achieve our potential.

The lacking component

One clear core component increasingly lacking is funding. In Australia, less than one per cent of government funding and grants is allocated to agriculture.

Start-up companies are now popping up in increasing numbers to experiment with and develop new capabilities in plant breeding, biologics, gene editing and microbiome research to create more sustainable input products. This has been made possible as the barriers to entry for start-ups have drastically lowered, with falling capital requirements. For example, over a 15-year period from 2001, the cost of genome sequencing fell from $100 million to around $1000 per genome.

This new breed of start-ups is vital to the creation of innovative products and processes. While many of these companies will fail by the very nature of research and experimentation, the concern is for those companies that fail due to lack of funding when they may well have hit upon something amazing, or be on the edge of a significant breakthrough.

Losing the contribution of these innovative early-stage companies has significant repercussions – not only for the individual businesses, but for the competitiveness of the Australian economy, the agtech industry and, potentially, world food supply.

Some of these early-stage companies are stuck in an early-stage funding trap sometimes referred to as the 'valley of death'. There can be a large gap between starting a business with funds from 'friends and family', and possibly a $50,000 capital injection from an accelerator or incubator, securing funds from angel investors or venture capital.

This funding gap or valley of death is where a high proportion of start-ups and early-stage businesses fail.

> One clear core component increasingly lacking is funding. In Australia, less than one per cent of government funding and grants is allocated to agriculture

Today in Australia, there are new tools available to help early-stage companies through this early funding challenge. While most Australians have heard of crowdfunding, not quite as many have considered how they may use it to help early-stage businesses.

Crowdfunding, in both reward- and equity-based forms, can be used to help bridge this valley of death.

New to crowdfunding

For those of you who are new to crowdfunding, it is simply a way to raise money from a large number of people (the crowd) who each contribute a relatively small amount.

Contributions are typically made through a web-based platform, and the widespread use of social media has turned crowdfunding into a global phenomenon. If you have looked at crowdfunding before, you will be aware that it comes in several different forms. For businesses looking to grow, or entrepreneurs planning a start-up, then debt-based, reward- or equity-based crowdfunding options are typically the forms to consider.

Debt-based crowdfunding involves several people lending money to the business and interest being paid on the debt. For pre-revenue or early-stage businesses without a steady income stream, this type of crowdfunding is typically not an option.

Reward-based crowdfunding is probably the most widely known type of crowdfunding, where supporters make pledges in return for products or rewards. This can often be successful for food and agtech businesses where there is a product that can be delivered to a retail customer.

Equity-based crowdfunding involves shares in the company being given away in return for an investment.

Equity-based crowdfunding was first used for unlisted public companies in Australia in January this year. It is expected to be available to proprietary companies at the end of 2018.

Reward- and equity-based crowdfunding in Australia

An organisation may decide to undertake a reward-based crowdfunding campaign where they have a product ready, or almost ready, to take to market and be sold or pre-sold to retail customers.

Over the past year, there has been a rise in the number of food businesses looking to use reward-based crowdfunding, as some local food producers struggle to obtain funds from banks to get their businesses started. Customers are more concerned today with where their food comes from and, when they have the choice, they prefer to support boutique local producers. What some business owners forget, however, is that crowdfunding is about so much more than just raising funds.

Crowdfunding can be as much about building brand awareness and getting early-stage customer feedback. Often these early supporters or adopters will become some of a business's biggest future brand advocates.

In the agtech sector, start-ups in the aquaculture and algae space, or in vertical farming, may, as an example, benefit from the use of reward-based crowdfunding.

Some organisations will not have a product that is plausibly delivered as a reward to retail customers. For these organisations, one option may be to consider equity-based crowdfunding.

At the moment in Australia, it will be necessary to convert to an unlisted public company in order to take advantage of the new equity crowdfunding provisions. If the various criteria are met, then it is possible for an eligible company to raise up to $5 million in any 12-month period.

Where businesses are serious about moving to the next level of scale, it is highly recommended that crowdfunding professionals are engaged to help create a campaign and drive traffic. While it is often talked about as being free to start a crowdfunding campaign, there is typically a budget required to deliver a successful one.

Crowdfunding is an exciting opportunity for the agtech sector as part of an early-stage enterprise's journey.

Many agtech start-ups, such as high-tech vertical farms and insect farms, as well as the production of new living ingredients like algae, are starting to capture the imagination of the public. It is therefore a perfect time to work to translate this interest into active engagement for the benefit of the Australian agtech sector.

If anyone would like further information about how reward- or equity-based crowdfunding can be used for their start-up, please contact Jill at jill@agcrowd.com.au or jill.s@readyfundgo.com.

Jill Storey will be speaking at AusAg & Foodtech Summit 2018.

AUSBIOTECH CORPORATE MEMBERS

360biolabs Pty Ltd
3M Australia Pty Ltd
60° Pharmaceuticals, LLC
AbbVie Pty Ltd
Acrux Ltd
Actinogen Medical Limited
AdAlta Limited
Agriculture Victoria Services Pty Ltd
Ainscorp Pty Ltd
Allens Patent & Trade Mark Attorneys
Alliance for Regenerative Medicine (ARM)
Alliance for Safe Biologic Medicines
AMGEN Australia Pty Ltd
Analytica Ltd
Anatara Lifesciences
Animal Biosciences, Inc.
Anteo Technologies Pty Ltd
Antisense Therapeutics Ltd
Arnold Bloch Leibler
Artificial Cell Technologies Australia Pty Ltd
AstraZeneca Pty Ltd
AusCann Group Holdings Ltd
Australia China Business Council (ACBC) - Victoria
Australian Agricultural Company Limited (AACo)
Australian National Fabrication Facility (ANFF)
Australian National University (ANU), Technology Transfer Office
Australian Nuclear Science and Technology Organisation (ANSTO)
Australian Proteome Analysis Facility (APAF)
Australian Red Cross Blood Service (ARCBS)
Australian Regenerative Medicine Institute
Avatar Brokers Pty Limited
Baillieu Holst Ltd
Baker IDI Heart and Diabetes Institute
Bard Australia Pty Ltd
BARD1 Life Sciences Limited
Bayer CropScience Pty Ltd
BDO
Bellberry Limited
Benitec BioPharma Limited
BIASSEX P/L
Billard Leece Partnership
Bio21 Molecular Science and Biotechnology Institute, University of Melbourne
Bioactive Laboratories Pty Ltd
Bioclub Australia Pty Ltd
BioDiem Ltd
Biointelect Pty Ltd
Bio-Link Australia
Biomedical Chitosan
Biomedical Research Victoria (BioMedVic)
BioMelbourne Network
Bionomics Ltd
BioPacific Partners
BioScience Managers Pty Ltd
Biotech Daily
Biotech Dispatch
BioTech Primer Inc.
BiotechGate
Biotron Limited
Bioxyne Limited
Blueprint Life Science Group
Bosch Australia Pty Ltd
Brandon Capital Partners
Brandwood Biomedical Pty Ltd
Bristol-Myers Squibb (Australia) Pty Ltd
Brooker Consulting
BTG Australasia P/L
Burnet Institute
Business Events Sydney
Caldera Health Ltd
Cancer Trials Australia
CareerLounge Pty Ltd
Celestino Pty Limited
Cell Therapies Pty Ltd
Cellmid Limited
Centenary Institute
Centre for Drug Candidate Optimisation
Ceramisphere Health Pty Ltd
Certara Australia
CharterNet Services Pty Ltd
Children's Medical Research Institute
Chrysalis Advisory
Chubb Insurance Australia Limited
City of Perth
Clarity Pharmaceuticals
Clinical Genomics Technologies Pty Ltd
CMAX Clinical Research Pty Ltd
Cochlear Limited
Coloplast Pty Ltd
Continuum Biosciences Pty Ltd
ConvaTec (Australia) Pty Ltd
Cook Australia Pty Ltd
CoSec Consulting Pty Ltd
Covance Pty Ltd
CPR Pharma Services Pty Ltd
CRC for Cell Therapy Manufacturing
Cryosite
CSIRO
CSL Limited
CTX CRC Limited
Curtin University - School of Pharmacy and Biomedical Sciences
Cyclopharm Limited
Cynata Therapeutics
Datapharm Australia Pty Ltd
Davies Collison Cave
De Motu Cordis Pty Ltd
Deakin Research Commercial
Deloitte Touche Tohmatsu
DendroCyte BioTech Pty Ltd
Dentons Australia Pty Ltd
Department for International Trade - British Consulate General
Department of Economic Development, Jobs, Transport and Resources (VIC)
Department of Environment and Science (QLD)
Department of State Development, Manufacturing, Infrastructure and Planning (QLD)
Dimerix Limited
DLA Piper Australia
Domainex
Dynek Pty Ltd
EAP MedTech Consulting Sdn Bhd
Edison Group
Elk OrthoBiologics Limited
Ellume
Elsevier
Emas Pharma Pty Ltd
EpiAxis Therapeutics Pty Ltd
Epichem Pty Ltd
Eppendorf
Epworth Research Institute
ERA Consulting (Australia) Pty Ltd
ESFAM Biotech
Eurofins | ams
Exigence
EyePoint Pharmaceuticals
Facet Life Sciences, Inc.
Factor Therapeutics
FB Rice
First Biotech Pty Ltd
Fitgenes Australia Pty Ltd
Flanders Investment & Trade Australia
Fledge Innovation Labs
Forbes Meisner Pty Ltd
FPA Patent Attorneys
Franke Hyland
French Embassy, Trade Commission - Business France Australia & New Zealand
Frost & Sullivan (Australia) Pty Ltd
Fusidium Pty Ltd
Future Asset Management International
Gadens Lawyers, Brisbane
Garvan Institute of Medical Research
GBS Venture Partners Pty Ltd
Genetic Signatures
Genome.One
Global Cleanrooms Pty Limited
Global Kinetics Corporation Pty Ltd
Global Orthopaedic Technology

GO Resources Pty Ltd
Gold Coast Health & Knowledge Precinct
Grant Thornton Australia Limited
Gretals Australia Pty Ltd
Grey Innovation
Griffith Hack
Griffith University, Griffith Enterprise
Hays Recruitment Services Australia
HDR
Health Industries South Australia
Heidrick & Struggles Australia Pty Ltd
Holman Webb Lawyers
Hudson Institute of Medical Research
Hydrix Pty Ltd
ide
IDT Australia Ltd
Imagion Biosystems
Immuron Limited
Immutep Limited
Imugene Ltd
Innate Immunotherapeutics Limited
Innofy Pty Ltd
Innovfusion Pte Ltd
Institute for Glycomics
Inter-K Peptide Therapeutics (Inter-K Pty Ltd)
IQVIA
Johnson & Johnson Innovation
Johnson Matthey (Aust) Ltd
Jumpstart Fertility Pty Ltd
Kazia Therapeutics Limited
King & Wood Mallesons
KPMG
La Trobe University, Innovation & Commercialisation
LBT Innovations Ltd
Liberty Medical Pty Ltd (Hollister/ Dansac)
Life Biosciences, Inc.
Linear Clinical Research Ltd
Lucid Health Consulting Pty Ltd
Luina Bio Pty Ltd
Macquarie University - Faculty of Medicine & Health Sciences
Madderns Patent & Trade Mark Attorneys
MAPI Life Sciences Australia Pty Ltd
Marken
MasterControl Inc.
Materialise Australia Pty Ltd
McCloud Consulting Group
Meat and Livestock Australia Ltd
Medibio Ltd
Medigroup EBI
Medlab Clinical Ltd
Medtronic Australasia Pty Ltd
Melbourne Convention Bureau (MCB)
Melbourne School of Engineering, The University of Melbourne
Merck Sharp & Dohme
Mesoblast Limited
Microba
Minomic International Limited
Mobius Medical Pty Ltd
Monash Innovation
Monsanto Australia Ltd.
Morgans Financial Limited
Motherson Innovations Australia
MTPConnect Ltd (MedTech and Pharma Growth Centre)
Murdoch Children's Research Institute
Murdoch University, Research & Innovation
My Medical Department
Nanosonics Limited
National Association of Testing Authorities Australia
Neuroscience Trials Australia
Neurosciences Victoria Ltd
NeuroScientific Biopharmaceuticals Pty Ltd
Newline Australia Insurance Pty Ltd
Next Science
Norton Rose Fulbright Australia
Novartis Pharmaceuticals Australia Pty Ltd
Novo Motologi Pty Ltd
Novotech
NSW Stem Cell Network
Nucleus Network
Numedico Technologies Pty Ltd
NZBIO
OccuRx Pty Ltd
OFX - Global Money Transfers
Omni Innovation Pty Ltd
On Q Recruitment
OncoSil Medical Ltd
OneVentures Pty Ltd
OPTALERT Australia Pty Ltd
Opthea Limited
Orthocell
Osprey Medical
Paradigm BioPharmaceuticals Ltd
Paranta Biosciences Limited
Patheon Biologics Australia Pty Ltd
Patrys Ltd
Peter MacCallum Cancer Centre
Pfizer Australia
PharmAust Limited
Pharmaxis Ltd
Phillips Ormonde Fitzpatrick
Phosphagenics Limited
Planet Innovation Pty Ltd
Plunkett Consulting Group Pty Ltd
PolyNovo Limited
Prana Biotechnology Ltd
PRAXIS Australia Ltd
Prescient Therapeutics Limited
Prime Accounting and Business Advisory Pty Ltd
Pronto Software Limited
ProTA Therapeutics Pty Ltd
Protagonist Pty Ltd
Proteomics International Laboratories Limited
QBiotics Limited
QIMR Berghofer Medical Research Institute
Queensland Alliance for Agriculture & Food Innovation (QAAFI)
Queensland University of Technology - Office of Research
qutbluebox Pty Ltd
R&D Capital Partners Pty Ltd
Race Oncology Ltd
Regeneus Ltd
ResApp Health Limited
Research & Business Partnerships, The University of Adelaide
Research Australia Limited
Research, Innovation & Commercialisation (RIC), University of Melbourne
Rhinomed Limited
Russell Kennedy Pty Ltd
Sanofi Genzyme
Sayco Pty Ltd
School of Biomedical Sciences, QUT
SeerPharma Pty Ltd
Sementis Limited
Seqirus Australia - a CSL Company
Shelston IP
Shimadzu Scientific Instruments (Oceania) Pty Ltd
Shire Australia Pty Ltd
Sienna Cancer Diagnostics Ltd
Sonic Clinical Trials Pty Ltd
Southern Star Research Pty Ltd
SpeeDx Pty Ltd
Spruson & Ferguson
St Vincent's Hospital Melbourne
Starpharma Holdings Limited
Suda Pharmaceuticals Limited
Swinburne University, Research & Development
Swisse Wellness Pty Ltd
Syneos Health
TechInSA
Telethon Kids Institute
Telix Pharmaceuticals Pty Ltd
TetraQ
TEVA Australia (Teva Pharma & Teva Pharmaceuticals)
TGR Biosciences Pty Ltd
Thailand Board of Investment, Australia (BOI Sydney Office)
The Biotechnology Program, The University of Queensland
The iQ Group Global
The University of Newcastle, Newcastle Innovation Division
The University of Sydney, Commercial Development & Industry Partnerships
The University of Western Australia, Office of Research Enterprise
The Walter & Eliza Hall Institute of Medical Research
Therapeutic Innovation Australia
Tonsley Innovation District
Translational Research Institute Australia
TruScreen Pty Ltd
UniQuest Pty Ltd
Universal Biosensors Pty Ltd
University of South Australia, Research & Innovation
University of Sydney, Engineering and Information Technologies
University of Wollongong - Innovation & Commercial Research (ICR)
UNSW - School of Biotechnology and Biomolecular Sciences
UNSW Knowledge Exchange
Vectus Biosystems Limited
Venture Valuation
Vestech Medical Pty Limited
Viralytics Ltd
Volpara Health Technologies Limited
WA Health Translation Network (WAHTN)
Wallonia.be - Export & Investment (Belgium)
WATERMARK Patent & Trade Mark Att.
WE Buchan Consulting
West Pharmaceutical Services
World Courier (Australia) Pty Ltd
Wrays
Zelda Therapeutics Pty Ltd

INDEX

BY JAMES FLETCHER, FINANCIAL ADVISER, BAILLIEU HOLST

Issuer Name	ASX	Principal Activity	First List Date	M Cap $m	Last Price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
AdAlta	1AD	Drug discovery and development using its technology platform to generate a promising new class of protein therapeutics, known as i-bodies	22-Aug-16	26.6	0.35	0.40	0.20	-4	-9	4	
AusCann Group Holdings Ltd	AC8	Cultivation, manufacture and distribution of medicinal cannabis products. Targeting medications for neuropathic and chronic pain	3-May-89	175.2	1.19	1.86	0.38	-1	-131	5	
Alchemia Limited	ACL	Drug discovery and development. Fondaparinux anti-coagulant drug	23-Dec-03	3.2	0.01	0.03	0.01	-0	-6	1	
Acrux Limited	ACR	Transdermal drug delivery platform technology	29-Sep-04	24.1	0.15	0.32	0.13	-9	-2	21	
Actinogen Ltd	ACW	Developer of lead candidate Xanamem for treatment of neurodegenerative disorders, including Alzheimer's	16-Oct-07	47.2	0.05	0.06	0.04	-1	-6	1	
Anteo Diagnostics Limited	ADO	Multi-component coatings for solid phase of immunoassays for biomarker development	7-Apr-00	18.4	0.02	0.03	0.01	-1	-2	0	
Adherium Ltd	ADR	Developer of digital technologies to monitor medication use in chronic respiratory conditions	26-Aug-15	18.3	0.11	0.20	0.07	-8	-1	10	
AFT Pharmaceuticals	AFP	Develops, licenses and sells a range of medical products globally	22-Dec-15	194.6	2.00	2.41	1.95	-12	-16	2	
Apiam Animal Health Ltd	AHX	iVet technology for real-time animal health monitoring, including on-farm welfare assessments	15-Dec-15	70.1	0.69	0.94	0.66	4	19	-3	1.60
Admedus Ltd	AHZ	Tissue engineering and vaccine development for herpes and HPV	24-Mar-04	68.2	0.24	0.40	0.20	-5	-5	7	
Analytica Limited	ALT	eHealth devices. PeriCoach system for stress urinary incontinence	25-Oct-00	20.0	0.01	0.01	0.00	0	-4	0	
Allegra Orthopaedics Ltd	AMT	Prosthetic implant tools	5-Dec-07	10.5	0.11	0.05	0.02	0	50	7	
Antisense Therapeitics ltd	ANP	Drug discovery and development. Antisense compounds for MS, DMD, acromegaly	20-Dec-01	9.7	0.03	0.04	0.01	-2	-2	1	
Antara Lifesiences Ltd	ANR	Natural, plant-based therapeutics for gastrointestinal diseases	16-Oct-14	28.7	0.58	1.83	0.58	-6	-10	21	
Avita Medical Ltd	AVH	Skin regeneration technology for the treatment of wounds, scars and skin defects	11-Aug-93	89.2	0.07	0.08	0.05	-2	-4	1	
AirXpanders Ltd	AXP	AeroForm tissue expander for breast reconstruction	29-Sep-04	26.8	0.09	2.63	0.75	-13	-1	8	
BioGene Technology Ltd	BGT	Insecticide product development. 'Qcide' and 'FLAVOCIDE' focused on insect control in agriculture and animal health	29-Nov-17	19.1	0.17	0.28	0.10	-1	-13	6	
Biotron Limited	BIT	Antiviral drug developer, HIV and hepatitis	24-Jan-01	10.0	0.02	0.04	0.01	0	-6	0	
Benitec Limited	BLT	Development of a proprietary therapeutic technology platform to provide long-lasting silencing of disease-causing genes	17-Feb-97	37.3	0.31	0.33	0.11	-7	-4	6	
Botanix Pharmaceuticals Ltd	BOT	Development and commercialisation of therapeutics for bone and joint disease	24-Jan-85	63.1	0.11	0.21	0.04	-1	-8	1	

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)
Bionomics Limited	BNO	Small molecule developer in areas of cancer and CNS disorders	21-Dec-99	253.5	0.52	0.64	0.35	-1	-43	5	
BPH Energy Ltd	BPH	Commercialising a portfolio of Australian biomedical technologies emerging from collaborative research from universities, medical institutes and hospitals	6-Aug-04	1.9	0.00	0.00	0.00	0	-1	1	
Brain Resource Limited	BRC	Provider of international database for human brain function	28-Aug-01	20.7	0.04	0.12	0.04	-7	-1	2	
BTC Health Ltd	BTC	Biopharmaceutical company focused on product development and commercialisation	29-Aug-00	24.8	0.19	0.24	0.16	-1	-14	2	
Bioxyne Ltd	BXN	Gut and immune health probiotic products, including a patented probiotic range	14-Dec-00	29.4	0.05	0.14	0.02	0	-11	0	
Capitol Health Ltd	CAJ	Provider of diagnostic imaging services to the Australian healthcare market	9-Jun-06	249.8	0.31	0.35	0.22	-1	-41	8	0.40
Cann Group Ltd	CAN	Research and development and cultivation to facilitate the supply of medicinal cannabis	4-May-17	329.0	3.05	4.55	0.55	-1	-231	53	
Cellmid Limited	CDY	Development of therapies targeting midkine in cancer, fibrosis and chronic inflammatory disease	9-Dec-05	24.8	0.44	0.58	0.35	-8	-6	5	
Cardiex Limited	CDX	Developer and international marketer of blood pressure at the heart device, SphygmoCor	9-Nov-05	15.4	0.03	0.05	0.02	-2	-2	1	
Cogstate Ltd	CGS	Diagnosis and therapeutic products for neurodegenerative diseases (also Alzheimer's and Parkinson's)	13-Feb-04	88.1	0.77	1.19	0.65	-3	-26	9	
CropLogic Ltd	CLI	Technology platform that improves crop yield	12-Sep-17	3.0	0.04	0.18	0.03	-4	-1	6	
Clover Corporation Limited	CLV	Supplies science-based oil products to the medical food market for infants and children	30-Nov-99	223.0	1.49	1.81	0.36	4	43	19	1.25
Compumedics Ltd	CMP	Designs and manufactures technologies for the diagnosis of sleep disorders, neurodiagnostics solutions and brain research technologies through the Compumedics Neuroscan brand	21-Dec-00	99.2	0.57	0.72	0.31	1	56	10	
Cochlear Ltd	COH	Manufacture and sale of cochlear implant systems for impaired hearing	4-Dec-95	11,449.1	197.21	205.53	139.44	388	51	401	280.00
CannPal Animal Therapeutics Ltd	CP1	Pet pharmaceutical company developing cannabinoid-based medicines for cats, dogs and horses	25-Oct-17	8.4	0.20	0.31	0.16	-1	-16	6	
Creso Pharma Ltd	CPH	Development and production of cannabis and hemp-derived therapeutic products and treatments for humans and pets	20-Oct-16	55.2	0.64	1.65	0.43	-18	-4	19	
CSL Limited	CSL	Development, manufacture and marketing of pharmaceutical and diagnostic products	8-Jun-94	89,674.9	197.30	199.89	119.01	445	44	617	192.02
Cryosite Limited	CTE	Collection, processing and long-term storage of blood stem cells	9-May-02	3.8	0.08	0.19	0.08	-2	-4	4	
Clinuvel Pharmaceuticals Limited	CUV	Developer of treatment for UV-related skin disorders. Lead product SCENESSE completed Phase III clinical trials for prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP)	13-Feb-01	523.7	11.24	13.52	5.91	13	89	57	
Cyclopharm Limited	CYC	Manufacturer and distributor of radiopharmaceuticals for imaging technology. Lead product is Technegas, a lung ventilation imaging drug	18-Jan-07	68.8	1.00	1.20	0.71	-2	-44	21	1.00
Cynata Therapeutics	CYP	Stem cell and regenerative medicine platform technology, Cymerus, for production of mesenchymal stem cells	20-Dec-07	125.5	1.32	1.58	0.53	-6	-21	10	
Dorsavi Ltd	DVL	Motion analysis device technologies for clinical, elite sports and OHS	11-Dec-13	20.2	0.12	0.39	0.10	-3	-4	5	
Dimerix Ltd	DXB	Development of therapeutic treatments identified using drug discovery platform, Receptor-Heteromer Investigation Technology (Receptor-HIT)	4-Feb-93	14.7	0.01	0.01	0.00	-3	-4	0	

Issuer name	ASX	Principal activity	First list date	M cap $m	Last price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
Ebos Group Ltd	EBO	Distributor of healthcare products	6-Dec-13	2,928.8	19.15	19.20	15.45	86	22	38	54.30
Ellex Medical Lasers Ltd	ELX	Production of ophthalmic instruments for treatment of impaired vision	12-Sep-94	86.2	0.62	1.25	0.55	-4	-17	37	
eSense Lab Ltd	ESE	Creates 'virtual plants' with commercial and medicinal applications. First plant targeted for re-engineering is cannabis	14-Feb-17	2.9	0.07	0.45	0.06	-4	-2	4	
Factor Therapeutics Ltd	FTT	Development of wound care therapeutics. Lead therapeutic VF-001 is a targeted growth factor being developed to treat venous leg ulcers	19-Mar-04	40.0	0.05	0.07	0.04	-1	-6	1	
Genera Biosystems Limited	GBI	Develops and commercialises molecular diagnostic tests based on AmpaSand bead technology	11-Jun-08	17.2	0.16	0.23	0.12	-3	-5	-5	
Gi Dynamics, Inc	GID	EndoBarrier: endoscopically delivered treatment for the management of obesity and type 2 diabetes	7-Sep-11	21.4	0.04	0.07	0.02	-2	-1	1	
G Medical Innovations Holdings Ltd	GMV	Remote healthcare-monitoring technology. Develops and markets clinical and consumer medical-grade health monitoring solutions	10-May-17	22.8	0.22	0.59	0.14	-15	-1	3	
Genetic Signatures Ltd	GSS	Molecular diagnostics company focused on development and commercialisation of its proprietary platform technology, 3Base	31-Mar-15	37.5	0.37	0.45	0.24	-3	-11	14	
Genetic Technologies Limited	GTG	Molecular diagnostics specialising in women's health. Lead product BREVAGenplus is a risk assessment test for non-hereditary breast cancer	30-Jul-87	24.4	0.01	0.02	0.01	0	-3	0	
Holista Colltech Ltd	HCT	Development and commercialisation of food ingredients and ovine collagen	26-Feb-04	16.6	0.08	0.20	0.06	-2	-5	1	
Imagion Biosystems	IBX	Detection and localisation of cancer and other diseases using nanoparticle technology. Proprietary MagSense bio-imaging detection technology	22-Jun-17	5.9	0.04	0.18	0.04	-5	-1	3	
IDT Australia Ltd	IDT	Manufacturer of pharmaceuticals and clinical trial management services	24-Sep-93	21.3	0.09	0.11	0.07	-12	-1	1	
Innate Immunotherapeutics	IIL	Immunomodulator microparticle technology	23-Dec-13	12.3	0.30	1.35	0.25	-19	-2	10	
Immuron Ltd	IMC	Oral immunotherapy products that target the human gut immune system and gut microbiome	30-Apr-99	48.5	0.34	0.60	0.14	-5	-8	4	
Immutep Ltd	IMM	Developer of novel immunotherapy agents treatments for cancer and autoimmune disease. Lead product candidate is eftilagimod alpha for breast cancer and melanoma	23-Jun-88	102.9	0.03	0.04	0.02	0	-8	0	
Imugene	IMU	Developer of HER-2+ gastric and breast cancer immunotherapies	2-Dec-93	77.1	0.03	0.04	0.01	0	-30	0	
Impedimed Limited	IPD	Diagnostic devices for lymph oedema, muscle wasting and metabolic disorders, utilising bio-impedance technology	24-Oct-07	162.9	0.43	1.07	0.35	-8	-6	11	
ITL Limited	ITD	Design and manufacture of healthcare devices and biological sampling systems	29-Oct-03	17.1	0.20	0.53	0.17	12	2	17	
Invitrocue Ltd	IVQ	Provider of bio-analytic solutions including in-vitro cell-based testing technologies and image analytics software for use in digital pathology	14-Dec-91	53.9	0.11	0.13	0.07	-1	-20	0	
Invion Ltd	IVX	Developer of treatments for inflammatory diseases	15-Feb-10	197.7	0.04	0.06	0.00	0	-8	0	
Kazia Therapeutics Ltd	KZA	Development of anti-cancer drugs	1-Sep-94	22.8	0.47	0.80	0.34	-13	-4	22	
LBT Innovations Limited	LBT	Automated systems for the preparation, screening, interpretation and streaking of microbiological specimens	31-Jul-06	22.1	0.12	0.37	0.09	-1	-11	6	
Living Cell Technologies Limited	LCT	Developer of live cell therapy products for treatment of neurological and metabolic disorders	1-Sep-04	14.3	0.03	0.28	0.02	-1	-4	1	
Lifehealthcare Group	LHC	Distributor of critical care medical devices and implant devices	5-Dec-13	175.7	3.68	3.70	2.02	15	25	25	15.00

Issuer name	ASX	Principal activity	First list date	M cap $m	Last price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
Lifespot Health Ltd	LSH	Medical diagnostic and monitoring technology using smartphones. BodyTel system for management of chronic diseases and My-Lifespot system for skin disease diagnosis	11-Jan-17	5.2	0.12	0.20	0.11	-3	-4	6	
Mach7 Tech Ltd	M7T	Imaging IT solutions, 3D printing and holographic projection provider	30-Nov-05	28.3	0.22	0.38	0.13	-15	-1	3	
Medlab Clinical Ltd	MDC	Research and development of novel bio-therapeutics to improve health outcomes in chronic disease, such as chronic kidney disease and obesity	14-Jul-15	111.3	0.54	1.20	0.46	-2	-23	1	
MedAdvisor Ltd	MDR	Mobile and web apps for individuals and carers to manage all aspects of prescription medication use	26-May-11	61.9	0.05	0.06	0.03	0	-14	1	
MediBio	MEB	Diagnostic tests for depression and other mental health disorders	29-Jan-01	28.4	0.13	0.46	0.12	-8	-2	6	
Medigard Limited	MGZ	Retractable safety devices for injection and blood collection	5-Feb-04	2.0	0.02	0.03	0.01	-1	-3	-1	
Medical Australia Limited	MLA	Distributor of medical devices, IV system and blood banking lab. Collection of human and animal biologics	20-Dec-04	11.6	0.09	0.09	0.05	0	28	4	
MMJ Phytotec Ltd	MMJ	Aims to commercialise medical cannabis and high-value based cannabis therapeutics	22-Jan-15	74.2	0.33	0.63	0.30	-8	-4	18	
Mesoblast Limited	MSB	Commercialisation of adult stem cell technology	16-Dec-04	737.3	1.59	2.15	1.19	-16	-10	16	
Monash IVF Group	MVF	Assisted reproductive technologies, genetic testing and ultrasound services	26-Jun-14	258.9	1.10	1.69	1.06	11	10	-38	7.90
Medical Developments International Limited	MVP	Medical and veterinary equipment, including pain management, resuscitation and asthma management products	15-Dec-03	344.4	5.79	8.07	4.76	3	223	-10	4.00
Micro-X Ltd	MX1	Develops and manufactures a range of mobile X-ray imaging systems for medical applications	22-Dec-15	40.4	0.28	0.48	0.27	-8	-4	6	
MGC Pharmaceuticals Ltd	MXC	Innovator in phytocannabinoid-based medicines within the biopharmaceutical industry	21-Dec-06	75.8	0.06	0.13	0.04	-1	-6	0	
MyFiziq Ltd	MYQ	Smartphone app to provide accurate circumference measurements to assist with management of diabetes and weight	17-Aug-15	25.3	0.32	1.65	0.03	-17	-2	1	
Mayne Pharma Ltd	MYX	Pharmaceutical commercialisation and manufacturing. Development of oral drug delivery systems	29-Jun-07	13,770.0	0.88	1.02	0.59	-11	-8	8	
Nanosonics Limited	NAN	Ultrasound probe disinfection: Trophon device	17-May-07	910.0	3.10	3.36	2.15	2	146	26	
Nanollose Ltd	NC6	Uses industrial organic and agricultural waste products to produce plant-free cellulose for use in the food and medical industries	18-Oct-17	5.6	0.16	0.38	0.11	-1	-12	5	
Neuren Pharmaceuticals Limited	NEU	Biopharmaceutical therapies for brain injury, neurodegenerative and neurodevelopmental disorders	3-Feb-05	272.8	2.75	3.60	1.12	-2	-145	1	
Novita Healthcare Ltd	NHL	Cognitive training program for children with attention difficulties	23-Sep-04	11.9	0.03	0.06	0.03	0	-9	1	
Noxopharm Ltd	NOX	Development of drugs to make radiotherapy more effective. NOX66 is the company's pipeline product	9-Aug-16	47.6	0.60	1.80	0.29	-15	-4	4	
Memphasys Ltd	MEM	Cell and protein separation systems	14-May-07	5.1	0.00	0.00	0.00	0	-1	0	
Neurotech International Ltd	NTI	Development and commercialisation of technological solutions for the diagnosis and treatment of neurological conditions. Flagship device is Mente Autism	4-Nov-16	12.5	0.15	0.37	0.10	-4	-4	4	
Nufarm Ltd	NUF	Crop protection and specialist seed company manufacturing and marketing products to help farmers protect crops against damage	10-Nov-98	2,870.7	8.64	9.60	7.74	37	23	334	12.80

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)
OBJ Limited	OBJ	Developer of transdermal drug delivery technology in pharmaceutical and cosmetic industries	29-May-00	47.0	0.03	0.06	0.02	0	-14	0	
Orthocell Ltd	OCC	Soft tissue cellular therapies for restoration of tendon and cartilage injuries	12-Aug-14	25.3	0.31	0.41	0.28	-2	-14	0	
Orion Health Group Ltd	OHE	Technology solutions advancing population health and precision medicine, including data management and creating personalised healthcare plans	26-Nov-14	207.7	1.06	1.25	0.56	-20	-5	8	
Optiscan Imaging Ltd	OIL	Microscopic imaging technologies for medical markets	8-Aug-97	25.5	0.06	0.12	0.06	0	-44	1	
Oneview Healthcare Plc	ONE	Software platform for patients in hospital and aged care facilities, including dietary services and care management	17-Mar-16	120.3	1.69	5.06	1.63	-71	-2	64	
Opthea Ltd	OPT	Developer of novel therapy OPT-302 for treatment of eye diseases	18-Apr-91	104.4	0.19	0.28	0.07	-8	-6	22	
Oncosil Medical Ltd	OSL	Brachytherapy device that implants a dose of beta radiation into a pancreatic tumour	15-Aug-05	156.0	0.24	0.26	0.09	-2	-13	1	
Osprey Med Inc	OSP	Technologies to reduce the amount of dye injected into patients during heart catheterisation procedures: DyeVert PLUS Contrast Reduction System.	2-May-12	49.2	0.15	0.51	0.14	-6	-2	12	
Oventus Medical Ltd	OVN	Medical devices for sleep apnoea treatment incorporating Oventus Airway Technology	19-Jul-16	22.1	0.30	0.78	0.30	-8	-4	15	
Pharmaaust Ltd	PAA	Developer of targeted cancer therapeutics for humans and animals. Specialises in repurposing marketed drugs	2-Oct-01	8.0	0.04	0.09	0.04	-2	-3	2	
Patrys Limited	PAB	Developing novel antibody therapies for a range of oncology indications	13-Jul-07	50.3	0.05	0.08	0.00	0	-23	0	
Paradigm Biopharmaceuticals Ltd	PAR	Biopharmaceutical company focused on repurposing the drug pentosan polysulphate sodium for the treatment of inflammation	19-Aug-15	102.9	0.81	0.90	0.24	-4	-18	4	
Probiotec Limited	PBP	Manufacturer, marketer and distributor of prescription and over-the-counter pharmaceuticals, medicines and consumer health products	14-Nov-06	73.2	1.21	1.34	0.43	5	23	30	2.25
Prana Biotechnology Limited	PBT	Developing first-in-class therapies to treat neurodegenerative diseases such as Alzheimer's, Parkinson's and Huntington's diseases. Lead candidate PBT2.	28-Mar-00	28.8	0.06	0.08	0.04	-1	-4	4	
Painchek Ltd	PCK	Smartphone app to provide pain assessment for those who are unable to communicate	1-May-12	31.5	0.05	0.10	0.02	0	-31	1	
Paragon Care Ltd	PGC	Provider of medical equipment, devices and consumables to the healthcare market	15-Oct-99	235.4	0.83	0.96	0.69	6	15	-12	2.98
Proteomics International Laboratories Ltd	PIQ	Focused on proteomics. Developed a platform technology for discovering diagnostic tests based on the differences in the protein make-up of people.	16-Apr-15	16.0	0.20	0.36	0.16	-2	-11	1	
Pro Medicus Ltd	PME	Provider of radiology information systems and diagnostic imaging	10-Oct-00	803.2	7.78	9.04	4.63	9	83	25	5.00
PolyNovo Ltd	PNV	Developer of biodegradable polymers for use in medical devices. Lead product is NovoSorb technology in the treatment of burns, surgical wounds and negative pressure wound therapy.	26-Nov-98	332.3	0.50	0.63	0.17	-1	-46	4	
Phosphagenics Limited	POH	TPM - Targeted Penetration Matrix built from vitamin E. Delivery technology for small and large molecules. Products include gels, skincare and a nutritional feed additive for animals	11-Aug-93	25.2	0.02	0.02	0.01	-1	-2	0	
Papyrus Australia Ltd	PPY	Sustainable technology that creates products from the trunk of the banana palm	15-Apr-05	1.8	0.01	0.05	0.00	0	-16	0	

Issuer name	ASX	Principal activity	First list date	M cap $m	Last price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
Prescient Therapeutics Ltd	PTX	Developer of anti-cancer drugs. Lead drug candidate PTX-200.	2-Jan-92	21.2	0.10	0.19	0.05	-1	-8	3	
pSivida Corp.	PVA	Long-term sustained drug delivery to treat back-of-eye diseases: Durasert technology	12-Jun-08	17.6	2.99	3.23	1.30	-82	-4	0	
Pharmaxis Ltd	PXS	Drug discovery to treat inflammatory and fibrotic diseases using amine oxidase inhibitor chemistry platform.	10-Nov-03	99.1	0.32	0.37	0.25	0	-66	3	
Phylogica Limited	PYC	Development of intracellular biological therapeutics using its Functional Penetrating Phylomers (FPP).	30-Mar-05	57.7	0.03	0.05	0.02	0	-12	0	
Qrxpharma Ltd	QRX	Development and commercialisation of biopharmaceutical products. Clinical program with dual opioids, morphine and oxycodone: Moxduo	25-May-07	4.6	0.03	0.00	0.00	0	-12	0	
Race Oncology Ltd	RAC	Development of chemotherapy drug Bisantrene for cancer, particularly acute myeloid leukemia	13-Jul-16	9.2	0.19	0.52	0.18	11	2	3	
ResApp Health Ltd	RAP	Developer of mobile medical applications for the diagnosis and management of respiratory diseases	12-Jan-05	79.1	0.12	0.37	0.06	-1	-14	1	
Recce Pharmaceuticals Ltd	RCE	Development of synthetic antibiotics to address the threat of antibiotic resistance	15-Jan-16	16.1	0.18	0.26	0.14	-3	-5	1	
Roto-Gro International Ltd	RGI	Automated farming system for producing high-quality plants indoors, including medicinal cannabis, pharmaceuticals and food products	10-Feb-17	26.9	0.35	0.71	0.25	-1	-33	2	
Regeneus Ltd	RGS	Cellular therapies focusing on osteoarthritis and other inflammatory conditions, cancer and wound healing	19-Sep-13	27.2	0.14	0.16	0.10	-2	-9	3	
Reproductive Health Science	RHS	Developer of chromosomal abnormality embryo testing in IVF cycles	5-Mar-87	24.7	0.28	0.28	0.10	-2	-12	1	
Resonance Health Ltd	RHT	Non-invasive medical imaging software services. MRI for liver fat, liver iron concentration and iron levels in bone marrow	2-Jan-92	10.5	0.03	0.03	0.02	-0	-42	0	
Rhythmn Biosciences Ltd	RHY	Development of an affordable blood test for the early detection of colorectal cancer - 'ColoSTAT'	7-Dec-17	105.0	0.20	0.37	0.15	-1	-16	0	
Ridley Corporation Ltd	RIC	Production of animal nutrition solutions including feed ingredients, and marketing and provision of rural products	13-Aug-87	407.9	1.33	1.62	1.25	8	17	59	4.25
Resmed Inc	RMD	Developer, manufacturer and distributor of medical equipment for diagnosis and management of sleep-disordered breathing	25-Nov-99	20,495.1	14.24	14.62	8.94	38	38	0	12.68
Rhinomed Limited	RNO	Nasal, respiratory and breathing technologies. Mute, a nasal device to assist with breathing through the nose, and Turbine, a nasal dilator	21-Sep-07	18.8	0.16	0.27	0.09	-7	-2	3	
Roots - Sustainable Agricultural Technologies Ltd	ROO	Developing and commercialising technologies to address problems faced by agriculture, including plant climate management and shortage of water for irrigation	7-Dec-17	9.4	0.35	0.67	0.25	0	0	0	
RSH Respiri Ltd	RSH	Devices for detecting and monitoring respiratory disorders	14-Jul-00	47.3	0.10	0.17	0.02	0	-30	0	
Reva Medical, Inc	RVA	Bioresorbable coronary scaffolds for the treatment of cardiovascular disease	23-Dec-10	90.8	0.22	0.83	0.18	2	10	29	
Stemcell United Ltd	SCU	Growth, reproduction and extraction of plants stem cells for medical and healthcare products	13-Jun-00	12.8	0.03	0.09	0.02	-1	-2	0	
SDI Limited	SDI	Research and development, manufacturing and marketing of specialist dental materials	7-Nov-85	62.4	0.50	0.66	0.42	4	13	36	2.40
Science Developments Pty Ltd	SDV	Research, development and commercialisation of polymers for dairy and food product manufacturing	2-May-02	4.0	0.01	0.02	0.01	0	-5	0	

Issuer name	ASX	Principal activity	First list date	M cap $m	Last price $	Yr H $	Yr L $	EPS c	PER	Asset B (c)	Div (c)
Sienna Cancer Diagnostics Ltd	SDX	Clinical translation of biomarkers using novel diagnostic technologies. First on-market product is based on technology for the detection of the biomarker telomerase	3-Aug-17	9.5	0.07	0.20	0.06	-1	-8	0	
Sonic Healthcare Limited	SHL	Laboratory medicine/pathology, radiology/diagnostic imaging and primary care medical services	30-Apr-87	10,655.8	25.20	25.34	20.61	110	23	-349	78.00
SciGen Limited	SIE	Develops, manufactures and markets human healthcare biotechnology-derived products. Focus on endocrinology, gastroenterology and immunology	15-Nov-02	3.4	0.07	0.07	0.02	0	16	-15	
Somnomed Ltd	SOM	Specialises in products for sleep apnoea. Lead product SomnoMed mandibular advancement splint (MAS)	27-Aug-04	140.0	2.30	3.93	2.08	-15	-15	29	
Starpharma Holdings Limited	SPL	Developer of dendrimer products. Lead product VivaGel for bacterial vaginosis. Dendrimer-enhanced docetaxel in clinical development for solid tumours	28-Sep-00	415.0	1.14	1.67	0.71	3	38	15	
Sirtex Medical Limited	SRX	Novel technology for liver cancer treatment. Radioactive particle, SIR-spheres	24-Aug-00	1,758.0	31.66	31.77	13.33	-40	-80	202	30.00
Suda Ltd	SUD	Oromucosal sprays for drug delivery treatment of off-patent drugs	24-Jan-02	6.1	0.01	0.02	0.00	0	-2	0	
Simavita Ltd	SVA	Wearable and disposable technologies for elderly incontinence	22-Feb-14	5.0	0.02	0.05	0.01	-2	-1	0	
TBG Diagnosticas Ltd	TDL	Development, manufacture and marketing of molecular diagnostic kits, instruments and services	22-Dec-95	14.1	0.26	0.30	0.14	-3	-2	7	
The Hydroponics Company Ltd	THC	Development and delivery of medical cannabis	4-May-17	49.1	0.57	1.15	0.19	-3	-18	12	
Telix Pharmaceuticals Ltd	TLX	Development and commercialisation of molecularly targeted radiation in the management of prostate, renal and glioblastoma (brain) cancer	15-Nov-17	85.8	0.66	0.85	0.46	0	0	0	
TPI Enterprises Ltd	TPE	Processor of narcotic raw material (NRM) for the international pharmaceutical industry	13-Aug-15	111.9	1.32	2.94	1.28	-23	-6	43	
Universal Biosensors Inc.	UBI	Specialist medical in-vitro diagnostic tests for point-of-care, including blood tests and C-reactive protein tests	13-Dec-06	48.5	0.27	0.43	0.20	0	-62	7	
Uscom Limited	UCM	Non-invasive medical devices in the field of cardiac, vascular and pulmonary monitoring	10-Dec-03	22.6	0.17	0.29	0.15	-2	-10	3	
Vectus Biosystems Ltd	VBS	Drug discovery and development company. Lead product VB0004 has anti-hypertensive properties, and anti-fibrotic activity in the heart and kidneys	23-Feb-16	20.6	0.88	1.47	0.81	-13	-7	-3	
Volpara Health Technologies	VHT	Research, development and manufacturing company that provides digital health solutions for personalised breast cancer screening	27-Apr-16	142.3	0.76	0.88	0.46	-6	-13	0	
Viralytics Limited	VLA	Development and commercialisation of oncolytic immunotherapies. Lead product candidate CAVATAK	15-Oct-86	485.6	1.75	1.75	0.59	-6	-29	13	
Virtus Health Ltd	VRT	Assisted reproductive services, diagnostics, genetic testing and day hospitals	11-Jun-13	461.4	5.81	5.93	4.97	37	16	-168	26.00
Vita Life Sciences Limited	VLS	Development and distribution of over-the-counter medicines, complementary, alternative, dietary supplements and health foods	23-Aug-07	43.6	0.80	1.13	0.69	5	15	43	3.75
Wattle Health Australia Ltd	WHA	Health and wellness products with scientific and nutritional benefits	15-Mar-17	162.5	1.19	2.80	0.50	-10	-11	10	
XRF Scientific Ltd	XRF	Manufacturer and marketer of instrumentation for scientific industries, including commercial laboratories	31-Oct-06	21.4	0.17	0.23	0.15	1	23	11	0.24
Zelda Therapeutics	ZLD	Investing in research and clinical trials to study medical cannabis for a variety of ailments	28-Jul-03	47.3	0.09	0.16	0.07	0	19	1	

Data current at 9 July 2018. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Baillieu Holst Stockbroking Ltd and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.

This quarter's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Quarter Return %
SIE	SciGen Limited	$0.05	82
PAR	Paradigm Bio.	$0.65	81
PVA	pSivida Corp	$2.99	62
OSL	Oncosil Medical	$0.23	57
CLV	Clover Corporation	$1.63	54
CMP	Compumedics Limited	$0.56	43
GSS	Genetic Signatures	$0.37	39
PAB	Patrys Limited	$0.06	33
IMM	Immutep Ltd	$0.03	30
RNO	Rhinomed Ltd	$0.18	30
RCE	Recce Pharmaceutical	$0.19	27
CSL	CSL Limited	$192.62	21
PBP	Probiotec Limited	$1.15	21
POH	Phosphagenics Ltd.	$0.02	21
NAN	Nanosonics Limited	$3.16	21
BGT	Bio-Gene Technology	$0.17	20
CAJ	Capitol Health	$0.33	19
IDT	IDT Australia Ltd	$0.10	18
AVH	Avita Medical Ltd	$0.07	17
GID	Gi Dynamics, Inc	$0.03	16

This year's top ASX healthcare sector performers

ASX Code	Company Name	Last Price	Year Return %
IVX	Invion Ltd	$0.03	285
PAB	Patrys Limited	$0.06	247
MYQ	Myfiziq Limited	$0.38	175
CAN	Cann Group Ltd	$3.50	172
CLV	Clover Corporation	$1.63	131
AC8	Auscann Grp Hlgs Ltd	$1.26	109
BXN	Bioxyne Ltd	$0.05	108
PBP	Probiotec Limited	$1.15	98
WHA	Wattle Health Au Ltd	$1.17	97
BOT	Botanix Pharma Ltd	$0.11	94
PNV	Polynovo Limited	$0.54	94
OSL	Oncosil Medical	$0.23	86
RSH	Respiri Limited	$0.10	81
IMU	Imugene Limited	$0.03	81
CYP	Cynata Therapeutics	$1.37	81
PAR	Paradigm Bio.	$0.65	81
PCK	Painchek Ltd	$0.06	81
NEU	Neuren Pharmaceut.	$2.97	78
VHT	Volpara Health Tech	$0.79	76
PTX	Prescient Ltd	$0.11	75

Data current at 9 July 2018. This information has been collated by company reports released to the ASX and contains general information only. It does not constitute financial product advice. Baillieu Holst Stockbroking Ltd and AusBiotech make no assertions as to the merits of any investment opportunities in the companies referred to in these articles.

NEW AUSBIOTECH MEMBERS

Ceramisphere Health PtyLtd

Ceramisphere Health is a recent spin-off from Ceramisphere, a privately owned micro-encapsulation company established in 2007. We are based in Sydney, where we undertake product development, scale-up, and production of silica-based drug delivery systems. Our current focus is the development of pioneering skin delivery–based solutions for small and large therapeutic molecules using our proprietary 'zero-waste' nanocomposite patch technology, with a particular emphasis on pain relief and the development of smart bioactive wound care products.

Dr Chris Barbé
Phone: 02 8011 1360 | Email: info@ceramispherehealth.com | www.ceramispherehealth.com

Exigence

We believe biotechnology innovation underpins solutions for human and animal disease, climate change, fuel alternatives, and food security, improving 'quality of life' for all. We've been addressing the challenging IT problems specific to biotech, pharma and life sciences since 1999. Exigence detects, protects and manages against cybersecurity risks, and designs IT frameworks meeting regulatory compliance needs from in-house to cloud solutions. Clients trust us with their data. Call for a confidential chat.

Mr. Iby Boztepe, Director of Professional Services
M: +61 408 888 653 | T: +61 3 9568 5437 | E: iby@exigence.com.au | W: www.exigence.com.au

La Trobe University

La Trobe University is a multi-campus university that is ranked in the top 1.4 per cent of universities worldwide. We have a strong history of building excellent teaching and research partnerships. La Trobe can provide co-location opportunities on our larger campuses for industry partners, and are keen to partner with organisations in the biotechnology industry to translate our research for the wider community.

Dr Craig Patch, Director, Innovation & Commercialisation
T: +61 3 9479 1681 | W: www.latrobe.edu.au

My Medical Department Pty Ltd

Welcome to your third-party medical department! We are a specialised pharmaceutical medicine consultancy, providing a full array of medical team functions throughout the product life cycle. Our innovative service provides the operations of a full medical department, only charging for what you actually use. As a physician-led team committed to upholding patient safety, we place a strong focus on the quality of our work and integrity of decision-making. Please talk to us about how we may help you.

Dr Catherine Ludwig
T: +61 450 690 678 | E: enquiries@mymedicaldepartment.com | W: mymedicaldepartment.com

Optalert Australia

Optalert was founded by Dr Murray Johns, a sleep research pioneer and the inventor of the Epworth Sleepiness Scale (ESS), used worldwide in sleep centres and research. Incorporating an objective, quantitative, and reproducible test, Optalert technology is the next generation in measuring drowsiness/wakefulness. Researchers have recently used Optalert technology to investigate connections into neurological conditions.

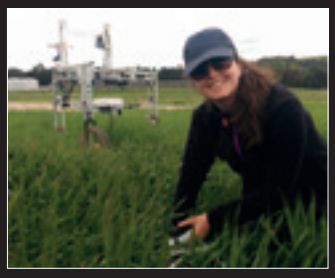
James Gorry, Executive Vice President Global Sales
Phone: +61 411 779 452 | Email: jgorry@optalert.com | Website: www.optalert.com

Thailand Board of Investment

Thailand Board of Investment (BOI) is a Thai Government agency under The Office of The Prime Minister of Thailand in charge of promoting valuable investment from overseas into Thailand, and Thai overseas investment, through a 'tax and/or non-tax' incentive scheme to foreign investors' eligible activities prescribed and granted by the Thai Government.

Miss Vorawan Norasucha, Director
T: +61 2 9252 4882 | +61 2 9252 4884 | E: vorawan@boi.go.th , sydney@boi.go.th

Grow your transformative agri-technology business in Canberra



The Centre for Entrepreneurial Agri-Technology – Australia's newest and smartest agri-tech hub – is located in the National Agricultural & Environmental Sciences Precinct. This precinct provides an unparalleled environment to engage and collaborate with next-generation researchers, industry and cutting-edge facilities. Backed by the Australian National University, CSIRO, leading agricultural peak bodies and the ACT Government, the new Centre will generate solutions to global agri-tech and environmental challenges.

To find out more about the Centre's research partnerships, co-location and translational opportunities, contact us at: CEAT@anu.edu.au

1: Growth facility courtesy of Robert Coe, IRRI. 2: LICOR Portable Photosynthesis System, supplied by ARC-CoETP
 3: Phenomobile courtesy of CSIRO/APPF.

AN INITIATIVE OF

Australian National University

IN PARTNERSHIP WITH

ACT Government | CBR CANBERRA | CSIRO

MO_CoS181251