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CONTENTS

Section	Page
Foreword	Or
Key findings	00
Contribution to the economy and value of the industry	0
Business sentiment in the industry	10
Financing, investing, listing and costs	12
Government policy	11
Methodology	1
About AusBiotech and Grant Thornton	19

FOREWORD

The 2018 AusBiotech Industry Position Survey reveals the strongest ever business sentiment across the sector.

Almost four-in-five (77 percent) respondents described the past twelve months as an 'excellent' or 'good' year, up from 72 percent in the 2017 survey, and the strongest result since it began in 2011.

Almost 90 percent of respondents said they expect to grow in 2018. This was also up on last year and another record result. None said their companies will contract.

The records do not end there with 73 percent expecting to hire more staff in 2018. This is up from 64 percent in 2017.

The number who described the environment as conducive to growing a biotechnology company has almost returned to 2016 levels after a fall last year in response to uncertainty over the future of the Research & Development (R&D) Tax Incentive.

The return of more positive sentiment towards the environment also comes as the recent announcement in the 2018-19 Budget of changes to the R&D Tax Incentive exempted investment in clinical trials from the new \$4 million annual cap on the refundable component.

AusBiotech welcomed the exemption as appropriate recognition of the sector's unique circumstances given the role of the R&D Tax Incentive in providing companies with non-diluting capital.

Our sector relies on an 'eco-system' comprised of interdependent components.

The survey has once again highlighted how respondents do not believe individual components of this 'eco-system' exist in isolation of each other. Policy-makers cannot make changes to one assuming it will not have wider implications.

The R&D Tax Incentive is the most critical program in supporting the Government's stated policy objective – to improve Australia's performance when it comes to the translation of R&D.

Over 90 percent of survey respondents said policy stability on the R&D Tax Incentive is 'very important' or 'important'.

In an increasingly globalised world, where capital can move freely to the most encouraging and supportive jurisdictions, sending the right signal on this centrepiece policy was critical.

It now sets the foundation, along with other policies like the \$500 million Biomedical Translation Fund, for a sustained period of positive sentiment.

Yet the survey reveals there is no room for complacency, with 80 percent reporting concerns over the long-term future of the R&D Tax Incentive given a series of changes and ongoing reviews.

The importance of this cannot be underestimated given almost 60 percent of respondents reported conducting clinical trials in the past year.

Policy-makers must continue to make the changes necessary to ensure Australia maintains its competitiveness and ability to attract investment in clinical trials.

The exemption under changes to the R&D Tax Incentive and the feasibility study for a one-stop shop for clinical trials are welcome and important steps. Yet other countries are working even harder to attract investment.

The survey has revealed a welcome increase in the number of companies with more than two years cash on hand - rising from 12 to 20 percent in the past year. Yet this is still well below the 2016 result of 27 percent. It is compounded by the dramatic decline in the number of companies with one to two years cash on hand (41 percent to 19 percent) and a jump in the number with just six to 12 months (19 percent to 29 percent).

Access to capital is important for the biotechnology sector because of the very long product development timelines. Unlike many other sectors that can generate revenue from day one, biotechnology companies can be pre-revenue for many years.

Access to talent is equally important. The survey confirmed the damage done by sudden and shock changes to the skilled migration program announced in April 2017. The changes were wound back after significant advocacy from the sector. Yet they seriously threatened the viability of some companies and provided further evidence of the risk to the sector when governments fail to consider the wider implications of ill-considered policy change.

Australia's biotechnology sector is a significant economic driver. Importantly, its contribution is consistently underestimated given research commissioned by AusBiotech reveals it is much larger than previously thought.

The Australian life sciences sector employs more than 232,000 people across 1,654 organisations.

Australia is consistently ranked as one of the world's top countries for biotechnology innovation. This is a source of great pride but also an indicator of future potential given the right policy settings and continued support.



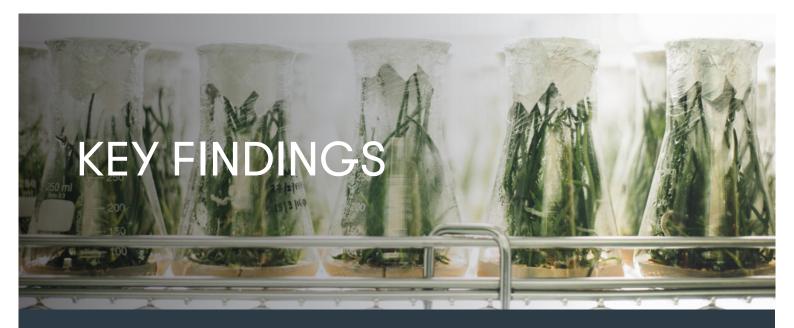
Lorraine Chiroiu
Chief Executive Officer,
AusBiotech

"A convergence of industry maturity, deal flow, regulatory advances, increased capital and development programs makes this the most buoyant I've seen the sector in my near-decade-long tenure at AusBiotech. The survey data agrees. The opportunity is ours to further build this industry towards its potential as a driver of our economy and quality of life."



Michael Cunningham National Head of Life Sciences, Grant Thornton Australia

"Businesses in Australia's life sciences sector are optimistic about their future growth, and rightly so. The Government recognition of clinical trials when altering the R&D tax exemption is a testament to the advocacy of AusBiotech and how the industry is being increasingly recognised for its contribution to the economy."





Biotech booming

"We are in boom times; good times," said the CEO of an SME medical technology development company, during the consultation this year. This year's results reveal this industry leader is not alone.

Business sentiment across the industry is the strongest on record. The Survey shows another jump, to 77 percent, in the number of companies reporting that last year (2017) was an 'excellent' or 'good' year. The vast majority (87 percent) expect their business to grow in 2018, a significant jump on last year's result and no respondent expected their business to contract.

A record 37 percent believe the Australian operating environment remains conducive to growing a biotechnology business, adding to 47 percent that felt the environment was neutral.

The employment outlook for 2018 has strengthened to the highest on record, with 73 percent of companies indicating an intention to hire, up from 64 percent in 2017.



Value of clinical trials recognised and supported

With over half (58 percent) of respondent companies reporting they conducted clinical trials in 2017, it is no surprise that industry support announced in the May 2018 Federal Budget has been well received.

The measures are aimed at boosting Australia's competitive advantage in clinical trials, including a recruitment campaign, new funding, the pledge of a feasibility study for a one-stop shop for clinical trials and an exemption from the \$4 million cap on the R&D Tax Incentive.



Snapshot shows a larger sector than expected

Research commissioned by AusBiotech reveals the magnitude of the life sciences sector, confirming there are more than 232,000 people employed in the Australian life sciences sector, across 1,654 organisations.

The study also confirms that the life sciences sector is a significant economic driver for Australia; it is a major employer of high-value jobs and Australia is globally competitive.

Positioned consistently in the world's top countries in biotechnology innovation, the research shows that 53 percent of life sciences organisations in Australia are industry-based, with 876 companies and approximately 30 percent of the workforce in the sector is employed by industry, just over 69,000 people.



Skills and talent attraction looms as significant issue

The strongest theme to come from the roundtable discussions conducted as part of this survey, was industry-specific skills and experience, and talent attraction and retention. Prompted by the sudden and damaging tightening of skilled migration visas in April 2017, the issue came into the spotlight as a widely-used tool to fill the skills gaps that exists in Australia. In this instance the gaps are in research and senior industry executives that are highly-skilled or experienced jobs that upskill the local talent pool.

CONTRIBUTION TO THE ECONOMY AND VALUE OF THE INDUSTRY

Sector 'snapshot'

Australia's Life Sciences Sector Snapshot 2017 (Snapshot 2017) confirms that the life sciences sector is a significant economic driver for Australia; it is a major employer of high-value jobs and Australia is globally competitive in life sciences.

A new sector 'snapshot' has revealed the magnitude of the life sciences sector for the first time, confirming that there are approximately 232,213 people employed in the Australian life sciences sector, across 1,654 organisations.

The Australian life sciences sector is a growing and maturing sector, with the nation well established as a leading location globally, encompassing companies in industry, funding bodies, government & regulatory, research institutes and support services.

The Snapshot 2017 was commissioned by AusBiotech to provide a comprehensive overview of the life sciences sector within Australia, in terms of company and employment numbers, sectors, states and gender distribution.

Positioned in the world's top countries for biotechnology innovation, the research shows that 53 percent of life sciences organisations in Australia are industry-based, with 876 companies and approximately 30 percent of the workforce in the sector is employed by industry, at around 69,108 people¹.

The Australian life sciences industry sector, once dominated by human therapeutics companies, now has 281 therapeutics companies and includes the larger and fast-growing sector in medical technology (devices and diagnostics) and digital health (325 companies), as well as a steadily-emerging sector in agriculture and food technology (270 companies).

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

Out of 876 companies in the industry sector, the majority are based in New South Wales (322), employing just over 26,000 people, closely followed by Victoria with 309 companies and the sector employing about 25,000 people.

Of the industry sector, about 84 percent are SMEs², which represents 733 of the companies within the industry sector.

Research institutes are the second largest employers in the sector, with approximately 65,780 employees. Of the research undertaken in these organisations, 69 percent is on health and biomedical research, and 66 percent of the research organisations are based in New South Wales (68) and Victoria (67).

In terms of gender equity, while female representation is around or above 50 percent for research institutes, funding bodies, government & regulatory and support services, females are under-represented in industry, with only 33 percent of the workforce found to be female. While pharmaceutical companies are leading the way with 45 percent, female representation decreases across the sector as seniority levels increase.

The large workforce shown in this Snapshot 2017 depicts a thriving Australian life sciences sector that is active and substantial - and well positioned to build Australia's capacity as a technologically-innovative country, vital for our economic future. It is largely agreed that high-tech industries generate globally competitive economies and sustainable, high-skilled jobs and Australia can compete on a world stage in the knowledge economy with a strong comparative advantage.

Along with the global trend, the shift from industrialisation to service and knowledge industries is pervasive and governments around the world are making strong and large commitments to build the foundation of innovation-driven economies. We live in a time where technological innovation, knowledge and networking are the drivers of our productivity. Australia has expertise and ballast in these areas to leverage for our economy's advantage.

^{1.} Consisting of medical technology δ digital health, pharmaceuticals and food δ

^{2.} As defined by the project, SMEs are companies that employ less than 100 people.

CONTRIBUTION TO THE ECONOMY AND VALUE OF THE INDUSTRY

Clinical trials

With over half (58 percent, up from 55 percent) of respondent companies reporting they conducted clinical trials in 2017, it is no surprise that support for clinical trials announced in the May 2018 Federal Budget has been well received.

After a decade of advocacy for key aspects of clinical trials, measures announced this year will enable Australia to keep its hard-won momentum in clinical trials and continue its growth in commercialising medical research.

The measures are aimed at boosting Australia's competitive advantage in clinical trials, including a recruitment campaign, new funding, pledge of a feasibility study for a one-stop shop for clinical trials and an exemption from the \$4 million cap on the R & D Tax Incentive.

Support for clinical trials traverses portfolios of 'Industry, Innovation and Science' and 'Health' and their initiatives, such as the Biomedical Translation Fund, the Medical Research Future Fund and strategies make Australia a preferred destination for clinical trials.

The Budget pledged \$248 million to allow more clinical trials to occur in Australia and support international collaboration and the development of a feasibility study to create a one-stop shop for clinical trials - intended to make it "easier for companies, sponsors and investigators to navigate the system and invest in clinical trials across Australia."

AusBiotech warmly welcomed the initiative to consider the feasibility of creating a one-stop shop for clinical trials, as this has been the focus of advocacy efforts for almost a decade. The AusBiotech Clinical Trials Advisory Group (ABCtag) will be active over the coming months to support this initiative.

In a sensible and overdue measure, the Government will remove customs tariffs from placebos and clinical trial kits that are imported into Australia from 1 July 2018. This too has been the subject of advocacy over many years and a welcome development.

International Clinical Trials Day, celebrated on or near 20 May each year, was the scene for the launch of a national awareness campaign to get more Australians into ground-breaking clinical trials, opening up access to new life-saving medicines and treatments.

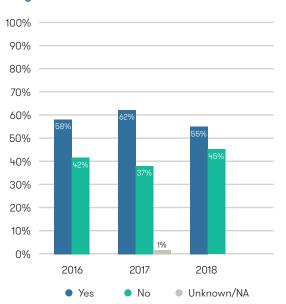
The Helping Our Health awareness campaign is an example, and will be led by the official ambassador, four-time AFL premiership player and Hawthorn Football Club Captain, Jarryd Roughead, who has a personal understanding of the importance and benefits of clinical trials after his own health scare.

The Government says it will invest \$2 billion in disbursements from the Medical Research Future Fund, including \$500 million in the Genomics Health Futures Mission, which over ten years will drive a new era in health care for Australians, and include funding more clinical trials in Australia.

The Million Minds Mental Health Research Mission will provide \$125 million over ten years, to assist an additional one million people to receive diagnosis and treatment, and support the translation of research into clinical trials.

A recent report by the Australian New Zealand Clinical Trials Registry, housed in NHMRC Clinical Trials Centre at the University of Sydney reveals 5.2 million people have participated in more than 10,000 clinical trials conducted in 2006-2015, with cancer the most frequently studied health issue and more than \$1 billion invested each year by both government and industry.

Do you undertake clinical trials?



DASHBOARD

35% of respondent companies are exporting

R&D spend for 2017 reported by 28 companies

69,108
people estimated to

people estimated to be employed in the industry in highly-skilled STEM-based jobs, with 26 companies employing 7,991 people

68%

of companies manufacture; 58% manufacture in Australia and 55% manufacture overseas, and 45% manufacture both in Australia and overseas

58% of respondent companies conducted clinical trials in

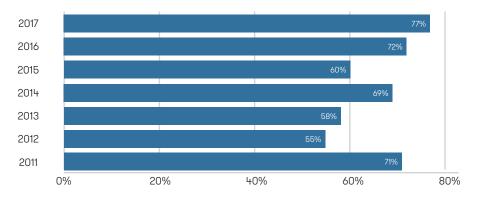
2017

\$2.7M

spent managing patent portfolios across 20 companies

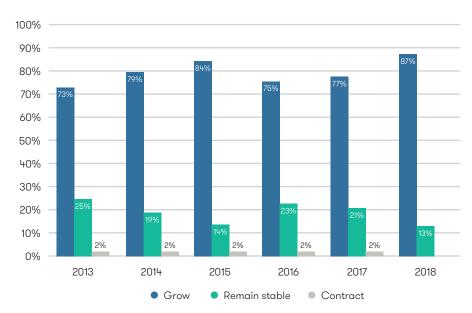
BUSINESS SENTIMENT IN THE INDUSTRY

Sentiment across the sector has reached record levels. The number of companies reporting an 'excellent' or 'good' year rose to 77 percent from 72 percent last year and just 60 percent in 2015.



Almost 90 percent expect their business to grow in 2018, up on last year, with a strong jump in the number who believe the Australian operating environment is conducive to growing a biotechnology company – up from 29 percent to 37 percent. This is almost a return to levels reported in 2016 (41 percent). Only 16 percent believe the environment is working against the biotechnology sector – down from 19 percent.

In 2018 do you expect your business to ...?



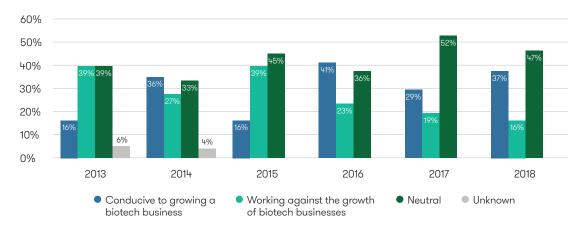
A record 37 percent believe the Australian operating environment remains conducive to growing a biotechnology business, adding to 47 percent that felt the environment was neutral. A record low of 16 percent thought the local environment was working against growing a biotechnology company.

BUSINESS SENTIMENT IN THE INDUSTRY

Comments suggested the strong 'neutral position' was a reflection of some of the elements that are supportive in the short and medium term, versus others that are not - particularly in the context of longer term growth and investment in Australia.

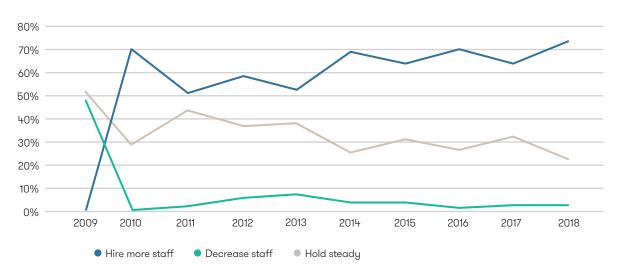
One respondent summed up by saying: "We remain encouraged by the Government's National Innovation & Science Agenda, and that the medtech and pharma industry has been recognised as an area of competitive strength and strategic priority for Australia's future economy...Nevertheless, barriers to growth still exist for our industry, including policy instability (especially in the area of IP) and a lack of government commitment to funding new medicines."

How would you describe the Australian operating environment? (economic conditions and public policy) from your company's perspective?



The employment outlook has also strengthened, with 73 percent saying they plan to hire more staff in 2018, up from 64 percent last year and the best result ever recorded.

Regarding staff levels, do you expect to?



FINANCING, INVESTMENT, LISTING AND COSTS

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

Cann Group, a leading developer and supplier of medical cannabis and the first company to be issued a medicinal cannabis cultivation licence in Australia, raised over \$70 million in funds over the year to supply the Victorian Government's epilepsy trial and other targets. Their first harvest took place in August and positive outcomes for patients participating in the trial has led to the government expanding treatments over the next two years and exploring options for export.

The Minderoo Foundation, the brainchild of mining billionaires Andrew and Nicola Forrest, committed \$75 million seed capital to create its Eliminate Cancer Initiative (ECI), with the end goal of making the disease non-lethal for the next generation. This funding allocation is certain to give biotech and research institutions working with clinical trials and drug development within the cancer sector a push in the coming year.

The contributions of private enterprise and angel investors have been complemented by significant commitments by State and Federal governments, who allocated millions of dollars to health and biomedical research programs, which make up 63 percent of all investments in the sector. Funds flowed in through the Medical Research Future Fund and its \$500 million Biomedical Translation Fund (BTF). The R&D Tax Incentive scheme continues to facilitate investment in biotechnology, though it is underpinned by feelings of uncertainty as companies grapple with potential caps to tax refunds and policy changes.

Ten biotech companies listed on the ASX in 2017 joining the 130+ existing listed life sciences firms, with radiopharmaceutical provider Telix Pharmaceuticals and US-based eye-care technology specialist Visioneering Technologies floating at \$50 million and \$33 million respectively.

Based in Melbourne, Telix is focusing on the unmet need in cancer diagnosis and care through its Positron Emission Tomography (PET) agent for imaging kidney cancer, and molecularly-targeted radiation (MTR) products that tackle prostate and brain cancers.

Visioneering Technologies is working towards bringing solutions to market for vision impairments such as presbyopia, myopia and astigmatism. The company plans to extend its NaturalVue product line and has a further seven patents pending.

In 2018, we've seen several acquisitions of Australian biotech players by Global giants for considerable sums, with Merck & Co snapping up Viralytics in a \$502 million deal and Sirtex Medical recently accepting China's CDH Genetech takeover bid for a cool \$1.87 billion.

Merck & Co's interest in Viralytics was spawned by the company's desire to complement and strengthen its own immune-oncology strategy, with Viralytics lead immunotherapy cancer product Cavatak, currently in Phase I and Phase II of clinical trials.

Sirtex Medical's technology to fight late-stage colorectal liver cancer, appealed to CDH Genetech, the Chinese company planning to grow the business significantly and realise the full potential of its cancer treatments.

Elastagen, a clinical stage company developing medical device products based on recombinant tropoelastin was also acquired by Allergan Plc, a leading global biopharmaceutical company, for \$120 million plus contingent, commercial payments.

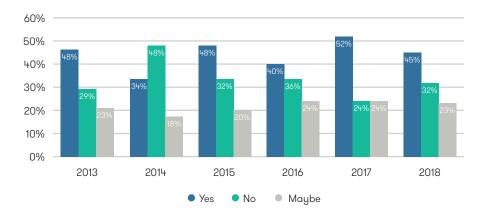
An optimistic outlook, albeit cautious optimism, for the biotech industry has resulted in many firms electing not to pursue capital raising activity in 2018, preferring to focus on sustainable growth and stability. Nearly a third of the companies (32 percent) surveyed indicated they would not be undertaking capital raising, while a further 23 percent said that capital raising was only a possibility. These numbers are roughly comparable to 2016, which was widely interpreted by market participants as a year of consolidation.

FINANCING, INVESTMENT, LISTING AND COSTS

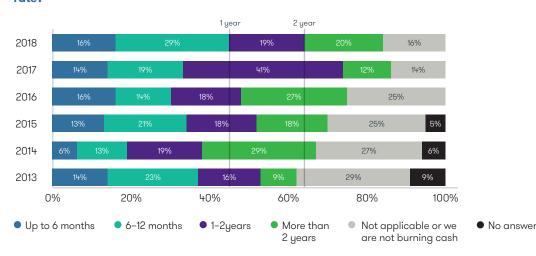
The underlying confidence from biotech companies is mirrored in the responses from 20 percent of market participants that estimated their cash on hand would comfortably sustain operations for the next two years and beyond. A further 16 percent stated cash flow concerns weren't applicable or their businesses were not burning cash, which is a strong indicator that revenues are meeting or exceeding expectations in the current climate.

Off the back of a largely successful 2017 for market participants, there is an overwhelming sentiment that 2018 will bring greater buoyancy to the sector, fuelling further employment and investment growth in the years to come.

Do you plan to capital raise this year?



How long do you estimate your cash on hand will last at your current burn rate?



GOVERNMENT POLICY



Changes in R&D Tax Incentive program

The survey picked up significant sector-wide concern over the future of the R&D Tax Incentive.

Over 90 percent of survey respondents said policy stability on the R&D Tax Incentive is 'very important' or 'important', and 80 percent reported concerns over its future.

This year's survey was conducted before the 2018-19 Budget that included changes to the program.

The survey was framed by anticipation of the Government's response to the review of the R&D Tax Incentive led by the Chair of Innovation and Science Australia, Mr Bill Ferris AC; Dr Alan Finkel AO FTSE, Chief Scientist of Australia; and Mr John Fraser, Secretary to the Treasury.

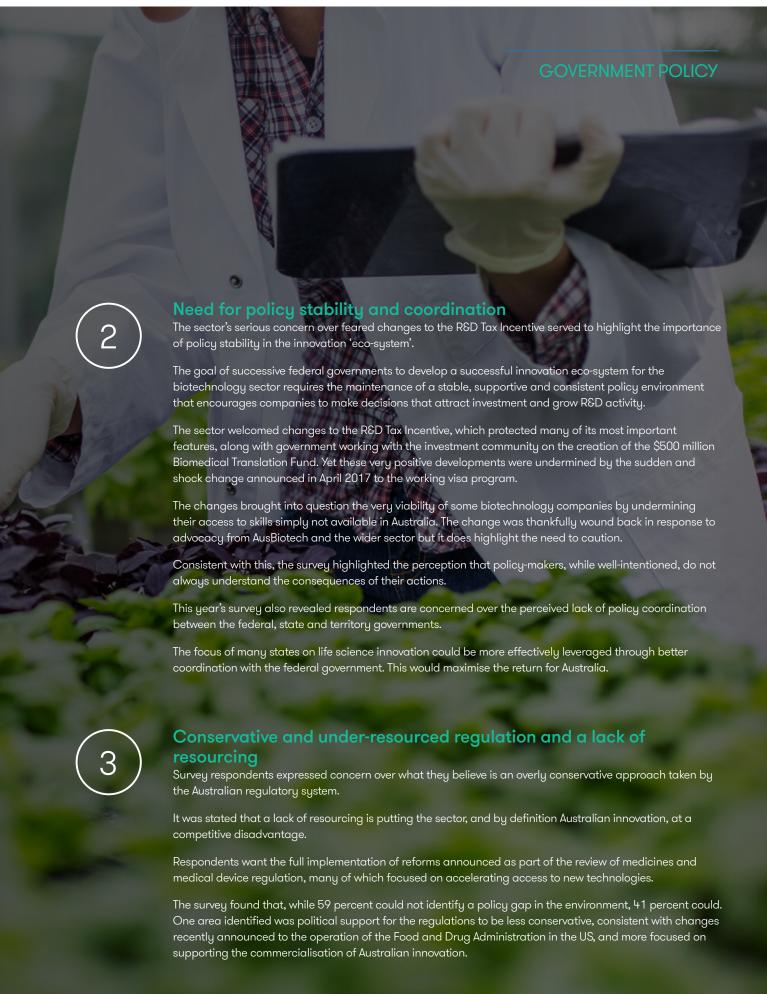
That review was followed by Innovation and Science Australia's 2030 strategic plan that argued for a move to direct funding for R&D over the current tax incentive.

Importantly, the changes announced in the 2018-19 Budget confirmed clinical trials would be exempted from the \$4 million annual cap on the refundable component.

The changes also included no lifetime cap for refunds, a coupling of the incentive to each company's tax rate and, for larger companies, a graduating reward premium for higher intensity and an increased cap.

AusBiotech welcomed the exemption of clinical trials from the annual cap as recognition of the program's critical role in supporting the development of life-changing and saving medicines and medical devices.

"By exempting clinical trials from a \$4 million cap and encouraging higher intensity in R&D, Australia will keep its hard-won momentum in clinical trials and continue its growth in commercialising medical research," it said in response to the Budget.





Themes from the CEO roundtables

"We can't get injectable cytotoxics for clinical trials made in Australia any more. Regulation has driven all such manufacturers out of the country. We are now reliant on overseas manufacturers, who often seem to have lower standards than our former manufacturers. Costs are correspondingly through the roof."

"Move core innovation strategy and funding away from government (and being subject to policy changes) to get a long term vision and insulate it to cuts as a national strategic imperative."

"Our sector cannot grow or compete without attracting talent and a clear commitment to career development in the sector."

"Do the government really believe that taxing companies excessively encourages local development?" "There is a lack of coordination between the Commonwealth and state governments on industry and innovation policy to maximise Australia's competitive strengths at a national level."

"The pervasive ignorance of politicians and decision-makers of our industry is damaging: they want to help but are surprised when they find 'unintended consequences', which we would see as completely predictable."

"Aggressively simplify regulatory requirements. Its growth is outstripping the industry."

"We say it over and over and it falls on deaf ears; we need policy stability."

"Continued investment in the R&D Tax Incentive is imperative for the biotech sector."

METHODOLOGY

This is the eighth Biotechnology Industry Position Survey conducted by AusBiotech and supported by Grant Thornton. The survey was conducted via mail/email during February 2018 and was followed by roundtable focus groups in February and March 2018. The survey was open to all ASX-listed and unlisted biotechnology companies, including AusBiotech members.

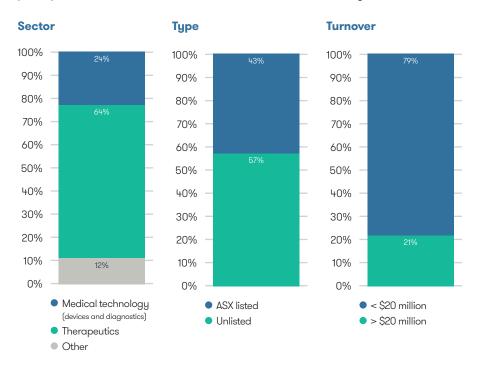
To complement the survey data, numerous companies participated in the roundtable discussions held in Sydney, Melbourne, Brisbane, Adelaide and Perth.

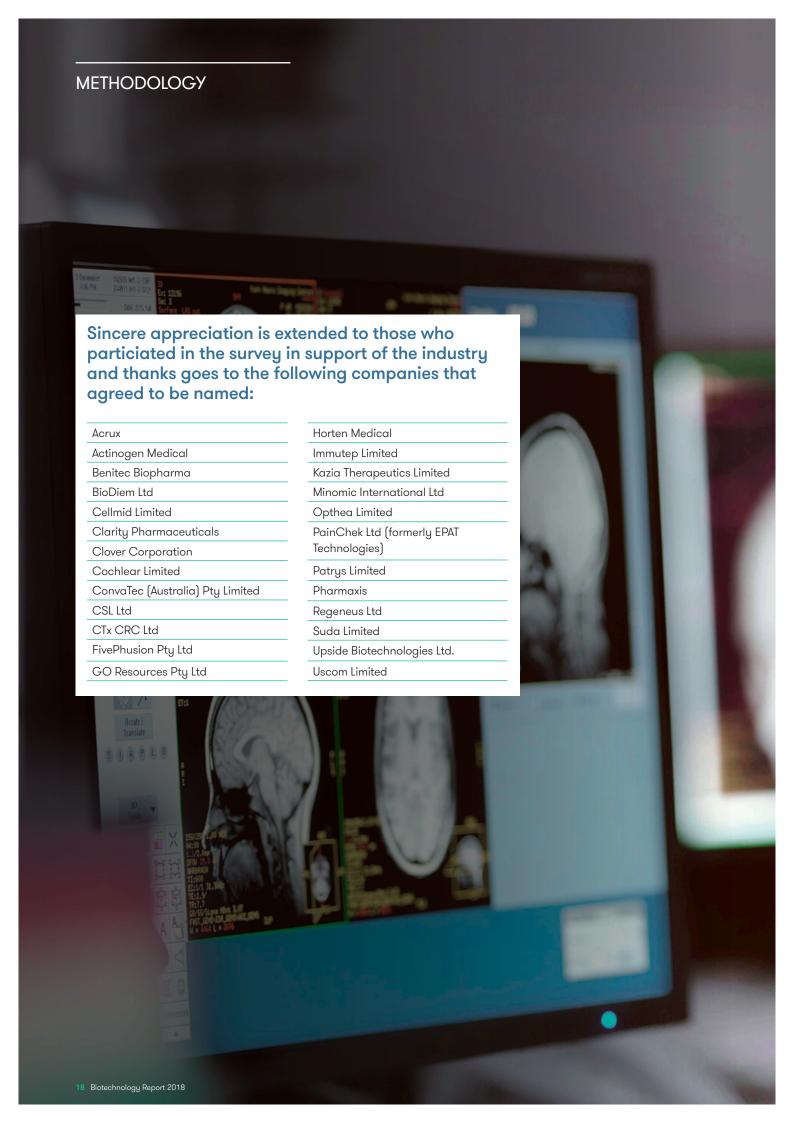
Companies were asked to submit information regarding their financial status, issues impacting their business, current outlook and plans for the future. This survey provides an independent perspective of the impact of the current economic and regulatory environment on the biotechnology industry.

Enquiries regarding this survey may be directed to AusBiotech (admin@ausbiotech.org / +61 3 9828 1400)

Analysis of respondents

Responses were received from 30 companies. In addition, over 80 companies participated in the roundtable discussions, held around the country.





ABOUT AUSBIOTECH AND GRANT THORNTON

About AusBiotech

AusBiotech is Australia's biotechnology industry organisation representing over 3,000 members, covering the human health, agricultural, medical devices and diagnostics, functional foods, environmental and industrial biotechnology industries.

AusBiotech is dedicated to the development, growth and prosperity of the Australian biotechnology industry, by providing initiatives to drive sustainability and growth, outreach and access to markets, and representation and support for members nationally and around the world.

AusBiotech is a not-for-profit organisation, with representation in each Australian state and in various special interest sectors. Active state committees and advisory groups provide a national network to support members and promote the commercialisation of Australian bioscience in the global marketplace.

AusBiotech has been working on behalf of members for more than 30 years, since it was established as the Australian Biotechnology Association and 15 years later changed its name to AusBiotech.

AusBiotech's membership base includes biotechnology companies, ranging from start-ups to mature multinationals, research institutes and universities, specialist service professionals, corporate, institutional and individual members from Australia and overseas.

If you want to know more, please contact us

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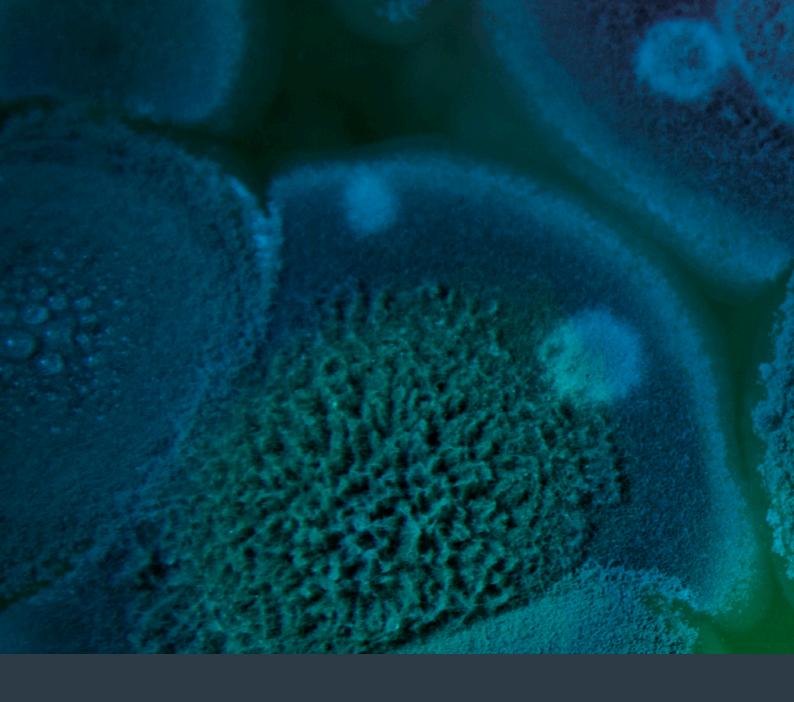
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More than 50,000 Grant Thornton people across over 135 countries are focused on making a difference to clients, colleagues and the communities in which we live and work. Through this membership, we access global resources and methodologies that enable us to deliver consistently high quality outcomes for owners and key executives in our clients.

Grant Thornton's Life Sciences team help pharmaceuticals, medical-devices, bio-engineering and other medical research companies to achieve real competitive advantage, now and into the future. A comprehensive range of services enables life sciences companies to secure their growth at all stages of development, from pre-clinical research to development, commercialisation and product sale.

If you want to know more, please contact us

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