KPMG

A Prosperous Future: Biotech

Biotechnology opportunities for Australia and the United States.

Prepared for the American Chamber of Commerce in Australia (AmCham)

October 2023

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Foreword

Australia's comprehensive relationship with the United States is vitally important for our nation's economic wellbeing and security. It has been shaped by shared history, democratic systems, values, cultural ties and common interests.

But what will that relationship look like into the future? Where will our economic and commercial connections and complementarities lie in a rapidly changing world?

Both countries are looking towards the future – a future characterised by a range of geo-strategic, geo-political and geo-economic issues, including rapid technological, climate and clean energy challenges. These pressures are accelerating and testing our nations' resilience while also creating new opportunities. The United States and Australia are committed to working together to face into this uncertain future.

Facing into a dynamic and volatile future, the United States and Australia need to ensure we build on the existing connections and focus carefully on identifying the opportunities of the future.

As a national partner of AmCham in Australia, KPMG is delighted to partner with and co-sponsor this 'A Prosperous Future' report series which to date has profiled opportunities for business collaboration in artificial intelligence (AI), digital economy, quantum computing, space and clean energy industries.

This report focuses on exciting opportunities for trade and investment in the rapidly growing biotech sector in the context of geopolitical change. It specifically examines opportunities for Australian companies to leverage and expand cooperation with US partners in R&D and clinical trials, to leverage Australia's vast supplies of biotech feedstock (e.g. sugar and agri waste), to attract investment to build biomanufacturing capabilities in both countries and create superior data and cyber infrastructure for strategic biotech advantage. The benefits to Australia would include tens of billions in trade and investment and tens of thousands in new, highly skilled domestic jobs.

We sincerely thank AmCham's CEO April Palmerlee, the AmCham executive team, and corporate members who have participated in this report. Our sincere thanks also to KPMG colleagues Thu Hoang, Dr Merriden Varrall, Tim Plenderleith, Evan Rawstron and Julie Bever for their enormous contributions towards this important research report series.

DR BRENDAN RYNNE
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AmCham foreword

The human existence is defined by discovery. Throughout history, discovery has led to prosperity.

AmCham and KPMG's report series *A Prosperous Future* has explored the economic potential of advancing collaboration in artificial intelligence, digital, quantum, clean energy, and space. These industries were identified for this series based on their potential to reshape our economies over the next 50 years. Already, we are witnessing this technological revolution.

Artificial intelligence is transforming the way we work and live, digital has become inextricable from the broader economy, developments in quantum challenge computing as we know it, the clean energy transition is underway with urgency and momentum, and the private sector is spurring the next generation of advancements in space with untold applications on earth.

This final report turns to one of humanity's original quests: understanding ourselves and the world around us. Our natural environment holds the key to many of the challenges we face today, and those that will confront us in the future.

How do we sustainably feed the growing global population? How do we fight back against infectious diseases, cancers, and pandemics? How can we use biotechnology to create green energy? How can bioinformatics lead to early diagnoses and new treatments that will save lives? Biotechnology is critical to answering these questions, and those we have not yet anticipated.

The multitude of collaborations across a diverse range of sectors contributes to the indelible strength of the economic relationship between the United States and Australia. This has been a constant theme throughout *A Prosperous Future: Emerging Tech*, *A Prosperous Future: Clean Energy*, and *A Prosperous Future: Space*.

The COVID-19 pandemic brought the importance of a strong domestic biotechnology sector and trusted international partners and supply chains to the fore, and this report showcases the opportunity to harness the unique US–Australia alliance, our complementary economies, research institutions, and trusted partnership to seize the economic opportunities in biotechnology.

AmCham congratulates Doug Ferguson, Dr Brendan Rynne, Dr Merriden Varrall, Julie Bever, and Thu Hoang for the important research undertaken for this report series and their contribution to the US–Australia economic and strategic relationship. We also thank AmCham's Sara James and Josh Edwards.

We commend *A Prosperous Future: Biotech* and the report series to anyone seeking a deeper understanding of the next generation of economic partnership for Australia and the United States.

APRIL PALMERLEE
Chief Executive Officer
AmCham Australia

Report foundation

As outlined in KPMG's 2021 introductory report, *A Prosperous Future: Key industries for Australia/US collaboration*, in consultation the Australian Department of Foreign Affairs and Trade, and the US Embassy in Australia, AmCham and KPMG identified six emerging industries will be key to the future of the US–Australia economic relationship: artificial intelligence, quantum computing, digital economy, biotechnology, space, and clean energy. This report focuses on biotechnology.

Executive summary

The pace and scale of change in our world is immense. An ageing population, increased prevalence of chronic disease, the threat of climate change and the advancement of technology are rapidly driving demand for solutions from the industry. The growth momentum is creating vast biotechnology trade and investment opportunities between Australia and the United States.

The global geopolitics of biotechnology

In the current volatile and competitive geopolitical landscape, characterised by a 'polycrisis' of interconnected global risks, countries are increasingly focused on safeguarding and enhancing their strategic and economic positions. Geopolitical alliances are forming as nations unite against common rivals, intensifying mutual distrust.

Biotechnology has emerged as a crucial arena for competition, with its potential to reshape global power dynamics. It offers opportunities for bolstering national security through advancements in agriculture, medicine, energy, and defence capabilities. However, the lack of international cooperation in biotech poses risks, including the misuse of biotechnology and bioweapons.

Despite biotechnology's potential to address pressing global challenges, geopolitical mistrust hampers its progress. In the years ahead, businesses may find opportunities in a wide range of biotech subsectors but will have to manage the shifts and developments in how countries cooperate – or do not – on biotech at the global level.

Biotech cooperation between the United States and Australia

The US Government has recognised the importance of international cooperation in advancing biotech research and achieving their goals for the biotechnology and biomanufacturing sector.

The United States has set ambitious targets, aiming to harness R&D to further societal goals over the next two decades across five key biotech applications, including climate change solutions, food and agriculture innovation, supply chain resilience, human health, and cross cutting advances. To attain the goals will require substantial prioritisation of R&D investments and other efforts across the US Government, as well as actions from the private sector; state, local, and tribal governments; and international partners.

There are a range of areas and ways where international partnerships feature in US goals for the sector, especially in research collaboration and supply chain resilience, including:

Expanding interdisciplinary and international cooperation in R&D (including research projects and data sharing) to leverage expertise across fields and drive innovation, while mitigating risks and reaffirming democratic values.

The United States and international partners can expand advanced biomanufacturing capabilities, including more regional biomanufacturing close to feedstocks to enhance supply chain resilience. When supply chain disruptions occur, manufacturers can shift production more efficiently, in coordination with international partners, rather than undergoing capital-intensive retooling.

The United States and international partners can collaborate to create a data infrastructure that better utilises the large data generated from R&D investments, including developing tools, capabilities, and standards in accordance with Findable, Accessible, Interoperable, and Reusable (FAIR) principles.

International collaborations will enable and support the necessary physical and cyberinfrastructure required to conduct fundamental R&D, ensure connections between researchers and end users, and translate new discoveries to the market at speed and scale.

Australia is among the US trusted allies and partners due to the two countries' longstanding commercial, people-to-people, and defence ties. This strong relationship is further strengthened through institutions for cooperation, including the bilateral alliance and the Five Eyes intelligence alliance, the Quadrilateral Security Dialogue (Quad), and the AUKUS (Australia, UK, US) agreement.

In addition to the relationship with the United States, Australia brings to the table certain strengths in biotech R&D and potential for biomanufacturing.

Australia's ability to assist the US achieve its goals

Australia's strengths in biotechnology are centred around its research and clinical trial capabilities. Excellent research facilities with world-renowned scientists, coupled with a flexible regulatory landscape have helped pave the way for biotechnology innovation.

Renowned research capabilities

Health and medical research remains one of Australia's strongest research areas, with over 60 percent of research outputs ranked as 'above' or 'well above world standard'. The Medical Research Future Fund (MRFF) is the main body for Australian medical research along with investments through National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC). Together, these bodies support scientific research and lay the foundation for the biotechnology industry in the country.

Notably, Australian leading universities and research institutes have strong capabilities in oncology, coinciding with the dominance of this area in Australian listed companies.

World-class clinical trials capabilities

Australia has unique strengths in undertaking clinical trials to test the efficacy and safety of medical products. Pharmaceutical, biotechnology and medical device companies commence around 1,000 new clinical trials each year, representing approximately A$1 billion in investments. The country's exceptional clinical trial researchers, a diverse patient pool, skilled workforce, English-speaking population, availability of secure and advanced infrastructure, a seasonal difference to northern hemisphere markets, a trusted regulatory system, and advanced digital capabilities also make Australia an ideal location for high-quality clinical trials.

Since 2017, Australia has boosted its competitive position in early-stage clinical trials (Phase I and Phase II) and oncology, pneumology, neurology, and ophthalmology trials – many of which overlap with the areas of high demand by US multinationals, while retaining its share of late-stage trials (Phase III and Phase IV).

Growing biotechnology industry and gateway to Asia

The number of Australian biotechnology enterprises rose by 66 percent from 487 in 2008 to 810 in 2022, with the workforce increasing by 51 percent. Australia's strength lies in the human health sector segment, which generates more than half of Australia's biotechnology revenue. The pharmaceutical manufacturing industry was valued at A$12.7 billion, and about 43 percent of its revenue was generated from exports in 2020–21, showcasing the industry's global nature.

Australia's geographical location and established trade agreements in the Asia-Pacific region put the country in a favourable position to emerge as a significant supplier of biotechnology products and processes. This geographical advantage proves especially beneficial for exports of food and medical products, which often demand cold chain distribution.

Growing investments in manufacturing and Australia's closeness to feedstock

The Australian Government is making significant investments into research commercialisation and growing the domestic manufacturing capability including the A$501 million Biomedical Translation Fund, A$1.3 billion Modern Manufacturing Initiative, A$2.2 billion over 11 years for the University Research Commercialisation package, and agreement with the Victorian Government and global mRNA company Moderna to establish a new sovereign vaccine manufacturing facility in Australia.

Carbon-based feedstocks are the main raw material and often the most substantial expense in biomanufacturing. Australia is a major producer and exporter of sugar, a highly cost-effective and efficient feedstock for biomanufacturing. Additionally, Australia generates substantial quantities of lignocellulosic biomass from agricultural waste, which could serve as a more sustainable feedstock for biomanufacturing, provided satisfactory fermentation efficiencies can be attained.

Moreover, overseas industry stakeholders have recognised that Australia's highly skilled workforce, shared cultural norms, and English-speaking business environment make it an appealing choice for potential collaborators and as a location for setting up new manufacturing facilities in the Asia-Pacific region.

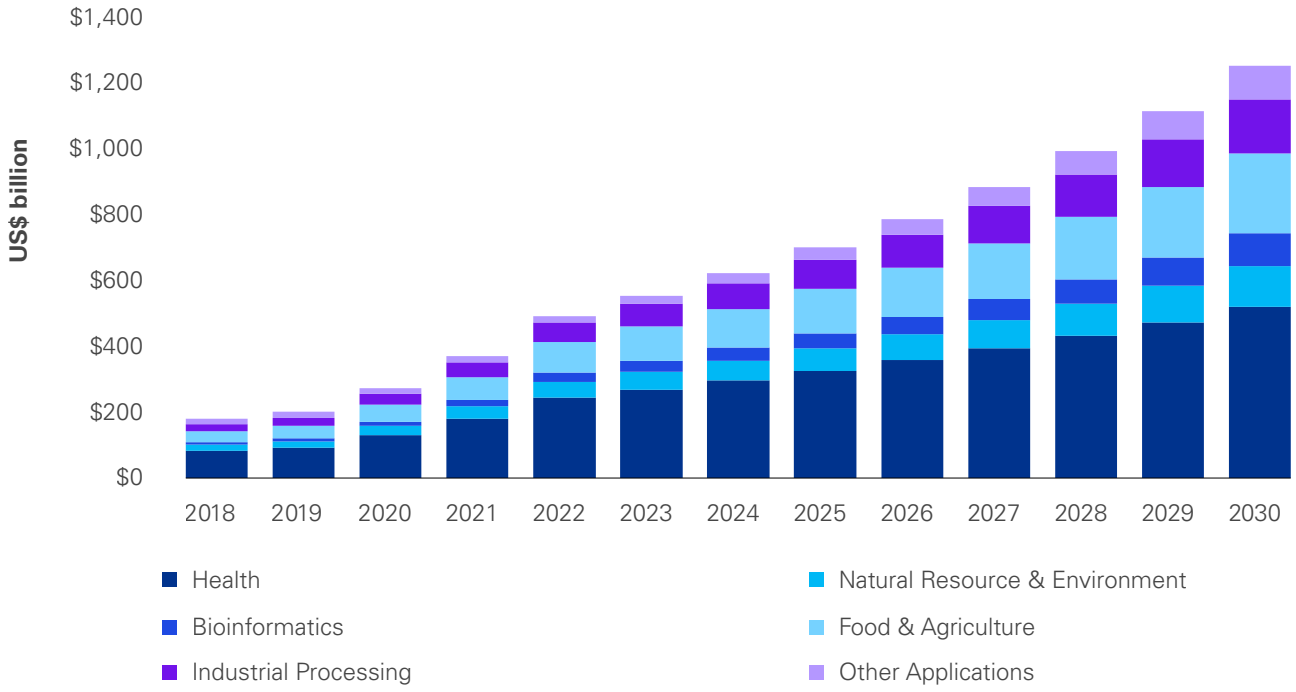
Size of the US biotechnology market

The US biotechnology industry is anticipated to witness robust growth towards 2030, with revenue expanding at a compounded annual rate of 12.4 percent. Total industry revenue is projected to grow from US$491 billion in 2022 to US$1,250 billion in 2030.

Health biotechnology is expected to remain the largest revenue generating segment and projected to grow by 9.9 percent on average each year towards 2030, supported by the development of novel therapeutic products. Its growth is bolstered by the increase in R&D in the biopharmaceutical industry; the increased prevalence of cancer, infectious diseases, and genetic disorders; growing healthcare expenditure on supporting the development of effective precision medicine; and the rise in biologics FDA approvals, especially in cancer therapy.

The **food and agricultural biotechnology** segment is expected to grow at a compounded annual rate of 12.7 percent over the forecast period, driven by the potential for improved seed varieties and enhanced rural connectivity through biotechnology applications in food production.

US BIOTECHNOLOGY MARKET ESTIMATES AND FORECASTS, BY APPLICATION, 2018–2030



Source: Grand View Research (2022)

In the **natural resources and environment** segment, substantial investments in green energy and biotechnology are poised to enhance the segment revenue in the post-Covid world. Similarly, the application of biotechnology in **industrial processing** is set to address the growing demand for sustainable energy sources and innovative materials.

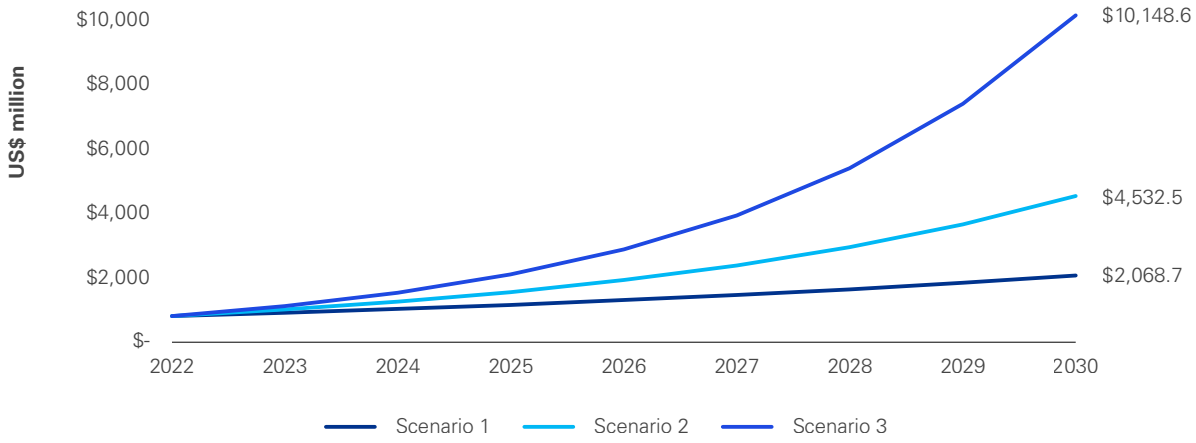
Bioinformatics is projected to grow at 17.4 percent each year on average over the forecast period. The expanding applications of artificial intelligence in disease diagnosis and drug discovery present promising opportunities, with research and government initiatives anticipated to contribute significantly to the segment growth.

Potential uplift in Australian exports to the United States

We have extrapolated three scenarios to estimate the benefit of an uplift in trade between the United States and Australia in the biotechnology industry from 2022 to 2030.

- In the first scenario, an average annual growth rate is calculated by assuming Australia maintains its historical share of trade to the rapidly growing US biotechnology industry.
- In the second scenario, we assume the value of exports from Australia from 2022 to 2030 grows at a historical rate after the COVID-19 disruptions.
- Scenario three assumes Australia can increase its share of trade to the United States by assuming Australia is able to maintain its strong historical growth before COVID-19.

SCENARIOS FOR INCREASING TRADE BETWEEN THE UNITED STATES AND AUSTRALIA



Source: KPMG analysis, US Census Bureau, Grand View Research

TABLE 2: INCREMENTAL CAPITAL STOCK AND LABOUR FORCE REQUIRED TO MEET TRADE-UPLIFT SCENARIOS, 2030

	CAPITAL STOCK (US$B, 2022)	FTE ('000)
Scenario 1: business as usual	2.3	6.9
Scenario 2: medium case	5.0	15.1
Scenario 3: accelerated	11.2	33.8

Source: KPMG analysis

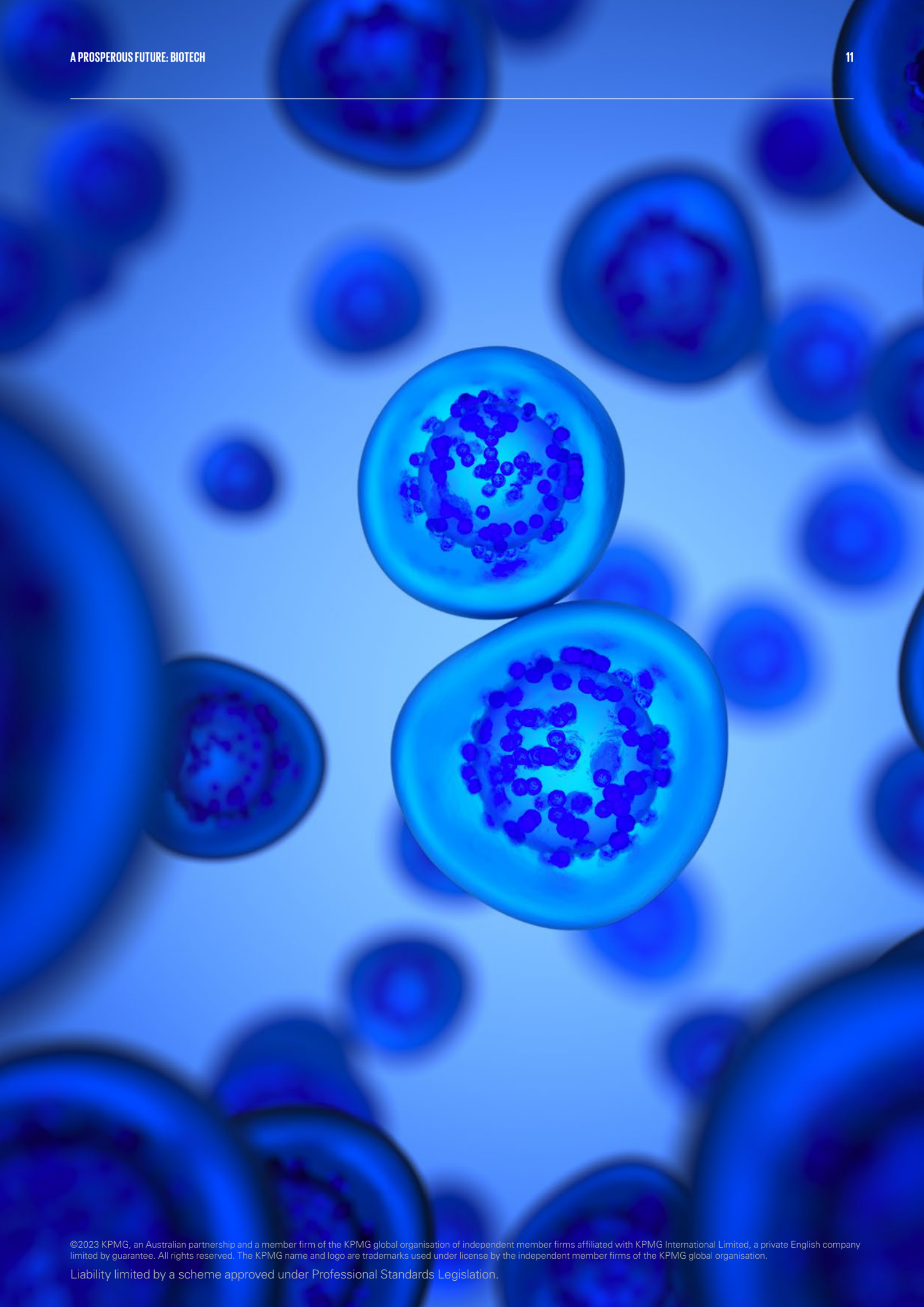
Getting this right could be a game changer for Australia. By the end of the decade, achieving accelerated growth could directly result in up to **US$10 billion in exports to the United States**, as well as **US$11.2 billion in incremental capital investment** and nearly **34,000 specialised, high-paid jobs associated with this trade uplift with the United States**. This does not include additional indirect economic benefits.

Achieving this depends on both industry and government working cooperatively to maximise the opportunities that will come with even stronger defence and security relationships that will arise under the AUKUS pact, as well as leveraging the successful Australia–US Free Trade Agreement.

Advice for Australian businesses expanding to the US market

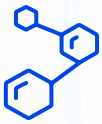
For the private sector to take advantage of this increased focus, the report identifies several key factors for success, including:

- Australian firms need to validate if a market exists in the United States early during the development of their products to avoid wasting resources. As the US market is very competitive, it is crucial to differentiate your products to stand out.
- Reimbursement opportunities help de-risk the development of a new technology. It is important for biotech start-ups to have a deep understanding of the reimbursement landscape, so that executives can plan financials with more precision and clarity of the end product.
- Building a global network of US pharmaceutical and biotechnology multinationals can lead to future partnerships and opportunities. Australian firms should also leverage introductions and spend time in the US market.
- Building partnerships with US multinationals requires understanding their needs. Researching their strategies, market segments, gaps, and areas they are interested in will help Australian firms bring solutions to the right problems.
- Australia can leverage its strength in R&D, clinical stage, and early product development to attract the US multinationals and expand its clinical trials sector.
- Fostering collaboration between research and industry can boost commercialisation for the research sector and help small companies access to expertise beyond their employee pool.



Glossary of terms

Biotechnology



Biotechnology is the application of biological processes for industrial and other purposes, especially the genetic manipulation of microorganisms to produce antibiotics, vaccines, hormones, agricultural resources, and products that advance health, commercial and production capabilities, and public safety.

R&D

Research and development

FDA

The United States Food and Drug Administration

Contents

Introduction

The desire to live better tomorrow than today is rapidly driving demand for solutions from emerging technology such as biotechnology.

As outlined in KPMG's 2021 introductory report, *A Prosperous Future: Key industries for Australia/US collaboration*, in consultation the Australian Department of Foreign Affairs and Trade, and the US Embassy in Australia, AmCham and KPMG identified six emerging industries that will both shape the living standards of our citizens and drive the strategic competition between states: artificial intelligence, the digital economy, quantum science, biotechnology, clean energy, and space technology.

KPMG released *A Prosperous Future: Emerging Tech*, the first report of the series in September 2022, *A Prosperous Future: Economic opportunities in the space industry*, the second report in April 2023, and *A Prosperous Future: Clean energy*, the third report in July 2023. These three reports explored opportunities for US and Australian technology partnerships in artificial intelligence, quantum science, the digital economy, space technology, and clean energy.

This report explores the last of the identified sectors, the biotechnology industry. The pace and scale of change in our world is immense. An ageing population, increased prevalence of chronic disease, the threat of climate change and the advancement of technology are factors rapidly driving demand for solutions from the industry. In the context of global economic uncertainty and vast technological change, the industry sector is likely to play a leading role in ensuring the prosperity and security for current and future generations. As such, it will become fundamentally important in global trade, investment, and broader economic development.

Similar to our previous reports, this report explores the industry's current state in the United States and Australia. This includes market size estimates, key companies, start-ups, how the technology has been adopted by various end-use industries, and a supply chain analysis.

The outlook for the industry and its potential impact are also discussed. To identify potential opportunities for Australia to participate in the US supply chain, Australia's strengths in the industry are assessed against the goals for biotechnology in the United States.

To understand the export potential for Australian businesses in the sector, AmCham and KPMG consulted with biotechnology companies who have succeeded in generating new business in the US and Australian markets.

The report also examines the elements in assessing the future export growth potential for Australia in the biotechnology industry. Leveraging Australia's strengths and aligning them to the opportunities in the United States has the potential for a significant uplift in the already strong trade relationship between Australia and the United States.

1.1

Purpose of study

AmCham and KPMG have undertaken a detailed assessment of the current and future growth potential of the biotechnology industry. The purpose of this study was to gain an understanding of how trade and investment between Australia and the United States in the sector could enable better outcomes for the two countries as opposed to 'going it alone'.

1.2

Introduction to AmCham and KPMG

The American Chamber of Commerce in Australia (AmCham) was founded in 1961 and now has offices in Sydney, Melbourne, Perth, Brisbane, Adelaide and Canberra. AmCham aids US and Australian companies by promoting trade, commerce and investment to and from Australia.

KPMG is a global network of professional services firms providing Audit, Tax and Advisory services. We operate in 146 countries and territories and in FY20 had close to 227,000 people working in member firms around the world. In Australia, KPMG has a long tradition of professionalism and integrity, combined with our dynamic approach to advising clients in a digital-driven world. We have approximately 8,800 people, including over 600 partners, with offices around the country.

1.3

Industry definition

Biotechnology is the application of biological processes for industrial and other purposes, especially the genetic manipulation of microorganisms to produce antibiotics, vaccines, hormones, agricultural resources, and products that advance health, commercial and production capabilities, and public safety.[1]

Biotechnology has many applications across the health, agriculture, marine, industrial, and environmental sectors. Applications of biotechnology are commonly categorised using a colour coding system consisting of three major colours: red, green, and white. These colours are used to describe the use of biotechnology in human health, agriculture, and industrial sectors, respectively. There are also other segments within the biotechnology industry.[2,3,4]

COLOUR CODE	OVERVIEW	DEFINITION
Red	Medicine and human health	Involves the production of vaccines and antibiotics, discovery of new drugs, regenerative therapies, construction of artificial organs and new diagnostics. It also includes genetic engineering to cure diseases through genetic manipulation for medical applications.
Green	Agriculture	Includes research into plant and animal genomics and health. Applications include selective breeding, genetic engineering, molecular markers, molecular diagnostics, vaccines, and tissue culture, to alter living organisms, or parts of organisms, to improve plants or microorganisms for specific agricultural uses.
White	Industrial	Consists of the application of scientific tools to develop environmentally efficient solutions through the use of microbes and enzymes. Compared to traditional manufacturing and chemical processes, enzyme catalysed processes are generally more efficient, leading to less industrial pollution and better resource conservation.
Other	Animal health technologies	Includes tools for improving farm animal reproduction programs, including genetic mapping methods to identify both disease-resistant animals and certain genes related to health weaknesses.
	Bioinformatics	Involves the collection, organisation, and analysis of biological information, particularly genomics and molecular modelling. This includes modelling of DNA, RNA, protein sequencing and other molecular databases for humans and plants.

Source: Richardson, A. (2022), Department of Health. (2022) and Kafarski, P. (2012)

1.4

Report structure

The remainder of this report has been organised into the following sections:

- This section (Section 1) has defined the purpose and the structure of this report, as well as the industry definition
- Section 2 describes the context on the geopolitical landscape
- Section 3 explores the biotechnology industry in the US and Australia
- Section 4 assesses the future export growth potential for Australia in the industry and provides advice for Australian businesses expanding to the US market
- Appendix A describes the methodology for estimating market size
- Appendix B presents supplementary information on the industry
- Appendix C lists a sample of US businesses in the industry
- Appendix D provides a bibliography list of references.

Geopolitical landscape

2

The current geopolitical environment is increasingly unpredictable and competitive. The World Economic Forum has declared a 'polycrisis',[5] consisting of multiple intertwined global risks. Geopolitics is a major factor in many of these risks, including geoeconomic confrontation, natural resource crises, and the failure to mitigate climate change. In response to this unpredictable and contested geopolitical outlook, countries are increasingly concerned about protecting and increasing their strategic and economic advantages over others, especially those considered to be rivals. Closer geopolitical alliances are developing as like-minded nations seek to combine forces against common adversaries. Increasing competition between these alliances is contributing to growing mutual mistrust.[6]

Biotechnology is a key domain of competition in this volatile environment. Nation-states in this mistrustful context understand the impact that some subsectors of biotech could have on the global balance of economic and military power, and the scope biotechnology provides for shoring up national security. Indeed, the Brookings Institution argues that biotech has the potential to "utterly transform geopolitics, economics and society in the 21st century".[7] This is because biotech creates the possibility for substantial relative and absolute gains in areas that build national security and support national interests across a very wide spectrum. Biotech innovations in agricultural productivity can enhance food security, and breakthroughs in medicine can boost the health of citizens. Novel biotech solutions to energy production will strengthen energy security. Biotechnology advances can also provide offensive and defensive biological weapons capabilities. Biotech can also advance DNA sequencing and databases, develop useful industrial enzymes and provide solutions to environmental challenges. In this volatile geopolitical context where an increasing number of areas are considered critical for national security, these are all examples of how being at the forefront of biotechnology can confer geopolitical advantage.

Biotechnology has the potential to create enormous benefits in the world but requires collaboration to fulfill that potential.[8] For example, when countries set policies that promote international collaboration in the biotech field of regenerative medicine, the whole field advances more rapidly.[9] Open global collaboration can also help to manage the risks that come with biotech discoveries – for example, by establishing shared safety standards and non-proliferation agreements.

On the flipside, a lack of cooperation impedes innovation and progress in biotechnology,[10] undermines its potential to create positives in the world, and indeed, increases the risks of creating serious harm. A study published by the Carnegie Endowment for International Peace in 2020 found that biotech competition and a resulting lack of shared global standards raises the risks of accidental and deliberate misuse of biotechnology, including bioweapons.[11]

The international response to the COVID-19 pandemic offers a clear illustration of how geopolitical dynamics shape the way countries collaborate, or compete, on a major global health and biotech challenge. While some countries did work together on vaccine development and supply for global health, for the most part, cooperation on development and distribution tended to be among wealthy 'like-minded' states,[i] following and deepening the lines of geopolitical competition.[12] Driven by what was termed 'vaccine nationalism', some countries chose to reject the import and use of vaccines developed overseas, a decision broadly understood to be to maintain national pride and protect the domestic biotechnology sector.[13] Embroiled in great power rivalry, major actors failed to provide the necessary leadership to drive global collaboration. International bodies like the World Health Organisation were unable to foster cooperation because of member states' conflicting priorities.[14] How geopolitical competition undermined biotech cooperation arguably prolonged the duration of the pandemic and disproportionately impacted countries in the Global South.[15] This in turn further ingrained mistrust and exacerbated fragmentation of the international system.

[i] Examples include the *Australia-Canada-Singapore-Switzerland-United Kingdom (Access) Consortium | Therapeutic Goods Administration (TGA)*, and *Joint EU-US action in the global fight against COVID-19 and towards a sustainable recovery | EEAS (europa.eu)*.

Where biotech discoveries are shared with other nations, it is more likely to be with like-minded ones – a tendency related to the 'friendshoring' trend that has been observed in many sectors. Perceptions of geopolitical trustworthiness and reliability are becoming an increasingly important enabler of cooperative biotech research.

As the Covid example demonstrates, international biotech cooperation is particularly difficult between actual and potential geopolitical rivals in a world becoming increasingly fragmented by mistrust and competition. Countries are concerned that such cooperation could erode their strategic and economic advantages. For example, when biotech breakthroughs can improve agricultural productivity, a nation-state may be inclined to keep these advances for use by its own national industries, or at least ensure that its domestic firms retain ownership of associated intellectual property. Where biotech discoveries are shared with other nations, it is more likely to be with like-minded ones – a tendency related to the 'friendshoring'[16] trend that has been observed in many sectors. Perceptions of geopolitical trustworthiness and reliability are becoming an increasingly important enabler of cooperative biotech research. When discoveries could impact national security, the stakes are even higher. Governments will increasingly strive to ensure that any biotech breakthroughs in the defence domain are only available to their domestic defence industries – and perhaps to close allies. And many biotech subsectors have 'dual-use' – civil and military – applications. In an environment of geopolitical volatility, nations are increasingly likely to judge that sharing dual-use biotech discoveries with potential rivals and adversaries is not in the national interest. The result is more competition and less collaboration in global biotech research.

Despite the potential for biotechnology to help solve many of the problems our planet faces, geopolitical mistrust means that biotechnology developments are being stymied. In 2016, the World Economic Forum predicted that biotech could deliver solutions to four of the world's most intractable problems: feeding the next billion, tackling disease, cleaning up pollution, and harnessing scarce natural resources.[17] Progress on these problems since that time has been patchy, at best. The geopolitically motivated tendency towards competition rather than cooperation is likely to be a significant reason for this slow and uneven progress. And many of the other obstacles – technical, ethical, and regulatory – are also exacerbated by geopolitical competition. There are many negative outcomes that flow from the global 'polycrisis' we now find ourselves in, but slower progress on biotech solutions may prove to be one of the most consequential – because of the acute and growing nature of the problems it is hoped that biotech could address. In the years ahead, businesses may find opportunities in a wide range of biotech subsectors, but will have to manage the shifts and developments in how countries cooperate – or do not – on biotech at the global level.

US and Australian biotechnology

3.1

US biotechnology industry

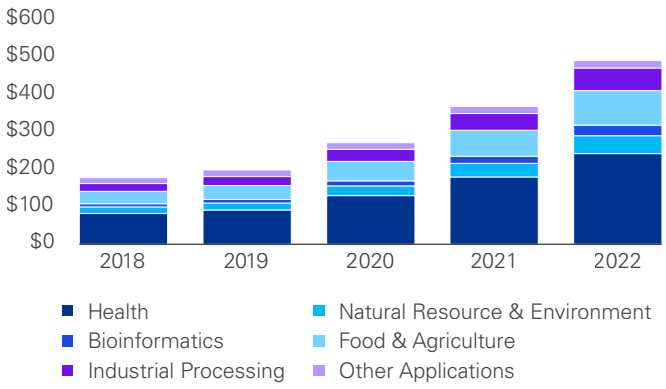
3.1.1 US biotechnology market by application

Health

Health-related applications dominate the US biotechnology market, capturing 49 percent of the industry revenue in 2022, driven by increased demand for advanced technologies and products. Over the past decade, this segment has witnessed rapid increase, with growing influx of large-scale investments and discoveries in genomics, molecular biology, cellular and tissue engineering, bio-imaging and new drug discovery, and delivery techniques bringing opportunities to improve diagnostic capabilities and expanding therapeutic options.

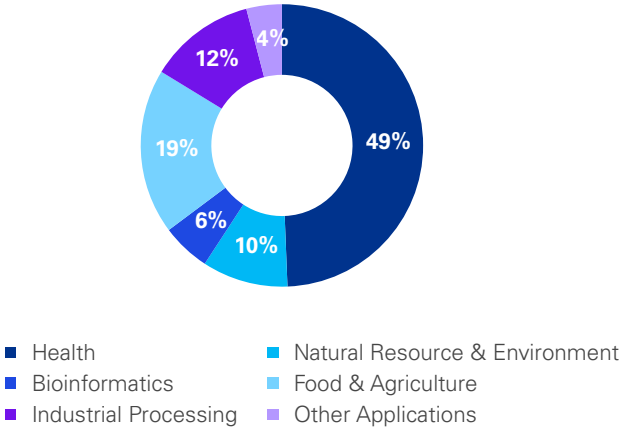
The COVID-19 pandemic has accelerated activities by many biotechnology and pharmaceutical manufacturing companies who rushed to develop vaccines and therapeutics, triggering massive investment into the field. In 2022, strong investment settled, and the monetary tightening in the latter half of the year led investors to move away from early-stage companies into established companies.[18]

FIGURE 2: INDUSTRY REVENUE BETWEEN 2018 AND 2022, BY END-USE INDUSTRY (US$ BILLION)



Source: Grand View Research (2022)

FIGURE 3: INDUSTRY REVENUE IN 2022, BY END-USE INDUSTRY



Source: Grand View Research (2022)

Natural resources and environment

In recent years, there has been a significant surge in the use of biotechnology tools for environmental applications. This growth is driven by technological advancements and discoveries, particularly in harnessing the beneficial properties of viruses and bacteria for environmental conservation to combat climate change and global warming. Challenges such as rising waste treatment costs, strict environmental regulations, and resource scarcity, especially in water and nutrients, are propelling the development of bioprocessing technologies for efficient wastewater treatment. These factors are expected to fuel the expansion of this sector in the coming years, with key trends including bioremediation, microbial enhanced oil recovery (MEOR), bio-electrochemical systems, industrial waste treatment, phytoremediation, biofuels, chromium phytotoxicity management, enhanced biological phosphorous removal (EBPR), and biosensors.

Bioinformatics

While not comprising a substantial share of industry revenue, bioinformatics has grown the fastest in recent years, with revenue increasing at a compounded annual rate of 36.5 percent from 2018 to 2022. This has been driven by the contribution from various areas such as pharmaceuticals, mathematics, physics, and the advent of emerging areas such as proteomics and genomics. The sector has seen a significant increase in data flow due to heightened R&D activities in biotechnology, expanding the scope of bioinformatics applications. These applications range from bioresource conservation, biology prospecting to product evaluation, meeting the outsourcing needs of the pharmaceutical and biotechnology industries and managing complex data for national programs.

Precision medicine, or personalised medicine – an approach that optimises therapeutics by considering personal factors such as individual gene variability, clinical and molecular information, environment, and lifestyle – has also been advanced due to increasing amounts of available data.[19]

Cloud computing has played a pivotal role in bioinformatics, offering scalable computing and storage, data sharing, and on-demand access to resources and applications, which is expected to further boost the adoption of bioinformatics tools in life sciences applications. Large-scale endeavours such as proteomics and genomics rely on bioinformatics for handling extensive datasets, with the introduction of next-generation sequencing technologies contributing to the segment growth.

Several companies, including 10x Genomics, Pacific Biosciences, and Nanopore technologies, have launched longer read sequences based on bioinformatics tools. Market players are also actively developing cloud-based bioinformatics solutions – for example, Illumina Inc introduced Illumina Connected Analytics (ICA) in January 2021, providing a comprehensive cloud-based data platform for large volumes of multiomic data.

Bioinformatics tools are increasingly finding applications beyond healthcare, extending to industries such as food and beverages, thereby contributing to the expansion of this segment.

Food and agriculture

The use of biotechnology tools in agriculture has seen rapid growth, encompassing molecular breeding, genetic engineering, molecular diagnostics, micropropagation, and conventional breeding. The emergence of novel genetic resources and genome modification tools is expected to enhance our understanding of plant biology. Additionally, the global acceptance of genetically modified (GM) crops, particularly insect-resistant and herbicide-tolerant varieties, has increased, contributing to the expansion of agricultural biotechnology.

Industrial processing

The application of biotechnology in industrial processing consists of the production of enzymes to create more sustainable processing and production of chemical products, materials and fields.[20] This is still relatively new but has the potential of offering a high return on investment for the US economy, stemming predominantly from the segment's ability to produce less costly and more environmentally friendly products.[21]

Organisations such as BioMADE (Bioindustrial Manufacturing and Design Ecosystem) actively work to establish a sustainable domestic bio-industrial manufacturing ecosystem, aiming to advance technology, boost competitiveness, expand the biomanufacturing workforce, and reduce investment risks in infrastructure.

With growing demand for industrial processing, initiatives such as the US Department of Defense's Synthetic Biology Manufacturing Innovation Institute (SynBio MII) are set to drive the growth of this segment.

Other applications

This segment encompasses biotechnology applications in medical devices, Contract Research Organisations (CROs), bioelectronics, Contract Manufacturing Organisations (CMOs), cosmetics, and digital health. It is poised for substantial growth due to rising demand for advanced medical devices, the emergence of bioelectronics, CRO/CMO facility expansions, and increasing awareness of digital health applications. As the demand for advanced therapies surges, drug developers are faced with the challenges of manufacturing capacity, leading to higher needs for contract research and manufacturing organisations.

Additionally, the global acceptance of genetically modified (GM) crops, particularly insect-resistant and herbicide-tolerant varieties, has increased, contributing to the expansion of agricultural biotechnology.

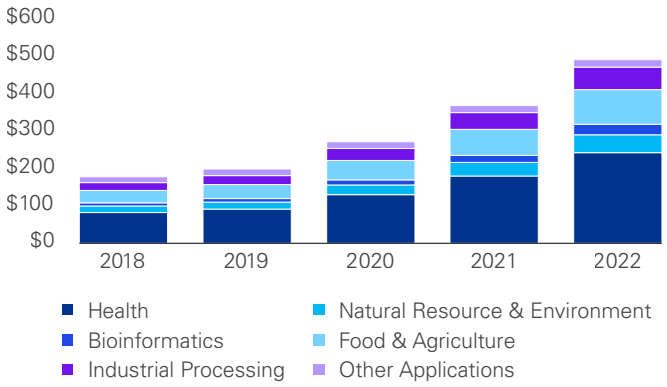
3.1.2 US biotechnology market by technology

The DNA sequencing segment captured a large share of industry revenue in 2022 and exhibited the strongest growth from 2018 to 2022.

The availability of government and private funding for development, presence of advanced technology framework to support rapid detection of chronic diseases, and high healthcare spending are some of the contributors to the dominance of DNA sequencing.

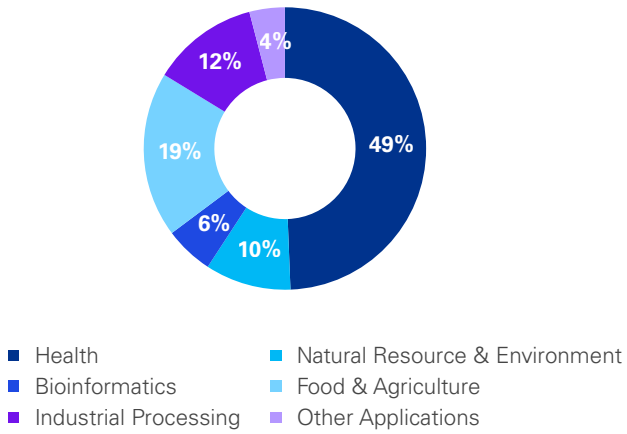
Increases in R&D investments, including the growing popularity of precision medicine, and the number of mature and emerging players investing in this area are also expected to drive the segment growth.

FIGURE 4: INDUSTRY REVENUE, BY TECHNOLOGY BETWEEN 2018 AND 2022 (US$ BILLION)



Source: Grand View Research (2022)

FIGURE 5: MARKET VALUE BREAKDOWN IN 2022, BY TECHNOLOGY



Source: Grand View Research (2022)

Nanobiotechnology has seen the second-strongest growth over recent years, following DNA sequencing. The increasing preference among physicians for nanomaterial-based products is driving substantial revenue growth, as nanotechnology-enabled medical technologies have a significant impact on disease detection, prevention, and treatment. Regulatory approvals for nanomedicine products have increased substantially since 1980, with 50 nanomedicines gaining FDA approval by 2021, further bolstering market prospects.

Nanotechnology is becoming a promising avenue for drug discovery and delivery, with researchers increasingly utilising nanobiotechnology, including nanocrystals and various nanoparticles. This technology also serves as a potent nanoplatform for effective therapeutics and diagnostics.

3.1.3 US biotechnology industry's supply chain

To understand the nature of the biotechnology industry in the United States, KPMG has investigated which countries and goods are involved in the industry's supply chain, including the number of shipments and values of imports.

Shipment of origin

Between 2017 and 2022, there were almost 140,000 recorded shipments of physical goods to US businesses operating within standard industry classifications (SIC) most relevant to the biotechnology industry. For more detail on SIC codes, please see Appendix B. This data includes imports for both machinery and equipment used by the biotechnology industry, as well as biotechnology products.

China ranks first in terms of shipments to US businesses, contributing 29.7 percent of total, followed by Germany (8.9 percent) and Hong Kong (6.5 percent). When combined, these countries export close to half (45.1 percent) of all biotechnology-related exports to the United States. Brazil, Japan and South Korea are also major exporters to US businesses, making up 17.2 percent of total shipments.

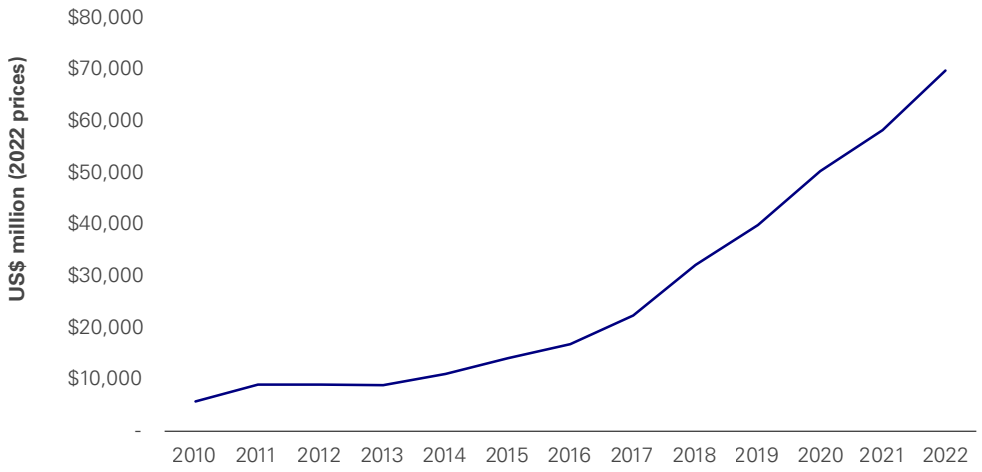
Australia only ranks 35th on this list and contributes 0.1 percent, given Australia has limited capability in the manufacturing of machinery and equipment used in biotechnology. However, the country does well in exporting biotechnology products as shown below.

Values of biotechnology product imports

Imports of biotechnology products to the United States have a focus on advances in genetics applied to the development of new drugs, hormones, and other therapeutic items.

The US biotechnology product imports in real terms (2022 prices) have grown steadily at a compounded annual growth rate of 23 percent from US$5.8 billion in 2010 to US$69.8 billion in 2022.

FIGURE 6: BIOTECHNOLOGY IMPORTS BY THE UNITED STATES



Source: US Census Bureau (2023)

Note: Nominal trade values have been deflated using the US GDP implicit price deflator.

The top five biotechnology product imports by the United States in 2022 were:

Immunological products for retail sale (24.9 percent of total biotechnology imports)	Diagnostic reagents based on an antibody test (25 percent)	Vaccines for human medicine (12.7 percent)	Immunological products with monoclonal antibodies (11 percent)	Antisera and other blood fractions (8.6 percent)
24.9%	**25%**	**12.7%**	**11%**	**8.6%**

TABLE 3: VALUES OF BIOTECHNOLOGY PRODUCTS IMPORTED BY THE UNITED STATES IN 2022

IMPORTS	VALUE (US$ MILLION)
Immunological products for retail sale, nesoi (kg)	$20,533.0
Diagnostic reagents based on an antibody test (kg)	$17,462.5
Vaccines for human medicine, nesoi (kg)	$8,866.6
Immunological products with monoclonal antibodies, not for retail (kg)	$7,655.3
Antisera & other blood fractions (kg)	$6,012.2
Polypeptide, protein & glycoprotein hormones, nesoi (gm)	$5,306.6
Human blood; animal blood prepared for therapeutics, nesoi (kg)	$1,029.5
Immunological products, mixed, not for retail sale (kg)	$914.0
Monoclonal antibodies, unmixed, not retail sale (kg)	$856.3
Sugars, chemistry pure (exc. sucrose, lactose, etc.) nesoi (kg)	$262.1
Immunological products, unmixed, not retail sale (kg)	$208.9
Hormones, prostaglandins, etc. nesoi (gm)	$195.9
Vaccines, toxins, cultures of micro-organism etc. nes (kg)	$185.7
Cell cultures, whether or not modified, nesoi (kg)	$101.1
Zika diagnostic or lab reagents, including kits (kg)	$53.6
Cell therapy products (kg)	$52.4
Prostaglandins, thromboxanes & leukotrienes (gm)	$31.2
Progestins not of animal or vegetable origin, nesoi (gm)	$21.1
Progesterone not derived from animal or vegetable materials (gm)	$11.8
Estrogens of animal or vegetable origin (gm)	$10.0
Vaccines for veterinary medicine (kg) $9.6	$9.6
Progestins of animal or vegetable origin, nesoi (kg)	$6.8
Estrogens not derived from animal or vegetable materials (gm)	$4.9
Somatotropin, its derivatives & structural analogues (gm)	$4.4
D-arabinose (kg)	$2.7
Malaria diagnostic test kits (kg)	$0.9
TOTAL	**$69,799.1**

Note: 'nesoi' stands for 'not elsewhere specified or included'.

Source: US Census Bureau (2023)

Ireland was the largest biotechnology product exporter to the United States, comprising 31 percent of total imports, followed by Germany (12.3 percent) and Belgium (11.5 percent). These top three exporters dominated more than 50 percent of total biotechnology product imports by the United States.

Ireland was the top exporter in four products, including immunological products with monoclonal antibodies (not for retail); diagnostic reagents based on an antibody test; polypeptide, protein, and glycoprotein hormones, nesoi; and cell therapy products.

Australia ranked 15th in the list of top exporters of biotechnology products (Table 4), contributing 1.2 percent, and was the third largest exporter of antisera and other blood fractions to the United States in 2022.

TABLE 4: TOP COUNTRIES EXPORTING BIOTECHNOLOGY PRODUCTS TO THE UNITED STATES IN 2022

RANK	EXPORTING COUNTRIES	VALUE (US$ MILLION)
1	Ireland	$21,649
2	Germany	$8,617
3	Belgium	$8,058
4	Switzerland	$4,336
5	Netherlands	$4,124
6	Japan	$3,704
7	South Korea	$2,741
8	Singapore	$2,651
9	United Kingdom	$2,542
10	Austria	$2,415
11	China	$1,948
12	Sweden	$1,279
13	Italy	$1,129
14	Spain	$974
15	Australia	$813

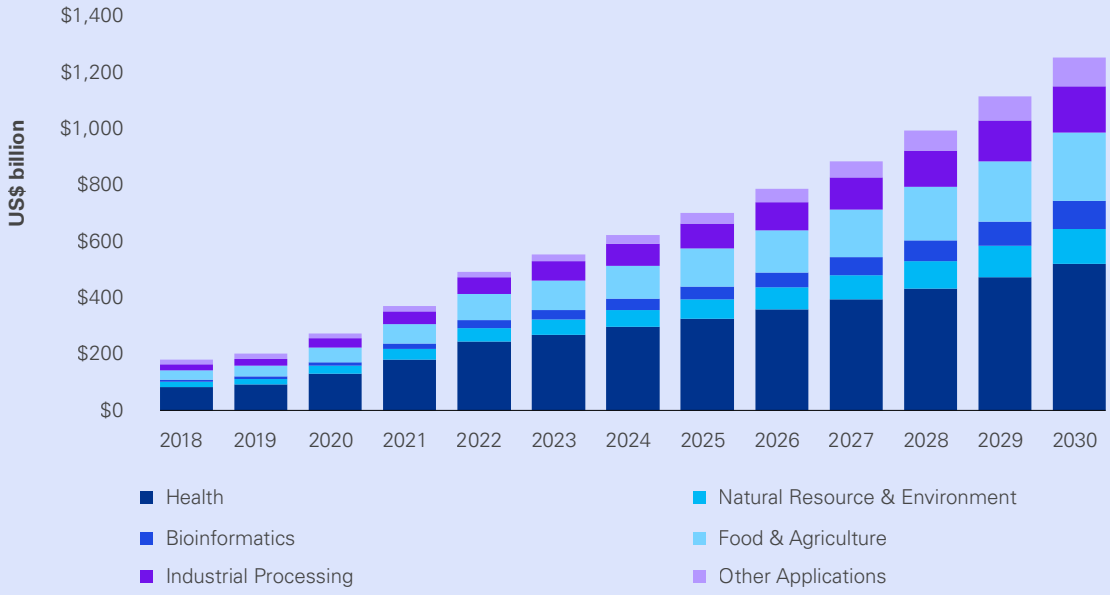
Source: US Census Bureau (2023)

3.1.4 Future potential of US biotechnology industry

Health biotechnology is expected to remain the largest revenue generating segment and projected to grow by 9.9 percent on average each year towards 2030, supported by the development of novel therapeutic products. Growth in the segment is bolstered by:

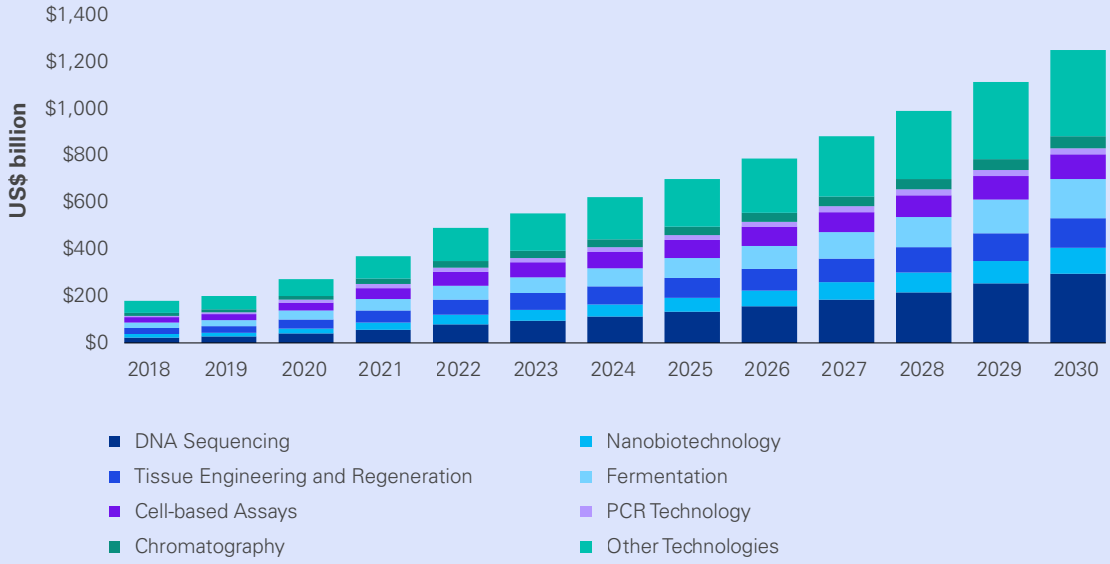
- the increase in R&D in the biopharmaceutical industry;
- the increased prevalence of cancer, infectious diseases, and genetic disorders, leading to more applications of biotechnology in diagnostics and treatment;
- growing healthcare expenditure on supporting the development of effective precision medicine; and
- the rise in biologics FDA approvals, especially in cancer therapy.

FIGURE 7: US BIOTECHNOLOGY MARKET ESTIMATES AND FORECAST, BY APPLICATION, 2018–2030



Source: Grand View Research (2022)

FIGURE 8: US BIOTECHNOLOGY MARKET ESTIMATES AND FORECAST, BY TECHNOLOGY, 2018–2030



Source: Grand View Research (2022)

The **food and agricultural biotechnology** segment is expected to grow at a compounded annual rate of 12.7 percent over the forecast period, driven by the potential for improved seed varieties and enhanced rural connectivity through biotechnology applications in food production. Genetic modification plays a central role in developing nutrient-enriched and high-yield crops. Higher awareness about biotechnology along with government-led initiatives – such as the Unified Website for US Biotechnology Regulation introduced in September 2020 by the EPA, USDA, and FDA, aimed at streamlining information on agricultural biotechnology products – are expected to further boost revenue growth.

In the **natural resources and environment** segment, substantial investments in green energy and biotechnology are poised to enhance the segment revenue in the post-Covid world.

Similarly, the application of biotechnology in **industrial processing** is set to address the growing demand for sustainable energy sources and innovative materials. The integration of biotechnology is anticipated to assist in developing scalable, sustainable, and cost-effective materials, contributing to the establishment of a circular net-zero carbon economy.

Bioinformatics is projected to grow at 17.4 percent each year on average over the forecast period. The expanding applications of artificial intelligence (AI) in disease diagnosis and drug discovery present promising opportunities, with research and government initiatives anticipated to contribute significantly to the segment growth.

Overall, the US biotechnology industry is anticipated to witness robust growth over the next decade, with revenue expanding at a compounded annual rate of 12.4 percent. Total industry revenue is projected to grow from US$491 billion in 2022 to US$1,250 billion in 2030.

Nonetheless, headwinds remain for the industry growth, including a typically slow and expensive regulatory approval process that creates barriers to developing and commercialising new technologies.[22] In addition, biotechnology companies rely on patents, which grant 20 years of protection, to safeguard their products and recoup substantial R&D costs. Without patent protection, there would be little incentive for biotech operators to invest in product development. Regulatory barriers affecting patents can impede biotech progress.[23]

3.2

Australia's capacity to participate in the value chain

3.2.1 The Australian biotechnology industry

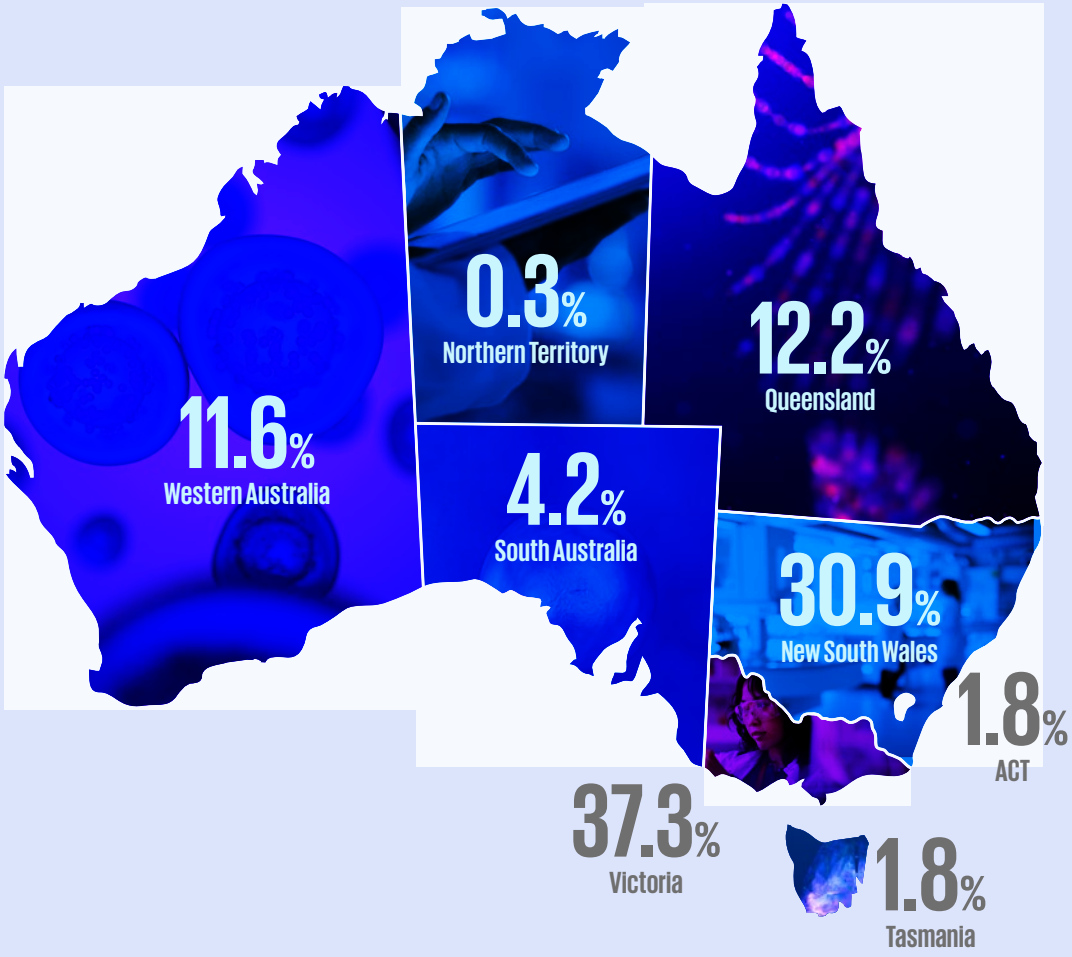
Biotechnology is a current and emerging technology and promises to have significant impact on the nation's economic prosperity, national security, and social cohesion.[24] The rise of the biotechnology sector has brought about new and enhanced treatments that are being used to better the lives of Australians.

In 2022, the biotechnology ecosystem is estimated to generate approximately A$10.3 billion in revenue, with over 810 enterprises and a workforce of more than 20,600 people.[25] Organisations in the sector range from research institutions, start-ups, to more established companies, such as CSL, that operate domestically and internationally.[26]

Australia has a strong global standing in health and medical research. The nation has an impressive history of academic accomplishments and scientific discoveries which have been awarded several Nobel Prizes in the fields of Medicine and Physiology.[27,28]

A 2022 survey of national R&D-driven health biotech sectors ranked Australia 5th in terms of research and translation, ranking them higher than countries such as United Kingdom in this category.[29] The sector's geographical distribution of these biotechnology organisations appear proportionate to the number of universities and research centres in a given state. Victoria leads the nation in the number of biotechnology establishments, followed by New South Wales and Queensland (Figure 8).

FIGURE 9: BIOTECHNOLOGY-RELATED ESTABLISHMENTS ACROSS AUSTRALIA



Source: Department of Health (2022)

3.2.2 Public investment in biotechnology in Australia

The Australian Government remains committed to developing the country's biotechnology capabilities. In its long-term strategic plan for Australian biotechnology, the Department of Health reported its commitment to create an ecosystem that promoted:[30]

- World-class research and innovation system supported by strong partnerships among academia, industry, health services, and consumers.
- A pipeline of innovative, high-quality biopharmaceuticals and medical technology products that attract global interest, while maintaining fit-for-purpose regulation.
- A globally recognised Australian medical products industry with the capability, capacity, and expertise to locally manufacture advanced and high-value medical products using sophisticated and safe processes.
- Access to national and international markets that facilitate product uptake and continuous cycles of product improvement.
- An ecosystem that supports high-quality research and its translation into commercial outcomes.

The Department of Health also announced the Australian Government's 10-year, A$6.3 billion, investment plan towards the Medical Research Future Fund (MRFF). The funding is intended to support research, innovation, and the commercialisation of research to further grow the nation's reputation as a global leader in medical research.

To achieve this, the investment was split into the following themes:[31]

- **A$1.4 billion** to support life-changing clinical trials, fund innovative treatments and advanced health care and medical technologies.
- **A$1.5 billion** to support large programs of work that facilitate collaboration between key researchers, health professionals and other stakeholders to tackle significant health challenges.
- **A$1.3 billion** to support domestic researchers by building their skills and capacity, support their research and assist them to develop and bring new research discoveries to the market.
- **A$2.1 billion** to convert research outcomes into practice by building the evidence base to support the adoption of best practice care in health care delivery.

In addition to funding towards R&D, the Australian Government is also making strategic investments into translating products into the commercial sphere and growing domestic advanced manufacturing capabilities in biotechnology. These include the A$501 million Biomedical Translation Fund, A$1.3 billion Modern Manufacturing Initiative, A$2.2 billion over 11 years for the University Research Commercialisation package, and agreement with the Victorian Government and global mRNA company Moderna to establish a new sovereign vaccine manufacturing facility in Australia.

3.2.3 Biotechnology products and services in Australia

The Australian Government's policy and funding programs have significantly contributed to the nation's strength in human health, agriculture, food production, industrial, and other key areas.[32] Table 5 below reports Australian biotechnology industry revenue in 2023 broken down by product and service segments.

TABLE 5: BIOTECHNOLOGY REVENUE (2023) BY PRODUCT AND SERVICE SEGMENT IN AUSTRALIA

SERVICE AREA	%	REVENUE IN 2023
Human health	53.7	A$5.8 billion
Agriculture	17.8	A$1.9 billion
Industrial	10.8	A$1.2 billion
Environmental and natural resource recovery	7	A$0.8 billion
Food production and processing	7	A$0.8 billion
Other services	3.7	A$0.4 billion

Source: IBISWorld (2023)

TABLE 6: BIOTECHNOLOGY APPLICATIONS BY SEGMENT IN AUSTRALIA

SECTOR	OVERVIEW
Human health 	Over half (53.7 percent) of the revenue generated by Australia's biotechnology is attributed to the human health sector. In 2023, the sector generated A$5.8 billion. There are a range of biotechnology applications in this sector, including, biologics and biosimilars, personalised medicine, genomics, medicinal cannabis, and regenerative medicines.[33] Australia is regarded as one of the best places globally to conduct clinical trials. Clinical trials form the backbone of R&D in the life sciences and facilitate the development of therapies, cures, medical devices, and diagnostics for patients in Australia and around the world.[34] The COVID-19 pandemic served as an example of the importance of the sector, with many industry players on the frontline of COVID-19 research, prevention and treatment. In August 2022, the Victorian government announced that an mRNA vaccine manufacturing facility was to be built at Monash University to assist in the national protection against future pandemics.[35]
Agriculture 	The agriculture sector is tipped to be one of fastest growing areas for biotechnology use in the future. The sector currently contributes 17.8 percent of Australia's overall biotechnology revenue. In 2023, the sector generated A$1.9 billion. Biotechnology applications in this sector are diverse, including selective breeding, genetic engineering, molecular markers and biofertilisers. Biotechnology is currently being used to produce GM crops, increasing farm productivity and output. For example, GM cotton accounts for approximately 99 percent of all Australian grown cotton. Aquaculture can also involve significant biotechnology applications. These applications aim to produce larger fish with less feed, improve spawning processes, and reduce the time needed for fish to gain market weight.
Industrial 	Industrial applications currently contribute 10.8 percent of Australia's overall biotechnology revenue, generating A$1.2 billion in 2022. Biotechnology is actively being used to develop more sustainable products and processes relative to traditional chemical processes. These processes include developing new biomaterials, biomasses, and biofuels, and using enzymes in chemical processes.
Environmental and natural resource recovery 	Applications in the environmental and natural resource recovery sector currently contribute 7 percent of Australia's overall biotechnology revenue, generating A$800 million in 2023. Biotechnology is being used to investigate greater manufacturing efficiency to lower production costs, industrial pollution, and improve resource conservation.
Food production and processing 	The food production and processing sector currently contributes 7 percent of Australia's overall biotechnology revenue, generating A$800 million in 2023. Biotechnological processes apply natural or engineered microbes to other products to extend shelf life, enhance nutritional characteristics, and preserve or create foods or industrial products. Firms are developing quality-enhanced foods through biotechnology research, including foods with lower saturated fats, increased vitamin content, and improved flavour and shelf life.

Source: IBISWorld (2022)

3.3

Biotechnology collaboration and trade opportunities with the United States

US goals for biotechnology and biomanufacturing

The White House has released its goals for the US biotechnology and biomanufacturing sector, outlining how the United States will harness R&D to further societal goals for the next two decades. Its key objectives, grouped into five key biotechnology applications, are:

- **Climate change solutions:** In 20 years, demonstrate and deploy cost-effective and sustainable routes to convert bio-based feedstocks into recyclable-by-design polymers that can displace more than 90 percent of today's plastics and other commercial polymers at scale.
- **Food and agriculture innovation:** By 2030, reduce methane emissions from agriculture, including by increasing biogas capture and utilisation from manure management systems, reducing methane from ruminant livestock, and reducing methane emissions from food waste in landfills, to support the US goal of reducing greenhouse gas emissions by 50 percent and the global goal of reducing methane emissions by 30 percent.
- **Supply chain resilience:** In 20 years, produce at least 30 percent of the US chemical demand via sustainable and cost-effective biomanufacturing pathways.
- **Human health:** In 20 years, increase the manufacturing scale of cell-based therapies to expand access, decrease health inequities, and decrease the manufacturing cost of cell-based therapies 10-fold.
- **Cross cutting advances:** In five years, sequence the genomes of one million microbial species and understand the function of at least 80 percent of the newly discovered genes.

To attain these goals will require substantial prioritisation of R&D investments and other efforts across the US Government, as well as actions from the private sector; state, local, and tribal governments; and international partners.

There are a range of areas and ways where international partnerships feature in the US goals for the sector, especially in research collaboration and supply chain resilience, including:

- Expanding interdisciplinary and international cooperation in R&D (including research projects and data sharing) to leverage expertise across fields and drive innovation, while mitigating risks and reaffirming democratic values.
- The United States and international partners can expand advanced biomanufacturing capabilities, including more regional biomanufacturing close to feedstocks to enhance supply chain resilience. When supply chain disruptions occur, manufacturers can shift production more efficiently, in coordination with international partners, rather than undergoing capital-intensive retooling.
- The United States and international partners can collaborate to create a data infrastructure that better utilises the large data generated from R&D investments, including developing tools, capabilities, and standards in accordance with Findable, Accessible, Interoperable, and Reusable (FAIR) principles.
- International collaborations will enable and support the necessary physical and cyberinfrastructure required to conduct fundamental R&D, ensure connections between researchers and end-users, and translate new discoveries to the market at speed and scale.

Opportunities for engagement with US biotech and pharmaceutical multinationals

Large US biotech and pharmaceutical multinationals have highlighted a range of sectors that are of interest to them. These are also areas where there are current and potential applications of biotechnology. These include:[36]

- **Infectious diseases:** HIV and hepatitis are the leading infectious disease therapeutics markets; the top six markets also encompass influenza, tuberculosis, malaria, and HPV.
- **Cardiovascular:** growth in the cardiovascular drug market is driven by the escalating prevalence of cardiovascular diseases and the expanding number of individuals with diabetes and obesity.
- **Oncology:** Immunotherapy is the dominant force in the worldwide cancer drug market, primarily because of its superior effectiveness and reduced side effects when compared to alternative treatments.
- **Central nervous system (CNS):** Mental health issues and degenerative disorders play a significant role in driving the increasing demand for CNS therapeutics worldwide. The growth is further propelled by advancements in neurological imaging technology, which aids in early diagnosis. In the past decade, over 50 drug candidates have successfully completed Phase 2 clinical trials for Alzheimer's disease, but none have advanced to Phase 3.

- **Diabetes:** drivers of market growth include the increased incidence of diabetes, the development of affordable and effective diabetes therapeutics, consumption of fast food, growing awareness on self-management of diabetes, and support from the government.
- **Immunology:** the four main indications in immunology are arthritis, systemic lupus erythematosus (SLE), psoriasis and inflammatory bowel disease (IBD). Growth in the market is underpinned by the increasing populations of many of the indications within immunology.
- **Ophthalmology:** The main factors propelling this market's growth include the worldwide growth of the elderly population, technological advancements, a higher incidence of eye disorders, increased healthcare spending, and a rise in cataract surgeries. Moreover, the increasing prevalence of intraocular eye disorders is anticipated to further boost market expansion in the coming years.

Australia's ability to assist the United States to achieve their goals

Australia's strengths in biotechnology are centred around its research and clinical trial capabilities. Excellent research facilities with world-renowned scientists, coupled with a flexible regulatory landscape have helped pave the way for biotechnology innovation.

Renowned research capabilities

The world-class capability of Australia's biomedical researchers was highlighted during the COVID-19 pandemic where Australian researchers led efforts to analyse the virus and develop a response.[37] Health and medical research remains one of Australia's strongest research areas, with over 60 percent of research outputs ranked as 'above' or 'well above world standard'.[38] The Medical Research Future Fund (MRFF) is the main body for Australian medical research along with investments through National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC). Together, these bodies support scientific research and lay the foundation for the biotechnology industry in the country.

Victoria houses a majority of biotechnology companies and research organisations. The state has 10 major medical research institutes and 10 teaching hospitals that conduct research. Research organisations include CSIRO, the Royal Melbourne Hospital, the Florey Institute of Neuroscience and Mental Health, the Peter MacCallum Cancer Centre, and the Walter and Eliza Hall Institute of Medical Research.[39]

Notably, leading Australian universities and research institutes have strong capabilities in oncology, coinciding with the dominance of this area in Australian listed companies.[40]

World-class clinical trials capabilities

Australia has unique strengths in undertaking clinical trials to test the efficacy and safety of medical products. Pharmaceutical, biotechnology and medical device companies commence around 1,000 new clinical trials each year, representing approximately A$1 billion in investments.[41] This strength is underpinned by Australia's regulatory system which is internationally renowned for its transparency, quality, and effectiveness in promoting innovation.[42]

The country's exceptional clinical trial researchers, a diverse patient pool, skilled workforce, English-speaking population, availability of secure and advanced infrastructure, a seasonal difference to northern hemisphere markets, a trusted regulatory system, and advanced digital capabilities also make Australia an ideal location for high-quality clinical trials.[43]

Since 2017, Australia has boosted its competitive position in early-stage clinical trials (Phase I and Phase II) and oncology, pneumology, neurology, and ophthalmology trials – many of which overlap with the areas of high demand by US multinationals, while retaining its share of late-stage trials (Phase III and Phase IV).[44]

Growing biotechnology industry and gateway to Asia

The number of Australia biotechnology enterprises rose by 66 percent from 487 in 2008 to 810 in 2022, with the workforce increasing by 51 percent.[45] Australia's strength lies in the human health sector segment, which generates more than half of Australia's biotechnology revenue. The pharmaceutical manufacturing industry was valued at A$12.7 billion, and about 43 percent of its revenue was generated from exports in 2020–21, showcasing the industry's global nature.[46]

Australia's geographical location and established trade agreements in the Asia-Pacific region put the country in a favourable position to emerge as a significant supplier of biotechnology products and processes. This geographical advantage proves especially beneficial for exports of food and medical products, which often demand cold chain distribution.[47]

Growing investments in manufacturing and Australia's closeness to feedstock

The Australian Government has recognised manufacturing as a key step to scale up successful products and bring them to the markets. Australia needs onshore manufacturing to position itself as an exporter of biotechnology products, capture economic and job gains, and lower the risk of supply disruptions.[48] The Australian Government is making significant investments into research commercialisation and growing the domestic manufacturing capability as discussed in Section 3.3.2.

Carbon-based feedstocks are the main raw material and often the most substantial expense in biomanufacturing. Consequently, having access to competitively priced feedstocks is vital for the economic viability of biomanufacturing. Australia is a major producer and exporter of sugar, a highly cost-effective and efficient feedstock for biomanufacturing. Additionally, Australia generates substantial quantities of lignocellulosic biomass from agricultural waste, which could serve as a more sustainable feedstock for biomanufacturing, provided satisfactory fermentation efficiencies can be attained.[49]

Moreover, overseas industry stakeholders have recognised that Australia's highly skilled workforce, shared cultural norms, and English-speaking business environment make it an appealing choice for potential collaborators and as a location for setting up new manufacturing facilities in the Asia-Pacific region.[50]

Moderna chooses Australia to build its first mRNA vaccine manufacturing facility in the Southern Hemisphere

US biotech company Moderna is building an mRNA vaccine manufacturing facility in Victoria – the first mRNA manufacturing facility in the Southern Hemisphere. The facility is expected to manufacture up to 100 million vaccine doses per year for respiratory viruses (e.g. Covid, influenza and respiratory syncytial virus).[51]

Modern will also set up a regional mRNA research centre in Melbourne, aimed to become a hub for research into respiratory viruses and tropical diseases across Asia-Pacific.

One of the reasons for building their first commercial-scale facility in Australia is cited to be because of Australia's excellent science and R&D ecosystem. "Australia is a great place to do clinical trials because Australian clinicians know how to run trials well," says Michael Azrak, General Manager, Moderna Australia & New Zealand, "Australia provides good infrastructure and facilities, regulatory support, medical expertise, and a diverse population for trial recruitment."

"We can collect trial data and get results back to the global study team in a timely way. This is partly due to local expertise. Australia is home to high standard CROs, universities and teaching hospitals that are well-versed with global requirements," says Azrak.[52]

Source: Australian Trade and Investment Commission

Australia's current challenges

Along with opportunities and Australia's ability to reach its potential, there remain challenges to address. A number of key issues include:[53]

Limited access to capital

Access to capital for commercialisation, clinical development and growth remains a key barrier. This has also echoed through KPMG consultations with Australian biotechnology companies. The lack of capital has driven companies to go public too early, while the funds available on the Australian Securities Exchange (ASX) are volatile and short-term, driven by retail investors who are generally impatient. In addition, it takes time to develop a biotechnology product, leading companies to use up their patent life and have their assets marked down. This results in negative return on investment, making early-stage biotech companies less appealing to institutional investors.

Australia can use the successful US funding model as a case study. In the United States, venture capital is typically a major source of funding for biotechnology companies, especially in the early stage. In contrast, Australia's venture capitalists are more risk-averse and invest mainly in the later stages of development.

There is a lack of companies growing through the commercialisation pathway and reaching market. More than 80 percent of companies developing therapeutics, diagnostics, devices, vaccines, and other technologies in Australia are pre-revenue, pre-market, and on a journey of commercialisation.[54] Comparatively few Australian-developed products have reached market yet.

This also raises the question of whether Australian universities and research institutes are effective in translating their primary research into the commercial space. Although many universities have created a Technology Transfer Office (TTO), the levels of success vary.[55]

In addition, gaps in technology transfer and commercialisation support are complex issues and require attention.

Uncoordinated incentives and structural supports

Incentives and structural supports along the pipeline are fragmented, inconsistent, and lack coordination. The R&D tax incentive is one of the key innovation policy programs – however, there has been excessive review into this incentive, creating a sense of uncertainty in the biotechnology industry. This can have a detrimental effect on investment in technologies. In addition, the recent cut by 1.5 percent to the R&D tax incentive will impact Australian competitiveness and hinder the Australian Government's innovation agenda.[56]

The uncompetitive corporate tax system in Australia also makes the country less attractive as a location for entrepreneurial manufacturing or as a base to commercialise locally developed intellectual property (IP) into international markets.[57]

A stronger and more supportive policy base is therefore necessary to attract new investment into Australia, grow Australian sovereign capacity and capability to research and manufacture locally, and boost Australia's international competitiveness.

Better coordination and alignment of investments across the biotechnology ecosystem will help break down silos and remove duplicated efforts across portfolios and jurisdictions.[58] Moreover, richer and targeted data collection efforts can help improve understanding of the ecosystem and identify gaps for improvements.[59]

Key learnings from the US and European markets

While the focus of the report is not to propose policies addressing challenges in the Australian biotechnology market, there are a number of key learnings from the US and European markets, notably Ireland, that Australian policy makers can consider to increase Australia's international competitiveness in attracting investment and trade:

- In Australia, the time it takes for new pharmaceutical products to reach the market can be a decade or longer, while the processes in the United States and Europe are significantly faster.[60]
- Ireland has a low headline corporate tax rate of 12.5 percent for active businesses and 25 percent for non-trading or passive income.[61]
- Patent box systems are common in many European countries, enabling preferential tax treatment of profits derived from exploiting IP. For example, in Ireland, their patent box incentive attracts a tax rate of 6.25 percent on profits derived from exploiting IP, compared to the 12.5 percent general corporate tax rate. This has led to a substantial shift in patent holdings towards countries with attractive tax regimes.[62]

Australia's export potential to the United States

4.1

Estimated trade uplift for increasing US engagement

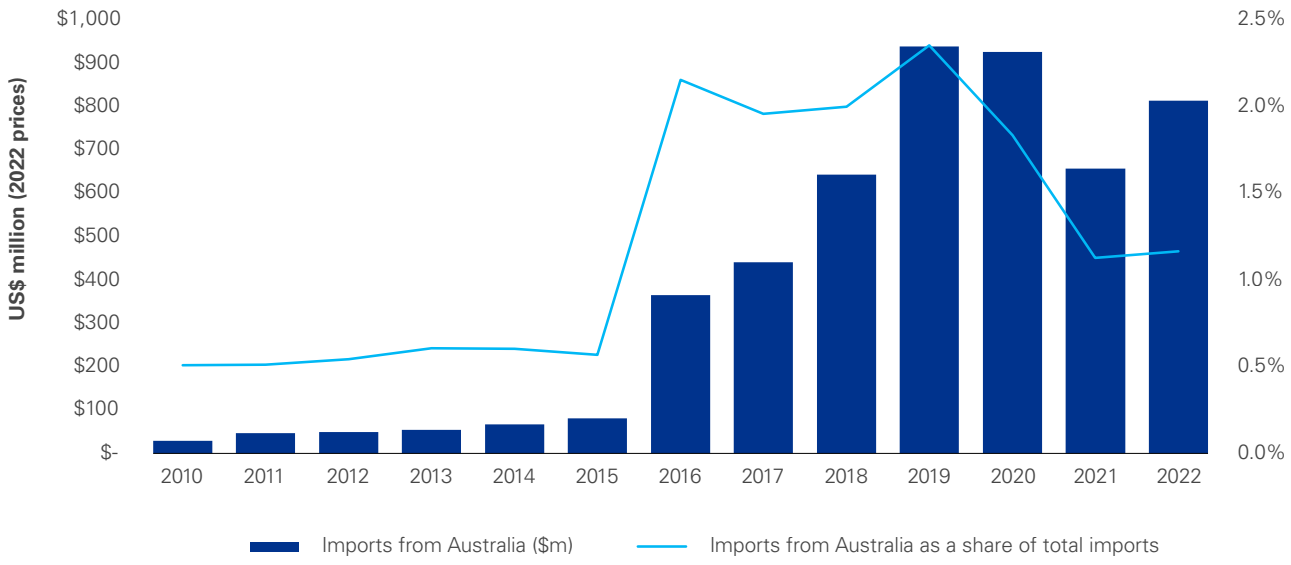
Australian real exports of biotechnology products to the United States jumped from US$80.2 million in 2015 to US$364 million in 2016 due to an increase in exports of antisera and other blood fractions. From 2016 to 2019, Australian biotechnology exports to the United States grew at an accelerating rate of 37 percent per annum on average.

However, growth stalled in 2020, and exports decreased by 29 percent in 2021.

The decline in exports over the pandemic can be attributed to the disruptions to transportation. Due to Australia's geographical isolation, it was more difficult to deliver products from Australia to the United States on time compared to exports from European countries.

The US biotechnology imports from Australia recovered slightly and reached US$812 million in 2022, capturing 1.2 percent of total imports. The top imported products in 2022 were antisera and other blood fractions, where Australia ranked 3rd and captured 12.3 percent of total US imports of this commodity.

FIGURE 10: AUSTRALIAN EXPORTS OF BIOTECHNOLOGY PRODUCTS TO THE UNITED STATES



Source: US Census Bureau

Note: Nominal trade values have been deflated using the US GDP implicit price deflator.

TABLE 7: AUSTRALIAN BIOTECHNOLOGY EXPORTS TO THE UNITED STATES (2022)

COMMODITY	COUNTRY	TIME	VALUE	SHARE OF TOTAL US IMPORTS OF THE COMMODITY (%)	AUSTRALIA'S RANK
3002120090 Antisera & other blood fractions (kg)	Australia	2022	$737,387,869	12.26	3
3002410000 Vaccines for human medicine, nesoi (kg)	Australia	2022	$64,140,854	0.72	9
3002905250 Human blood; animal blood prepared for therapeutics, nesoi (kg)	Australia	2022	$4,436,847	0.43	20
3002140090 Immunological products, mixed, not for retail sale (kg)	Australia	2022	$3,262,939	0.36	14
3002150091 Immunological products for retail sale, nesoi (kg)	Australia	2022	$1,555,882	0.01	27
3002490000 Vaccines, toxins, cultures of micro-organism etc. nes (kg)	Australia	2022	$597,160	0.32	16
2937190000 Polypeptide, protein & glycoprotein hormones, nesoi (gm)	Australia	2022	$563,197	0.01	16
3822120000 Zika diagnostic or lab reagents, including kits (kg)	Australia	2022	$388,038	0.72	15
3002150011 Diagnostic reagents based on an antibody test (kg)	Australia	2022	$172,963	0.00	29
3002130010 Monoclonal antibodies, unmixed, not retail sale (kg)	Australia	2022	$161,512	0.02	17
3002140010 Immunological products with monoclonal antibodies, not for retail (kg)	Australia	2022	$92,904	0.00	22
3002510000 Cell therapy products (kg)	Australia	2022	$29,880	0.06	11
3002420000 Vaccines for veterinary medicine (kg)	Australia	2022	$18,131	0.19	9
3002590000 Cell cultures, whether or not modified, nesoi (kg)	Australia	2022	$14,655	0.01	21
Total	Australia	2022	$812,822,831	1.16	15

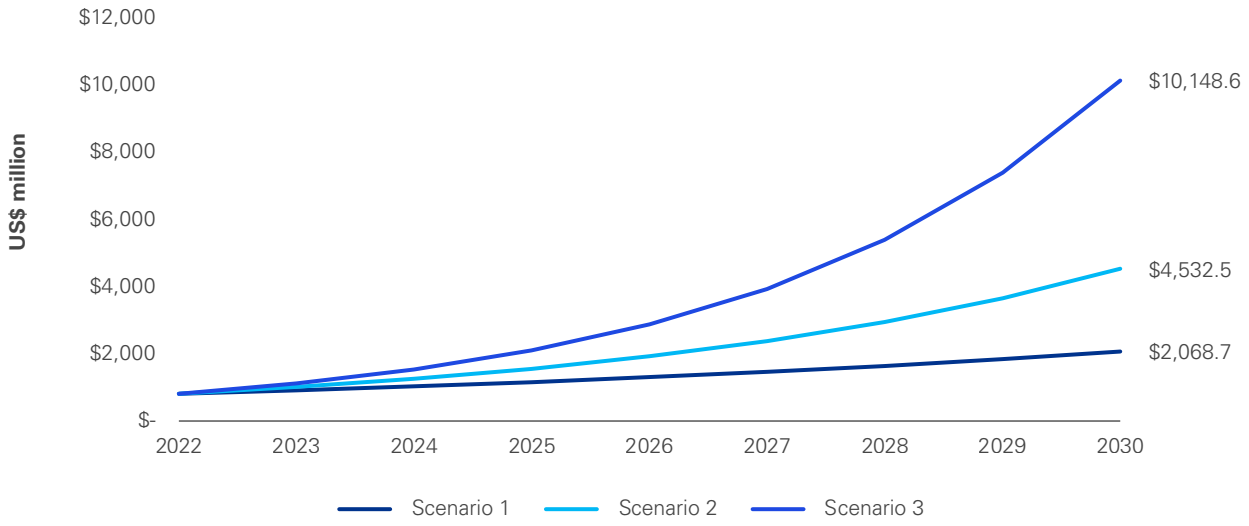
Source: US Census Bureau

Australian biotechnology exports to the United States year-to-date as of July 2023 were US$639 million (2022 prices), reaching nearly 80 percent of the annual value in 2022. This suggests Australian biotechnology exports are poised for a strong performance in 2023.

We have extrapolated three scenarios to estimate the benefit of an uplift in trade between the United States and Australia in the biotechnology industry. In all scenarios, the value of biotechnology exports is estimated from Australia to the United States between 2022 and 2030.

- In the first scenario, an average annual growth rate is calculated by assuming Australia maintains its historical share of trade to the rapidly growing US biotechnology industry.
- In the second scenario, we assume the value of exports from Australia from 2022 to 2030 grows at a historical rate after the COVID-19 disruptions.
- Scenario three assumes Australia can increase its share of trade to the United States by assuming Australia is able to maintain its strong historical growth before COVID-19. This scenario represents growth in trade between the two nations due to increased exports in national strategic goods, as a result of arrangements such as AUKUS.

FIGURE 11: SCENARIOS FOR INCREASING TRADE BETWEEN THE UNITED STATES AND AUSTRALIA



Source: KPMG analysis, US Census Bureau, Grand View Research

Table 8 summarises the estimated value of exports from Australia to the United States as a share of the US domestic industry revenue across the three scenarios. Across all scenarios, Australia maintains a small share of the total US industry size, despite the significant increase for Australia's exports.

This highlights that the export potential is more constrained by Australia's capacity to commercialise new inventions, rather than by a lack of opportunity in the United States. It also highlights that under the 'business as usual scenario', Australia could miss out on the opportunity to increase its market share and generate US$10 billion in exports to the United States if its growth in trade does not return to the strong pre-Covid trajectory as outlined in Scenario 3.

TABLE 8: TRADE SCENARIO ESTIMATES AS A SHARE OF US DOMESTIC INDUSTRY REVENUE

	BIOTECHNOLOGY
Australia exports to US 2022 (US$ million)	812.8
% of US domestic industry revenue	0.2
US imports from Australia as a share of 2030 US industry revenue	
Scenario 1: 'business as usual'	0.2
Scenario 2: medium case	0.4
Scenario 3: accelerated	0.8

Source: KPMG analysis

4.2

Investment and employment implications

To enable greater participation of Australian businesses in the supply chain of the US biotechnology sector requires Australian firms to have an adequate workforce as well as the necessary physical capital. Underlying KPMG's figures for the trade potential scenarios, is a corresponding increase in capital expenditure and increase in biotechnology-sector jobs.

Using information from various ABS datasets, including the national accounts and datasets pertaining to multifactor productivity estimates, KPMG has estimated the incremental capex spend and employment that would be necessary in order for the trade uplift forecasts to be achieved. We note these are broad estimates using industry-wide averages and apply the latest available capital labour ratios. Table 6 presents KPMG's estimates of necessary investment in new capital stock and incremental FTE workers required to achieve the potential trade-uplift forecast laid out in the previous sub-section.

As can be noted from Table 6, the Australian economy stands to benefit from stronger ties with US biotechnology firms. The expected investment and employment outcomes in scenario 3 are nearly five times the benefits compared to the 'business as usual' scenario. Through greater trade linkages with US biotechnology firms, Australian companies can improve efficiency by increasing investment in new technology. Furthermore, intellectual capacity and necessary biotechnology-related knowledge and skillset would be developed by recruiting and retaining graduates in the sector.

TABLE 9: INCREMENTAL CAPITAL STOCK AND LABOUR FORCE REQUIRED TO MEET TRADE-UPLIFT SCENARIOS, 2030

	CAPITAL STOCK (US$B 2022)	FTE('000)
Scenario 1: business as usual	2.3	6.9
Scenario 2: medium case	5	15.1
Scenario 3: accelerated	11.2	33.8

Source: KPMG analysis

4.3

Advice for businesses expanding to the United States

To understand the export potential for Australia-based businesses in the biotechnology sector, AmCham and KPMG consulted companies who have been successful in generating new business in the United States and Australian markets. We have also complemented key learnings gleaned from the consultations with our own research.

Market validation and product differentiation are critical

Firms need to determine their market early during the development of their products or services to avoid wasting resources when commercialising. Before expanding into the United States, firms also need to ensure there is a market in the United States. As a full-scale launch can be costly, businesses should consider limiting market releases and targeting specific geographical areas, then expanding into another market later.

The US market is highly profitable but very competitive. Therefore, Australian businesses should conduct a competitive analysis and find their differentiating points to stand out.

Deep understanding of the reimbursement landscape can determine commercial success

Reimbursement opportunities help de-risk the development of a new technology – if a technology or product is not eligible for reimbursement, it will be challenging to find investors or securing funding for R&D or commercialisation.[63] Therefore, early in the development phase, it is crucial for biotech start-ups to find out different forms of reimbursement, which vary across markets, so that executives can plan financials with more precision and clarity of the end product.[64] Understanding the reimbursement landscape is also important as the type of approval and clearance from FDA can change the reimbursement pathways.

Build a global network

There are conferences and events Australian businesses can attend to build network with US multinationals, which can lead to future partnerships and opportunities. Australian businesses should also leverage introductions and spend time in the US market. The major event for the biotechnology and pharmaceutical industry is the annual BIO International Convention.[65]

Building these relationships is work of multiple years, so businesses should start the discussion early. Australian businesses can also consider taking a delegation to the US markets to visit pharmaceutical corporates that may not otherwise travel to Australia.[66] Importantly, Australian businesses should identify target companies and be ready to demonstrate to them how their products or services can help the US firms implement their strategies and create a competitive edge.

Building partnerships with US multinationals requires understanding their needs

In order to build relationships and potential partnerships with major US pharmaceutical and biotechnology companies, it is crucial to understand their needs. Australian businesses research the strategies and market segments of these US companies, their gaps, as well as areas they invest in or under-invest in, which will help Australian businesses bring the solutions to the right problems.

Australian businesses can utilise similar tools and techniques that US companies use in market analysis and look up clinical trials to identify areas of demand. In addition, public databases can provide secondary data for firms' research.[67]

Focusing on and promoting areas of interest to the US multinationals where Australian businesses have strengths, such as oncology, neurology, can increase the perception of a substantial scale in the Australian biotechnology industry.[68]

Leverage strengths in R&D and early product development

Australia provides a great launchpad for R&D, clinical stage, and early product development. The country has a good health and university system, great medical research, highly skilled labour, a high functioning hospital system, and access to a large patient sample. In addition, the regulatory environment in Australia also accelerates the clinical trial stage for pharmaceutical companies, assisting them to get an FDA approval faster than if they did it in the United States. These are the strengths that the Australian clinical trials sector can leverage to attract the US multinationals.

Foster collaboration between research and industry to boost commercialisation

Greater synergy between the research sector and businesses will enable sharing of expertise and resources, leading to innovative ideas and products. Through collaboration with university and research institutes, small biotech companies can gain access to research, training, and expertise beyond their employee pool, as well as receive investment-grade funding. For the research sector, collaboration with the industry leads to commercialisation of their research output, and helps scholars ensure their work is relevant to the industry.

Joining an incubator is a great way to gain access to further collaborations. The University of Melbourne, the Walter and Eliza Hall Institute (WEHI), and CSL have recently launched a new biotechnology incubator, backed by A$65 million in industry and government investment. The incubator is aimed at accelerating the translation of medical research into biotech inventions and commercial outcomes and fostering new collaborations. Start-ups will have access to technical support and technology platforms that are usually expensive.

Appendices

Appendix A: Market size estimates

This appendix outlines the methodologies used to estimate the market size and trade opportunity for the biotechnology sector.

Market size

The market size for each of the target sectors in the US captures the direct revenues for biotechnology products by businesses selling these products. These estimates are provided by Grand View Research, which uses a combination of data mining of its proprietary database, consolidation of company reports and other financial statements, and interviews with key opinion leaders in the industry.

Appendix B: Supplementary industry information

Using the Panjiva database, we have extracted import data on the Biotechnology industry in the United States. In extracting this data, we have restricted our search to:

- Goods imported to the United States between 2017 and 2022
- Consignees with a Standard Industrial Classification (SIC) code relevant to the Biotechnology industry
- Inputs with a Harmonised System (HS) code relevant to the Biotechnology industry.

The following SIC codes were provided by Grand View Research (GVR):

SIC CODE	DESCRIPTION	FTE
Biotechnology		('000)
8731	Commercial Physical and Biological Research	6.9
8732	Research and Development in Biotechnology	15.1

Source : Grandview Research (2022)

Limitations

There are limitations to this approach. First, the SIC code system was last revised in 1987 and therefore may not fully capture emerging industries. Searching by SIC codes is also likely to include or exclude data relevant to the industry scope we are interested in. Second, Panjiva only has information on shipments rather than values of trade.

To overcome these limitations, we have complemented the supply chain analysis with biotechnology trade data from the US Census Bureau.

Appendix C: Sample of US businesses by size

Company	Company size	Ownership	Location
Psomagen, Inc.	small cap	Listed	Maryland
Emergent BioSolutions, Inc.	small cap	Listed	Maryland
Invitae Corp.	small cap	Listed	California
Organogenesis Holdings, Inc.	small cap	Listed	Massachusetts
Amyris, Inc.	small cap	Listed	California
Sequenom, Inc.	small cap	Unlisted	California
Personalis, Inc.	small cap	Unlisted	California
Progenics Pharmaceuticals, Inc.	small cap	Unlisted	New York
Kolon TissueGene, Inc.	mid cap	Listed	Maryland
23andMe Holding Co.	mid cap	Listed	California
Intercept Pharmaceuticals, Inc.	mid cap	Listed	New Jersey
MiMedx Group, Inc.	mid cap	Listed	Georgia
Coherus BioSciences, Inc.	mid cap	Listed	California
Keryx Biopharmaceuticals, Inc.	mid cap	Unlisted	Massachusetts
REGENXBIO, Inc.	mid cap	Unlisted	Maryland
Ambrx Biopharma, Inc.	mid cap	Unlisted	California
Moderna, Inc.	large cap	Listed	Massachusetts
Biogen, Inc.	large cap	Listed	Massachusetts
Syneos Health, Inc.	large cap	Listed	North Carolina
Illumina, Inc.	large cap	Listed	California
Charles River Laboratories International, Inc.	large cap	Listed	Massachusetts
Anacor Pharmaceuticals, Inc.	large cap	Unlisted	California
Five Prime Therapeutics, Inc.	large cap	Unlisted	California
Provention Bio, Inc.	large cap	Unlisted	New Jersey
AbbVie, Inc.	ultra cap	Listed	Illinois
Gilead Sciences, Inc.	ultra cap	Listed	California
Amgen, Inc.	ultra cap	Listed	California
Regeneron Pharmaceuticals, Inc.	ultra cap	Listed	New York

Source: Factiva, KPMG research

Note: Small cap refers to market cap of less than US$400m, mid cap between US$400m and US$1b, large cap between US$1b and US$50b, and ultra cap over US$50b.

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