THE McKell Institute

THE MCKELL INSTITUTE

# BIO-SAVVY

## HOW AUSTRALIA CAN BUILD A STRONGER BIOTECHNOLOGY INDUSTRY

OCTOBER 2016

# ABOUT THE MCKELL INSTITUTE

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Damian has led projects on innovation and commercialisation for governments in Chile, Brazil, Panama, Vietnam, Fiji and France. He is currently leading a component of a World Bank project in Indonesia and the Philippines on business development and innovation. He is also currently the International Consultant on Vietnam's National Innovation Training Program, funded by the World Bank.

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Marieke is a member of the McKell Institute's policy team and has contributed to a wide range of research since 2014.

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She is currently the President of the Australian Swimmers' Association, and contributes to *The Huffington Post Australia* website.

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# FOREWORD

The end of the resources boom and the decline of traditional manufacturing has left Australia in a precarious economic position. Although our banking and professional services sectors are still tracking strongly, economic growth in other industries has been weak or negative.

Biotechnology represents an opportunity to turn our fortunes around. Prime Minister Malcolm Turnbull has identified the need to foster innovation within our nation; and has recognised that while we produce world-class research, we have trouble transferring our research into economic gain.

This has been felt strongly in Australia's biotechnology industry, which, while recording modest growth of 3.1 per cent over the past ten years, has been outpaced more than three to one by a worldwide growth rate of 10 per cent throughout the same period. Net income growth has been even poorer – worldwide figures have outpaced Australia's net income by an incredible 220 per cent.

Biotech has always held the promise of stratospheric growth, but as yet it hasn't delivered due to a lack of leadership and coordination from Government and industry. This report identifies the impediments to the Australian biotech industry, and makes a series of recommendations to help biotech take off.

Most of the recommendations are directed at Government, but the industry must also take responsibility for reform. We will only be able to reap the rewards promised by biotech if a concerted and coordinated effort is made by all involved to reform key areas.

It's important to remember that this is a competitive race. Other nations are investing heavily in their domestic biotech industries. While we currently hold the upper hand, particularly in measures of quality research outputs and a highly-educated workforce, we need to be savvy about targeting our investments to the areas that most need them, and do it quickly. This is an industry that cannot afford complacency.

**The Hon John Watkins**
**CHAIR,**
MCKELL INSTITUTE

**Sam Crosby**
**EXECUTIVE DIRECTOR,**
MCKELL INSTITUTE

# SCOPE

## Pfizer Australia

As Australia faces the challenges that come from the end of the mining boom and a shift away from traditional manufacturing, the Australian biotechnology industry is an important area of leading edge innovation and true economic opportunity.

With strong coordination among stakeholders and clear policy settings, biotechnology in Australia can be fostered to maximise its potential and compete on a global scale, from discovery through to commercialisation and manufacturing.

This report aims to understand the challenges faced by the Australian biotechnology industry today and explore a range of policy recommendations that can unlock its value to benefit all Australians.

It is indeed an important and exciting time for biotechnology in Australia. Pfizer Australia supports the contribution of this report to the national conversation necessary to inform public policy in this area.

**Melissa McGregor**
**MANAGING DIRECTOR**
PFIZER AUSTRALIA

# EXECUTIVE SUMMARY

> Biotechnology is a field of boundless possibilities. It holds the potential to cure cancer, to solve world hunger, and to reverse climate change. Products resulting from biotechnology are already allowing humans to live longer, healthier lives; to be more environmentally sustainable; and to produce more with fewer resources. As a scientific field of endeavour, biotechnology is equivalent today to what personal computing was in the 1980s; sitting on the precipice of exponential growth.

Still relatively young, biotech presents a unique opportunity for governments who invest early and aggressively in this industry to transform their economies. As a future-facing industry, biotech will create high paying jobs in the knowledge and advanced manufacturing sectors.

For a country like Australia, with a very well educated, English-speaking population; world-class research and scientific institutions; a stable political and regulatory environment; a great lifestyle; and a fair amount of entrepreneurial flair; biotechnology represents a unique opportunity for national economic transformation.

The end of the mining boom, and the decline of many traditional manufacturing industries has led the Australian economy down a dangerous path. While our professional services and banking sectors are strong, they mask the plight of many other industries that are struggling; and outside the capital cities, recent jobs growth has at best been stagnant. Australia needs a concerted and coordinated effort to invest in the next industry in which we can excel.

Australia, however, is not acting in a vacuum. Other governments have also targeted biotech as an industry to be fostered. While Australia currently ranks well on many international benchmarks, many of our regional neighbours are investing heavily in the industry and are expected to outperform Australia within the coming years. South Korea, Singapore, China and Taiwan are injecting significant government and private funds into biotechnology, and embarking on regulatory reform programs to attract large international firms to their shores.

This report focuses on how to protect Australia's position as a top investment destination for biotechnology, and assesses ways to improve that position and the industry, to give Australia the best chance of competitive advantage in the future.

Although biotechnology is a broad field, we have chosen to specifically focus on the largest sector within biotech - human health. However, many of the recommendations proposed here will necessarily have positive flow-on effects to the broader industry.

The report begins by mapping the Australian biotech industry, and benchmarking it against our major competitors. It then discusses the three main problems that beleaguer the industry: a lack of speed through the development pipeline; a lack of clear policy direction by the government; and the fact that the industry is notoriously poor at attracting investment - and proposes recommendations to mitigate and rectify these issues.

Although this report is organised around the three main problems identified, many of the issues and recommendations overlap, alluding to the complexity of the industry and the importance for a coordinated vision and plan. The report concludes with a final call to government for bipartisan support of the industry: any young industry requires government support in its teething years, but none more so than biotech. However, the potential payoff for this industry is far greater than many others before it. The warning is that Australia cannot afford to stall. Our competitors are moving quickly, and we must counter their efforts to ensure we are the ones who reap the rewards from a strong biotechnology industry.

# RECOMMENDATIONS

## RECOMMENDATION 1

### The Government should better resource the Therapeutic Goods Administration

- Australia should follow the US Government's lead and contribute the equivalent of two-thirds of the TGA's current budget of $142 million, resulting in a cash injection of $95 million to kick-start the process of TGA reform.
- The TGA and industry should advocate for further legislative reform in order to set Australia on the same path as the US.

## RECOMMENDATION 2

### The industry should create a taskforce to map the path to legislative reform in the regulatory process

## RECOMMENDATION 3

### The Government should introduce more competitive intellectual property legislation

- Australia should increase data exclusivity arrangements to more closely match that of our major trading partners.
- Current IP legislation should be continued and extended with the unique requirements of the biotechnology industry in mind.

## RECOMMENDATION 4

### The Government must commit to and extend basic tax incentives

- Following the lead of the UK and other jurisdictions, so called 'Patent Box' policies should be introduced in Australia.
- The R&D Tax Incentive should be reinstated, strengthened and better targeted, and the Government should demonstrate to the industry that the policy has bipartisan support.

## RECOMMENDATION 5

### Australia needs to develop an appropriate venture capital system

- A proportion of Australia's superannuation savings should be directed towards investment in Australian innovations.
- The Government should conduct a review into how Australia's venture capital system can be more effectively utilised, and what mechanisms might be required in order to attract high-net worth individuals to invest in Australian ventures.

## RECOMMENDATION 6

### An intellectual property pooling organisation to represent Australian research should be established

- Australian Universities should create an organisation similar to the UK's Imperial Innovations in order to pool IP and assist in commercialising promising biotech research.

## RECOMMENDATION 7

### Government funding should be provided to AusBiotech

## THE DIFFICULTIES OF MEASURING THE BIOTECH INDUSTRY IN AUSTRALIA

The OECD defines biotechnology as the application of science and technology to living organisms (and parts thereof) in order to alter living and non-living materials for the generation of knowledge and development of products and services. This definition is deliberately broad enough to encompass the wide range of products and applications attributable to biotechnology, but as a result, estimating the size of the biotech sector in Australia is very difficult. The definition of what constitutes a 'pure' biotechnology company and/or sector varies among institutions gathering industrial data.

# PART ONE: BENCHMARKING THE AUSTRALIAN BIOTECH INDUSTRY

### The biotechnology industry is expected to continue growing

Biotechnology in Australia has grown at an average of 3.1% per year for the last 10 years. And with an increase in the demand for biotech products like human therapeutics and diagnostics – we can expect to see continued growth given the right policy settings in the coming 5 years. The sector is expected to grow at a rate of 4.4 per cent a year until 2021. Figure 1.1 illustrates the sector's projected growth in terms of revenues and industry value added, expected to reach $8,675m and $3,018m respectively in 2021.

It is also expected that the consolidation trends currently characterising the pharmaceutical sector will spill over into the biotechnology sector, and pharmaceutical companies will continue acquiring biotechnology start-ups to gain access to product pipelines and technological platforms.[2] Rapid advancements in new fields of science and engineering have facilitated new innovations in the biomedical domain, and an increasing convergence between physical and biological technology platforms.[3]

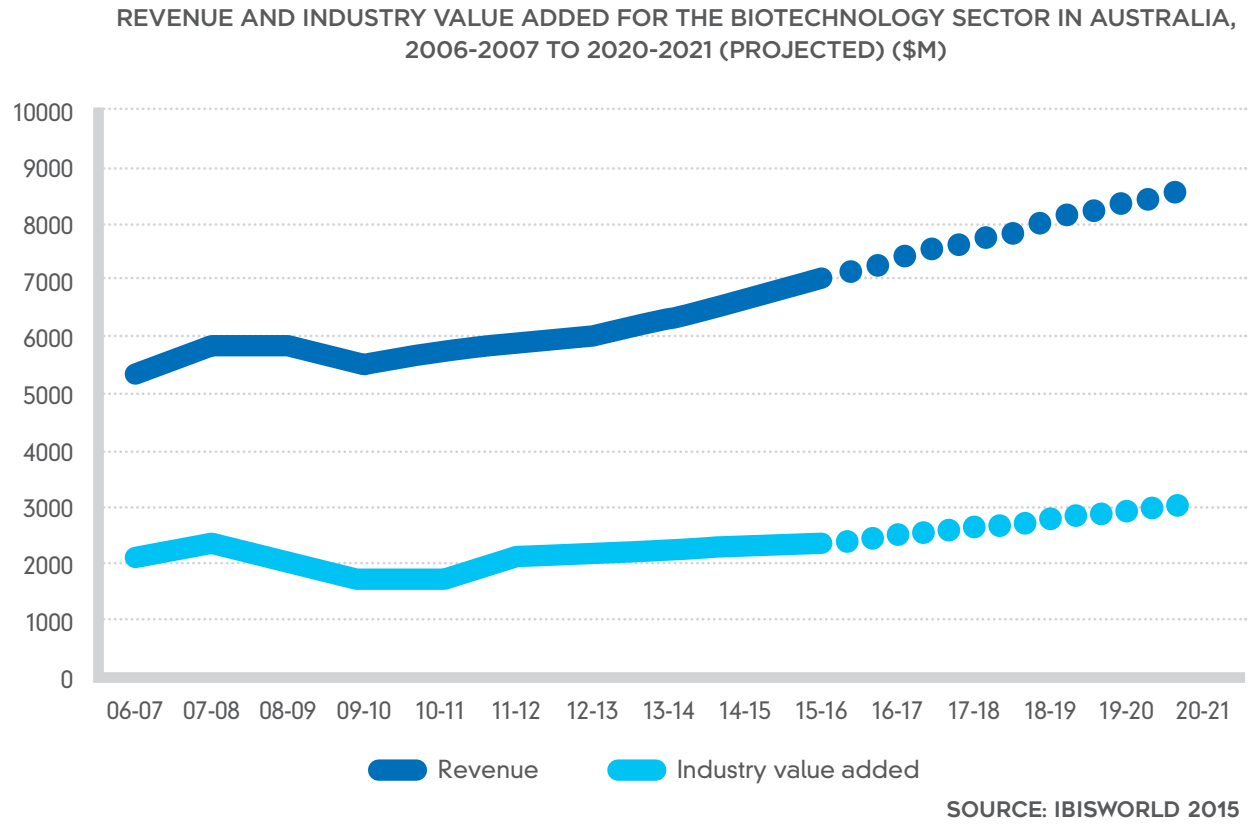
Such advancements in Australia's biotechnology sector offer substantial investment opportunities, and this is only expected to increase as healthcare spending continues to grow with our ageing population and increased demand for new healthcare products and techniques.[4]

As there is not an official classification for biotechnology companies in the Australian and New Zealand Standard Industry Classification, the majority of available biotechnology company data at the industry level is drawn from publicly listed companies. The Australian Stock Exchange (ASX) classifies the biotechnology sector as a subgroup of the larger sector labelled 'Health Care'. Other subsectors within the Health Care sector include pharmaceutical, medical practice, pathology operators, life sciences and medical device companies. Yet according to IBISWorld, the biotechnology industry covers biotechnology research and development, licensing, product manufacturing and product wholesaling, and companies that focus on medical devices are not included in this industry.[1]

As such, it is inherently difficult to measure the relative success or failure of the biotechnology industry in Australia. Biotech is pervasive throughout many sectors: from animal health to agriculture, the industrial chemicals sector to human health. This report has chosen to focus specifically on the human health application of biotechnology – a broad enough industry in itself – both for ease of measurement and because human health biotech is an industry large enough to warrant separate inquiry.

The following section begins by assessing the health of the biotech industry globally and domestically. It then attempts to benchmark the Australian human health biotechnology sector against our international competitors. It finds that whilst Australia might compare favourably on a range of metrics, the size and success of our largest biotechnology company, CSL, is distorting figures at the national level. When CSL is removed from industry figures, it is clear that the biotech industry is performing well below expectation in Australia.

**FIGURE 1.1** The biotechnology sector in Australia




SOURCE: IBISWORLD 2015

## Biotech employment will also continue to grow

In general, most of the Australian biotechnology companies are research-intensive small to medium-sized enterprises operating in the start-up or growing/expansion phase. These mostly comprise spin-offs from universities and other research organisations.[5] The sector recorded 479 companies during the 2014-2015 period, and is expected to remain relatively stable in the next few years, comprising 484 companies by the end of 2020.[6]

After a minor decline from 2004 to 2005, employment for public biotechnology businesses grew from 8,820 in 2006 to 13,140 in 2011.[7] CSL accounts for approximately 15 per cent of biotech employees in Australia, employing around 1900 people, mostly at their international head office in Melbourne.[8] Considering the entire set of 400 therapeutics and diagnostics and approximately 500–900 medical technology companies operating in Australia (which accounts for a large part of the value chain around biotechnology in the country), the broader sector employs in excess of 45,000 Australians.[9]

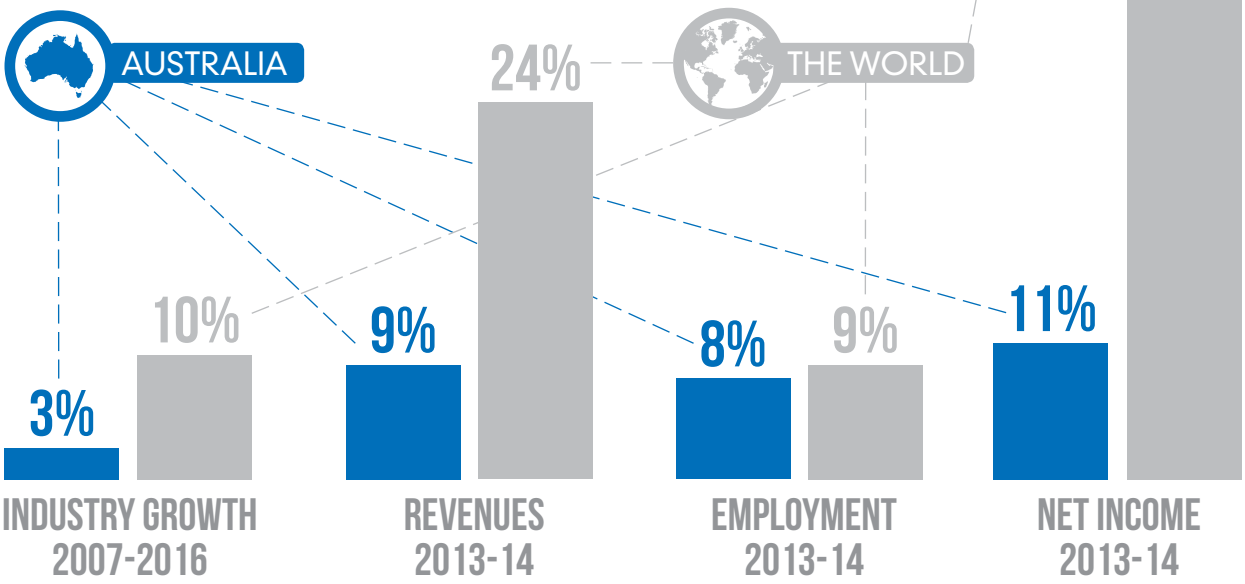
The Australian Government Department of Employment expects that the biotechnology industry will continue to record steady employment growth of 4.3 per cent annually until 2020; this is compared to 1.7 per cent employment growth for all industries in Australia.[10]

## Australia's biotech industry is being outperformed

While Australian growth is invariably positive, the worldwide biotechnology industry has been growing at a rate more than three times that of the Australian figure: at 10 per cent over the previous ten years.[11] At the worldwide level, revenues grew 24 per cent between 2013 and 2014; employment growth was 9 per cent and net income grew an incredible 231 per cent. There is no doubt that the international biotechnology sector is currently in a boom.[12]

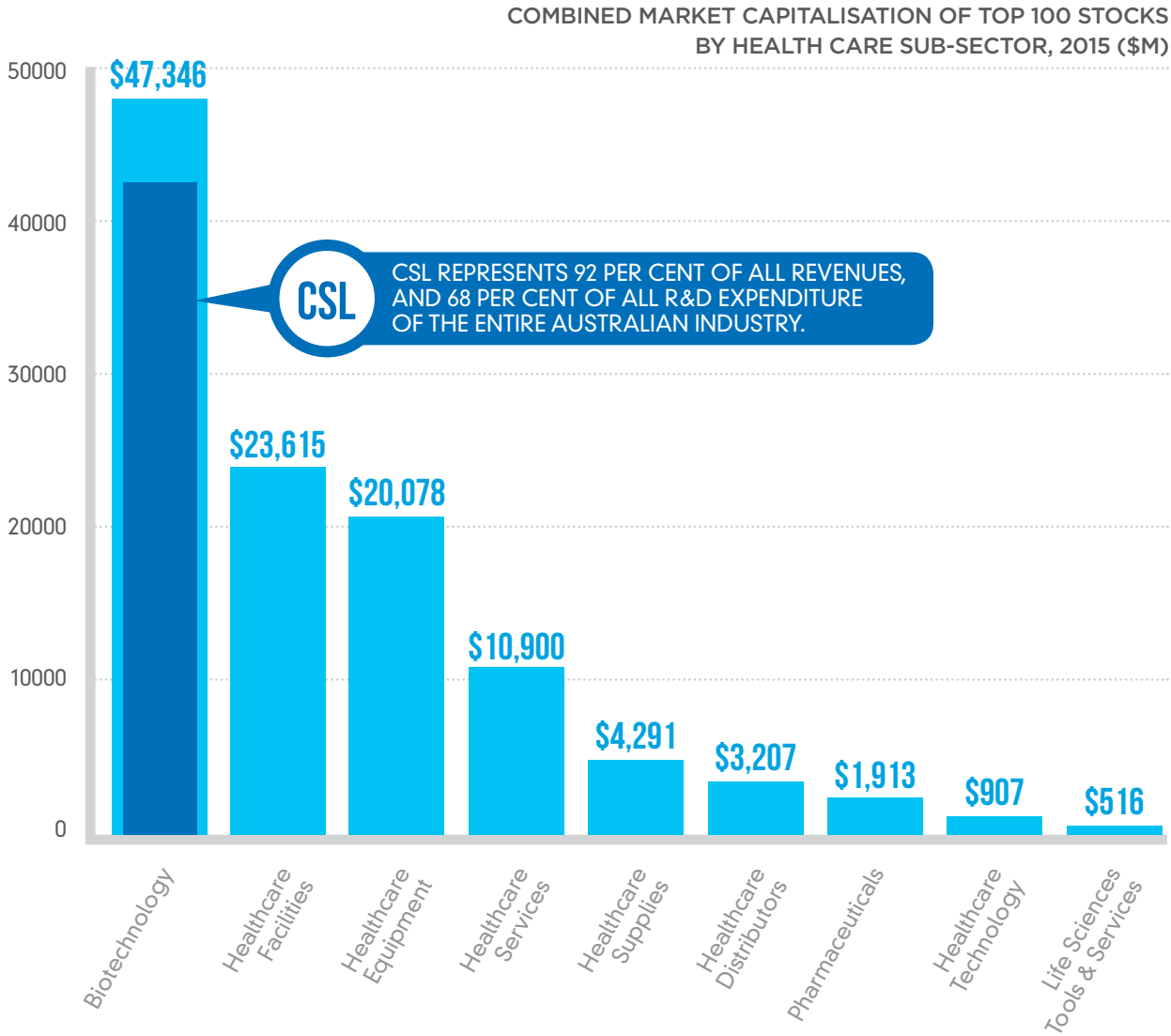
However, in Australia biotechnology growth was more modest. Between 2013 and 2014, biotechnology revenues grew 9 per cent; employment grew 8 per cent; and net income grew just 11 per cent.

**FIGURE 1.2** Biotech growth rates in Australia and around the world



However, it is important to note that the biotechnology industry in Australia consists of two very disparate groups: CSL, Australia's most successful biotech company that has built its 100-year-old success on the back of blood plasma products; and the rest. ***Of the entire Australian industry, CSL represents 92 per cent of all revenues, and 68 per cent of all R&D expenditure.***[13]

**FIGURE 1.3** Market capitalisation among sectors, (August 2015)




SOURCE: AUSTRALIAN STOCK EXCHANGE, 2015

This report acknowledges and applauds the success of CSL, however, it is important to note that the reality of Australian biotech is far less healthy than an initial glance at the statistics suggests. Extensive public funding has been directed at biotechnology in Australia over decades. If Australia was a single investor it would be very unhappy with its return on investment from biotechnology to date. We argue in this report that this can be turned around with the right policy leadership.

Australia is a substantial global contributor of fundamental research, as is evidenced by its comparatively large contribution of 3 per cent of the world's research publications achieved with only 0.3 per cent of the global population.[14] In terms of the number of publications in top journals per 1,000 population, Australia ranks 5th ahead of the UK, United States, France and Germany, but behind smaller Scandinavian countries.[15] Additionally, Australia's citation rates are world class, ranking higher than most of our major competitors.[16]

A signification proportion of this biotechnology research comes from Australia's CSIRO. The national research institution ranks in the top 1% of the world's scientific institutions in 15 research fields, including molecular biology & genetics, microbiology and biology & biochemistry.[17] Additionally, Australia is the 5th highest ranked nation amongst the world's top 200 universities by five key subject fields, with particularly strong performances in life and agriculture sciences, engineering and computer science.[18]

In addition, R&D expenditure in Australia increased on average by 6.6% a year between 2000 and 2011, a substantially higher rate than the OECD average growth rate of 2.7%.[19] However, this growth is largely due to the fact that Australia began from a very low base of R&D expenditure. Australia still spends less on R&D than the OECD average in terms of both gross (GERD) and business expenditure (BERD) measures.

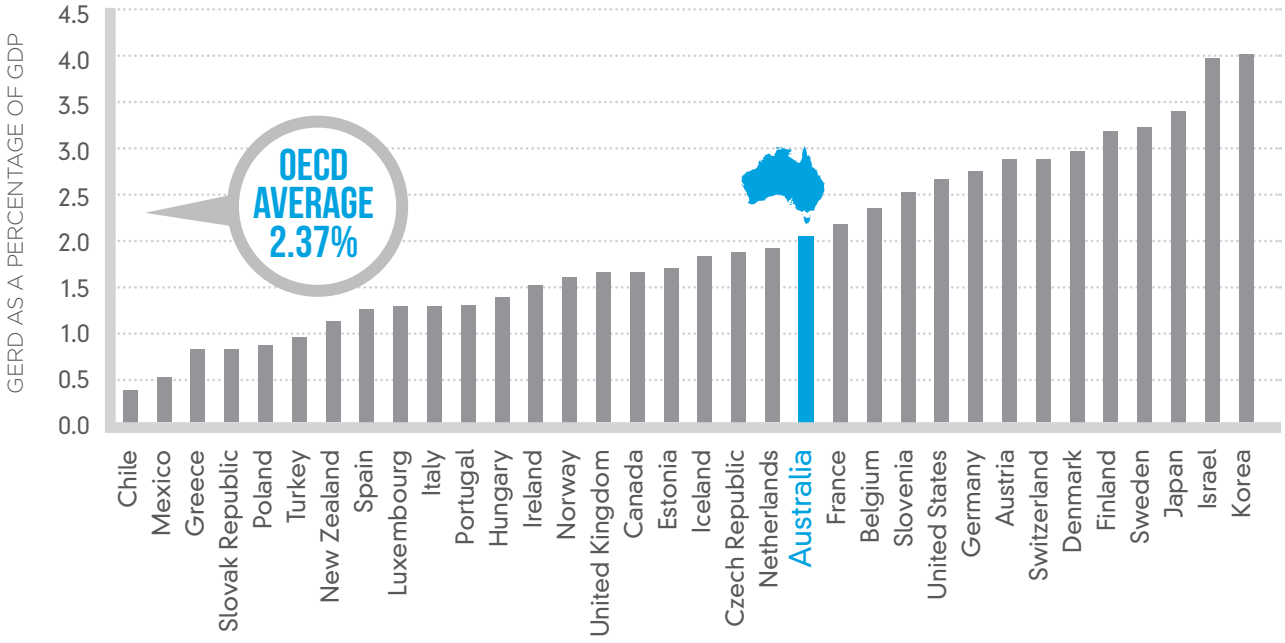
**FIGURE 1.4** Comparative performance among global biotechnology industry players

| Public Company Data | Us | Europe | Australia | Australia Without CSL (approx.) | Canada | Total |
|---|---|---|---|---|---|---|
| Revenues | $93,050 | $23,992 | **$5,794** | **$464** | $260 | **$123,096** |
| R&D Expense | $28,831 | $5,576 | **$681** | **$218** | $299 | **$35,387** |
| Net Income (loss) | $10,618 | $3,255 | **$1,066** | **$85** | ($87) | **$14,852** |
| Market Capitalisation | $853,862 | $162,149 | **$42,177** | **$3,374** | $5,227 | **$1,063,415** |
| Number of Employees | 110,090 | 58,770 | **13,370** | **11,470** | 1,380 | **$183,610** |
| Number of Public Companies | 403 | 196 | **52** | **51** | 63 | **714** |

SOURCE: ERNST & YOUNG 2015 NOTE: FIGURES ARE IN US$.

**FIGURE 1.5**

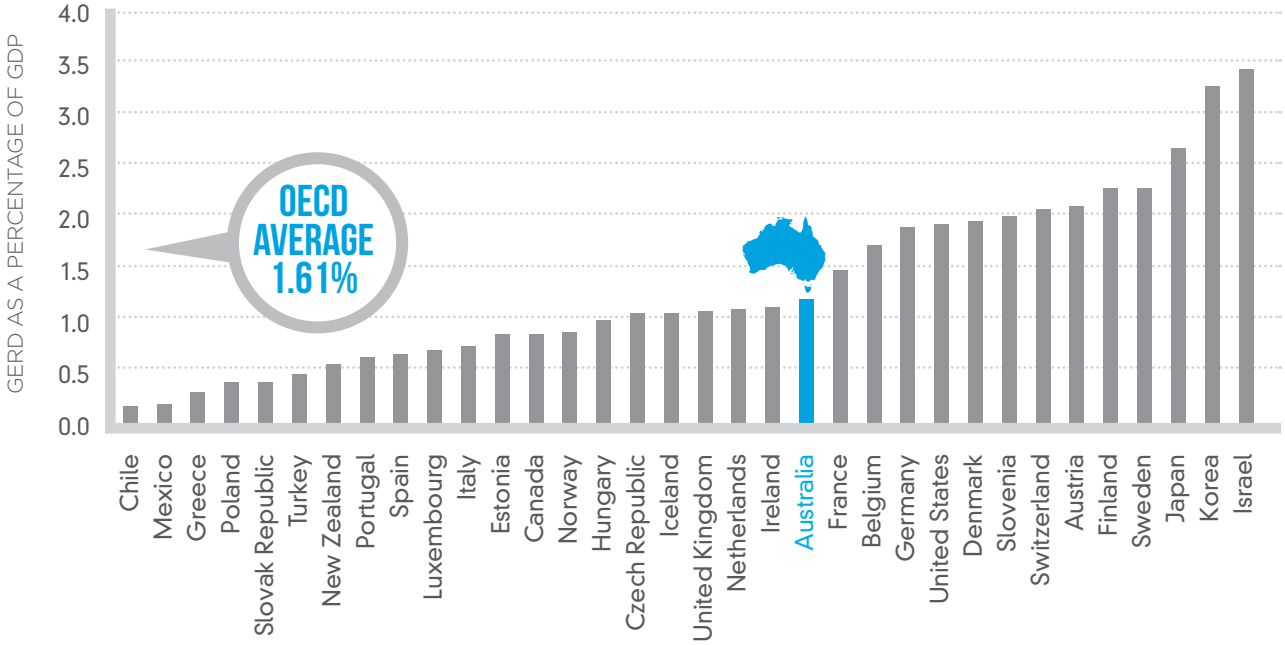
Gross expenditure on research and development as a percentage of GDP, OECD nations




SOURCE: COMPILED FROM OECD STATISTICS, MAIN SCIENCE AND TECHNOLOGY INDICATORS. DATA IS FOR 2013 OR LATEST AVAILABLE YEAR.

**FIGURE 1.6**

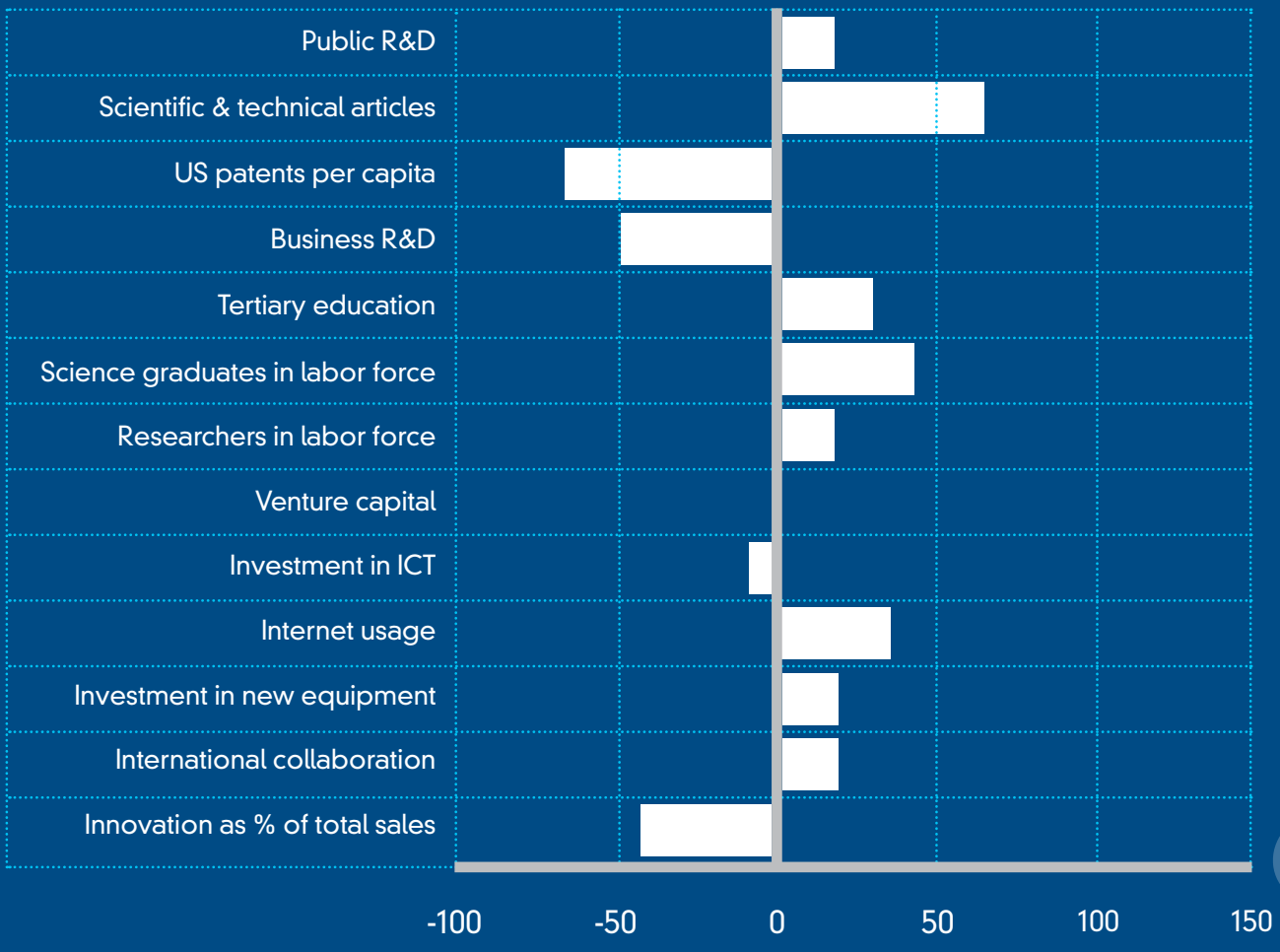
Business expenditure on research and development as a percentage of GDP, OECD nations




SOURCE: COMPILED FROM OECD STATISTICS, MAIN SCIENCE AND TECHNOLOGY INDICATORS. DATA IS FOR 2013 OR LATEST AVAILABLE YEAR.

While Australia contributes beyond our fair share of fundamental research to the global knowledge base, we consistently perform below average on the experimental development indicator of R&D. Innovations usually emanate from a strong base of fundamental research, like that conducted by universities and the CSIRO in Australia, which then can be utilised in applied research. The successful research will then progress through the pipeline to experimental development: this report argues that the best organisations to conduct this phase of research is the private sector.

**FIGURE 1.7** Australia's innovation performance compared to the OECD average (percentage difference)




SOURCE: DEPARTMENT OF EDUCATION, SCIENCE AND TRAINING (2005)

## Successful Australian biotech mergers and acquisitions are rare

Successful exit strategies for biotech companies almost always depend on alliances, followed by a merger or acquisition (M&A) with a large pharmaceutical company. Rarely does a biotechnology firm take its candidates through to market. Typically, in the drugs and vaccines space, significant de-risking of the technology has been achieved by the end of Phase IIb clinical trials, where efficacy, safety and dosage are well established and significant results over competitor products achieved. As such the biotech pipeline has always dovetailed in to that of the pharmaceuticals.

M&As in the US which involve biotech companies of similar age to many Australian companies have been in the range of US$5B to $45B. While there is no need to denigrate our biotech successes, our largest biotech M&A so far has been Spinifex, purchased by Novartis for a total of AU$1B. Not only then are our successes fewer than would be expected of a thirty-year-old, globally-focussed industry, the M&As which have been achieved are relatively small compared to many of the M&As which are occurring globally. In 2015 alone, US$300 billion worth of M&As were achieved in the US across 166 deals (beating the previous best of $250B across 137 M&As in 2014).[20]

**FIGURE 1.8**

Australia's biotech industry – relative performance

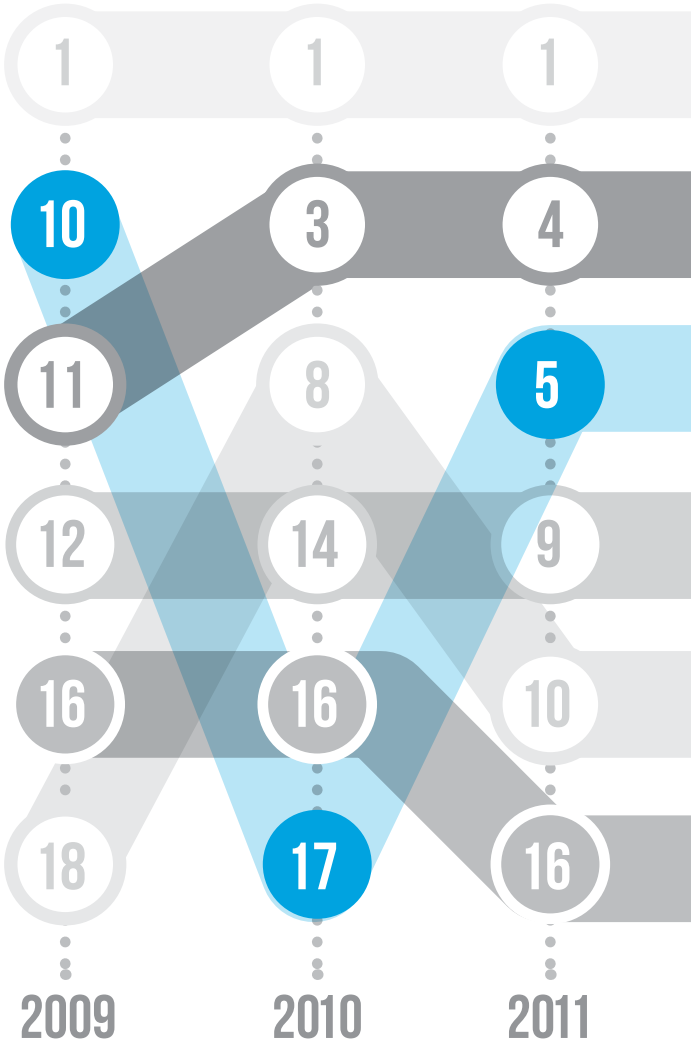
# AUSTRALIA'S TRAJECTORY IN THE SCIENTIFIC AMERICAN WORLD VIEW (BIOTECHNOLOGY) -SCORECARD RANKINGS FROM 2009-2015

## Measuring Australia's potential

The set of metrics employed for country-level comparison and analysis of biotechnology industries varies across the literature. This report draws upon the number of public biotechnology companies as the base metric to identify the top 5 most relevant biotechnology nations in order to examine the relevance of the Australian biotechnology sector from an international perspective. The countries examined are: United States, Canada, United Kingdom, France and Germany (Australia ranks 2nd globally for this metric).[21]

The metrics and scorecard indicate the extent of Australia's potential, but also identifies Australia's weakness in terms of putting that potential to use.

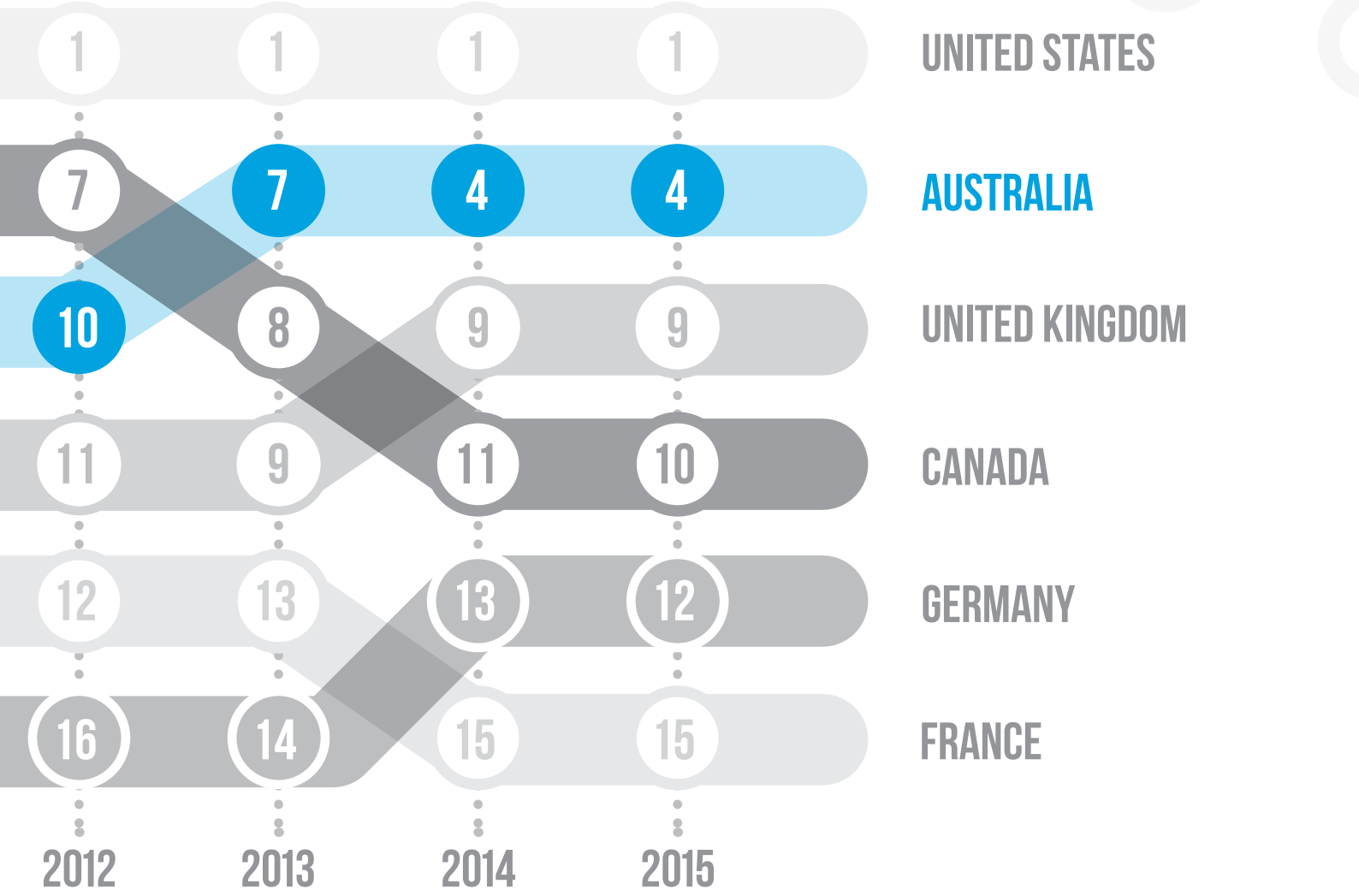
The following section maps Australia's position in terms of input metrics and output metrics. Input metrics measure Australia's 'talent base', whereas output metrics measure Australia's utilisation of that talent for commercial gain.



## Innovation potential and Intensity

The 2015 Scientific American's Worldview Scorecard, an annual ranking of countries by their biotechnology innovative potential, places Australia in 4th behind the United States (1st) and ahead of the United Kingdom (9th), Canada (10th), Germany (12th) and France (15th). Australia has managed to outrank these nations in a period of four years, from 17th place in 2010, to 4th place in 2014 (and the same ranking again in 2015). Figure 1.8 shows how Australia has progressed throughout the history of the ranking system compared to the rest of the countries under analysis. Bear in mind however that these figures include CSL; without which, our rankings would be much less impressive.[22]

The Scientific American Worldview Scorecard uses biotechnology 'intensity,' among 6 other metrics, to rank countries by their innovation capacity. This metric is a composite of: public companies per million population; public company employees per capita; public company revenues by GDP; biotechnology patents by total patents filed under the Patent Cooperation Treaty; value added of knowledge and technology-intensive industries; and Business Expenditure on Research and Development (BERD). Australia ranks 3rd globally on this measurement of innovation capacity behind the United States (2nd), but ahead of the United Kingdom (12th), Canada (14th), France (16th) and Germany (23th).[23]



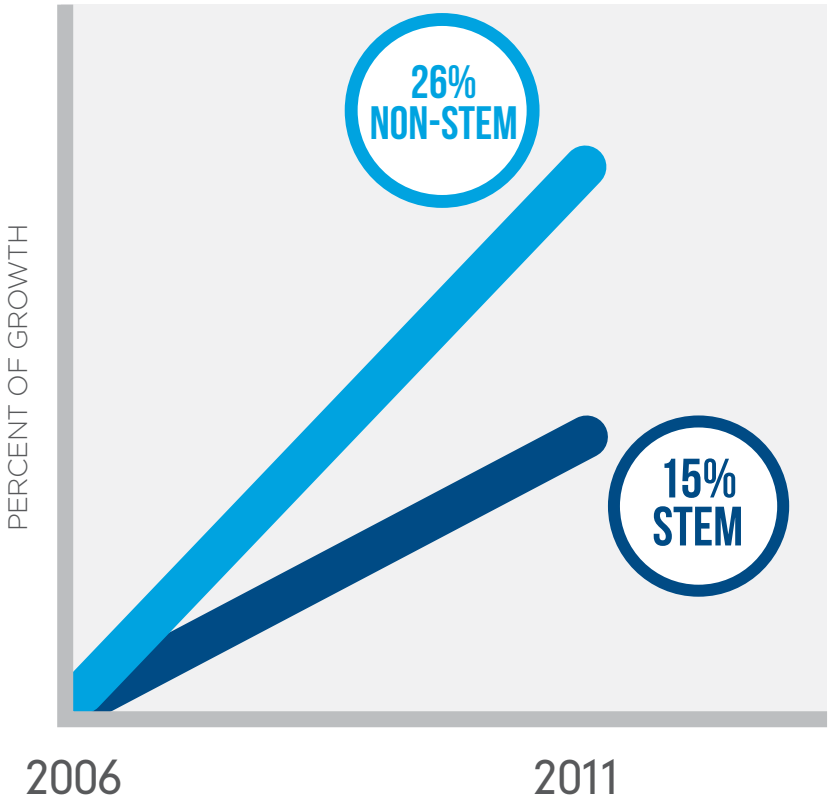
## Skilled workforce

In terms of the quality of education and workforce supporting biotechnology innovation by country, Australia ranks 4th in proportion of PhD graduates in life sciences per million population, behind the United Kingdom and Canada (tied in 2nd place) but ahead of the United States, France and Germany.[24]

However, Australia's number of STEM (Science, Technology, Engineering and Maths) graduates are growing at a much slower pace than those graduating from other fields of study. Between 2006 and 2011, the quantity of STEM graduates grew at a cumulative 15 per cent; whereas the number of non-STEM graduates grew at a much higher rate of 26 per cent.[25]

In absolute terms, the proportion of STEM graduates actually declined between 2001-2011, from 21.7 per cent of all university graduates to 16.5 per cent.[26]

**FIGURE 1.9**
Growth of STEM vs. Non-STEM qualified population 2006-2011




SOURCE: AUSTRALIAN GOVERNMENT, CHIEF SCIENTIST, 2016

In addition, the level of primary and high school students participating in and performing well in STEM fields is dropping across the nation. Compared to other countries, Australia's international standardised testing results have been slipping in the STEM subjects since the early 2000s, and the gap between the highest and lowest socioeconomic quintiles has grown to two and a half years' worth of schooling.[27]

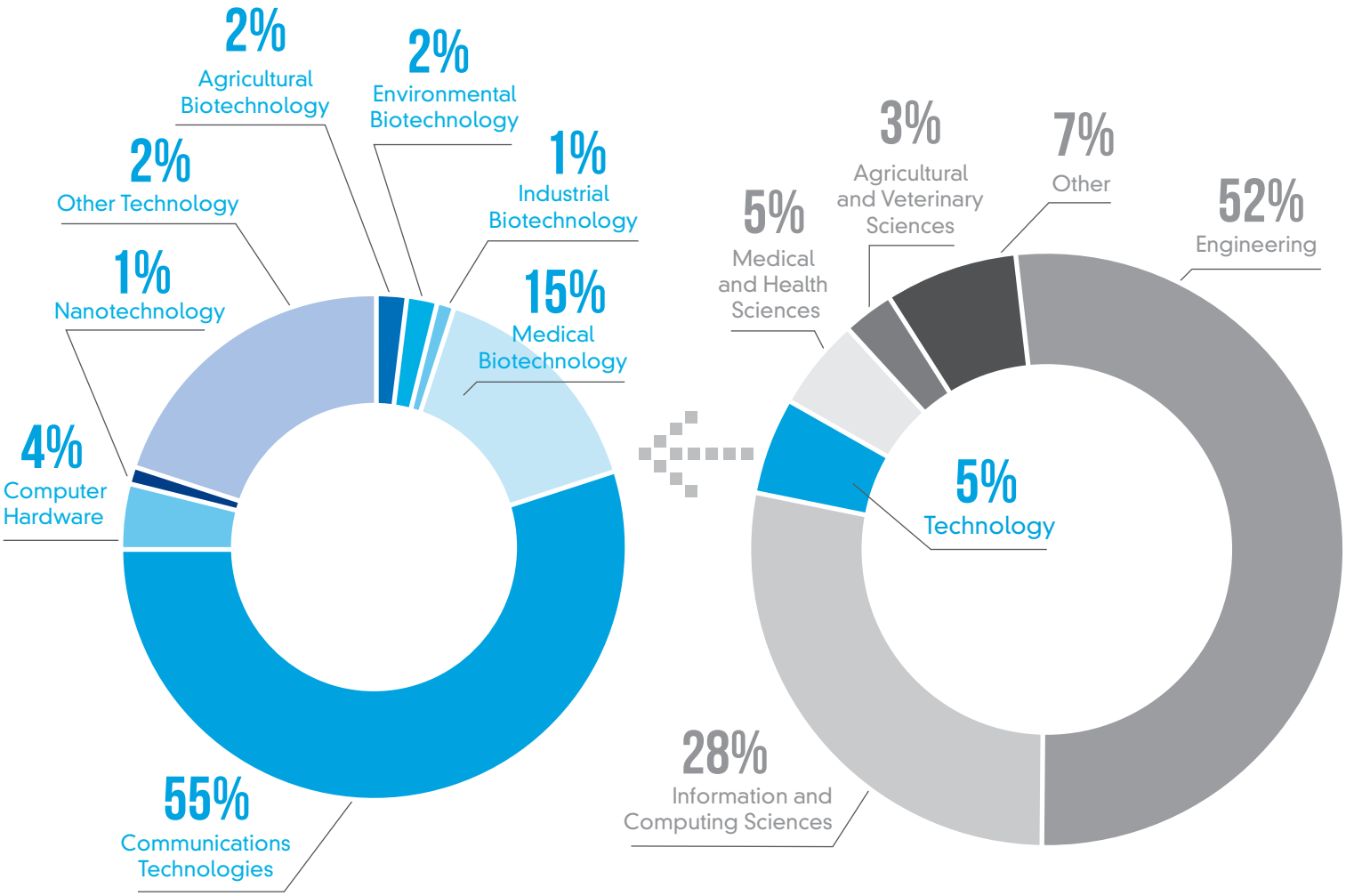
These statistics indicate that while Australia might currently have an educated and experienced workforce in the STEM fields, the pipeline is thinning.

Unfortunately, because biotechnology hasn't been the success the country thought it would be 20 years ago, career prospects for scientists and technicians in biotech fields are not strong. Pay rates are not favourable compared to many other industries and professions, so talent retention remains a challenge. As a result, biotechnology programs at Australia's universities have either limped along or declined and died. So the stock of trained biotechnology scientists and technicians is diminishing as students move to more promising fields. As such, if biotechnology were to recover, there would be a shortage of qualified young professionals to fill its ranks.

## R&D expenditure on biotechnology activities

Regarding research efforts, the Australian Bureau of Statistics (ABS) reported business expenditure on R&D concerning biotechnology as $184.3m for the 2010-11 period, representing 1% of the total business expenditure on R&D during that period and 20% of the total business expenditure on R&D concerning the "technology" field of research.[28]

**FIGURE 1.10**
Business expenditure on R&D (BERD) by research field 2011

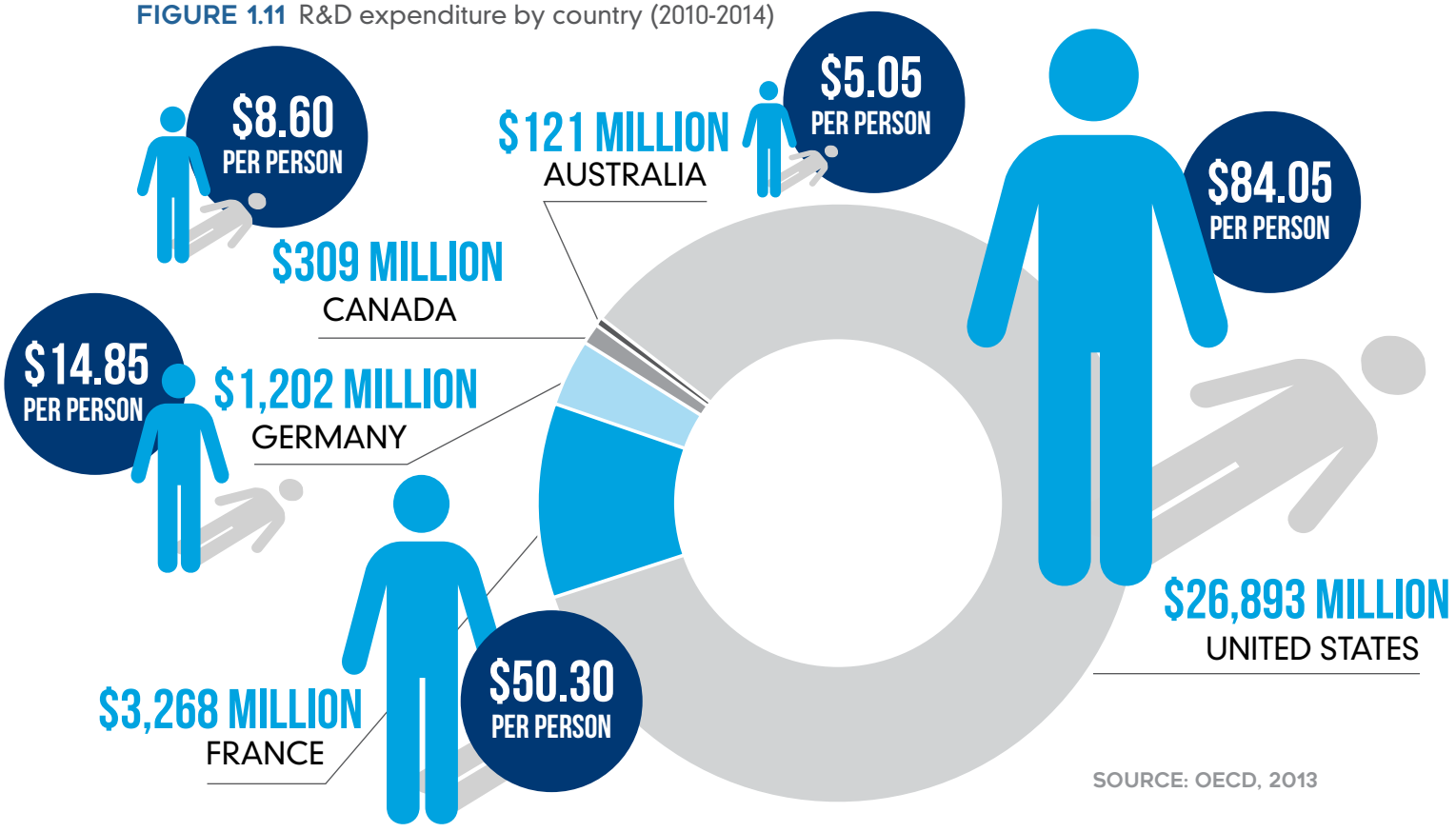



SOURCE: ABS, 2014

In terms of the distribution of R&D business expenditure by biotechnology sub-fields, medical biotechnology was the dominant field of biotechnology research with approximately three times the level of expenditure on other biotechnology sub-fields combined.[29] By size of expenditure, medical biotechnology is followed by agricultural biotechnology, then environmental biotechnology and, lastly, industrial biotechnology.[30]

There is a significant gap on biotechnology-related R&D expenditures between Australia and the rest of the key biotechnology nations. The OECD[31] reports that the total biotechnology R&D expenditure for Australia was US $121m (2010), while the United States spent $26,893m (2012), France spent US$3,268m (2012), Germany spent US$1,202m (2014) and Canada spent US$309m (2013). Although the years used in the OECD report varies by country, it is likely that this gap remains to date given the size of the differences. The Australian biotechnology industry spends less than 0.5 per cent of US biotechnology R&D total expenditure, and only a third of Canadian expenditure, even though our industry is much larger than Canada's.

**FIGURE 1.11** R&D expenditure by country (2010-2014)

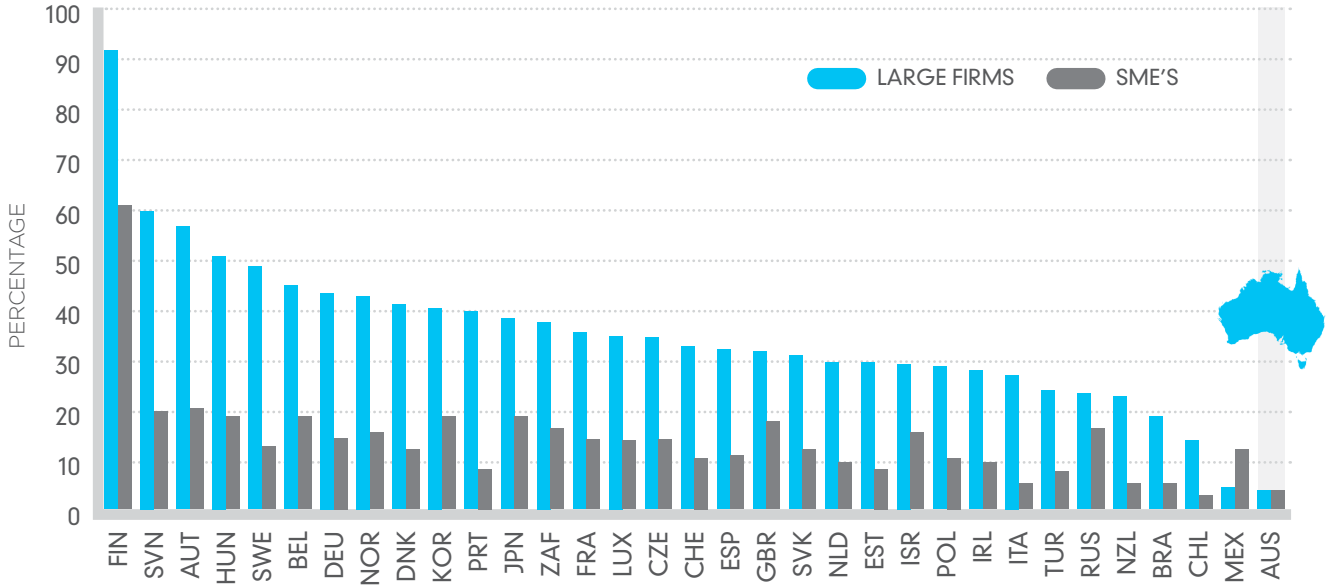



SOURCE: OECD, 2013

While Australia may currently be performing well on other key metrics, traditionally we have been quite poor in our investment in R&D. R&D investment is a key contributor to a nation's productivity, and is indicative of competitiveness and GDP growth for the future. While Australia's investment in R&D has been growing faster than our competitors for the past few years, those figures hide the fact that our investment has come from a very low base: we have a long way to catch up to the rest of the world in terms of expenditure on research and development.

Australia relies on our public institutions to conduct R&D, such as our universities and the CSIRO. The problem with this reliance is that we are also lacking in our ability to create linkages between industry and research.

**FIGURE 1.12**
OECD collaboration between research institutions and firms, by size of firm (2008-2010)




SOURCE: OECD, 2013

## Research collaboration with firms

A 2014 report from the Office of the Chief Scientist found that Australia ranks 32nd out of 33 OECD countries for research institution to industry collaboration with small and medium sized businesses (SMEs), and last for collaboration with large companies.[32] If biotechnology is an industry – a question insiders have been asking themselves for 20 years – it has always been too fragmented an industry to build a strong collaborative model.

Collaboration between research and higher education institutions and industry is imperative to the process of commercialisation of research. While many Australian universities have created their own Technology Transfer Offices (TTOs), these have experienced varied levels of success. Commercialisation is not a core capability of Australia's universities. This point is discussed at greater length later in this report.

## Market value

Market capitalisation of public biotechnology firms' outstanding shares provides a comprehensive understanding of the overall value of the biotechnology sector at the national level. In this regard, the US is the global leader with a total market capitalisation close to six times that of the rest of the world combined. However, on this metric Australia has the second largest market value of public biotechnology firms (more than US$35billion), followed by the UK and well ahead of Germany, France and Canada.[33]

## Revenues

For the second year in a row, Australia held the world's second greatest public biotechnology company revenues ahead of the United Kingdom, France, Canada and Germany, but well below the United States.[34]

In terms of the industry's growth trends, revenues from biotechnology public companies grew by 9% during the 2013-2014 period. While countries such as Canada have recorded a decrease during the same period, the United States and Europe grew by 29% and 15% respectively.[35] Again, these figures are distorted by the biotech behemoth CSL, which recorded revenues in excess of US$5.5billion for the 2013-14 financial year, and grew 7.6 per cent during the same period.[36]

## Number of patents

Australia holds a high technological advantage in biotechnology compared to the rest of the OECD countries. This is measured as the share of biotechnology patents relative to the share of total patents. Australia ranks world's 4th best with an index of 2.3, ahead of the United States (1.8), United Kingdom (1.5), Canada (1.3), France (1.2) and Germany (0.7).[37]

However, Australia files far fewer total patents than all the other comparison nations, and so the total number of biotechnology patents filed each year is fewer than all except Canada.

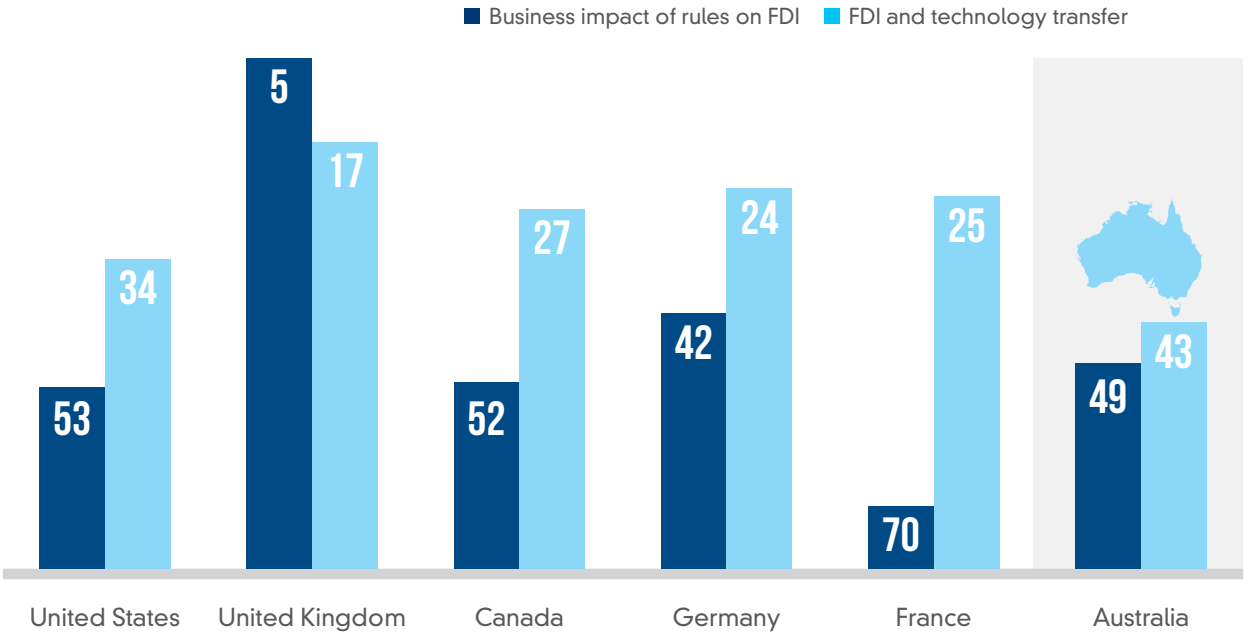
**FIGURE 1.13** Total number of patents filed in 2013, by country

| Country | Total number of patents filed (2013) | Number of biotechnology patents filed (approximate) |
|---|---|---|
| Australia | 1,789 | 41 |
| Canada | 3,168 | 41 |
| France | 7,726 | 93 |
| Germany | 17,206 | 120 |
| United Kingdom | 6,194 | 93 |
| United States | 57,266 | 1031 |

## Foreign investment

Foreign direct investment is an important source of growth in biotechnology sectors worldwide.[38] According to the World Economic Forum,[39] Australia is better positioned than the United States, Canada and France in the way that current federal regulations encourage foreign direct investment. This is presented as "Business impact of rules on FDI" in Figure 1.14. In terms of new technology brought by foreign investment, Australia ranks 43rd globally, but shares a comparative disadvantage against the rest of countries under analysis. That disadvantage relates to the lack of history of technologies and IP farmed in by Australian biotechnology companies, as Clinuvel Pharmaceuticals did with its SCENESSE technology originally from the University of Arizona. Technology traversing Australia's borders either way has proven difficult. This has limited our competitiveness in a global industry. Although these metrics are not a direct measure of the biotechnology sector, they provide an estimation of a country's capacity to attract capital from overseas.

**FIGURE 1.14** The global competitive index rankings for foreign direct investment




SOURCE: ERNST & YOUNG 2012

**THE NEXT THREE SECTIONS proceed with identifying the three main problems that plague the biotechnology industry in Australia. Those identified problems are: the lack of speed at which a new product can progress through the development pipeline; the lack of clear policy leadership from the Government; and the level of fragmentation within the industry. These issues are hindering Australia's competitiveness in the international marketplace, and are impeding growth within the domestic industry. Each section outlines a range of recommendations which both the Government and industry can implement in order to make immediate and lasting changes to the trajectory of Australian biotech.**

# PART TWO:
# THE NEED FOR SPEED

> In biotechnology, speed is everything. Speed through the development pipeline increases the likelihood of reaching the market before competitors. Speed creates a fillip to revenue, return on investment, effective patent life and the ability of sponsors to then switch resources to their ensuing R&D pipeline candidates. But it also benefits the community, by allowing life-enhancing, prolonging and improving medicines to be available to patients sooner; and with stipulations under government legislation, at reasonable prices to the public health system.

The flow-on effect of speed can further be felt in the government budget: improved medicines at reasonable prices supports productivity through enhanced whole-of-life productivity, and less call on public health resources. With an ageing population and growing health expenditure, the Australian government is expected to spend about 13 per cent of GDP on health by 2049-50, up from a current 7 per cent, and so the need for better and more cost effective medicines will only increase over the coming decades.[40] The purpose of this section is to analyse those factors that are most inhibiting speed in the Australian biotechnology industry, and to outline potential solutions.

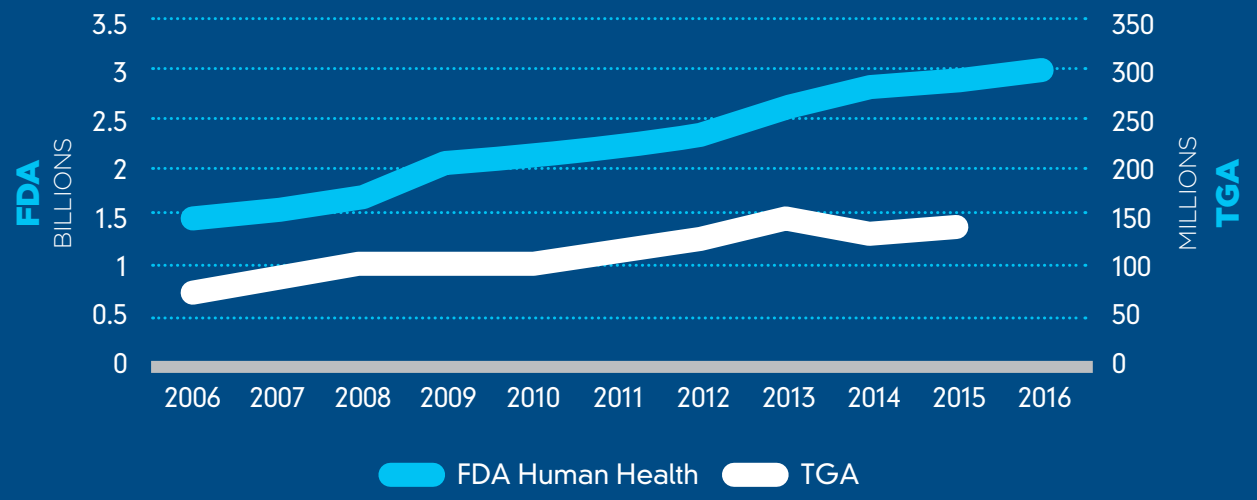
It has seemed almost inevitable for the duration of the industry's existence that drugs and vaccines in Australia will take longer to progress through development pipelines. Australia's regulatory system does not compare favourably with drugs and vaccines developed in the US. ***Put simply, being in Australia slows technologies and companies down.***

The greatest impact on the development time for drugs and vaccines is the amount of time spent in development, review and regulatory review and approval. The evidence available indicates that the regulatory landscape that dominates biotechnology (especially drugs and vaccines for human health, and to a lesser extent medical devices, cellular therapies and non-pharma genetic therapies) is unnecessarily complex and time consuming.

The benchmark regulator globally is the US Food and Drug Administration (FDA). This is hardly surprising, as the US remains the largest health and medical market in the world. By comparison, Australia spends 9 per cent of its GDP on healthcare, while the US spends over 17 per cent. With a GDP of US$16.77 trillion, US healthcare spending totals US$2.85 trillion – a figure that is almost twice Australia's GDP.

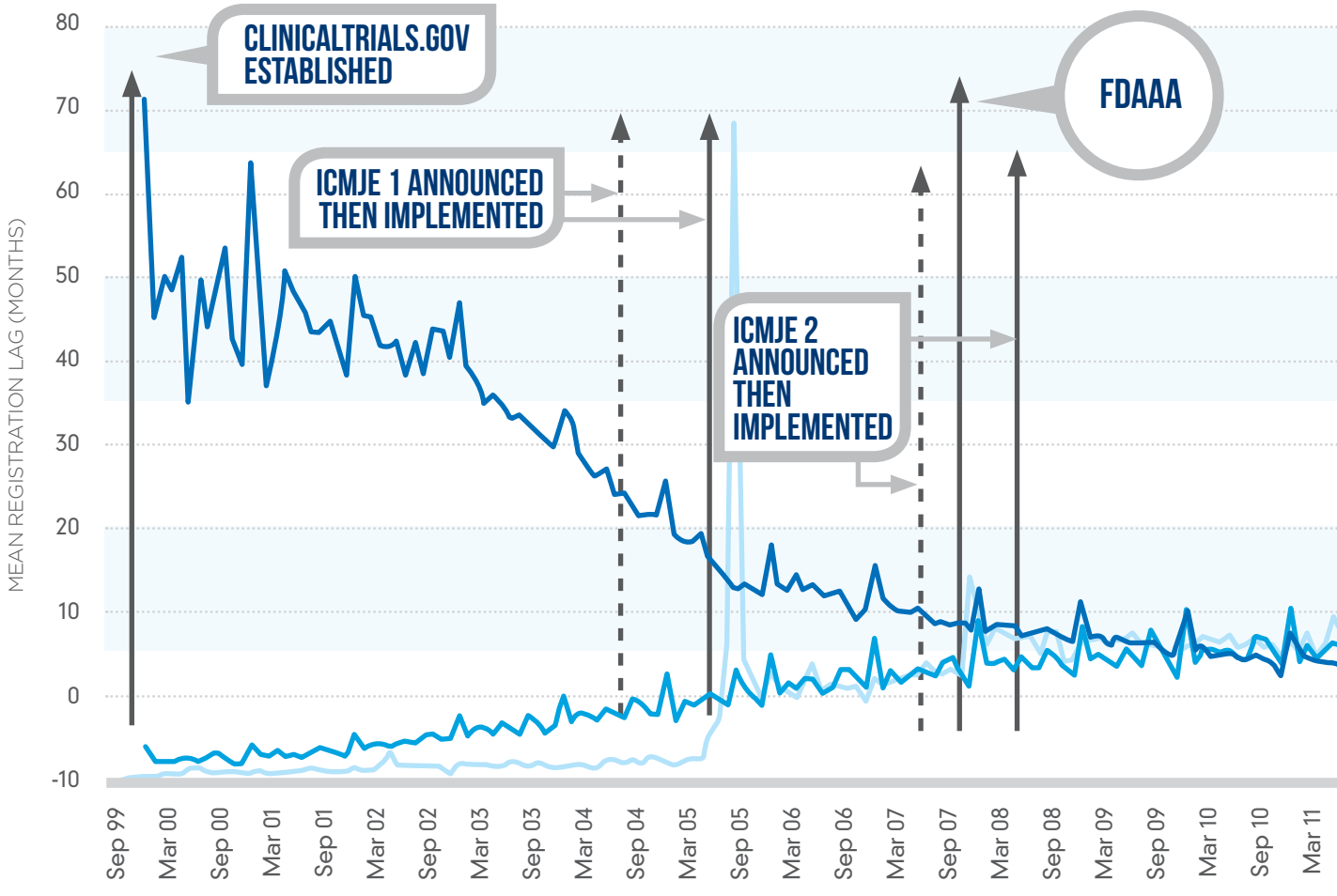
In Australia, new pharmaceutical products can often take a decade or longer to get to market, however in the US, there have been recent examples of medicines under the Breakthrough Therapies Designation (BTD) that have made it to market in less than one year. Europe, too, has a process that will soon allow new medicines to get to market as quickly as in the US. If Australia does not keep up with these developments, our industry will be greatly impacted. The following section outlines the historical and explanatory reasons for why our development takes as long as it does, but also provides recommendations to ensure Australia can keep up with world standards.

**FIGURE 2.1** FDA and TGA funding




SOURCE: US FOOD AND DRUG ADMINISTRATION, 2016 AND AUSTRALIAN GOVERNMENT, DEPT OF HEALTH, 2016

**FIGURE 2.2** The impact of regulatory events in the US – registrations of clinical trials behaviour



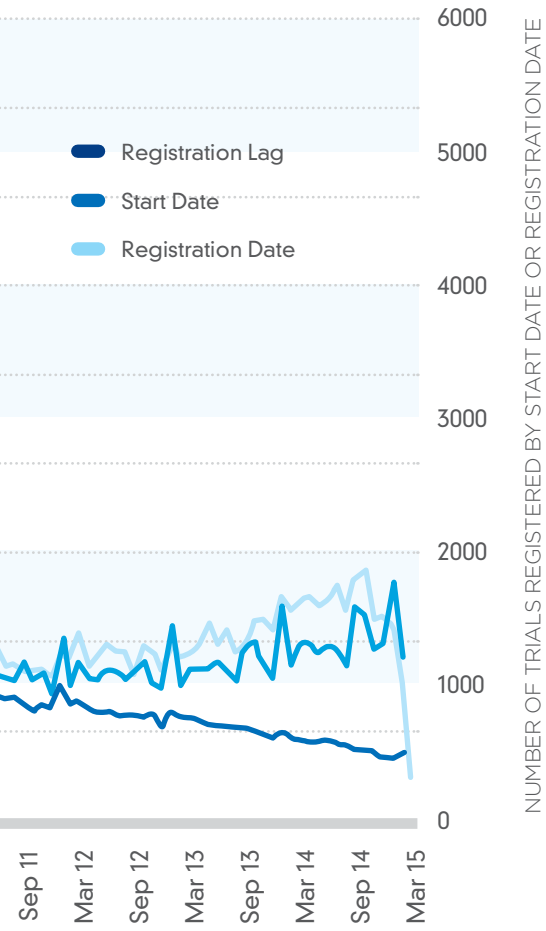

SOURCE: COMPILED FROM CLINICALTRIALS.GOV DATA

## The Therapeutic Goods Administration isn't keeping pace

Australia is widely recognised as having a transparent, high-quality and effective regulatory system,[41] ranking 7th worldwide in terms of quality of regulatory environment for the promotion of innovation.[42] In regards to research, Australia remains as one of the top nations to conduct clinical trials, given our quality medical research infrastructure, world-class healthcare system, reliable clinical data which is of the highest international standard, and an ethnically diverse, English-speaking population.[43]

However, if we compare the annual budgets of the US's FDA and Australia's Therapeutic Goods Administration (TGA) we can see a disparity emerging. The TGA's current budget is AU$142 million.[44] The FDA's current budget, by comparison, is more than 44 times larger at US$4,745 million,[45] at current (October 2016) exchange rates, this is closer to AU$6.3 billion. In addition, there is a quarantined amount of US$490 million within the FDA budget to specifically fund breakthrough therapy designations (BTDs), which allow for the faster progression of new therapies through the regulatory pipeline.

Further, the FDA's annual budget has increased over recent years (see Figure 2.1). Compare this with the funding the TGA receives and the picture becomes quickly and abundantly clear. The TGA is falling behind the FDA and it has very limited means of catching up under current policy settings.




## Regulation makes big impact in number, speed and transparency of biotech clinical trials

The preeminent global clinical trial registry ClinicalTrials.gov was created as a part of the US FDA Modernisation Act of 1997 (FDAMA). FDAMA required the U.S. Department of Health and Human Services, through the US National Institutes of Health (NIH), to establish a registry of clinical trials for both federal- and privately-funded trials conducted under investigational new drug applications. The NIH and the FDA worked together to develop the site, which was made available to the public in February 2000.[46] Data has been made increasingly searchable and registration rates have dramatically increased since it was first commissioned in 2000, as the light blue line in Figure 2.2 shows.

Figure 2.2 clearly demonstrates the impact that regulation has on industry behaviour. Prior to the enactment of FDAMA, very few sponsors of clinical trials published their results. Following FDAMA's implementation in 1997, registrations of clinical trials gradually increased. However, in 2005 further regulation was introduced by the International Committee of Medical Journal Editors (ICMJE) that declared that positive clinical results could not be made public without registration on ClinicalTrials.gov.

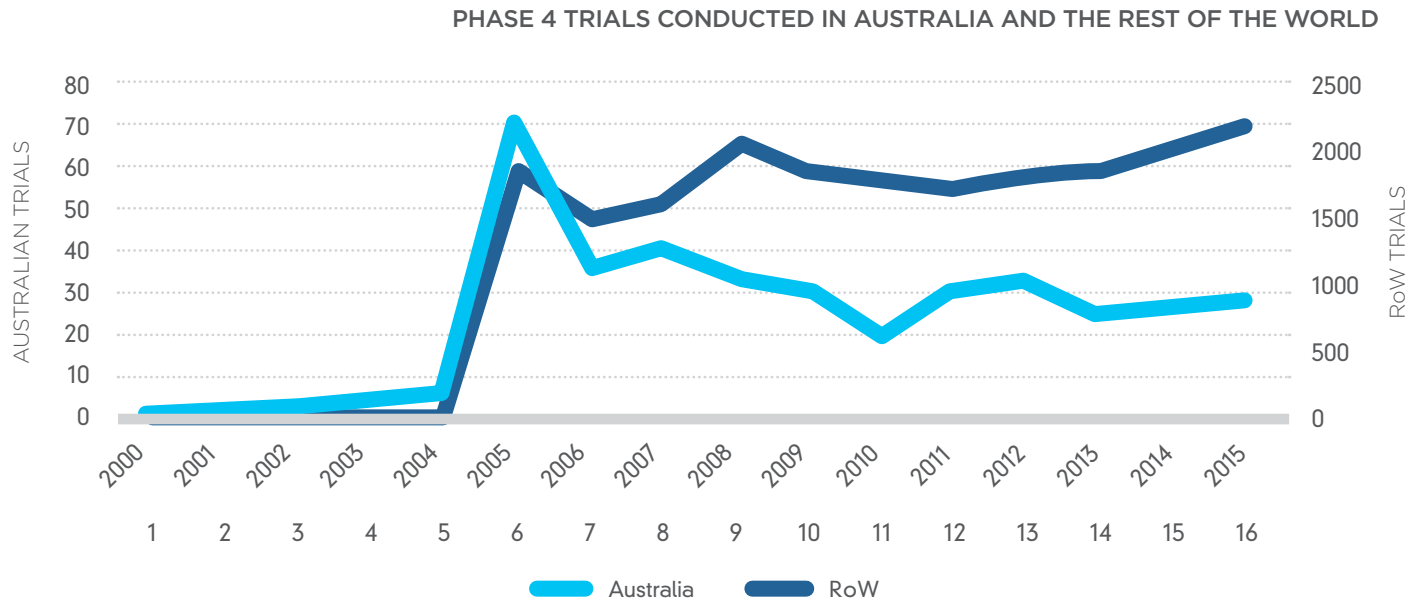
The introduction of both FDAMA and ICMJE has altered the behaviour of sponsors, thereby improving the quality and transparency in the industry; and improved the speed at which clinical trials are conducted. The dark blue line in Figure 2.2 shows the lag time between starting and registering a trial. As can be seen, that lag has dramatically reduced since the introduction of both pieces of regulation.

## The increased funding to the US FDA is affecting Australia's ability to compete

Funding tells part of the story. However, to understand the impact of the legislative framework that has been developed in the US and Australia, the effect of the differential capabilities that have been developed, and the market and geographic attraction, we can look at the number of trials that have been conducted in Australia and in the US.

Figure 2.3 below charts the number of Phase 4 trials for Australia and the rest of the world (RoW) since the turn of the century. Phase 4 trials are those studies occurring after FDA has approved a drug for marketing – including post-market requirement and commitment studies required of or agreed to by the study sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use."[47] As can be seen, since the introduction of the ICMJE stipulation regarding publishing successful clinical trial results in 2005, the number of Phase 4 clinical trials conducted in Australia has dropped off significantly.

**FIGURE 2.3** Australia v the Rest of the World on clinical trials registered




SOURCE: CLINICALTRIALS.GOV

This is likely to reflect the gravitational pull of the FDA, as more firms choose to conduct trials in the US to take advantage of the faster regulation processes brought about by the large increase in funding. As an example, in Australia the usual development time for a new medicine is between 10 and 15 years; in the US, one recent new medicine progressed to market in less than one year.

The significance of this is that when late-stage clinical trials are conducted overseas, they are more likely to then be commercialised and regulated in that overseas market. When Australian candidates are developed in foreign markets, the revenues are lost to us, and then under the Pharmaceutical Benefits Scheme, Australian taxpayers once again subsidise the same medicines that the taxpayer paid to develop.

## Following the FDA's example

While the FDA is by far the most attractive regulatory authority with which to register an innovation, there is evidence that other jurisdictions are following in the FDA's path.

The United Kingdom is reportedly considering establishing a Breakthrough Therapies Designation system similar to the US example, in the hopes of streamlining the regulatory process and reducing development times.[48]

The European Medicines Agency (EMA), the counterpart of the FDA and TGA in Europe, has recently launched a scheme called *Prime*, which will decrease assessment times by up to a third – from 210 days to 150 days, as well as provide other support measures that will help promising medicines to get to needy patients faster, and incentivise pharmaceutical companies to invest in revolutionary medical products.[49]

Australia already has one fast-track service available as a template on which to base further reform. The *Clinical Trial Notification* (CTN) scheme which supports rapid development of unapproved therapeutic goods is having a positive effect, despite its application being limited. Nevertheless, companies such as Mesoblast and Regeneus have benefitted from this forward-looking and innovative development (which took nine years from the Federal Government commitment to the legislation) in progressing their cellular therapies more rapidly to market. The benefits can also be witnessed in Mesoblast's current market capitalization of $744m.

However, some industry insiders would suggest that the CTN scheme could be greatly improved, and international developments in regulatory reform will allow Australia to learn from our competitor's experiences, and create a competitive system for the TGA.

The next section discusses the first and most important recommendation of this report: to provide more funding and resources to the Therapeutic Goods Administration. Considering the US, the UK and the EU all now have increased funding to, and updated the processes of their respective medicines regulatory authorities, it is imperative that Australia keeps up with international regulatory developments in order to compete in the international marketplace.

# RECOMMENDATION 1

## The Government should better resource the TGA

In order for Australia to compete with the US, EU and UK, our processes must be comparable.

In order to achieve this, the Australian Government must address the resourcing gap for the Therapeutic Goods Administration. Speed can only occur through better processes; which can only occur through more funding, and better targeted resources.

The 2015 Government Review of Medicines and Medical Devices Regulation made the recommendation that medicines which had already been approved in a different market by a comparable national regulatory authority should be fast-tracked through the TGA.[50] The Government recently accepted this recommendation, and while it is invariably a positive step toward reform, it only goes so far to address the widening gap between the TGA's capabilities and those of the FDA.

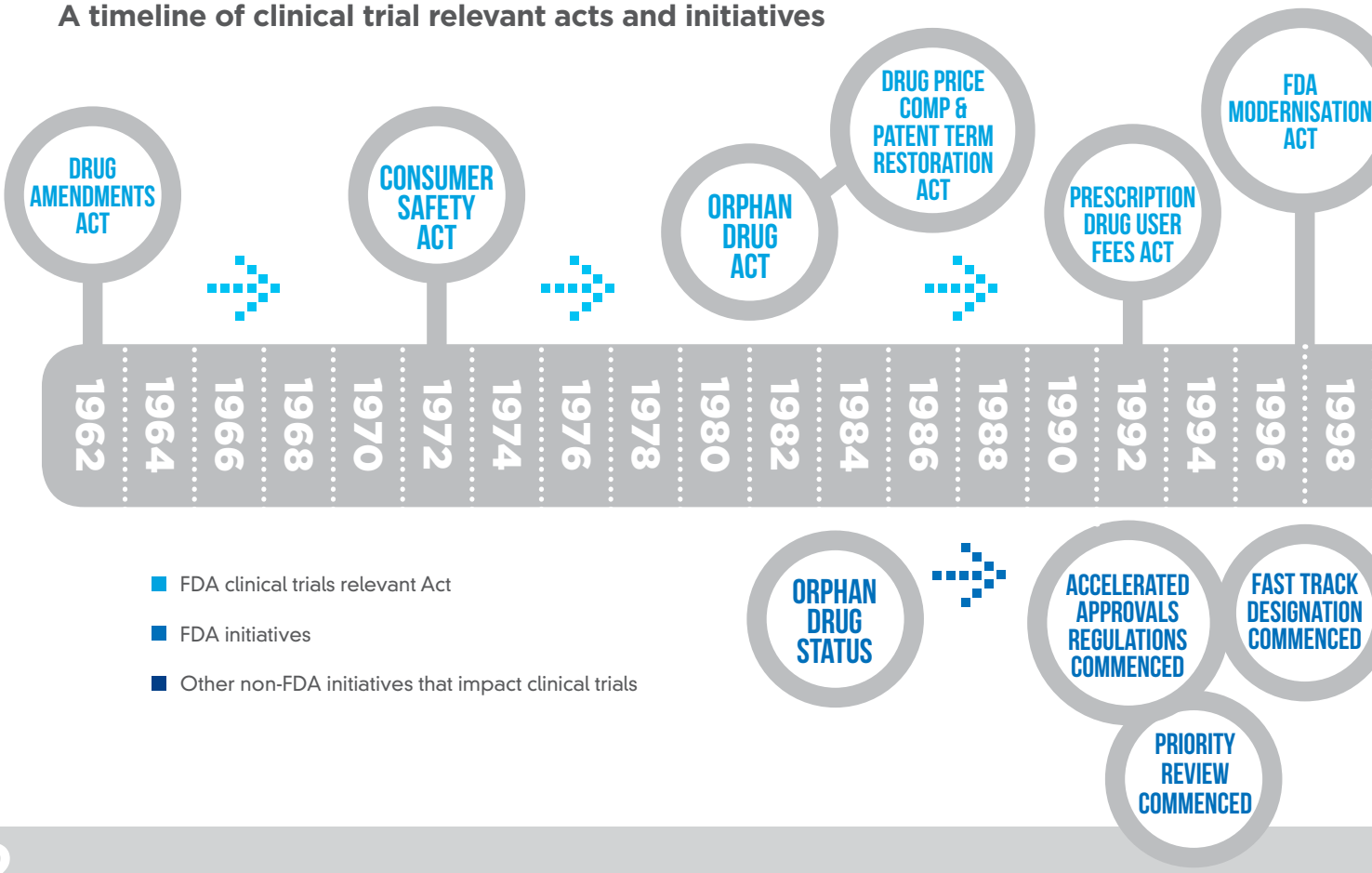
The arguments for dramatically improving funding from the Federal Government to the TGA are eminently straightforward. Only a little more than one quarter of the US$4.73 billion budget for the FDA in 2016 is derived from user fees: the remainder is funded by the US Government. This fact demonstrates the US Government's understanding of its obligations not only to design, develop and implement legislation that supports a regulatory framework that keeps pace with technological and industry developments, but to provide the means by which the FDA can deliver on its commitments. In contrast, the TGA is almost entirely dependent on user fees for its budget. This means that new initiatives are much more difficult to resource for the TGA than for the FDA, as user fees obviously only come into effect once a new product is introduced.

It is important to recognise that the TGA itself operates in a competitive regulatory environment. If it increases user fees before it delivers improvements, companies will simply migrate to more supportive jurisdictions, most notably of course to the largest healthcare market, the US.

**This report vigorously recommends that the Australian Government should provide the TGA with a large injection of funding, in order to assist**

**FIGURE 2.4** History of key legislation and amendments that have led to shorter clinical trials in the US

### A timeline of clinical trial relevant acts and initiatives



**the biotechnology industry in Australia to regain competitiveness, and to attract investment to the human health biotech sector.** This recommendation builds on and complements the centrepiece recommendation made by the McKeon Review of Health and Medical Research in Australia, which recommended that the NHMRC should be better resourced in order to better support the commercialisation of medical research.

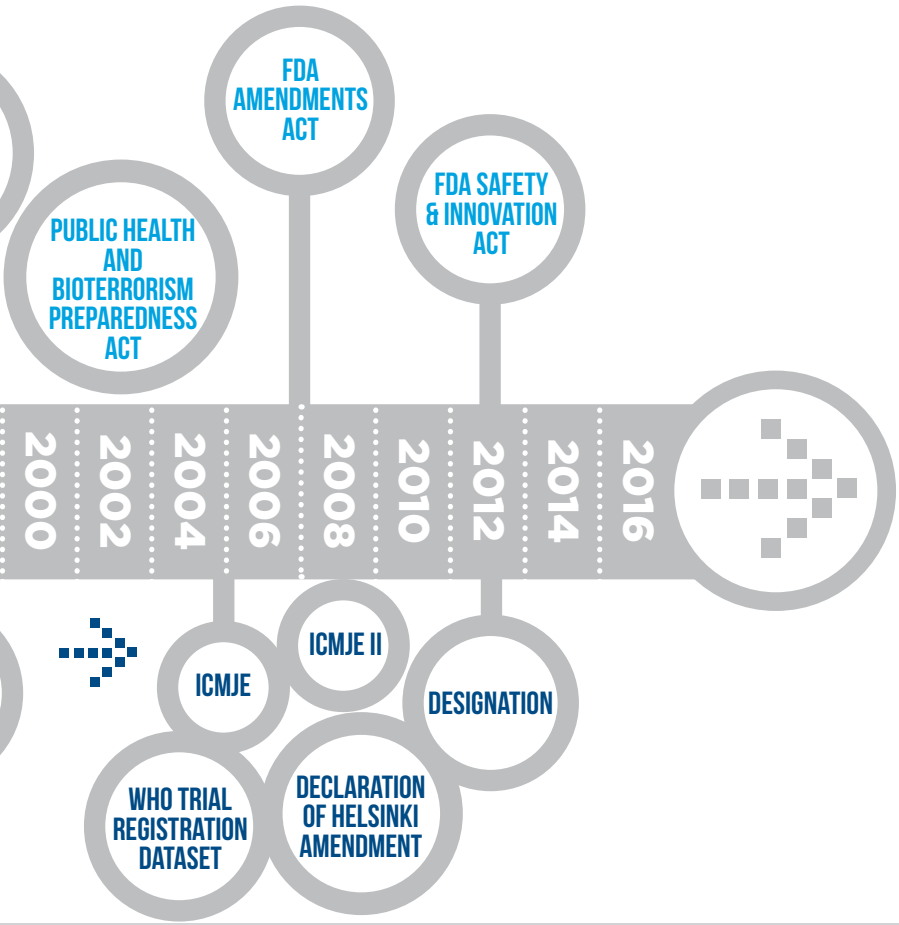
The following section further makes the case for a large injection of Government funding to the TGA, and details what it might take in order to reform the TGA into a globally-competitive regulatory authority.

## The Government should invest in the TGA as a matter of ethics

As the TGA is fully-funded by users, any increase in fees in order to increase the resources of the TGA will be a direct burden on the industry, reducing the impact of the measure. The regulatory regime in place is deemed to be an essential measure to ensure the safety of drugs, vaccines and medical devices, but it is also a major component of the funding of the TGA. In order to broaden the offering and improve the service offerings of the TGA, extra funding must come from the government.

This necessity can be witnessed in relation to the orphan drug market – relating to medicines that are used for rare diseases. The markets in which these medicines can make a large difference are by definition small, and pharmaceutical manufacturers will not invest in those medicines if the costs (both financial and otherwise) are prohibitive.[51] This point leads us to a question of ethics: patients who suffer from rare diseases should have access to medicines where they exist in the same manner that patients who suffer from common diseases do. Ethically, the (small) size of the market should not be a deciding factor in whether to develop new medicines; and so the government should invest in further removing the barriers to entry for such candidates.[52]

While we recognise that a capability exists for the TGA to waive evaluation fees for drugs that can demonstrate they are only applicable to a small population, this capability is administered only on a case-by-case basis. We believe this capability should be applied more strategically and proactively.




### Main purpose of relevant section of each Act/initiative

- Drug Amendments Act 1962 –Amends the 1938 Food Drug and Cosmetics Act (FD&CA); FDA acquires effective control of the clinical trials process, including pre-clinical trials
- Consumer Safety Act 1972 –increased requirements for safety and efficacy of biologics prior to approval
- Orphan Drug Act 1983 –grants status to any drug that treats rare disease –defined as affecting less than 200,000 people in the US.
- Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) 1984 –enables generic manufacturers to use safety and efficacy results in the pioneer drug's NDA.
- Prescription Drug User Fees Act (PDUFA) 1992 –authorizes FDA to charge fees to manufacturers for undertaking reviews. Introduced Priority Review and Accelerated Approvals. Reauthorization of PDUFA under each ensuing Act referred to as PDUFA 2-5.
- FDA Modernization Act (FDAMA) 1997 –Reformed regulation of food medical products and cosmetics. Established clinical trials reporting requirements. Expanded comprehensiveness of reviews.
- Public Health and Bioterrorism Preparedness Act 2002 – protection of drug supply.
- FDA Amendments Act (FDAAA) 2007 –expands reporting requirements of trials to expand the types of trials required to be reported and report results.
- FDA Safety and Innovation Act (FDASIA) 2012 –included Breakthrough Therapies Designation

## The FDA went through 50 years of reforms – but Australia can fast-track that process with concerted effort

Figure 2.4 provides some perspective on how large a task is facing the Federal Parliament if we are to play catch up with the FDA. It has taken 50 years, with an intense effort in the last 30, for the legislative and regulatory framework to be built that has culminated in clinical trials with faster duration from lab to market for a very small proportion of total trials.

Australia's catch up will not be easy. From a legislative perspective the US has invested many years of concerted effort to bring the TGA to this point. But this does not mean that Australia cannot piggyback on the back of the US' learning, and take the best sections of the policies and transplant them in the Australian regulatory environment. It will just require a concerted and coordinated effort to do so.

## How Australia can catch up

Two key urgent actions are required to assist the TGA, and through it Australia's biotechnology industry to commence it's catch up: legislation, and associated funding. The extensive legislative program undertaken by the US and reflected in Figure 2.4 has not been matched in Australia. The TGA's legislative program has been limited to:

### PRIMARY LEGISLATION

- the *Therapeutic Goods Act 1989* (the TGA Act)
- the *Therapeutic Goods* (Charges) *Act 1989* (the Charges Act)

### DELEGATED OR SUBORDINATE LEGISLATION

- the Therapeutic Goods Regulations 1990
- the Therapeutic Goods (Charges) Regulations 1990
- the Therapeutic Goods (Medical Devices) Regulations 2002.

There has been no significant change in the TGA legislation that affects the biotech industry since 1990. Compared to the legislative process undertaken by the US FDA, it is clear why Australia has fallen behind on this measure.

However, it is heartening that Australia has successful templates that can be followed in order to remove some of the trial and error from the process of reform. However, the reality is that legislation is a long and slow process. Despite much discussion in the right direction in Australia led by the TGA to follow the FDA's lead, there has been no evidence to date that the debate has permeated Federal politics.

**It is recommended that the TGA further advocate for legislative reform in order to set Australia on the same path as the US.**

The legislative program must be supported by an extensively enhanced funding program so that the TGA can be much more strategic in its agenda than it is permitted to be currently. For a regulator, operating budgets that rely almost entirely on user fees do not result in regulatory leadership.

The gold standard for federal funding comes from the US FDA in that the US Government contributes two-thirds of the FDA's funding. **It is therefore recommended that Australia follow in this lead, and contribute the equivalent of two-thirds of the TGA's current budget of $142 million, resulting in a cash injection of $95 million to kick-start the process of reform.**

While we recognise that the current economic climate might render this recommendation somewhat difficult to argue for, we believe that the benefits to the industry and to the Australian economy of a strong biotechnology industry will be far greater than any initial cash injection to broaden the capabilities of the TGA.

# RECOMMENDATION 2

## Industry leaders should create a taskforce to map the path to legislative reform

In order for the legislative reform advocated for in recommendation one to take place, a taskforce should be established consisting of the following industry players:

- A group of large Australian biotech firms (such as CSL);

- A group of major international pharmaceutical companies (such as Pfizer);
- The TGA;
- Ausbiotech;
- Medicines Australia;
- Senior Federal Government representatives;
- Some key representatives from Australia's most successful health and medical institutions; and
- A select group of representatives from some smaller biotech firms.

There is a wealth of information and experience already within the Australian biotechnology industry, but in order for Australia to capitalise on that experience, cooperation and communication between the main industry players must take place. The goal of the taskforce would be to develop a timeline and pathway to legislative and funding innovation.

The benefits of this have been mentioned earlier in this report. Speed is everything in terms of competitiveness in the field of biotech, and in order for Australia to become and remain competitive in the global biotechnology market, the TGA must be properly resourced.

The purpose of the taskforce is to draw upon the experience of the variety of industry players to ensure Australia's system does not repeat any mistakes of our competitors, and that it suits the local conditions. The benefits of engaging large pharmaceutical firms in this discussion are:

- Large pharmaceutical companies have core expertise in clinical trials and experience and knowledge of the system at work within the FDA (for instance, large pharmaceutical companies account for the majority of BTD, Orphan Drug, Fast Track and Accelerated Approvals);
- They can assist in providing relevant evidence to the Federal Government for the funding and administrative improvements (backed by legislation) that the TGA needs;
- The institutional strengthening role is an important one for large pharma companies in this process as well, as they can potentially partner with firms from emerging countries to assist in progressing through the TGA process more rapidly, whilst maintaining involvement in US market entry.

Large pharmaceutical firms and the FDA can bring capabilities, soft infrastructure and support. Large pharmaceutical companies in the US have between them sponsored over 50,000 clinical trials, whilst the FDA has regulated over 200,000 clinical trials. This has provided each with extensive experience in the process. Add to this the shift for the FDA from regulator to effective collaborator in recent years, building on the 30 years of experience of fast tracking starting with Orphan Drugs in 1984, and culminating in Breakthrough Therapies Designation in 2012; the effects of which are rippling through the entire pharmaceutical and biotechnology industries. Australia just needs the ripples to reach our shores more quickly.

Large pharmaceutical companies certainly have a role to play to make the Australian environment more attractive. For example, Pfizer is listed as a sponsor on 2949 clinical trials on the ClinicalTrials.gov database. Australia's largest homegrown company in this industry, CSL, is listed as a sponsor on 97 trials. Pfizer has had more clinical trial experience than all of Australia's biotechnology companies put together and is also the most prominent sponsor in expedited program trials. This fact means Pfizer is at the cutting edge of clinical development for the most advanced biotechnologies coming through the pipeline.

While expedited programs are very obviously attractive to both desperate patients and biotechnology firms, it is important to note that long regulatory approval processes are in place for a reason: to ensure new medicines are safe to use. This is why it is of utmost importance for Australia to involve experienced organisations and the FDA in the design of an expedited programme for Australia's regulator.

It is imperative that a coalition of industry players is gathered in order to pool the knowledge and experience gained from doing business in the US, the UK and Europe. A taskforce would map out the path to Australia's legislative reform of the TGA, making sure that any mistakes made by others would not be repeated here; and that the system is designed with the Australian environment in mind.

# PART THREE: THE NEED FOR STRONG POLICY LEADERSHIP

At a time when many of Australia's competitors have invested heavily in research and innovation infrastructure, Australia has had a lack of clear policy leadership from governments. In fact, there have been many more reports and inquiries into key innovation policy programs, such as the R&D Tax Incentive, in the past ten years than there have been actual decisions regarding policy. The list of public inquiries into Australia's innovation systems, research efforts, and incentives for innovation is long, but still there is no consensus about direction for the industry, and as such, Australia's competitors are pulling ahead.

The UK introduced a 'patent box' policy in 2012, which came into effect in 2013, and which gives patent owners favourable tax incentives on profits generated by that IP. As a result, GlaxoSmithKline announced a £500 million investment and the first new manufacturing facility in 40 years for the UK. One year later, the company announced another £200 million investment, with Roger Connor, GSK's President of Global Manufacturing and Supply, stating:

"The establishment of the patent box has transformed how we see the UK as a place to invest. As a result, last year we announced we were building our first new factory in the UK for 40 years. The investments announced today are in addition to that and will allow us to harness new technologies that have the potential to deliver a step-change in how we make medicines."[53]

While a sceptic might see this news as a large pharmaceutical company taking advantage of tax shifting to lower taxing jurisdictions, the UK will see an increase in jobs and investment, and will reap the rewards of both. In any case, such a scheme can be tweaked to ensure companies base their manufacturing or research operations within Australia's borders, to ensure tax revenue from payrolls and other profits are captured here.

However, Australia has no such coordination of policy, and as such, is missing out on opportunities for investment by large multinational companies.

In addition to the other issues identified in this report, a lack of clear policy leadership by the Australian Government is reducing Australia's ability to compete in the international arena on biotechnology. It is disappointing to those in the industry, because Australia has all of the necessary ingredients, but as yet, it just hasn't had the right cook.

The following section will begin by mapping the multitude of government support mechanisms around Australia in order to better understand the current environment for biotechnology innovations. As can be seen, the states all offer different levels of support to the biotechnology industry, with no overarching strategy or coordination of policy amongst them. It will then identify recommendations that can be enacted by Government in order to better equip the Australian biotech sector with the requisite tools to succeed. The first recommendation discusses the need for a more competitive suite of intellectual property laws in order to drive investment to Australian shores. To further this aim, the next recommendation is a call for the Federal Government to reinstate and strengthen basic tax incentives. As will be shown, excessive review into the R&D Tax Incentive has created a sense of uncertainty in the industry, which has most likely decreased investment in new technologies. The recent slashing of the R&D Tax Incentive by 1.5 per cent by the Government will likely have a detrimental effect to our international competitiveness, and do nothing to further the Government's Innovation Agenda.

However, by far the most important recommendation is that the biotechnology industry urgently requires a clear policy direction from the Government and bipartisan commitment to that vision. Without such a commitment, the industry will continue along its current trajectory, and continue to lose ground to its competitors.

## Current federal government and industry support programmes

At present, there are numerous support programmes for biotechnology from both government and industry, particularly within medical research. The following is an example list and brief description of each.

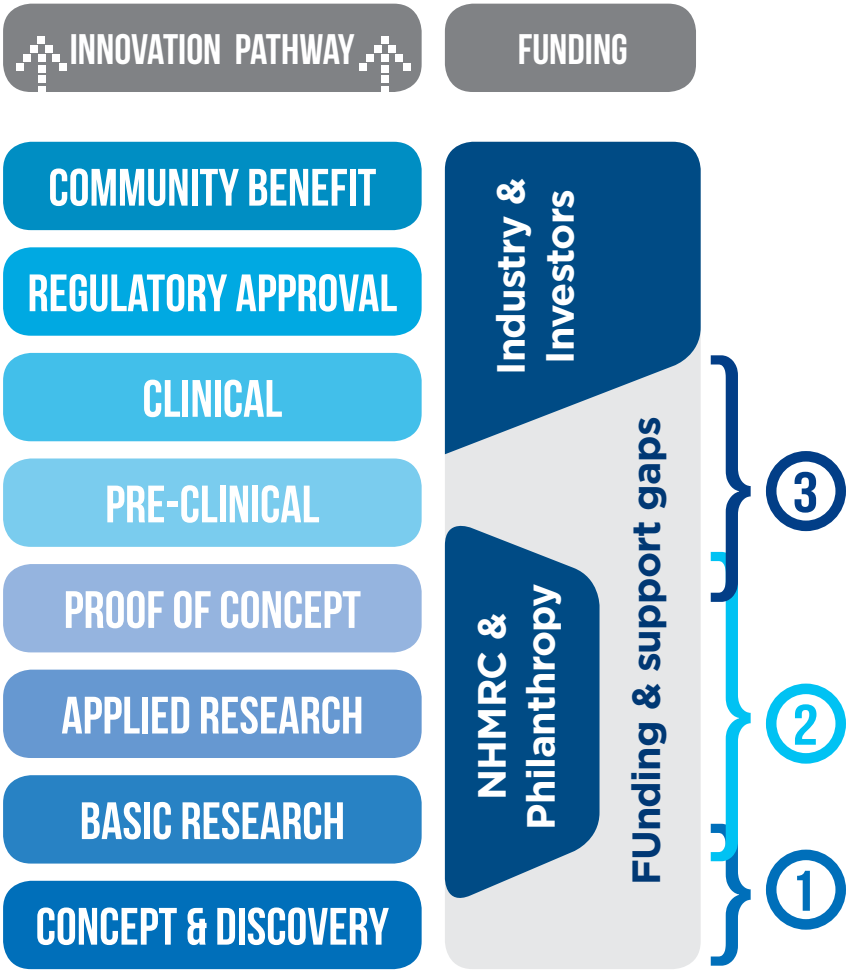
### BIOMEDICAL TRANSLATION FUND

The Biomedical Translation Fund consists of a $250m grant aimed at stimulating the commercialisation process (i.e. clinical trials, regulatory and marketing approvals) for promising biomedical innovation. The Fund will be established in 2016, and funding will be taken from the Medical Research Future Fund for the first two years.[54]

### BIOPHARMACEUTICAL DEVELOPMENT FUND

BioPharmaceuticals Australia (BPA) established this fund in 2014 as a program to support Australian research and not-for-profit organisations in facilitating access to biopharmaceuticals facilities. It also supports acceleration of commercial translation by co-funding access to pivotal development services,

**FIGURE 3.1**
Funding gaps in the innovation pathway




1. Original innovation and discovery not competitive for NHMRC grants. Young researchers, early discoveries and new paradigms that need support to become competitive and stand on their own two feet.
2. Support for strategic collaborative research activities focussed on advancing research and validating directions. Providing access to the additional research skills not available through currently available funding.
3. Often referred to as the "valley of death" this is the area where research is required to attract and compete for potential investors and collaborators. Funding mechanisms often do not support or encourage contract research activities necessary to answer critical research questions.

as well as the development of therapeutic proteins generated in mammalian cell culture. It consists of a $2 million grant over a two-year period. Though it has been designed to support Queensland-based entities, companies based in other states can also apply for 75 per cent of the grant.[55]

## NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL (NHMRC) AND AUSTRALIAN RESEARCH COUNCIL (ARC)

A large proportion of Australian Federal Government research grants are awarded and administered by the NHMRC and the ARC. These are a significant source of funding for medical and biotechnology research conducted at research institutions.[56] Around 33 per cent of Australian biotechnology companies have received NHMRC funding for their research.[57]

## MEDICAL RESEARCH FUTURE FUND (MRFF)

In 2015 the Australian Government announced the establishment of a $20 billion Medical Research Future Fund (MRFF) for medical research and innovation over the medium to longer term, and it is expected to reach its target capital level by 2020.[58] As it seeks to support stronger partnerships between researchers, healthcare professionals and the government, it will also contribute to the development of related sub-sectors such as biomedical sciences and biotechnology.

## NATIONAL FOUNDATION FOR MEDICAL RESEARCH AND INNOVATION (NFMRI)

The National Foundation for Medical Research and Innovation (NFMRI) supports innovative biomedical research by awarding funding grants to research that is not funded under other government programmes. The Foundation aims to bridge the gap in funding for early-stage projects that don't qualify for traditional NHMRC or ARC grants, or are promising but are subject to 'valley of death' funding issues.

## MTPCONNECT

MTPConnect was formed as a not-for-profit organisation in November 2015 as a part of the Federal Government's $248 million Industry Growth Centres Initiative to accelerate the rate of growth of the MTP sector, with the aim of establishing Australia as a hub for medtech, biotechnology and pharmaceuticals companies in Asia-Pacific.[59] The Industry Growth Centres Initiative was established across a variety of strategic industries and aims to enable national action on key issues such as regulation reform, skills, collaboration and commercialisation.[60]

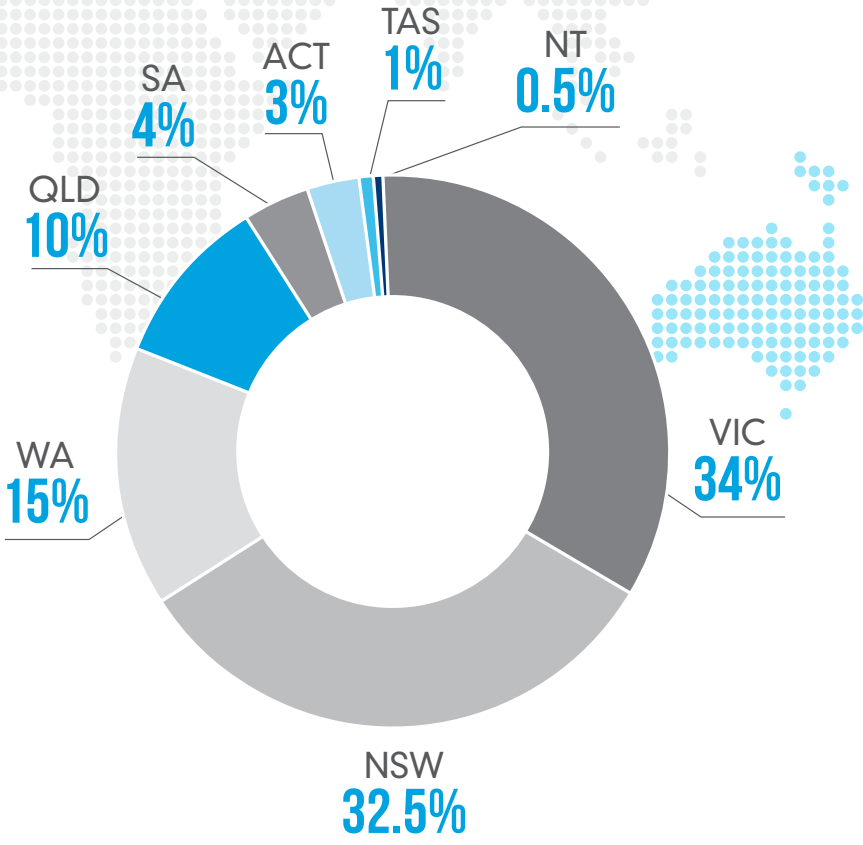
## Mapping Australian biotech: State-by-State

In addition to the Federal-level funding programmes, Australian state governments are also developing and implementing independent regional initiatives in the biotechnology sector. Each state has strong medical research programs, some having specialist expertise in areas including bio-remediation, bio-discovery, agricultural biotechnology, industrial biotechnology and biomedical devices.[61]

In terms of business intensity, Victoria has the largest concentration of biotechnology establishments with 34 per cent of total businesses in 2015, followed closely by New South Wales (32.5 per cent), Western Australia (15 per cent) and Queensland with (10 per cent).[62]

The following section briefly discusses the differing levels of support each state government gives to the biotechnology sector. As can be witnessed, the support each state gives the industry varies widely. The industry could benefit vastly from a national strategy and coordination between the states.

FIGURE 3.2
Proportion of biotechnology companies by Australian State




## VICTORIA

Victoria's biotechnology sector is the largest in Australia and has particular strengths in medical and agricultural fields including oncology, neurosciences, regenerative medicine and genetics of dairy cattle and pasture grasses. This strength is perceived to be the outcome of years of bi-partisan government support to the industry. The Victorian Government provides support to the industry through a variety of funding grants and programmes designed to attract and foster greater investment within Victoria's borders.

In 2011, the Victorian Government unveiled Victoria's Technology Plan for the Future – Biotechnology, a $55 million plan to support the biotech sector in the state through the promotion of biotech-enabled innovation, including stimulation of demand-driven new product development, linking industry with capability, and improving firms' competitiveness. The plan also supports capability development by improving access to R&D infrastructure and expertise, as well as facilitating international trade and investment programs.[63]

In addition, "Enabling Technologies Skills Strategy – Biotechnology" is a state program to boost Victoria's biotech industry capabilities and skills for turning new ideas and technologies into valuable products and services, as well as to support the spread of enabling technologies from the biotech sector to other Victorian businesses and industries. It also includes capability development in commercial and business development skills, and bioinformatics and computation biology skills.[64]

The State's Practical Drug Development Program is a skill-based development program, which provides

training and mentoring to project managers on an ongoing-basis by specialist advisers and places them in biotechnology companies to complement existing drug development capabilities.[65]

The $100m Victorian Life Sciences Computation Initiative (VLSCI), funded by the Victorian Government in partnership with IBM Research – Australia, aims to expand the technological platform for biotechnology research and grow the Victorian skills base in bioinformatics and computational biology through a range of programs, as well as to enhance engagement with industry.[66]

The Victorian State Government has also recently given funding toward a Melbourne-Monash Universities joint research translation enterprise. Each university contributed $25 million and the state government gave $10 million for the establishment of the biomedical accelerator, which is expected to help address the first 'valley of death' in funding that is a significant barrier in translating research into commercial products. The project is modelled on Harvard University's Blavatnik Biomedical Accelerator, and will pool research coming out of both universities. The two universities currently produce about half of all of Australia's biomedical research.[67]

The state hosts about 150 biotechnology companies, 13 major medical research institutes, 10 teaching hospitals, 9 universities and a range of clinical trial operators and contract research organisations. The Victorian biotechnology industry recorded sales of $7.6bn in 2011, and it comprises around 68 per cent of the aggregate value of Australia's top 20 listed biotechnology firms.[68]

Victoria's life sciences companies directly employ 6,000 people, with an estimated 2,300 in R&D roles. Multinational corporations employ a further 4,200 people. The biotechnology giant CSL has its international headquarters based in Melbourne, employing a total of around 1900 people.[69] The state's broader life sciences sector employs more than 22,000 people.[70]

The state not only has two universities in the global top 20 biomedical rankings as well as world-class biotechnology precincts, it also has developed a shared infrastructure between universities, research institutions, hospitals and private companies to encourage knowledge sharing.[71] Resulting from this strong infrastructure coupled with concerted government support is an industry that is driving Victorian growth.

## NEW SOUTH WALES

The state hosts around 120 biotechnology companies, world-class research institutions, and it is a major centre for clinical trials in Australia. Sydney is the nation's centre of pharmaceutical manufacturing and hosts a considerable group of global pharmaceutical companies and local generics, such as Pfizer, Merck and AstraZeneca.[72]

However, the level of State Government support to young enterprises or entrepreneurs is much lower than in Victoria. The Research Attraction and Acceleration Program (RAAP) is an $18 million fund designed to support innovation and investment in the State's research and development capacity. The program designates $8 million purely to research in Information and Communication Technology, and does not prioritise medical or biotechnological research.

In addition, the NSW Government has established a set of 'knowledge hubs,' with one to focus on medical technology. The MedTech Knowledge Hub is coordinated by the Medical Technology Association of Australia (MTAA) and the aim is to improve collaboration between academia, government and industry in the field of medical technology. The State Government recently awarded MTAA a grant of $150,000 to establish this knowledge hub.

## WESTERN AUSTRALIA

As the state's traditional strengths are in the mining and agriculture sectors, the biotechnology industry in Western Australia is focused mainly on agricultural, industrial and environmental areas, although it also hosts a number of leading human health companies and research institutes. It comprises around 50 biotechnology companies focused on a range of areas including agricultural biotechnology, molecular biology, genomics, proteomics for research on plants, animals and microorganisms, gene technology and crop biotechnology, among others.[73]

Perth's Murdoch University hosts a collaborative research hub named the Western Australian State Agricultural Biotechnology Centre, which allows open access to research facilities for multiple users: both public and private. The goal of the incubator is to become an "internationally recognised centre for research and development in both agricultural and veterinary biotechnology".[74]

## QUEENSLAND

The biotechnology industry in Queensland is formed by 86 core biotechnology companies and 47 biotechnology-related research institutes employing about 6,000 researchers.[75] The industry shares expertise in health and medical biotechnology, drug discovery, clinical trials, tropical health and sub-tropical agricultural biotechnology.[76]

From the 2007-2011 period, Queensland's biotechnology sector grew at a compound annual growth rate of 16.8 per cent. Employment and salary expenditure also experienced positive growth during that period, although expenditure in areas such as R&D and capital decreased.[77] The estimated income for Queensland biotechnology companies in 2011 was $597 million[78] and $1.07 billion for biotechnology-related institutes.[79]

Since 1998, the Queensland government has invested over $600m in a number of major biotechnology institutes including Biopharmaceuticals Australia, Institute for Molecular Bioscience, Australian Institute for Bioengineering and Nanotechnology and the Eskitis Institute for Cell and Molecular Therapies.[80]

In 2011, two Queensland-based life sciences research organisations placed in the top 10 recipients of NHMRC funding: The University of Queensland and the Queensland Institute of Medical Research.[81]

In 2010 the Queensland Government committed US$25 million to a Bio-Venture fund which supports the commercialisation of new biotech products from around the world and including research and technology produced by Queensland's biotech industry. Similarly, the Queensland Government is also involved with the Medical Research Commercialisation Fund, which provides funding for early-stage medical research to promising projects. One recent investment by the fund (which is also supported by a coalition of venture capital funds) was the largest ever in a biotech startup, which gave $15 million to Queensland's Vaxxas, to further develop a new needle-free vaccine delivery system.[82]

Most recently in June 2016 the Queensland Government released a 10-year road map for Queensland Biofutures: a plan to make Queensland's biotech industry into a $1 billion per year export-focussed industry by 2026. This plan focuses on biofutures, which refers to the industrial biotech and bioproducts sector specifically, and also encompasses the agricultural sector. Actions to date that have been identified in the plan include Innovation Partnerships, which give grants to research organisations to partner with industry; Research Fellowships, which provide post PhD researchers with funding for 3 years to undertake research with industry that addresses Queensland's science and research priorities; and the Business Development Fund, which gives funding to emerging Queensland businesses "at the forefront of commercialising innovative research or ideas".[83] Future actions will take these programmes further to provide more support and funding to promising research or companies undertaking projects in innovative fields that relate to Queensland's BioFutures Plan.[84]

## SOUTH AUSTRALIA

The state currently supports around 40 biotechnology firms, and most of them are located in various precincts as with other states. In South Australia these are based in and around Adelaide and includes the Florey Precinct and the Waite Research Institute, among others.[85]

BioSA is a government agency that offers incubation and business services and funding to innovative biotechnology companies in South Australia, with a focus on exporting South Australian products to a global market. It has operated for the past 15 years and has two incubation facilities, and offers repayable grants of between $50,000-250,000 to eligible businesses.[86] The SA Premier's Research and Industry Fund provides support and funding to innovative organisations through the Research Consortia Program, the Innovation Voucher Program, and the Cooperative Research Centre Assistance Program.

# RECOMMENDATION 3

## The Government should introduce more competitive IP legislation

As a part of the Innovation Agenda, the Government has recently commissioned another review of Australia's intellectual property legislation. This review comes after a series of reviews conducted by the Advisory Council on Intellectual Property up until 2015, as well as the Pharmaceutical Patents Review which was completed in 2013. The Trans Pacific Partnership also regulates intellectual property across signatory states, although is yet to be ratified. While there has been a lot of activity in intellectual property legislation in recent years, action still needs to be taken by Australia to make our system more competitive.

Australian patents currently provide a formal 20 years of protection for certain types of human health inventions, however, given the nature of biotechnology development, the effective patent life - the time remaining once the technology finally arrives on market- is often far less. The time from discovery to the release is often around 10 to 15 years, giving many biotech patents in the human health sector an effective patent life of less than 10 years, and reducing the value of the patent to the developing company. Some companies apply and are successful for patent extensions, however these are not guaranteed.[87]

In addition, Australia's data exclusivity provisions are far shorter than for our major trading partners and competitors. Data exclusivity relates to the clinical test data that is required by the regulatory authority in order to approve a new medicine or product; and protects innovators from the manufacturers of generics accessing the data in order to produce a similar product. It runs parallel to patent protections and provides protection for a period of time following the marketing approval of a new medicine when competing firms may not access the innovative firm's safety or efficacy data.[88] It is especially important to biotechnology manufacturers, and particularly to those manufacturers of biologics, where the method of manufacture is the source of the IP, rather than the molecule or product itself.[89] Exclusivity means that biosimilars are prevented from competing with originator biologic drugs for a period well beyond the effective patent life. This has also led developers to opt for biobetters rather than biosimilars as they seek originator status to overcome exclusivity limitations. Such moves in response to this policy intervention point to exclusivity being an effective legislative tool.

Patents and data exclusivity provisions are complementary and serve to incentivise innovation in distinct ways. Patents provide protection for "innovations that meet the standards of patentability and are novel, nonobvious, and useful."[90] In terms of biotechnology, this can represent both breakthrough discoveries and incremental improvements. Patent life is usually a standard length and does not take into account the length of time required to develop the product for market.

In contrast, data exclusivity protects the large investment required to ensure the safety and efficacy of a new therapy for use, and is applied from the date of when the therapy is approved for marketing. It protects innovative firms from competitors using their results from clinical and preclinical trials.[91]

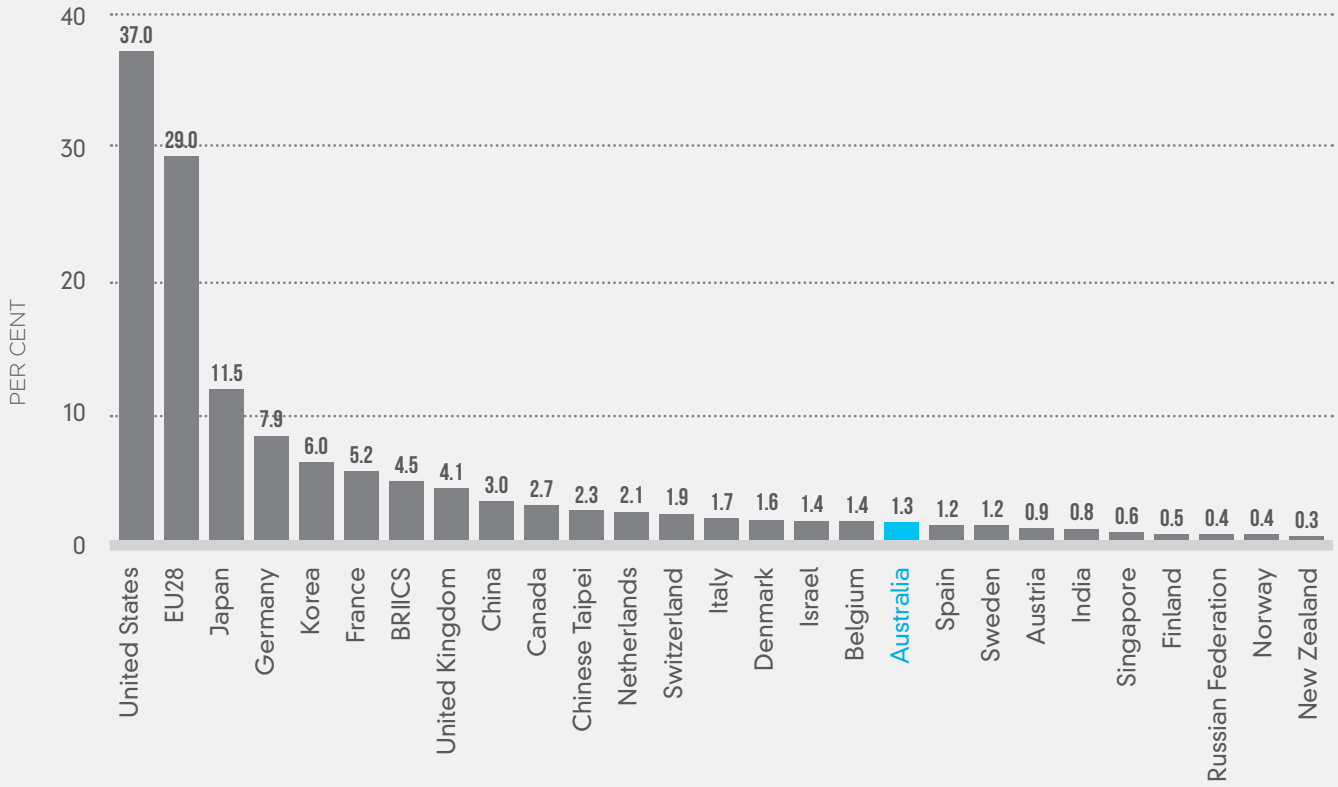
## BOX 3.1
## Data and market exclusivity provisions around the world

The United States offers manufacturers of biologics a period of protection from biosimilars (products that are akin to generics) entering the market for a total of 12 years. Those 12 years run concurrently to a four-year period of data exclusivity, which prohibit competitors from accessing clinical data from the original product's clinical trials. These exclusivity arrangements are separate to and run alongside patent provisions.[92]

Australia does not offer market exclusivity provisions, but the TGA provides data protection for five years for all prescription medicines.[93]

Australia's data exclusivity provisions lag our major competitors: besides the US, which offers a total of 12 years exclusivity, the EU offers up to 11 years; Japan offers 8 years; and Canada also offers 8 years. China and Russia provide six years of data exclusivity to innovative firms.[94]

**FIGURE 3.3** Relative share of global biotechnology patents 2010-2013




SOURCE: OECD 2015

However, the recent Productivity Commission draft report on Australia's Intellectual Property Arrangements has made a series of recommendations that will likely have a detrimental effect on the biotech industry. The most consequential recommendation is regarding the changes to patent life extensions, or extensions of term (EoTs). Pharmaceutical manufacturers can apply for an EoT if there have been delays in development. The Productivity Commission argued that these EoTs should be better targeted to only those patents that have been delayed directly because of the regulatory process.[95] However, two of Australia's largest venture capital firms have argued that this stipulation will directly disadvantage Australia's patents in a globally competitive market.[96]

The other recommendation made by the draft Productivity Commission report is to cap the data exclusivity provisions for Australian innovative businesses at five years, rather than bringing the provisions into line with Australia's competitors. The Productivity Commission instead makes the case that the Australian Government should seek the cooperation of the US, EU and our other trading partners in order to share protected data. However, data exclusivity is a hotly contested issue in every jurisdiction. We therefore argue against this recommendation and instead suggest that Australia should be following our competitors on this policy issue.

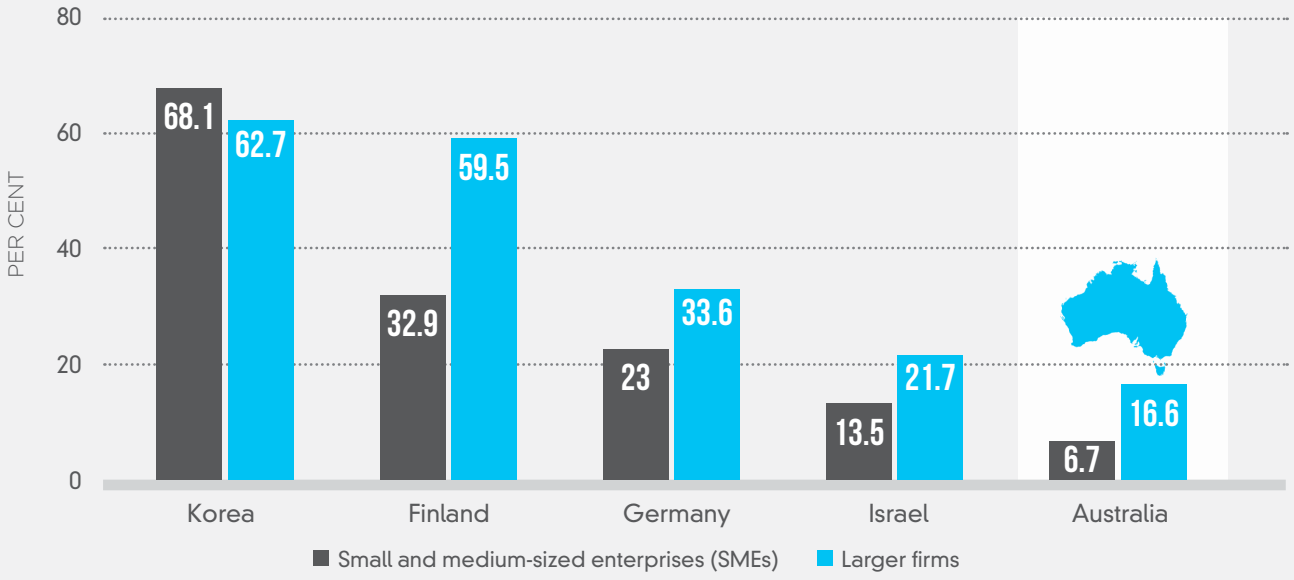
It is imperative that Australia remains competitive in Intellectual Property legislation, as IP laws are a piece of the puzzle in attracting and retaining investment in biotechnology. As has been discussed previously in this report, Australia is very good at conducting research, but we fall behind in transferring that research into commercial benefits. The below chart displays one indicator of this skill: although Australia produces 3 per cent of academic research, we only register around 1.3 per cent of the world's biotechnology patents, sitting below regional neighbours such as Japan, China, Korea, and Chinese Taipei; and well below Canada, which has been shown earlier in this report to have a much smaller industry than Australia.

Providing a competitive IP system is one step in the process to ensure Australia attracts investment, but most importantly, retains the commercialisable research that the Australian taxpayer pays for through the ARC, NHMRC, the universities system, and other research grants and organisations. If Australia does not offer competitive IP legislation, no matter the other reforms and subsidies we make, firms will still choose to develop their innovations overseas, and this will cost Australia in economic growth, jobs, and in terms of the government budget.

**This report recommends that Australia should increase data exclusivity arrangements to more closely match that of our major trading partners.**

**We also recommend that current IP legislation is continued and extended with the unique requirements of the biotechnology industry in mind.**

**FIGURE 3.4** The number and type of businesses receiving government funding for innovation




SOURCE: OECD SCIENCE, TECHNOLOGY AND INDUSTRY SCOREBOARD 2015.

# RECOMMENDATION 4

## The Government must commit to and strengthen basic tax incentives

Intellectual property legislation is one part of the puzzle to attracting investment and fostering a strong biotech industry. Another part is to provide basic incentives to encourage innovation.

Tax incentives for research and development and intellectual property generation are now common place amongst the developed world. Nations are competing against one another in terms of providing incentives to attract leading companies to research, register patents, develop and manufacture products within their jurisdiction. Biotechnology is particularly attractive to governments because of the opportunities the industry presents for the future of health, advanced manufacturing and the economy.

As such, Australia must be careful not to be left behind on basic legislation. In the early 1990s, Australia was one of the only nations in the OECD that offered companies an incentive for conducting R&D; however, over time this incentive has become the norm in the OECD, with 28 of the 34 OECD nations now offering a tax incentive for research and development conducted within private organisations.

Similarly, patent box policies, which provide a preferential tax rate for profits derived from patents registered within a country, are quickly becoming the norm amongst developed nations. Twelve countries have adopted a patent box policy – eleven European nations plus China – in order to attract mobile IP income, and to encourage innovation.[97]

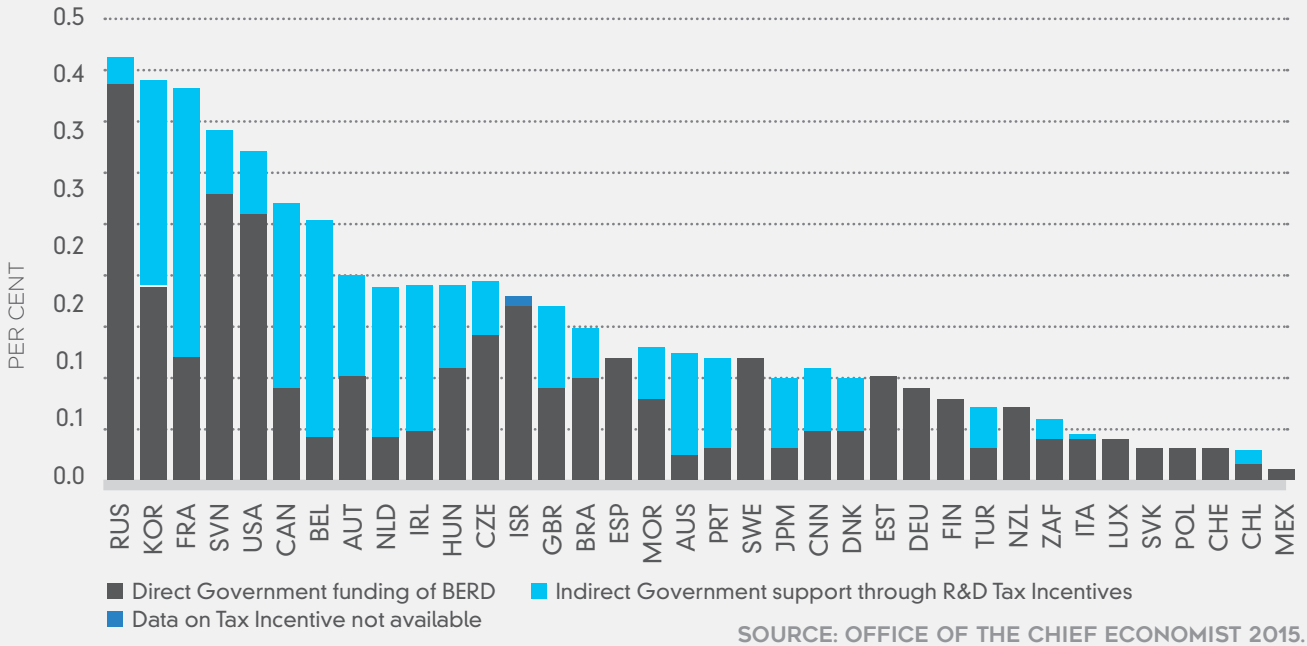
The Office of the Chief Economist published a report assessing the literature on patent box policies around the world in November 2015. It found that Australia is one of the lowest spenders on direct funding for business R&D: ranking 34th in the world. In terms of indirect funding, Australia is ranked 18th, largely due to the R&D Tax Incentive.[98]

Government support for R&D is even more important in an industry such as biotech. In most industries, wages represent the largest cost component of a business. However, in biotechnology, research and development costs represent a larger component of expenses than any other item: wages account for around 18 per cent of the typical biotech business' costs, while R&D represents 21 per cent.[99]

## Australia's policies must keep pace with the world

Patent box systems are popular in many European countries, and they work by enabling preferential tax treatment of profits derived from the exploitation of IP. The version of the patent box incentive

**FIGURE 3.5** Direct government funding of business R&D and tax Incentives for R&D, 2011




SOURCE: OFFICE OF THE CHIEF ECONOMIST 2015.

implemented in Ireland, for instance, attracts a tax rate of 6.25 per cent on profits derived from the exploitation of IP, compared to the 12.5 per cent general corporate tax rate. The Swiss version allows a preferential tax rate of between 0 and 12 per cent while the corporate tax rate is 21 per cent. In the UK, the patent box incentive provides a 10 per cent tax rate on revenues from patents, while the normal corporate tax rate is 23 per cent.[100]

While there are some issues with double counting that need to be addressed when establishing the legislative regime, the economic impact is invariably positive. This has led to significant shifts in patent holdings towards countries with favourable tax regimes. For instance, as discussed above, GlaxoSmithKline is consolidating IP and has announced US$800 million in new investment to the UK as a consequence of the patent box regime.[101]

**This report advocates strongly for Patent Box policies to be introduced in Australia.** The policy has already been adopted in over fifty countries, and hasn't been abandoned by any. Most importantly, the program has been successful in the UK, France, Germany, Ireland, Spain, Netherlands, Hungary and Belgium for some years now, having been first introduced in Ireland in 2001. The policy has been in play in the UK since 2013, and is already in its second round. So the added restrictions introduced such as the tax incentives applying only to the R&D expenditure of the UK based company, already provides a new and improved template for Australia to follow. It is beyond time for Australia to introduce Patent Box policies. Just as important is how well this policy is integrated with other initiatives.

**The other recommendation we make is to reinstate, strengthen and better target the R&D Tax Incentive, and make the industry aware that the policy has bipartisan support.** Uncertainty over the continuation of the R&D Tax Incentive has plagued the industry over the last decade, leading to a likely lower level of research and development output, and the possibility that decisions about where to base operations have not favoured Australia.

Since 2003 there have been ten inquiries that have assessed the efficacy of the R&D Tax Incentive (often amongst other government policies and programs). In 2011, the government increased the incentive from 125 per cent to 150 per cent for small businesses (defined as with a turnover of less than $20 million per year) and 133 per cent for larger businesses. However, since then another four inquiries have considered the R&D Tax Incentive and the Senate just recently approved a cut to the Incentive by 1.5 percentage points. This has led many in the industry to complain that the uncertainty is hurting the industry and the cut will make Australia less competitive in the international market.[102]

# PART FOUR: AUSTRALIAN BIOTECH NEEDS TO GET BETTER AT ATTRACTING INVESTMENT

> Although Australia produces world class research, we are notoriously bad at commercialising that research. One of the reasons for this is that on average, we are poor at attracting investment into our technology development. This also reflects the reality, already addressed in this report, that unlike the US, the majority of our R&D is publicly funded. Commercialising publicly funded research is simply more difficult because it is not a core capability for universities, whereas it is for business.

Australia's research institutes and universities rarely combine efforts to deliver research that can be progressed from lab to market; and often it is the role of the biotech or pharmaceutical company to coordinate commercialisation efforts alone.

This problem can in part be addressed by strong policy leadership emanating from the Federal Government and Opposition. This is an industry which requires a long-term outlook, therefore it is imperative that the policy direction is given bipartisan support. However, government support will only go so far in addressing this issue. Leadership and collaboration must come from within the industry, in order for biotech to truly blossom.

This can be driven in part by a stronger and more heavily financed AusBiotech: the industry organisation provides the best aggregated voice for the industry, both within the domestic sphere and internationally, but has been operating on a shoestring budget for years.

Additionally, there is an opportunity for Australia to generate more interest in the commercial aspects of our research by pooling intellectual property produced by Australian universities and research institutions. Currently, no single institution produces quite enough research to gain the attention of attractive international investors, but pooling the IP will allow Australian research to gain a better platform from which to promote itself on the international market.

This section also contends that the Australian venture capital system should be reimagined in order to attract more suitable investors for the biotechnology industry. Due to the long development timelines and risky nature of the industry, biotech requires capital from patient investors, who are willing to take a risk on products that are worthy of investment. However, the current venture capital system in Australia is unlike its US counterpart, in that it is far more risk-adverse. The Government can foster a more suitable venture capital sector for biotech by providing incentives and targets for investing in the industry.

The following section begins by giving a brief explanation of the disconnected Australian biotech ecosystem, and then progresses by discussing the type of investors we should be attracting with a coordinated approach. Part four concludes with three recommendations that will assist the industry to collate resources in order to benefit individual organisations, as well as the system as a whole.

## Australian businesses could be better at collaborating with research institutions

As an indicator of science and technology, the OECD collects data on the collaboration between businesses and universities or research institutions in each member country. In both the SME and large business categories, Australia consistently falls well below the OECD average on this measure of innovation. The below table is adapted from the recent Australian Government Innovation System Report (2015) which shows that Australia ranks 26th out of 26 countries for collaboration between businesses and universities/research institutions.

**FIGURE 4.1** OECD comparison of collaboration between firms and research institutions

| Indicators | Australia's Score | OECD Average | OECD Ranking |
|---|---|---|---|
| Percentage of innovation-active SMEs collaborating on innovation | 24.0% | 31.7% | 24th/31 |
| Percentage of innovation-active large firms collaborating on innovation | 33.1% | 55.5% | 29th/31 |
| Percentage of innovation-active SMEs collaborating with universities or other research institutions | 2.1% | 14.4% | 26th/26 |
| Percentage of innovation-active large firms collaborating with universities or other research institutions | 3.0% | 36.6% | 26th/26 |

The *National Innovation and Science Agenda* released by Prime Minister Malcolm Turnbull in November 2015 called for greater collaboration between Australian scientists in academia and industry, however it has been argued that the systemic culture of Australian universities inhibit collaboration. This is in part due to the way that success is measured: by the number of publications and rates of citation per researcher or university. When researchers are focused on producing publications, innovation and collaboration is a distant promise.[103]

Collaboration benefits organisations as the exchange of ideas leads to innovative new products and processes. In addition, collaboration positively affects productivity and economic growth: the academic research shows that the best performing knowledge-led economies are also the world leaders in collaboration between universities and businesses. The benefits of this collaboration are four-fold:

1. Collaboration helps to prepare work-ready graduates;
2. It makes research students interested in working in the private sector;
3. It encourages some students to start businesses of their own; and
4. Collaboration facilitates the flow of ideas from universities to businesses.[104]

Geographical proximity fosters collaboration, which is why clusters often form in cities around certain industries: for example, the Silicon Valley technology cluster in Northern California is considered one of the most innovative places on Earth. The New South Wales Government has identified this and has allocated a nominal sum to establish a series of technology clusters around the state. As mentioned previously, the Medical Technology Association of Australia (MTAA) is responsible for the biotechnology cluster; however, given the very small amount of funding ($150,000) attributed to this initiative, it is unclear what the outcomes might be.

## The problem with speculative capital

Investors in Australia looking for a speculative return have displayed a notable alternation between two industries – biotechnology and mining, more specifically mining exploration. While these two industries appear on the surface to be very distinct there are many aspects that overlap. For each:

- The industry is global with players operating freely across many national borders;
- The industry is capital intensive;
- The industry is knowledge intensive;
- High technology solutions are constantly being sought and developed;
- The technical knowledge to operate in the industry is often beyond the understanding of investors;
- Discovery research must be conducted prior to commercialisation;
- Discovery is followed by claim staking of property;
- From discovery, there is a long lead time before the product is ready for market;
- The investment is high risk and speculative;
- The returns from blockbusters are potentially enormous;
- The industry is dominated by small and medium firms,
- The industry dovetails into an adjacent established industry;
- There is never any contact with final consumers for industry participants; and
- The adjacent industry is dominated by some of the world's largest companies.

As a result, it is often the case that the fortunes of the two industries see-saw in Australia. While the resources boom pushed many mining exploration companies' share prices to record highs, biotechnology stocks languished. As the mining exploration and construction boom recedes, some biotech stocks are reaping the benefits.

The problem for biotechnology is that the blockbusters are so few and far between. In an era of rapid news cycles and constant communication, not many investors are willing to wait ten to fifteen years to reap rewards. The high attrition rate of candidates in the pipeline, when pipelines for many players in Australia are thin to begin with, accentuates the attrition, threatening the existence of each company.

However, biotechnology is an industry that holds great potential: for industry players, for the economy, for the government, and for citizens. As Australia makes the transition from a commodity-based economy into a broader industry base, advanced manufacturing and research-based industries such as biotechnology stand to both gain considerably, and present an opportunity to grow into a large employer of Australians. The industry just needs to gain the attention of a different type of investor in order to accelerate to the next level.

## Targeting sovereign wealth funds

Currently sovereign wealth funds globally are seeking safe investments with minimal expectations of return in the short to medium term, making them ideal investors for Australia's biotechnology industry. It will be easier to attract the large sovereign wealth funds if the profile of Australian Biotech is aggregated and marketed with a single voice by AusBiotech.

There are currently large amounts of money emanating from sovereign wealth funds in countries such as Norway, Sweden, Canada and Japan which are simply looking for returns that are non-negative. Sovereign wealth funds are an excellent form of patient capital, far less susceptible to the oscillations of retail investors between mining exploration and biotech, and with significant amounts to invest. For these funds, finding an investment that does not offer a negative return is their key current requirement. Australia offers a stable environment for investment, due to world class science and research institutions and a stable political environment. What has been missing for a winning formula is the level of institutional investment that would allow more rapid progress of candidates through the development pipeline, thereby making Australian biotech firms more competitive and enhancing the potential for return from investment.

Sovereign wealth funds offer some opportunities, but the most obvious opportunities come from companies in the same space. Large pharmaceutical companies to date have dabbled with Australia, but have not been attracted to invest on a large scale.

## It won't take much to attract further investment from large pharmaceutical companies

The relationship between large pharma companies and emerging biotechs is generally symbiotic, with large pharma companies relishing access to the rapid developments in science and technology which have continued to accelerate over the last three decades; such as genetic biomarkers, genomics (particularly including genome-wide-association), related products such as mAbs, and the integration of companion diagnostics with therapeutics. These biotechnologies augment the diminishing small molecule pipeline large pharmaceutical companies have faced over the same period.

However, the impact of revenue falls on both small and large molecule drugs as they come off patent has been increasingly felt by large pharma companies. This has led to waves of M&As between the large pharma companies, as well as spin-offs that split biotechnology from the more traditional products of major companies – for example AbbVie from Abbott Laboratories, or Baxalta from Baxter. The purpose is to achieve economies of scale and improve cost structures. However, this does not augment pipelines. It is here that biotechnologies provide the opportunity to sustain strong revenue streams by strengthening the pipeline of products that potentially offer years of revenues before patent expiry.

It is therefore in the best interest of not only Australian biotechnology firms, but also large pharmaceutical companies, that Australian biotech is represented with a collective voice. When the industry is fragmented, small opportunities do not seem worth the investment; however, when the industry is represented properly and a range of opportunities are presented, large pharmaceutical and biotech companies can be more easily enticed to Australian waters.

# RECOMMENDATION 5

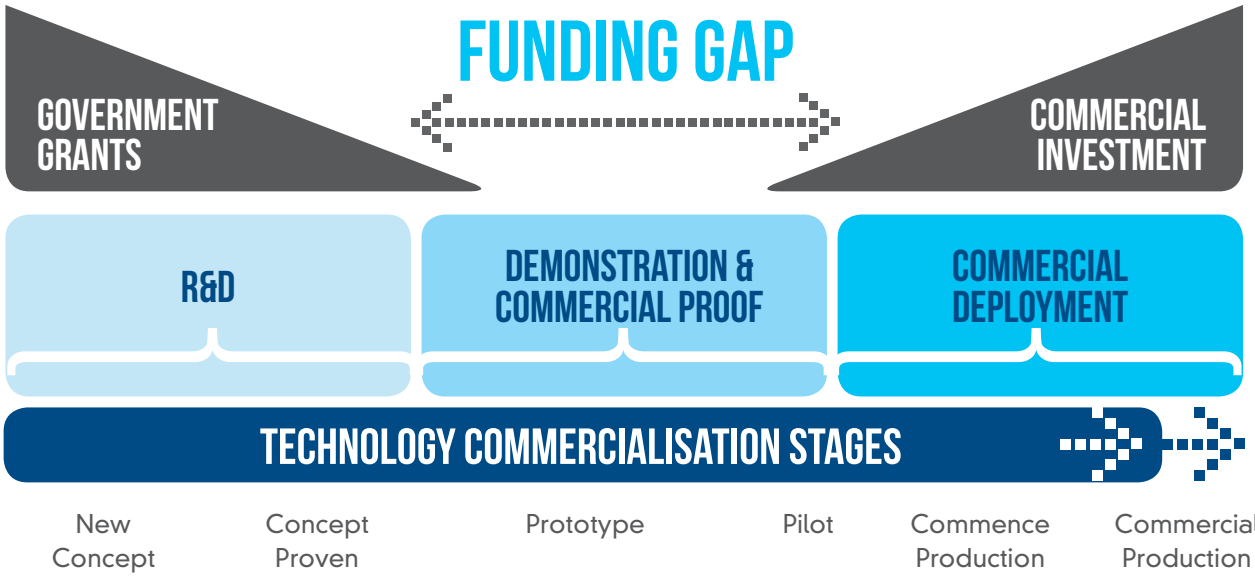
## Australia needs to develop a new venture capital system

In developed economies, venture capitalists play an important role in innovation. Venture capitalists in the US have funded exploration in science and technology since the 1880s, when industrialists and oil barons such as the Vanderbilts and Rockefellers began to take risks on promising investments that had the potential to change the world. These investors saw it as their duty to provide an alternative form of capital to promising businesses.

In contrast, Australia's venture capital system was born more than a century later out of the 1987 stock market crash, as an alternative form of capital. Created by government, Australian VC more closely resembles the banking system than the venture capital system in the US. The decision making processes and risk appetite also correspond more closely with banks than with that of entrepreneurs. Australian venture capitalists are as a result more conservative, investing mainly only in the later stages of development, once a company has displayed a track record of growth; and investing vastly smaller tranches than in the US, with a focus on financials rather than on the technology and the teams behind the technology. This is evidenced by the fact that figures for venture capital investment in early stage ventures in Australia is just half that of the OECD average, at 0.007 per cent of GDP.[105]

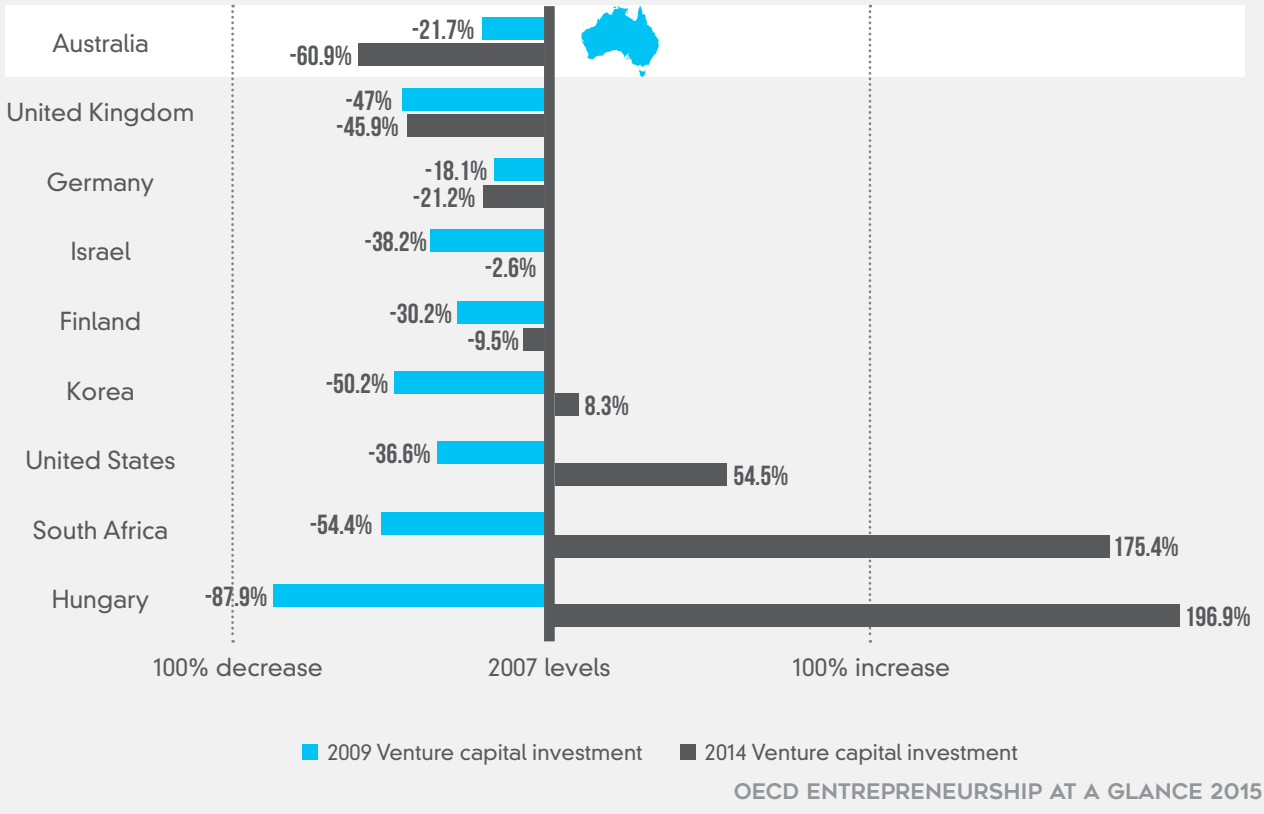
The risk-adverse nature of Australian venture capitalists can be further witnessed in the recovery of venture capital around the world since the hit of the global financial crisis. Since then, VC has recovered in most places, but in Australia it has taken much longer. Our industry in 2014 was 60 per cent smaller than it was in 2007, and latest Australian Bureau of Statistics figures suggest the recovery has remained slow. [106]

**FIGURE 4.3** The funding gap that venture capital can address




SOURCE: AUSTRALIAN GOVERNMENT 2012

**FIGURE 4.4** Venture capital investment post-GFC




OECD ENTREPRENEURSHIP AT A GLANCE 2015

The risk-adverse nature of Australian VCs has very severe implications for innovative firms, and in particular, biotechnology.

Biotechnology in Australia is still dominated by research, and early development up to Phase II clinical trials. Only two or three Australian companies have the capacity to cover the $100-500 million it costs to progress a medicine through Phase IIb and Phase III trials. As such, the goal for most biotechnologies (whether they have a start-up company as their commercial vehicle or not) is to progress to a point at which they can be noticed by the major investors, alliance/licensee partners, or M&A partners that will fund the completion of the development to market launch and beyond.

The challenge is to progress the candidate through key milestones as quickly and as convincingly as possible. This requires extensive financial commitment, soft infrastructure (development skills, financial skills, networking skills, management skills) and hard infrastructure (laboratories, sophisticated equipment, hospitals, and supplies) to achieve. Rapid progress reduces the risks investors and partners face in getting the technology to market where it can begin to provide a return on their investment.

The challenge for the biotechnology industry is that the successful exit strived for depends on reducing the risk of failure (ie. derisking). These risks don't only reside in the scientific and technical domains, there are extensive regulatory risks, financial risks, competitive risks, and risks associated with the capability of management to run a successful company. If a biotechnology can be taken on an optimal path through its pipeline, it derisks it as an investment for potential investment suitors.

However, the limited risk appetite of Australian VCs has led to either the venture capitalists seeking a rapid turn-around with an IPO, or the companies themselves viewing an IPO as the strategy of choice to gain the much needed equity injection to sustain their R&D. As such, by the mid-2000s there were more listed biotechs in Australia than in the US.

## How the Government can foster a new venture capital system

Australia's superannuation savings have been a major basis for the economic vibrancy of the Australian economy since the Labor Government introduced compulsory contributions in 1983, culminating in over $2 trillion of national savings today. **This report repeats the calls made elsewhere to direct a proportion of Australia's superannuation savings towards home-grown innovations.** This reform is especially important to the success of the domestic biotechnology industry, which desperately requires funding to bridge the gap in the twin 'valleys of death' in clinical trials funding.

However, Australia's high net worth individuals and global companies need also to be encouraged to drive a renaissance in the biotechnology industry in Australia. This will not be a policy led initiative, but it can be policy enabled. Tax incentives and offsets to provide strong encouragement for high net worth individuals to become systematically involved directly in venture capital, either through leading funds, or pooling their resources into private funds, will establish initial steps toward this renaissance. **This report calls for the Government to conduct a review into how Australia's venture capital system can be more effectively utilised, and what mechanisms might be required in order to attract high-net worth individuals to invest in Australian ventures.**

However, in order for Government-led initiatives to have the greatest effect, the biotechnology industry itself must cooperate in order to become the successful, job-creating industry for Australia's future. The following section details the problem of fragmentation amongst industry players, and recommends some solutions to mitigate the problem.

# RECOMMENDATION 6

## An intellectual property pooling organisation should be established to represent Australian research

It is the sixth recommendation of this report that Australia should follow in the footsteps of the UK-based Imperial Innovations to pool intellectual property (IP) in order to better package research for commercialisation.

Only unique institutions such as Harvard and MIT can truly regard their intellectual property base as to be so substantial that investors and partners alike will flock to them. Other major intellectual property generators, such as Imperial College London (through Imperial Innovations), Oxford University (through Isis Innovation Ltd) and Cambridge University (through Cambridge Enterprises) – each significant producers of intellectual property in the biotechnology field – have chosen to increase their profiles and attractiveness to potential suitors by combining their intellectual property (see the case study box to the right). This has led to considerable success in attracting global investors by combining rather than competing with rival technologies.

Australian universities and research institutions are yet to learn this lesson. As a result, Australian research fails to gain traction among venture capitalists and large biotech and pharmaceutical companies, due to the inability to speak with one voice in order to get noticed.

This problem has been magnified by the fact that Australian universities and the CSIRO compete against one another in terms of research. This protectionist psychology has led to the industry becoming very fragmented, and has detracted from the industry as a whole.

There are of course examples of successful collaborations between Universities, health and medical organisations, companies and research institutes in Australia: shared IP is nothing new. The issue is that the collaborations are case-by-case, without a level of organisation or strategy. An organisation that is designed to pool IP and assist in the commercialisation of Australian research would have wide-reaching benefits for the entire industry.

**It is therefore the recommendation of this report that Australian Universities should create an organisation similar to the UK's Imperial Innovations in order to pool IP and assist in commercialising promising biotech research.**

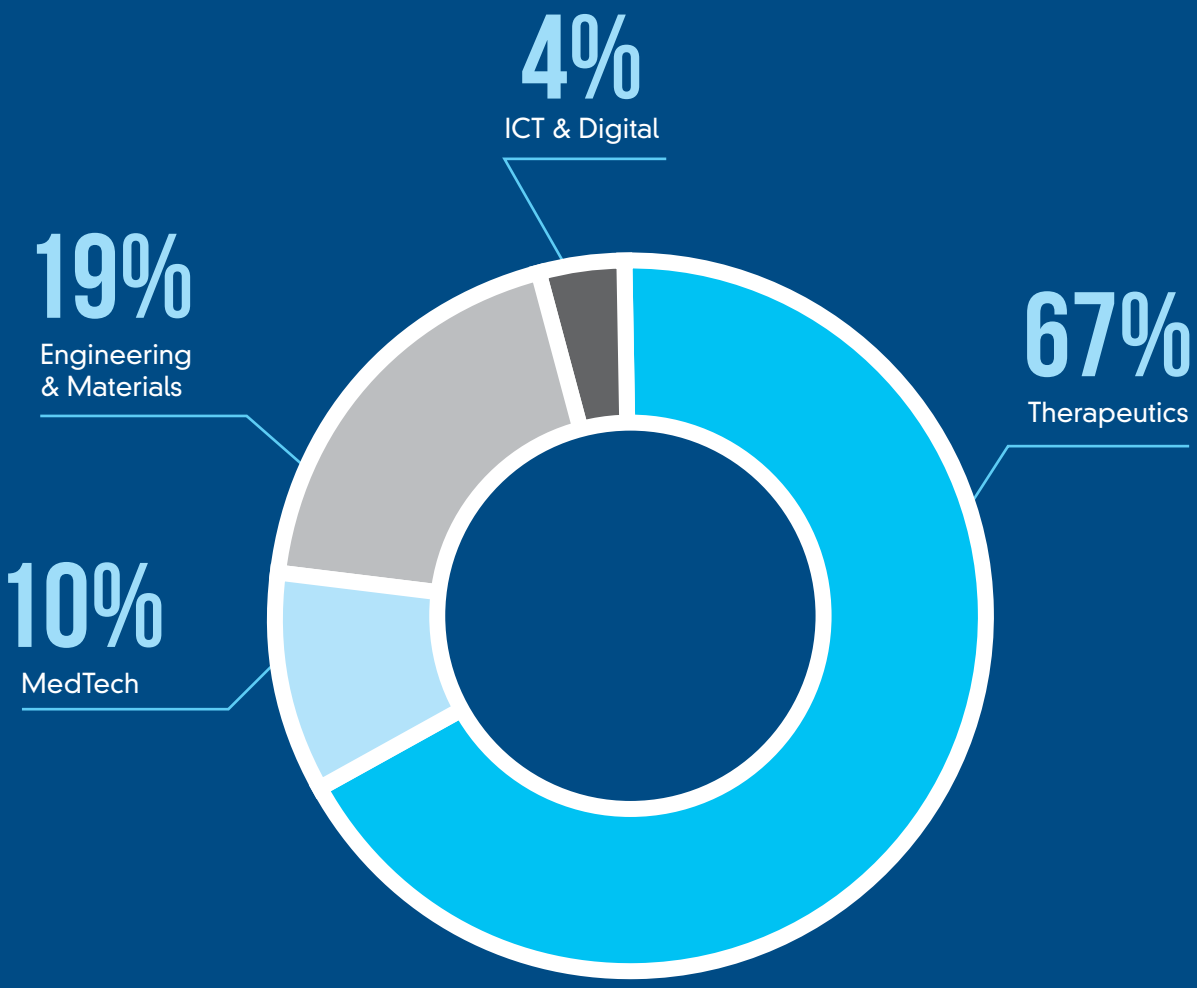
### Imperial innovations – A template for success in pooling IP

**Formed out of the Technology Transfer Office (TTO) of Imperial College London in 1986, Imperial Innovations was initially designed to protect and exploit commercial opportunities arising from research within the University. Since 2011, it has also made investments in research from the Universities of Cambridge and Oxford, and University College London.**

**Imperial Innovations can now claim to be one of the world's best bodies representing research. It is now a publicly listed company with investments in technologies valued at £233 million, of which therapeutics accounts for £155 million.**

**Imperial supports scientists and entrepreneurs in the commercialisation of their research, including by assisting in licensing IP, leading the formation of new companies, recruiting high-calibre management teams, and by providing investment and encouraging co-investment. After floating on the London Stock Exchange in 2006, Imperial Innovations has provided direct financial investment into a variety of technologies resulting from research within these institutions.**

## IMPERIAL INNOVATIONS CASE STUDY




**The international profile gained by pooling intellectual property has been substantial. However, coordinating the IP has been another story, requiring a very strategic outlook on all the research conducted across the four universities, and delicate negotiation to encourage collaboration over duplication of effort.**

**Imperial Innovations identifies four particular areas of expertise, shown in the diagram above. As at 31 January 2016, the value of the top 10 investments in the portfolio stood at £232.6 million while the total portfolio was valued at £355.1 million.**

### How to practically establish a coordinating agency for Australian Research

It is recommended that a coordinating agency for pooling and promoting intellectual property be established in Australia. This agency should be commercial in nature, and designed to attract international sponsors to commercialise biotechnology research emanating from Australia's universities, CSIRO and research institutes.

This initiative would require Federal Government support and guidance through the initial development phase.

Intellectual property protocols may not be overly difficult to establish, given that most research is funded under the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC). IP ownership would rest with the institution, however protocols in which all IP is included in a national annual audit would identify overlaps and opportunities.

The parcelled IP would be much more sophisticated than is typically the case currently. Enhancing the IP and promoting it more effectively to potential suitors would increase the seller's premium on the IP and better returns. The strong research commercialisation universities such as University of Queensland and University of Melbourne may see less benefit as their commercialisation capabilities are already advanced. However, the vast majority of universities, research institutes and the CSIRO would see significant new opportunities and new revenue streams open before them.

This initiative will allow Australia to capture the value it generates through research activities, leading to economic and health benefits for the Australian people. This is not a call in the wilderness. A similar proposal and early steps toward establishing a 'one-stop-shop' for Australian IP was undertaken by Commercialisation Australia, then Accelerate Commercialisation, under the lead of Doron Ben-Meir. Unfortunately, due to funding restrictions and Mr Ben-Meir taking up the role as the inaugural Executive Director of Research, Innovation and Commercialisation at the University of Melbourne, this initiative appears to have lost momentum.

## RECOMMENDATION 7

### Government funding should be provided to AusBiotech

AusBiotech is the representative body for biotechnology firms in Australia. Member-funded, it is the collective voice of the industry, advocating at both the domestic and global levels. However, it is grossly underfunded and as such, is not living up to its potential.

**The Federal Government should provide funding to support AusBiotech, Australia's peak biotechnology organisation.**

BIO, the US's Biotechnology Innovation Organization is a hugely successful organisation with substantial global presence. Memberships span 40 different countries. Its conventions attract 15,000 industry players, venture capitalists, private equity, research institutes, politicians and government agencies from all countries which have a biotechnology presence each year. BIO is the global biotech deals hub, and its success and presence brings substantial revenues with which to market itself and its members.

Conversely, AusBiotech has around 3000 members and the convention attracted around 1000 delegates in 2015.[107] AusBiotech receives very little Federal Government funding support, and relies almost exclusively on its membership. AusBiotech's very limited resources affect its ability to promote itself and its members effectively, and gain a voice globally. While the organisation is doing a great job with the resources it does have, its potential is not being reached.

If Australia is to gain a voice among the global cacophony, AusBiotech must be funded more strategically. AusBiotech fundamentally needs priming through funding from the Federal Government. A substantial injection of funding is not only needed to make up for twenty years of neglect under Governments of all persuasions, it is absolutely necessary to support AusBiotech's ability to overcome the marketing and lobbying presence of the larger and better resourced industry bodies, such as BIO and the UK's Biotechnology Industry Association.

Providing more funding to AusBiotech will allow the organisation to be the aggregate voice for

the industry at an international level, assisting in attracting two instrumental groups to Australia: patient capital, in the form of sovereign wealth funds or international superannuation/pension funds; and large pharmaceutical and biotechnology companies, which will provide an important source of experience and options for young biotechs to partner with or be acquired by the global giants.

Providing more funding to AusBiotech will speed its progress toward meeting its aim "to build an appropriate environment to enable companies to grow, help them globalise and position Australia as a significant biotechnology industry for increasing international investment and interest."[108]

## The biotech industry requires a coordinated response

This recommendation should be enacted in concert with the other recommendations in this report, particularly those to pool IP, and to provide more funding to the TGA. If done so, the Australian biotech industry will have a strong platform for promoting the industry in a more effective way in order to attract new investors and large pharmaceutical/ biotechnology companies to our shores.

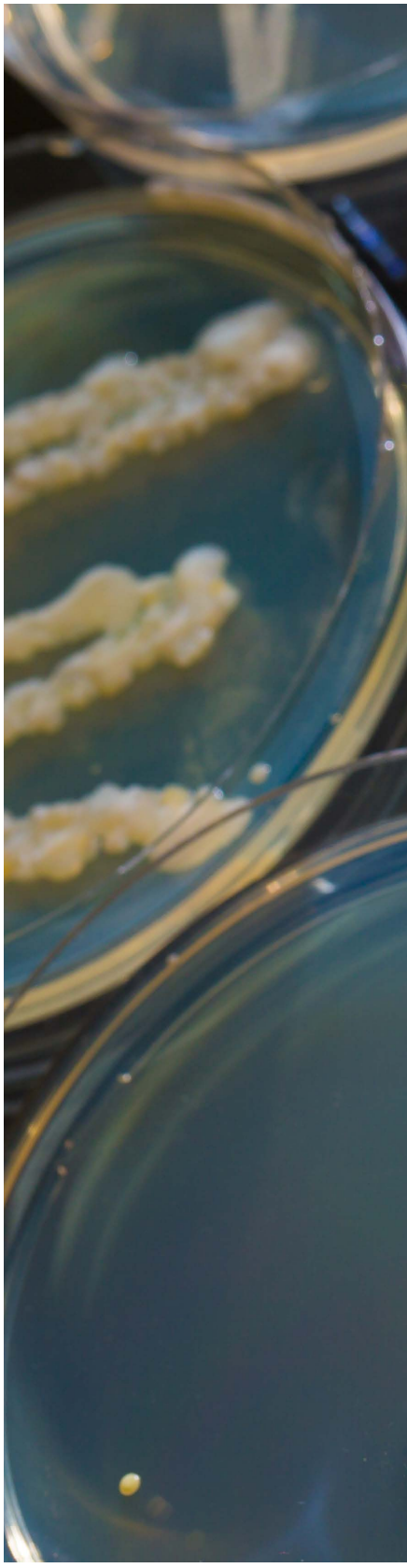
The purpose of pooling assets and aggregating the profile of Australian biotech will be to attract investors, such as sovereign wealth funds, that are too large to bother dealing with individual companies, research institutions, or even state governments. National representation from an industry peak body is the only way for the industry to get noticed on a global scale.

The second target is is large pharmaceutical and biotech companies. Little investment has been directed to Australia to date from these sources. This is most likely because in comparison to what has been on offer in the US and Europe, nothing looked sufficiently attractive in Australia to invest in. Pooled IP, national representation and a national coordinating body for IP deals, as well as attracting more extensive involvement in the renewal of the regulatory system in Australia, will all direct far more attention to our shores.

Although Australia excels at scientific research, our ability to commercialise that research can be improved, and this can only happen by attracting investors and experienced organisations to the domestic industry, and in the process, integrating Australia better into the global biotechnology investment ecosystem.

# CONCLUSION

> The world is on the precipice of an exciting new era. Biotechnology is a field that will permeate all of our lives, and provide solutions to some of the world's most pressing problems. Biotech will help cure cancer, HIV/AIDS, and many other diseases; it will assist the world to move into a carbon-neutral state; it will allow us to feed the 9 billion souls projected to inhabit the Earth by 2050.



Australia has a small window of opportunity to reap the benefits of the natural competitive advantage we have in biotech. We have an educated population with an entrepreneurial spirit; we have excellent research facilities and infrastructure; and our political and regulatory environments are stable and credible.

However, we also have some shortcomings. Our main regulatory authority, the TGA, is grossly underfunded, and this is leading to our development timelines for drugs and vaccines to blow out compared to our major competitors. Our basic legislation regarding tax incentives and intellectual property are either lagging, or not doing their job due to regulatory uncertainty; and while we dither on policy leadership, our competitors are delivering coordinated programs designed to attract investment and foster innovation. Finally, our industry is disconnected from one another. We have one of the lowest collaboration rates in the developed world, and it is affecting our ability to develop our world class research into commercialisable products that will deliver jobs and other economic benefits to our nation.

This report has attempted to lay bare the shortcomings of the biotechnology industry and provide recommendations to counter those deficiencies. It is our hope that both the Government and the industry will take advantage of the unique position we currently find ourselves in, and coordinate and invest in the industry now, while we still have the chance. If we don't, then Australia will lose the opportunity we have to solidify our position as a world leader in biotechnology, and all the benefits – economic, social, and otherwise – that leadership would entail.

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