

Biotechnology

INDUSTRY POSITION SURVEY

2017

Conducted by



Partnering with



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Foreword

The year was the strongest on record for the biotechnology sector but its leaders remain concerned over the fate of the R&D Tax Incentive.

The 2017 AusBiotech CEO Industry Position Survey reveals a clear majority of respondents report that the past year was an 'excellent' or 'good year', up significantly on the year before, and the strongest result since the survey began.

More also expect to grow in the year ahead as the sector works to build on the progress of recent years.

Yet their optimism is tinged with caution due to uncertainty over the future of the R&D Tax Incentive.

This caution is evident in significant falls in the number of respondents who described the environment as conducive to growing a biotechnology company and the number of companies reporting an intention to hire. The sector now views the environment as 'neutral'.

The result is concerning and deeply disappointing given the range of policy commitments in support of the sector made by governments at all levels. Yet it once again highlights the importance of recognising the operating environment, not least the full range of policy settings, as an 'eco system'.

The survey shows respondents do not believe individual components of this eco system exist in isolation of each other. Policy-makers simply cannot make changes to one component assuming it will not have wider implications.

The benefit of the federal government's policy support for the sector, including the \$250 million investment in the Biomedical Translation Fund, is undermined by the ongoing uncertainty on the R&D Tax Incentive.

The R&D Tax Incentive is the most critical program in supporting government's own stated policy objective – to improve Australia's performance when it comes to the translation of R&D. In an increasingly globalised world, where capital can move freely to the most encouraging and supportive jurisdictions, sending the wrong signal on this centrepiece policy carries huge risk.

The biotechnology sector significantly views Australian support for the sector through its attitude to the R&D Tax Incentive. Yet government cut the value of the incentive in 2015 and then followed with a review. The review has recommended changes that will have a profoundly negative impact on the sector.

Around half of survey respondents said proposed changes to the program, specifically the \$2 million cap on cash claims, represents a fundamental risk to employment, their ability to attract investment and compete globally.

If government is listening then it will know the survey found preservation of the program in its current form is the most-commonly cited, unprompted concern for our sector's future.

The threat to the R&D Tax Incentive is made worse by the dramatic fall in the number of companies with more than two years' cash on hand.

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

The R&D Tax Incentive provides non-equity diluting capital as companies navigate the pre-revenue product development period.

The survey found the number of companies with two years' cash on hand fell to just 12 per cent. This is the worst result since 2013. In addition, over 40 per cent of companies have just one to two years' cash on hand. A record number of companies are planning to raise capital.

Foreword cont.

The challenge for the sector, and Australian policy-makers, could be compounded by proposed changes in the US that will provide a tax credit for expenses related to contracted research. The fact is that winding back support for the sector in Australia is set against the backdrop of other countries working even harder to attract its investment.

The issue with the R&D Tax Incentive simply goes to the very heart of Australia's global competitiveness. An already challenging local regulatory environment for clinical trials could be made worse by changes to program that could see investment shift from Australia to the US.

The policy challenges are set against the backdrop of a sector with the potential to lead Australia's transition to an innovation-based economy.

According to the McKell Institute's Bio-Savvy report, the Australian biotechnology sector is expected to grow at an average annual rate of 4.4 per cent, reaching \$8.67 billion in aggregate revenues by 2021.

A more recent blueprint published by the CSIRO showed how the medical technologies and pharmaceuticals (MTP) sector could add \$18 billion and 28,000 new jobs to the Australian economy over the next eight years.

All this potential, which successive governments have worked with the sector to create, remains contingent on the maintenance of a policy environment that supports growth in the innovation 'ecosystem'. The 2017 AusBiotech CEO Industry Position Survey shows the sector believes maintenance of the R&D Tax Incentive is central to achieving this.



Glenn Cross
CEO, AusBiotech

"Australia's life science sector continues to grow and prosper adding significant economic benefit for the Australian people. Much now depends on the public policy decisions of the current federal government as they could decimate the sector with one poor decision concerning the R&D Tax incentive."



Michael Cunningham
National Head of Life Sciences, Grant Thornton Australia

"With foreign jurisdictions working harder to attract our great companies to their shores, it's critical that the Australia government introduces a globally competitive tax regime and provides the stability in the operating environment for our companies to grow and prosper."

Key findings

1 A good year in the rear-view mirror for life sciences, but uncertainty reins for year ahead

Companies reported that last year was the strongest on record, but sentiment is tentative for the year ahead as the Australian industry awaits a key decision on the R&D Tax Incentive that may significantly worsen the environment for life science SMEs.

72 per cent of respondents described the past year as an 'excellent' or 'good' year, the strongest result since the annual survey began and up from 60 per cent in 2016. In the year ahead, 77 per cent of respondents say they expect to grow, compared to 75 per cent last year.

However a sharp drop in manufacturing and a softening of employment intention, on top of large fall in the conduciveness of the environment for growing a life sciences business, point to an indecisive environment and a wait-and-see approach.

Companies planning to increase their staff this year fell to 64 per cent, from last year's all-time high of 70 per cent. The net result will see companies hire up to 91 new position in 2017, significantly down from 218 new roles last year.

Only 29 per cent of respondents said the environment was conducive to growing a biotechnology company, down from a much healthier 41 per cent last year. The drop is explained by a sharp rise in those who view the environment as neutral, which increased to the majority of 52 per cent.

2 R&D Tax Incentive under serious threat

Commercialisation of Australian medical research is under serious threat if the package of measures put by the 'Ferris, Finkel, Fraser' Review of the Research & Development (R&D) Tax Incentive is adopted and Australia's medical technology, biotechnology, and pharmaceutical (MTP) sector is urging the Federal Government not to devastate Australia's most innovative industry.

The R&D Tax Incentive is the most critical centre-piece program in the translation of Australia's world-class research into treatments, cures, diagnostics, medical devices and vaccines. The program has been successful in helping attract more investment in R&D and fostering a strong Australian life sciences clinical trials and R&D sector.

The changes proposed, especially the \$2 million cap, will have significant, disproportionate and negative impact on the MTP sector. Only around 5.5% of research expenditure registered for the R&D Tax Incentive relates to MTP, however comments from the Report's authors that the impact of the \$2 million cap will be "slight" or that other policy measures, like the investor incentive or the Biomedical Translation Fund, will balance out damage, fail to understand the impact that is likely in the sector, its broader ecosystem, or the nature of clinical trials.

49 percent of companies said the R&D Tax Incentive was the issue that most concerned them at a Federal Government level and the strongest request for the up-coming budget was for the policy to be left alone and not impose the proposed \$2 million cap.

Respondents said implementing a \$2 million cap will impact the ability to employ staff for 58 per cent of companies, while 46.5 per cent of companies will be have a reduced capacity to employ STEM graduates, 81 per cent will be affected in their capacity to attract investment and 75 per cent will be less able to compete globally.

Companies were on average able to leverage the non-dilutive capital provided by the R&D Tax Incentive at \$8 for every dollar spent and the preservation of the program remained clearly the most-commonly cited, unprompted concern for the industry's future.

Key Findings

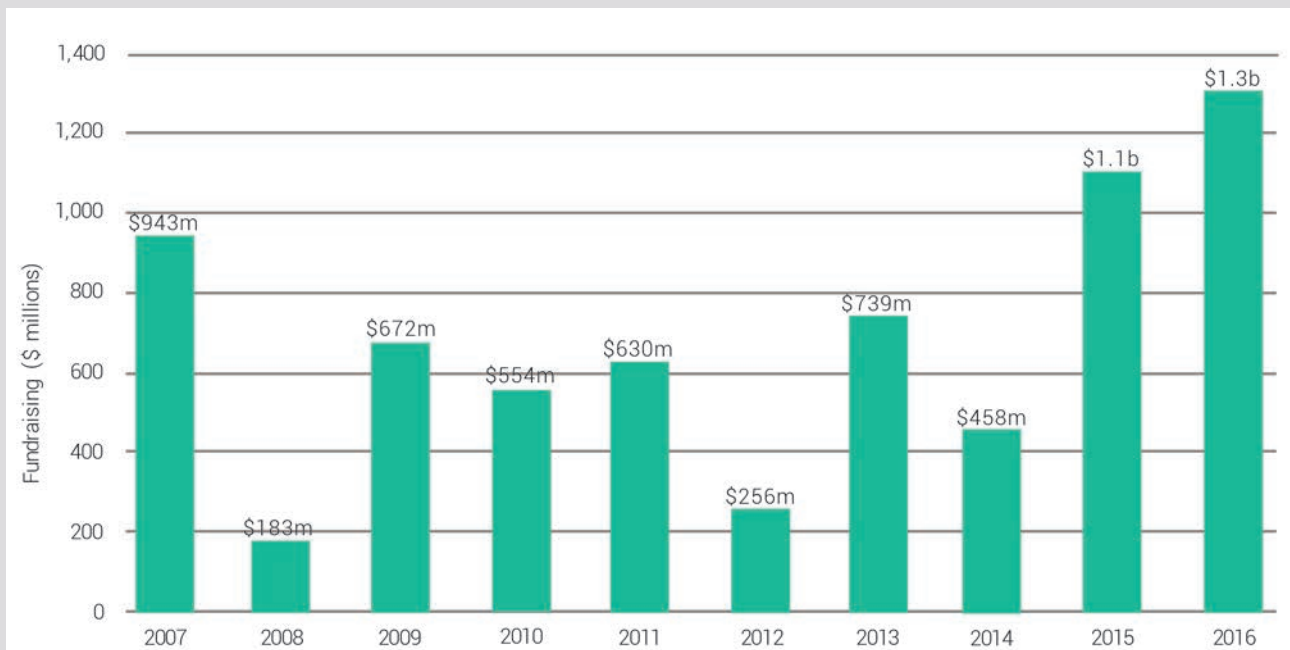
3 The quest for capital remains top of mind

With the threat to non-equity diluting capital flow into the sector, the sharp drop in companies with more than two years' cash-on-hand is concerning. Access to capital for companies developing new technologies remains the issue that keeps CEOs, MDs and directors awake at night.

Despite 43 per cent of companies raising capital in the last 12 months, the number of companies with more than 24 months' capital was only 12 per cent, the lowest point since 2013 and 41 per cent of companies has between one and two years' cash on hand.

The R&D Tax Incentive plays a key role in providing cash flow to the sector, however Australian technology companies will take a further hit as the US-based counterparts are buoyed by news of the bipartisan bill that to enable a tax credit for expenses of contracted research. The Bill was introduced in the US House of Representatives in April 2017 – a move that is expected to put Australian clinical trials at a further disadvantage.

The number of companies planning to raise capital rose sharply to 51 per cent (up from 40 per cent last year) and the highest portion of the industry on record. A further 24 per cent said they might raise capital this year.



Contribution to the economy and value of the industry

Since the mapping of the human genome, biotechnological innovation has been viewed by countries around the globe as the foundation-stone of our future, with endless possibilities. It is anticipated that it will underpin our economy and provide solutions to intractable problems of human and animal diseases, ageing populations, fuel alternatives and food security.

Sectors such as regenerative medicine, treatments in immuno-oncology, gene editing, 3D printing and digital health solutions are providing staggering new possibilities to improve our quality of life.

For our part, Australia is well on its way to achieving this vision of a successful bio-economy. The latest Scientific American, Worldview Scorecard 2016 ranked Australia in the top five globally, for the third consecutive year.

Since its emergence in the early to mid-nineties, and despite the challenges of the global economy and the degree of difficulty in building a biotechnology and life sciences sector, Australia has achieved a great deal. Australian biotechnology boasts a raft of success stories and a world-class industry. Australia currently has around 100 ASX-listed life sciences companies, with a market capitalisation of \$93.74 billion.

The Australian biotechnology industry is expected to continue growing according to the McKell Institute's Bio-Savvy report (2016) and has grown at an average of 3.1 per cent each year for the last 10 years.

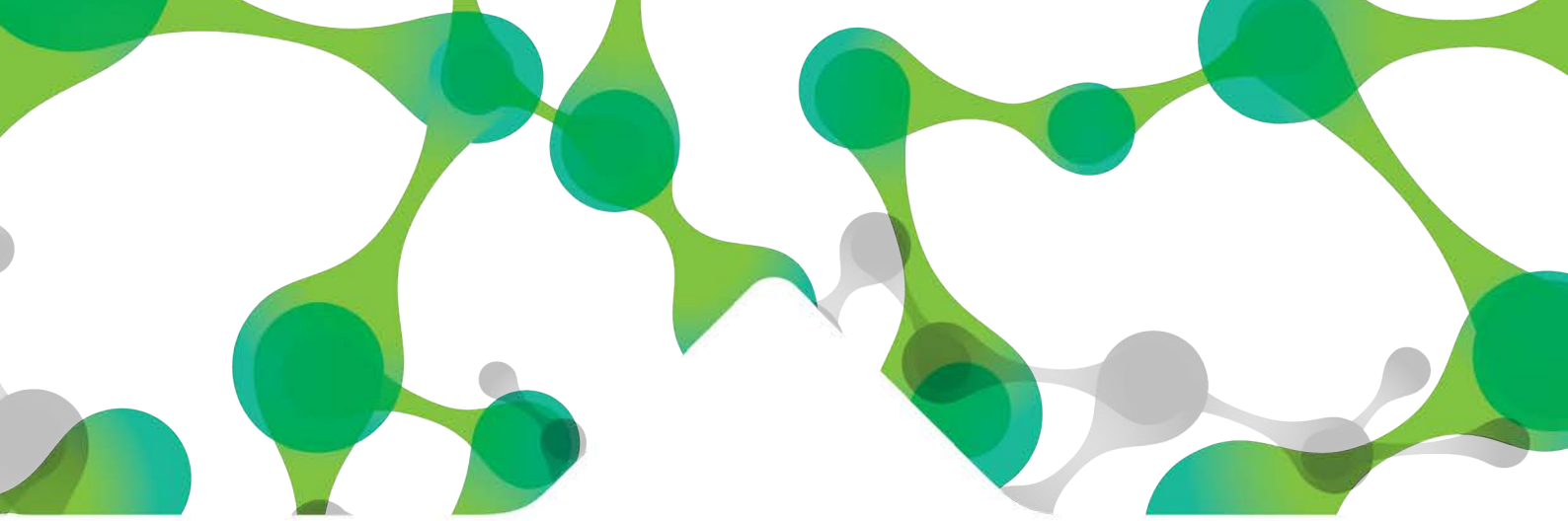
The Report notes that with an increase in the demand for biotech products like human therapeutics and diagnostics, Australia can expect to see continued growth given the right policy settings in the coming five years. The sector is expected to grow at a rate of 4.4 per cent a year, reaching \$8.67 billion in revenues by 2021.

More recently, the CSIRO, has launched a blueprint for how the medical technologies and pharmaceuticals (MTP) sector could add \$18 billion to the Australian economy and about 28,000 new jobs within the next eight years in The Medical Technologies and Pharmaceuticals Roadmap (2017).

The roadmap, which is aligned with the MTP Connect industry growth centre, says the sector is expected to grow to almost \$3 trillion globally by 2025 and sets out a path for how Australia could become an "important player" in the MTP sector in the global landscape.

The roadmap outlines four main areas on which Australia could capitalise, based on global trends and our existing advantages:

- Smart devices, implants and bionics
- Accelerated pharmaceutical development
- Manufacturing high-value pharmaceuticals
- Diagnostics, informatics products and services.



30%

30% of respondent companies are exporting. The 14 companies that exported in 2016 reported a total export value of \$222 million for the year, a portion of the total \$4 billion in annual exports.

\$334.5M

39 companies reported their R&D spend for 2016 at \$334.5 million, of a total \$901 million spend across the industry.

3,722

42 companies employ 3,722 people and the industry is estimated to employ 48,000 people, in highly-skilled STEM-based jobs.

\$169.6M

Spend on clinical trials for 2016 was \$169.6 million for 23 companies. The industry is estimated to be worth around \$1 billion annually.

52%

52% of companies manufacture: 30% manufacture in Australia and 37% manufacture overseas, 15% manufacture both in Australia and overseas.

62%

62% of respondent companies conducted clinical trials in 2016.

\$12.2M

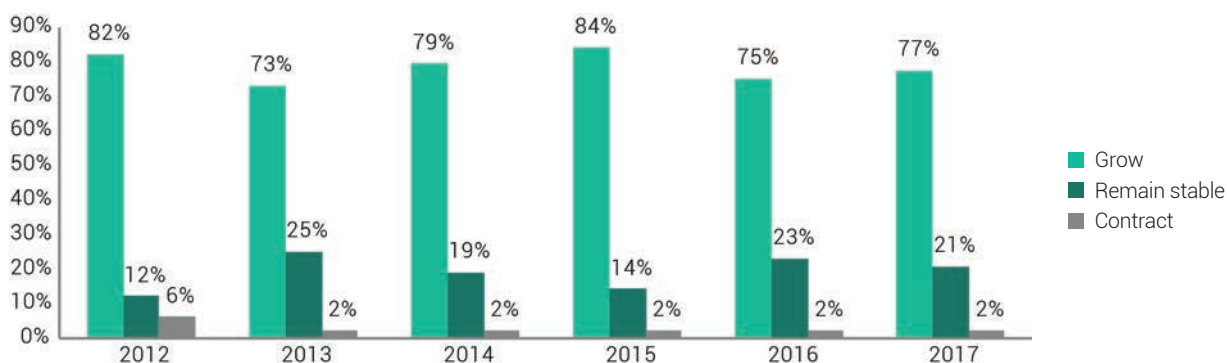
For 37 companies, the collective value of managing patent portfolios is \$12.266 million, with an average of \$371k and a median of \$120k.

Business sentiment in the industry

Sentiment across the sector is mixed. While the Survey shows a significant jump in the number of companies reporting an 'excellent' or 'good' year – 72 per cent compared to 60 per cent in 2015 – capital is an emerging issue. The situation is made worse by proposed changes to the R&D Tax Incentive.

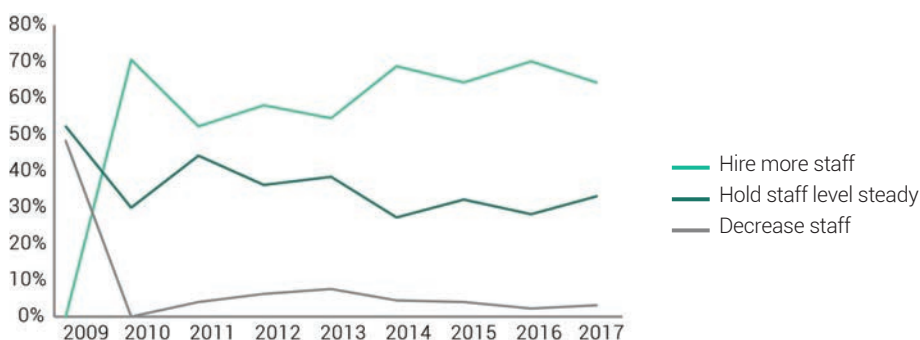
Over three quarters expect their business to grow in 2017, largely in line with last year's result. Importantly, only 29 per cent believe the Australian operating environment remains conducive to growing a biotechnology business – down from 41 per cent in 2016. One-in-five believe the local environment works against growing a biotechnology company.

In 2017 do you expect your business to?



The employment outlook has weakened, with 64 per cent of companies indicating an intention to hire, down from 70 per cent in 2015. The most worrying result was the dramatic fall in the number of new positions, down from 218 to just 91. Of these, around one-third are in a combination of scientific, clinical, engineering and product development roles.

Regarding staffing levels, do you expect to?



Financing, investment, listing & costs

Although some Australian biotech companies took a step back from capital raising in 2016 – with 43 per cent of respondents reported seeking new funds in 2016 compared to 57 per cent in 2015 – the total volume of biotech capital raising indicates a period of unprecedented strength.

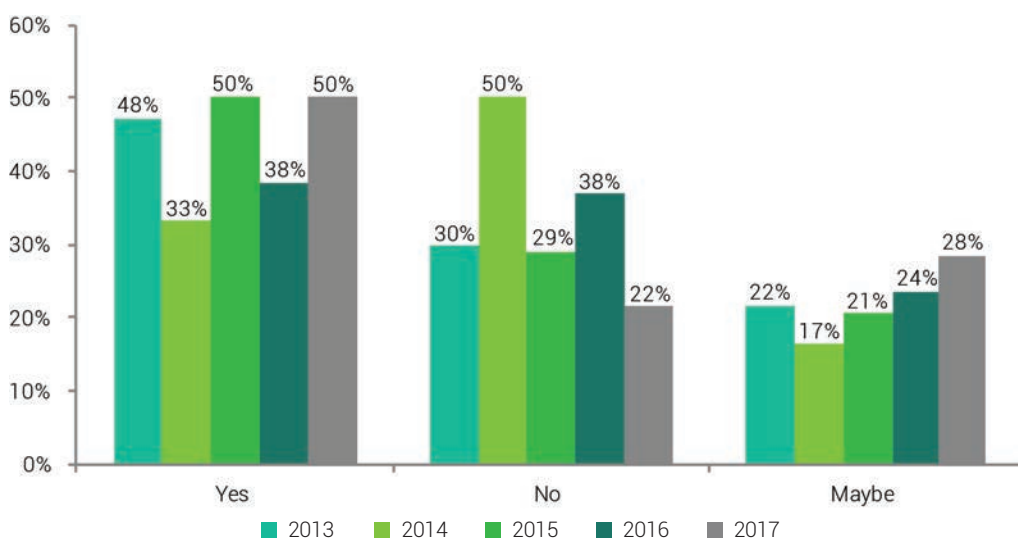
Across the sector, almost \$1.384 billion was raised in 2016, although the vast majority of this figure is comprised of Mayne Pharma's \$888 million capital raising to acquire 42 generic medications from Teva Pharmaceutical Industries. However, the fact that the Adelaide-based company was successful against an extremely competitive global field to secure the deal, it's a huge boon for the local sector and demonstrates the increasingly significant role Australia is playing on the international biotech stage.

Other significant recent transactions include the raisings undertaken by Mesoblast and AirXpanders, valued at \$53 million and \$45 million respectively.

Ellex Medical Lasers also undertook a \$10.3 million raising in 2016 to help drive global expansion of its iTrack surgical laser. The iTrack is one of only three devices the US Food and Drug Administration has approved to treat glaucoma.

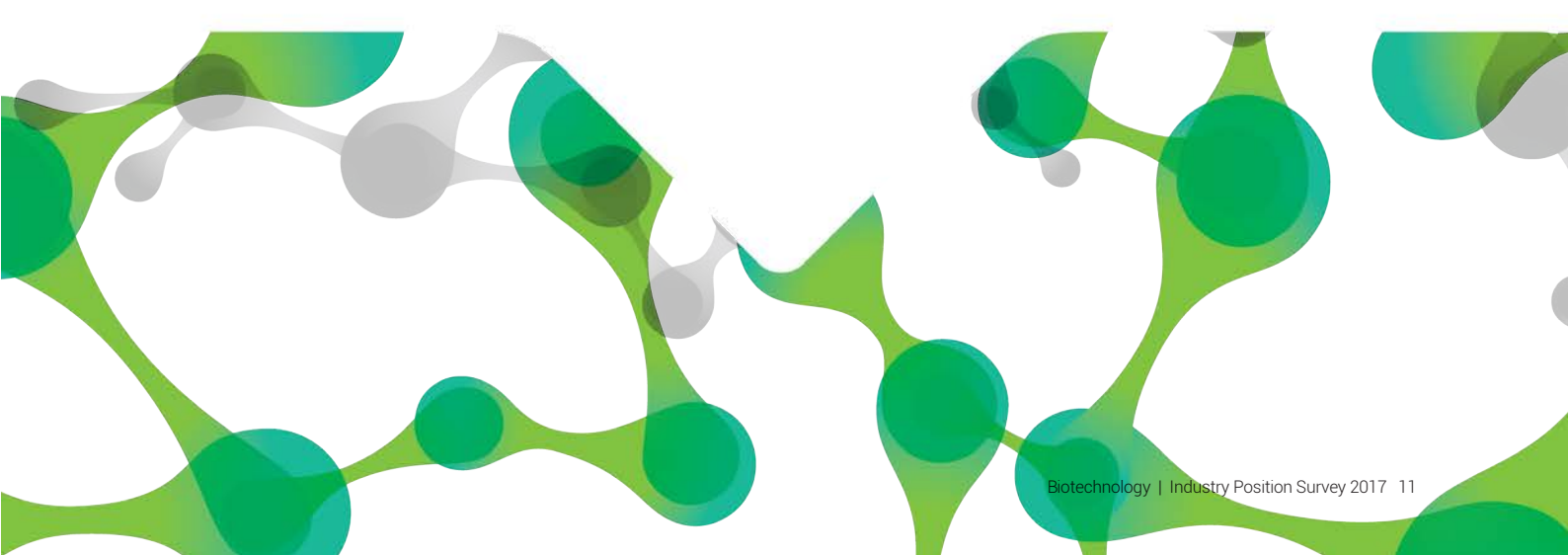
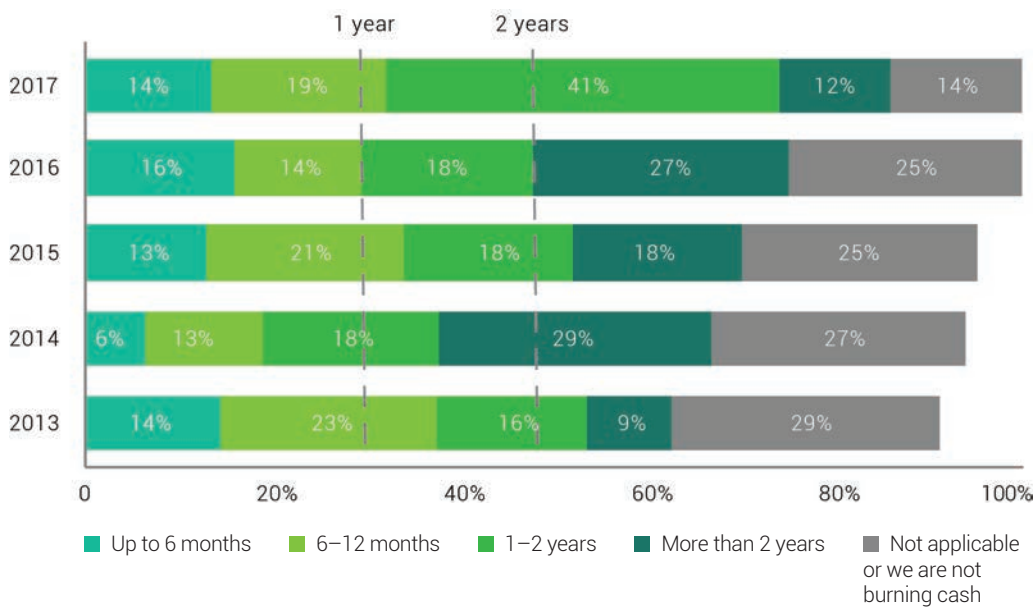
The slight dip in respondents seeking capital last year may point to 2016 being a consolidation year for many firms. This analysis is supported by the more than 50 per cent of respondents that indicated they are definitely intending to raise capital in 2017, with a further 24 per cent indicating that a capital raising is possible. This contrasts starkly with our previous survey, which found that only 40 per cent of firms intended to raise capital at the beginning of 2016.

Do you plan to raise capital this year?



Recent financial figures – and responses throughout this year’s survey – indicate a confident, optimistic Australian biotech sector with ambitious plans for the rest of 2017 and beyond.

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



Government policy

Fears realised over R&D Tax Incentive

In last year's Survey, respondents expressed significant concern over government's intentions in relation to the R&D Tax Incentive, with 90 per cent describing program stability as 'very important' or 'important'.

Over 80 per cent said they were concerned about the review 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.

Unfortunately, these concerns were realised in 2016 with the review recommending a raft of changes to the program, including a \$2 million cap on annual cash claims.

AusBiotech has led opposition to the changes, highlighting the risk to the sector, given the unique nature of its reliance on the program, and to Australia's goal of transitioning to an innovation-based economy.

Over 70 per cent said they have concerns about proposed changes recommended by the Review, with 58 per cent saying the proposed \$2 million cap on cash claims will undermine their ability to employ staff, including interns and STEM graduates, while 75 per cent say it will undermine their ability to compete globally.

Highlighting the program's importance to the sector, over 80 per cent said it makes it easier to attract direct investment locally and globally. One-in-five identified access to capital as a policy issue of most concern, making it second only to the R&D Tax Incentive.

AusBiotech has expressed significant concern over the potential impact of the changes on clinical trials. More than four-in-five Survey respondents (85 per cent) agreed that exempting clinical trials from the cap would benefit their company.

The sector awaits government's response to the recommendations.

Need for policy and political stability

The sector's concern over proposed changes to the R&D Tax Incentive highlights the importance of policy stability in the innovation 'ecosystem'.

Government's goal to develop a successful innovation ecosystem requires the maintenance of a stable, supportive and consistent policy environment that encourages companies to make decisions that attract investment and grow R&D activity.

This has been consistently shown in previous surveys and is shown again this year.

Almost 90 per cent of Survey respondents agreed that stability in the operation of the R&D Tax Incentive is 'very important' or 'important'.

Yet proposed changes to the R&D Tax Incentive, coming on top of changes in 2015, are only fostering instability and undermining the sector's confidence in Australia.

This is evident in declining perceptions of the operating environment. Only 29 per cent of Survey respondents believe the Australian operating environment remains conducive to growing a biotechnology business – down from 41 per cent in 2015. One-in-five believe the local environment works against growing a biotechnology company.

While 77 per cent expect their business to grow in 2017, this is being put at risk by policy instability and the potential decision to undermine the R&D Tax Incentive.

Government's response to the recommended changes to the R&D Tax Incentive is an opportunity to reinforce its commitment to innovation and the Australian biotechnology sector.



Intellectual property

The Survey reveals concern over the Productivity Commission's recommendations to substantially wind back intellectual property protection for pharmaceuticals.

In a series of recommendations contained in a report last year, the Commission called for the winding back of the five-year patent term extension, saying it should "be carefully targeted, and only available in instances of unreasonable regulatory delay."

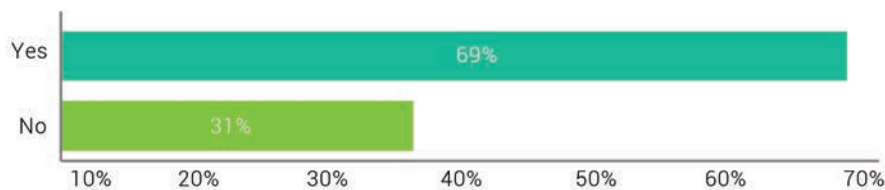
It also recommended against any further extension to the current five-year data protection period for biologics.

AusBiotech has spoken out against the recommendations, highlighting recent decisions of government to dismiss similar findings of previous reviews, including the 2013 Pharmaceutical Patents Review.

Almost 80 per cent of Survey respondents agreed their companies would be negatively impacted by any decision to remove or limit the current five-year patent term extension. Almost 70 per cent of respondents also expressed concern over data exclusivity remaining at five-years.

Government is yet to respond to the Productivity Commission's report.

Are you concerned by data exclusivity provisions remaining at five years?



"The recommendations from the Productivity Commission's review are a retrograde step and places Australia out of step with the developed nations. It also does not support the innovation agenda nor recognise Australia's potential contributions to science and potential financial returns. It's bad policy when most countries are going in the reverse direction."

Comment from industry leaders

The McKell Institute said in its Bio-Savvy report (2016): "Australia... is not acting in a vacuum. Other governments have also targeted biotech as an industry to be fostered. While Australia currently ranks well on many international benchmarks, many of our regional neighbours are investing heavily in the industry and are expected to outperform Australia within the coming years."

"South Korea, Singapore, China and Taiwan are injecting significant government and private funds into biotechnology, and embarking on regulatory reform programs to attract large international firms to their shores."

"The critical value of the R&D Tax Incentive is predictable access to cash flow. We're ready to march in the streets if the program is threatened."

"Specialist skills and expertise are sadly lacking in Australia. And any wonder; we're losing our good people overseas and they're not coming back. What's the incentive?"

"Government still don't seem to understand the issues that are specific to biotech."

"Australia is fertile ground for biotech industry and world leading in niches, which is why we've made it this far."

"Australian Government just doesn't seem to understand that it is competing on the world stage to keep IP-based companies here. Other governments are keen to have us move there. They offer us great incentives and assistance, not to mention tax holidays."

"The environment is infinitely better than it was 10 years ago, thanks to the R&D Tax Incentive."

"Digital health companies are the new frontier of medical devices. We are seeking talent that sits at the nexus of software and medical. We compete against Google and Apple for staff."

"The Australian environment is so complex, with ever-changing laws, programs and rules. Regulators need to provide a clear and transparent path to market."

"The big change [1 January 2017] in university funding arrangements should see industry collaboration suddenly become important. This is a good thing as it will change the dynamic..."

"We need more, dedicated industry analysis, to be able to grow investment in biotech."

"So much of what we do, needs new thinking and new models."



Methodology

This is the seventh Biotechnology Industry Position Survey conducted by AusBiotech and supported by Grant Thornton. The survey was conducted via mail/email during February 2017 and was followed by roundtable focus groups in March and April 2017. The survey was open to all ASX-listed and unlisted biotechnology companies, including AusBiotech members.

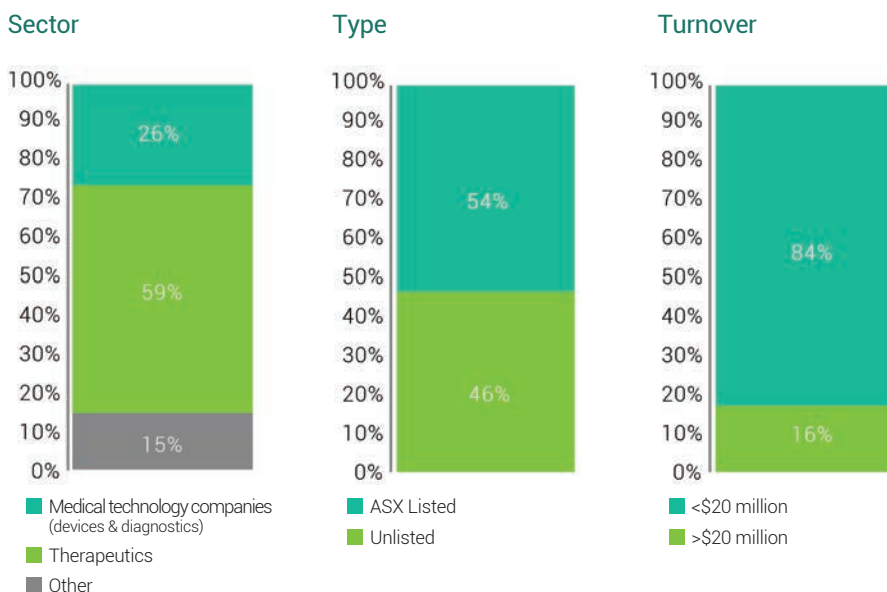
To complement the survey data, numerous companies participated in the roundtable discussions held in Sydney, Melbourne, Brisbane and Perth.

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/ 03 9828 1400).

Analysis of respondents

Responses were received from 46 companies. In addition over 60 companies participated in the roundtable discussions, held around the country.



Sincere appreciation is extended to those who participated in the survey in support of the industry and thanks goes to the following companies that agreed to be named:

Acrux	HaemaLogiX Pty Ltd
Actinogen Medical	Janssen (Johnson & Johnson)
AdAlta	Kyyron Pty Ltd
Amgen Australia	Living Cell Technologies Ltd
Analytica Ltd	Mesoblast Ltd
Benitec Biopharma	Minomic International Ltd
Bioplatfoms Australia	Neuren Pharmaceuticals
Biotron	NeuroScientific Biopharmaceuticals Pty Ltd
Bioxyne Limited	Occurx
Bluechiip Ltd	Patrys Limited
Calimmune	PolyNovo
Cancure Ltd	Regeneus Ltd
Cell Therapies Pty Ltd	Resonance Health
Cellmid	Rhinomed
Clinical Genomics	SUDA Ltd
Cook Medical	Vestech Medical Pty Ltd
Elastagen Pty Ltd	Vudbenk Life Science Australia Pty Ltd
Global Kinetics Corporation Limited	
Global Orthopaedic Technology	

About AusBiotech and Grant Thornton

About AusBiotech

AusBiotech is a not-for-profit organisation, which has 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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Grant Thornton Australia has more than 1,000 people working in offices in Adelaide, Brisbane, Cairns, Melbourne, Perth and Sydney. We combine service breadth, depth of expertise and industry insight with an approachable "client first" mindset and a broad commercial perspective.

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