



THE MCKELL INSTITUTE

BIO-SAVVY

HOW AUSTRALIA CAN
BUILD A STRONGER
BIOTECHNOLOGY
INDUSTRY

OCTOBER 2016

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William McKell made a powerful contribution to both New South Wales and Australian society through significant social, economic and environmental reforms.

For more information phone (02) 9113 0944 or visit www.mckellinstitute.org.au

ABOUT THE AUTHORS

DAMIAN HINE



Damian is an Associate Professor in Innovation and Commercialisation at the University of Queensland Business School.

An evolutionary economist, his main areas of interest lie in the crossroads of innovation and strategy, in the field of

dynamic capabilities. Damian is the author of two books and multiple articles in some of the world's top innovation and science journals. He has also written papers for ASX200 firms, State and Federal agencies, the OECD, and UNESCO.

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.

MARIEKE D'CRUZ



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

She holds a Bachelor of Arts with a double-major in International Politics and Media and

Communications from the University of Melbourne, and is currently completing a Master of Public Policy at the University of Sydney. Marieke has also been a professional athlete, having represented Australia at the Olympics, World Championships and Commonwealth Games in swimming.

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

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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.
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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.
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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.
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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.
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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.
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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

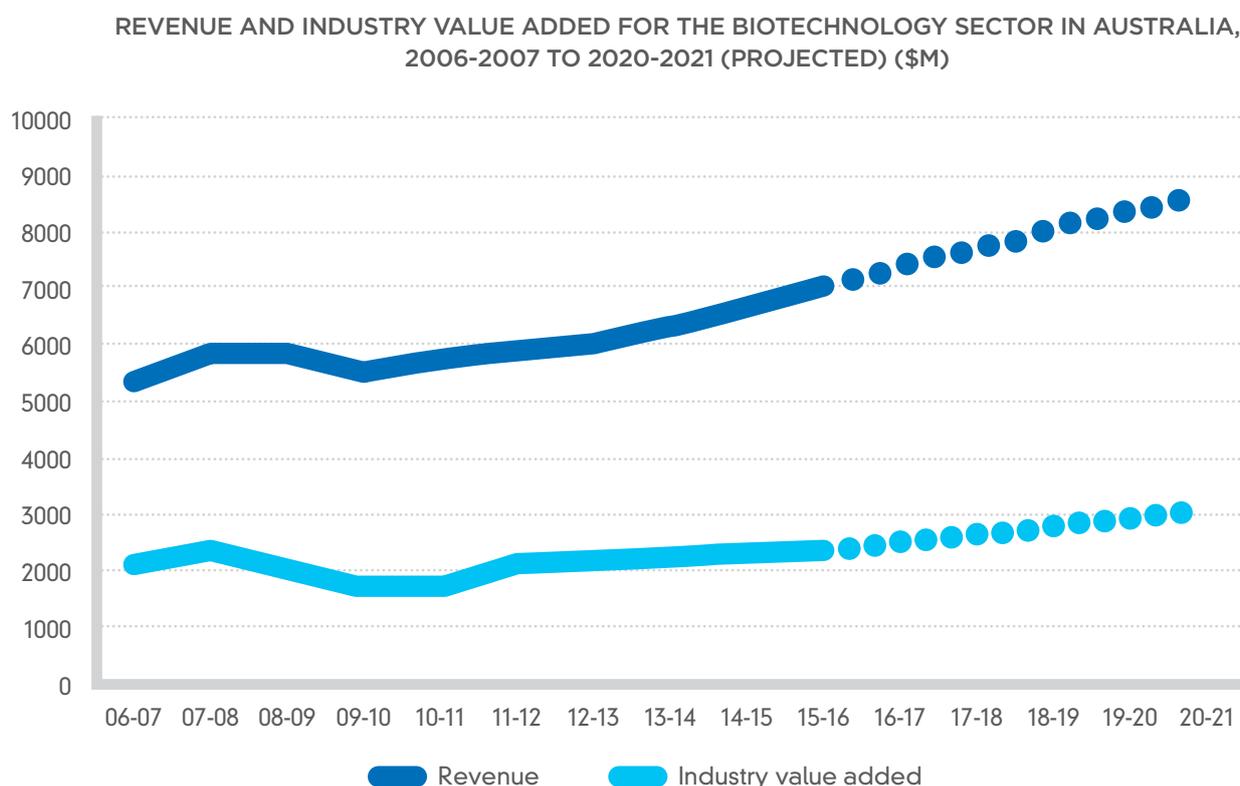
As there is not an official classification for biotechnology companies in the Australian and New Zealand Standard Industry Classification, the majority of available biotechnology company data at the industry level is drawn from publicly listed companies. The Australian Stock Exchange (ASX) classifies 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

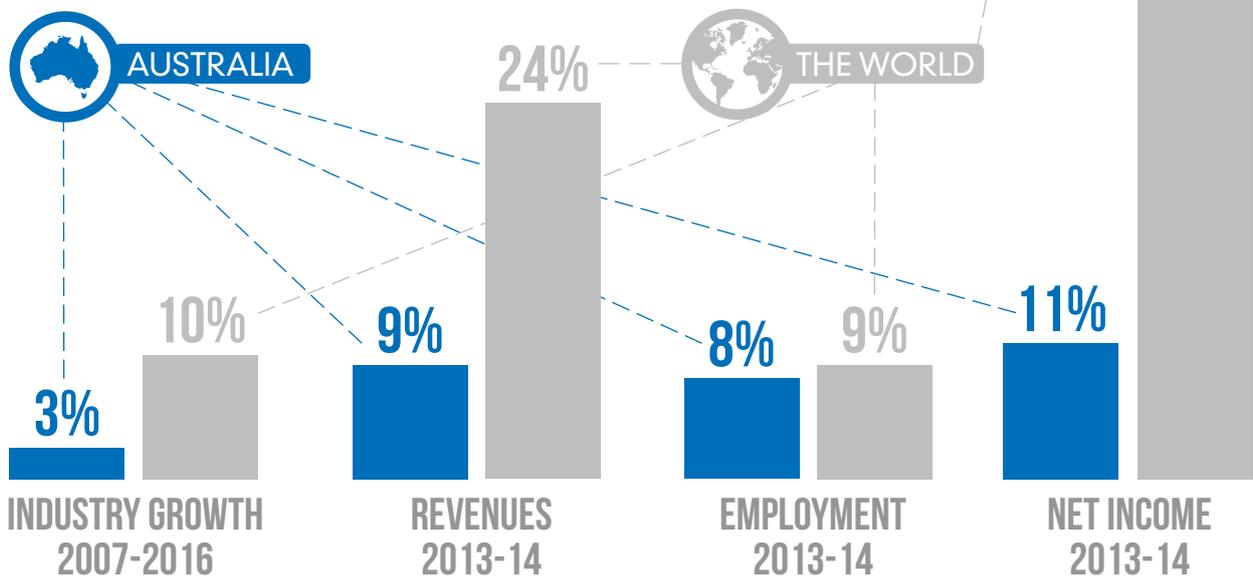
Australia's biotech industry is being outperformed

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.

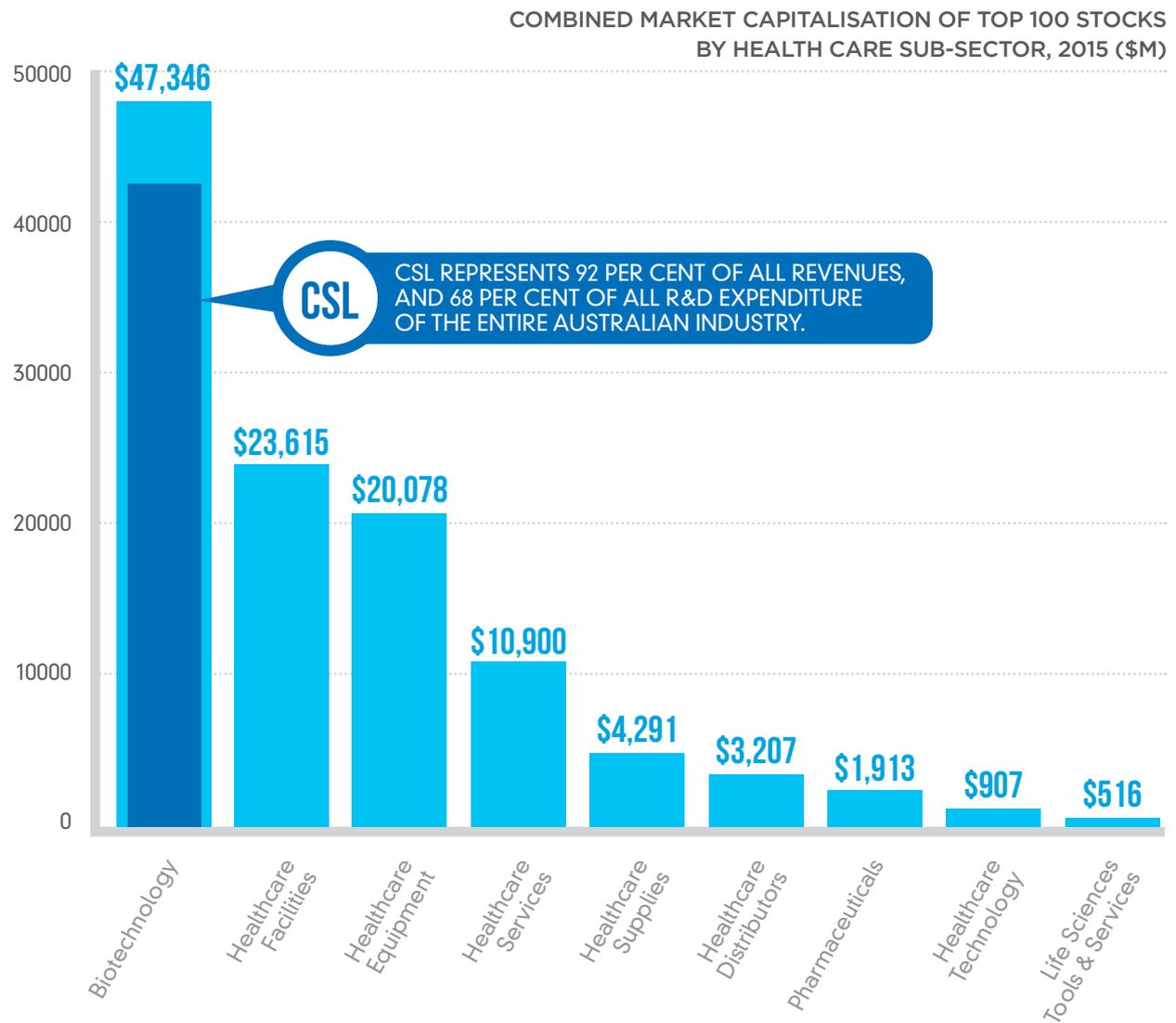
231%

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.**¹⁵

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.

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

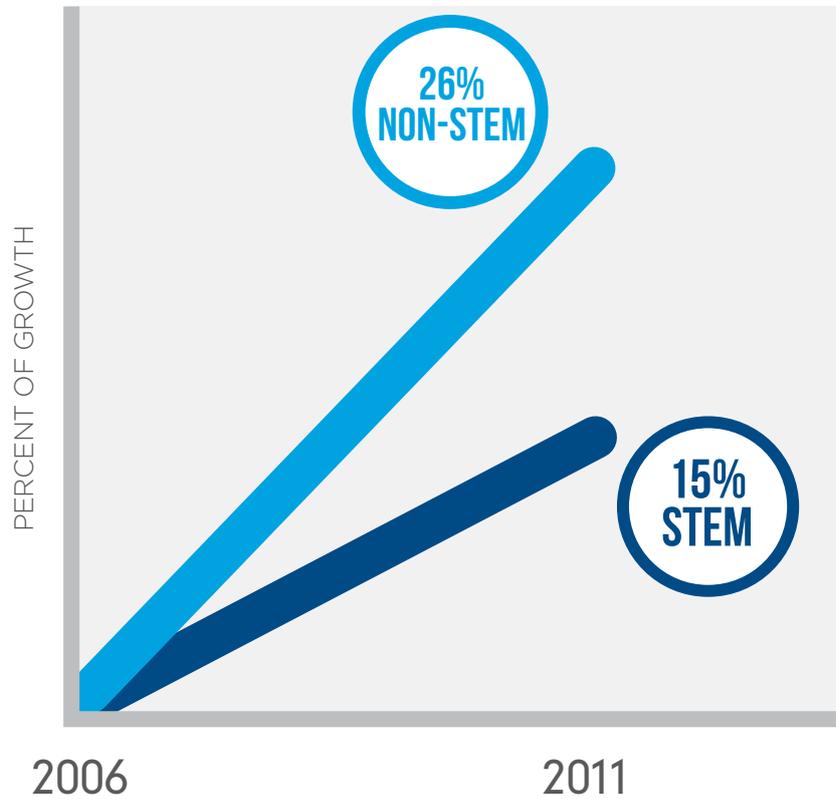
In addition, the level of primary and high school students participating in and performing well in STEM fields is dropping across the nation. Compared to other countries, Australia's international standardised testing results have been slipping in the STEM subjects since the early 2000s, and the gap 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

FIGURE 1.9

Growth of STEM vs. Non-STEM qualified population 2006-2011



SOURCE: AUSTRALIAN GOVERNMENT, CHIEF SCIENTIST, 2016

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.

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.

