

# Biotechnology

INDUSTRY POSITION SURVEY 2016

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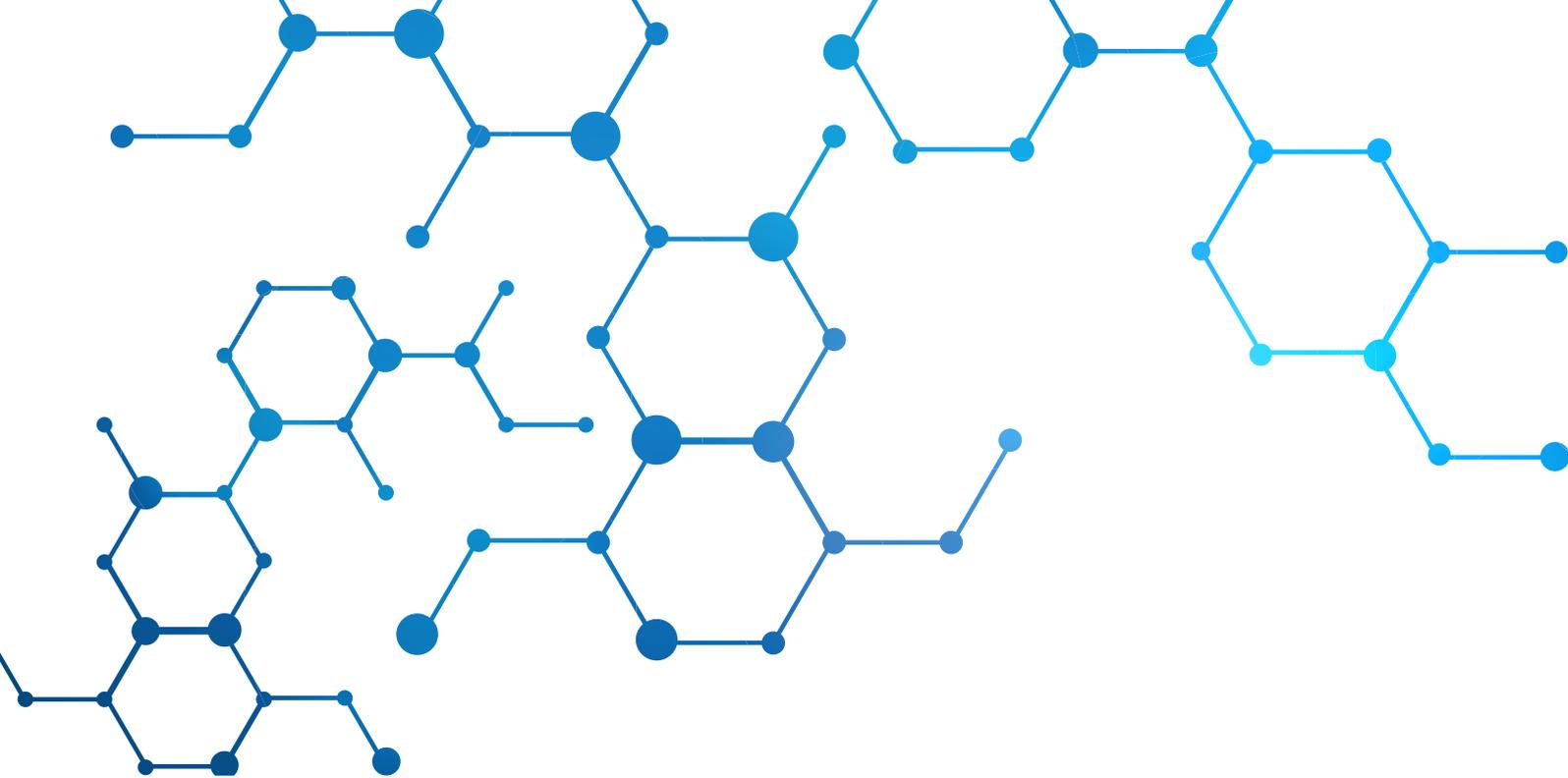
  
**AusBiotech**  
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

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# Foreword

Biotechnology continues to be front and centre of Australia's post-mining boom economic transition. The sector has been a pivotal contributor to Australia's economy since it emerged over three decades ago. Yet the past year has seen increasing recognition of this growing contribution by government, media, local and global investors, but concerns remain.

We have global recognition of the sector's quality, reflected in major deals, including Novartis' acquisition of Spinifex Pharmaceuticals for as much as AU\$1 billion and AstraZeneca's licensing agreement with Starpharma that could deliver over half a billion AUD.

The 2016 AusBiotech CEO Industry Position Survey reveals the importance of these deals to boosting the confidence of our sector – the interest and investors are there. They also have the added impact of showing key decision-makers in government and the investment community that we have and do deliver for Australia.

The timing of these deals and the emergence of companies across the sector has been pivotal given the Government's renewed focus on innovation. There has been a significant change with political and policy decision-makers publicly recognising the importance of our sector to Australia's future prosperity.

Prime Minister Malcolm Turnbull announced the National Innovation and Science Agenda last December, including \$250 million for a Biomedical Translation Fund (BTF) as the first investment from the \$20 billion Medical Research Future Fund.

Matched with private sector funding, the BTF will operate on a commercial basis and provide targeted support for companies with technologies in mid to late stage development. Its aim is to help address Australia's well documented poor performance in the commercialisation of R&D, a reality that is consistently reinforced by international reports.

The announcement reflected a wider change in the approach to innovation in the second half of 2015, a theme picked up by the Survey. Leaders reported a 'bandwagon effect' with increased interest from states beyond the traditional drivers of Victoria and Queensland.

Policy appears to be heading in a better direction given the contrast with last year's Survey, when our leaders expressed significant concern over the failure of Australia's policy-makers to adequately respond to an increasingly competitive global environment.

The full benefit of this new direction is yet to materialise and we are looking for more action from decision-makers in the Federal Government.

The sector's response has been positive to recent developments in the commercial and policy environment, with 75 per cent of Survey respondents saying they expect 2016 to be a year of growth. This contrasts with 2015. Only 60 per cent of respondents described the year as 'excellent' or 'good'.

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**In one of the more significant turnarounds in this year's Survey, 41 per cent of respondents said the environment in Australia (economic conditions and public policy) was now conducive to growing a biotechnology company, up from just 16 per cent last year.**

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Importantly, 70 per cent expect to hire more staff, up slightly from last year's 64 per cent and broadly in line with 2014 (69 per cent). This intent to hire is yet another clear signal of the sector's potential contribution to Australia's transitioning economy. It also goes to the importance of education policy and the need to ensure our tertiary education institutions remain globally competitive and continue producing high quality graduates, particularly in science.

Significant issues of concern remain, particularly in relation to the R&D Tax Incentive, inadequate responses to other policy issues and general political instability, which will be an enduring theme in 2016 given the current Federal Election.

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## Foreword cont.

The Survey shows leaders remain concerned over the constant tinkering and reviews of the R&D Tax Incentive, with 90 per cent saying program stability is 'very important' or 'important', and 81 per cent saying they are concerned about the recently completed 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. The outcome of the Review is yet to be revealed.

The concern is legitimate given the Government has already imposed an expenditure claim threshold of \$100 million. It also remains committed to cut claims by 1.5 per cent, despite the legislation being prorogued before the May Federal Budget and the failure of this measure to win parliamentary approval.

The Federal Election gives Australia's political leaders an opportunity to resolve this sense of uncertainty impacting a sector that maintains strong bipartisan political support.

Our sector is also dealing with the Government's incomplete reform of employee share schemes. While it recognised the need to reverse changes made by the previous government, its 2015 reforms had the effect of largely excluding our sector who are listed, which only undermines its desire to create a fully supportive policy ecosystem.

Part of the issue could be a lack of understanding of our sector amongst key decision-makers in government, an issue identified in the Survey, which reported a level of frustration over their knowledge of biotechnology and R&D.

The appointment earlier this year of experienced biotechnology executive Sue MacLeman to lead the Government's Medical Technologies and Pharmaceuticals Industry Innovation Growth Centre (MTPConnect) was an important signal that there is recognition of the need for sector expertise in supporting the development of policy. Yet more is needed and we look forward to a deeper appreciation of the business agenda and the issues that rely on great public policy.

The number of companies manufacturing in Australia was down slightly compared to last year, from 52 per cent to 45 per cent. It remains higher than the 38 per cent that reported manufacturing in 2014. Around 70 per cent of companies are manufacturing, the same level as 2015.

AusBiotech continues to pursue reforms that will support the creation of an environment more conducive to advanced manufacturing, The Australian Innovation and Manufacturing (AIM) Incentive, which would provide a tax incentive for companies to retain intellectual property and manufacturing in Australia, is recognised by over 80 per cent of Survey respondents and also enjoys strong support. A recent report by the Trade and Investment Commission agrees that this strategy is one that should be considered by Government to keep Australian IP on-shore and encourage manufacturing.



Dr Anna Lavelle  
CEO, AusBiotech

"Australian life sciences companies have attracted more than \$2 billion in deal flow over the last 18 months, which is bolstering confidence and showing success is not theoretical."



Michael Cunningham  
National Head of Life Sciences | Grant Thornton Australia  
"The industry is expecting positive growth in the next 12 months. To ensure the momentum continues the Government needs to provide an environment where Australia's biotechnology companies have consistency and stability around R&D tax and other incentives."

# Key findings

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## 1 Confidence remains strong and sets some records

Companies planning to increase their staff this year are at an all-time high with 70 per cent of companies intending to hire staff this year (up from 64 per cent last year and 69 per cent in 2014), with 30 companies intending to recruit to 213 identified new roles.

Interestingly, 41 per cent of respondents said the environment was conducive to growing a biotechnology company, up from 16 per cent last year and higher than the 35 per cent reported in 2014. It seems to be the highest result ever recorded (24 per cent in 2012). Almost 23 per cent said the environment worked against growth of a biotech company, down from 39 per cent last year.

Almost 60 per cent of respondents described the past year as an 'excellent' or 'good' year. This was down from the previous survey (69 per cent) but compares well to 58 per cent (surveyed in 2014 reflecting on 2013). In the year ahead, 75 per cent of respondents say they expect to grow, 23 per cent expect to remain stable and only 2 per cent anticipate a contraction.

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## 2 All eyes on the R&D Tax Incentive

The R&D Tax Incentive was confirmed as the most significant Government program for promoting innovation in the private sector, which plays a pivotal role in motivating and attracting research, development and clinical trials to be conducted in Australia. It is the most critical centre-piece program in the translation of Australia's world-class research into treatments, cures, diagnostics devices and vaccines.

Over 90 per cent of respondents said policy stability on the R&D Tax Incentive was 'very important' (72 per cent) or 'important' (18 per cent) and 81 per cent said they're concerned about the review.

The preservation of the program remained clearly the most-commonly cited, unprompted concern for the industry's future.

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## 3 Smart science needs smart money

Access to capital for companies developing new technologies remains a critical issue. While the R&D Tax Incentive plays a key role in providing non-equity diluting cash, Australian technology companies face unique challenges and sit at a disadvantage compared to their US-based counterparts.

Respondent companies lament the lack of understanding of their unique business model amongst investor and policy makers.

The number of companies planning to raise capital dropped slightly to 40 per cent, down from the same position last year (48 per cent), but up on the 33 per cent recorded in 2014. A further 23 per cent said they might raise capital this year.

The number of companies with less than 12 months' capital was around 30 per cent, down from 34 per cent last year, but still up on 19 per cent in 2014.

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## 4 Policy stability key

Perhaps due to the latest review of the R&D Tax Incentive, a strong theme of the past year – and certainly in the survey – has been a growing chorus of yearning for Government policy programs to have continuity for stable periods.

To build an innovation ecosystem in R&D-intensive industries, it is critical to maintain a stable, supportive and consistent policy environment to encourage businesses to make strategic decisions around R&D activity and attract additional investment.

Pre-revenue companies in tax loss are reliant on investment (venture capital, issuing equity, etc.) and grants to complete their R&D programmes and reach commercialisation. The constant reviews, threats and tweaks to industry support programs are unsettling for biotechnology developers, who have long development cycles – and undermine business confidence. The negative impact that uncertainty has on product development/innovation companies is destabilising and program changes cause one of the greatest costs, in practical terms.

# Contribution to the economy and value of the industry

Biotechnology has been recognised for its comparative advantage for Australia, demonstrated by state and Federal government's strategic plans and more recently in the National Innovation and Science Agenda.

Australia is well on its way to achieving this vision of a successful bio-economy. Supported by a long history of biotechnology innovation, with the Cochlear implant and the cervical cancer vaccine among the most-often-cited examples, Australia has good credentials on the global stage.

Australia is amongst the world leaders for biotechnology, boasting the largest listed biotechnology sector as a proportion of GDP in the world. Adjusted for population, it has one of the largest and fastest-growing public markets for biotechnology and yields some of the greatest public revenues across the globe. And being home to one of the largest groups of global graduate students, Australia's strength in biotechnology promises to grow.

## 43%

43% of respondent companies are exporting, down from 48% past year. Of these 17 companies reported an estimated value, which totals \$807 million, up substantially from \$158 million in 2015.

## \$2.5BN

41 of the responding companies reported their R&D spend for 2015 at an aggregated \$2.5 billion, up from \$889 million in 46 companies in 2015.

## 4,920

46 companies employ 4,920 people (compared to 55 companies employing 4,929 people in 2015).

## 213

The industry respondents will create 213 new jobs after 239 new jobs were created in 2015.

## 71%

71% of companies manufacture: 46% manufacture in Australia and 50% manufacture overseas, 25% manufacture both in Australia and overseas.

## \$34.4M

55% of respondent companies conducted clinical trials in 2015, totally approximately \$ 34.4 million in investment.

## \$8.08M

Respondent companies had a combined spend of \$8.08 million to manage their patent portfolio.

## \$48.6BN

The combined market cap of 46 responding companies is \$48.6 billion.



## Clinical trials: innovation at its finest

Clinical Trials (CTs) have an important role to play in Australia's economy, healthcare and social fabric, with benefits far beyond helping develop new treatments. About 2,000 Australians take part in CTs each year. They assist in the improvement of the healthcare system, providing early access to unapproved treatments, as well as providing valuable economic activity and providing high-level Australian jobs in the clinic, science and research.

CTs, according to the Clinical Trial Action Group (CTAG) Report, are worth around \$1 billion to the Australian economy annually. This includes around \$650 million of foreign investment, with Australia attracting trials from around the world. Australia's work to be internationally competitive will attract further foreign investment and a greater share of returns to the economy.

Industry is at the forefront of conducting CTs as the largest investor in clinical research in Australia, estimated to spend more than 10 times as much as the Federal Government's research funding body, the National Health and Medical Research Council.

CTs are a critical component in the development process of bringing new therapies, devices and diagnostics to patients and monitoring once a product is in use. The primary reason for conducting a CT is to assess safety and efficacy. This investment in Australia brings valuable economic activity and is building a research ecosystem to benefit Australians.

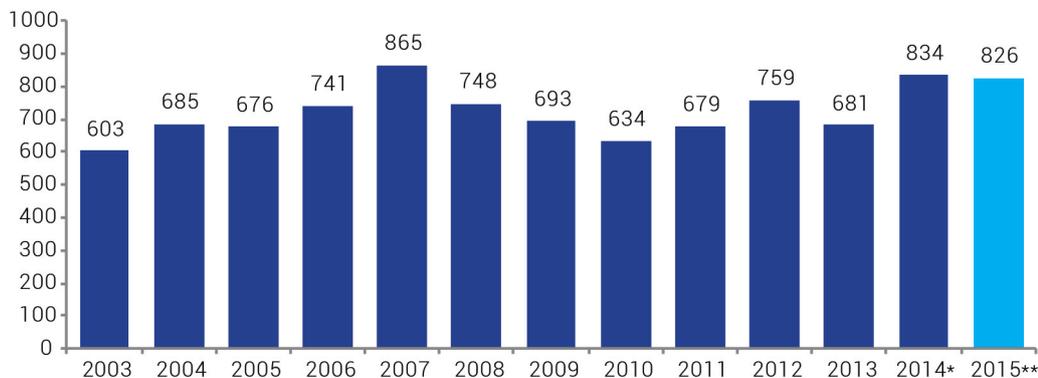
The Austrade Industry Capability Report (Clinical Trials), points out the distinct advantages that Australia presents as a place to conduct CTs (<http://www.austrade.gov.au/Buy/Australian-Industry-Capability/Health-and-Wellbeing/default.aspx>)

It notes Australia's competitive advantages in its transparent and effective regulatory system, the attractive R&D Tax Incentive, good intellectual property protection - Australia has one of the strongest and most stable IP systems in the world, ranking 11th in the world (out of 142 countries) on the International Property Rights Index.

Australia is currently playing to its strengths in the area of pre-clinical trials and early phase clinical trials, where strong R&D capabilities are required and it is less dependent on patient numbers. It is a segment where Australia has a competitive edge.

The Federal Government's Clinical Trial Notification scheme is hailed as an exemplar on the world stage and captures (and reports) the following statistics on trials initiated in Australia.

### Number of new clinical trials - Medicines

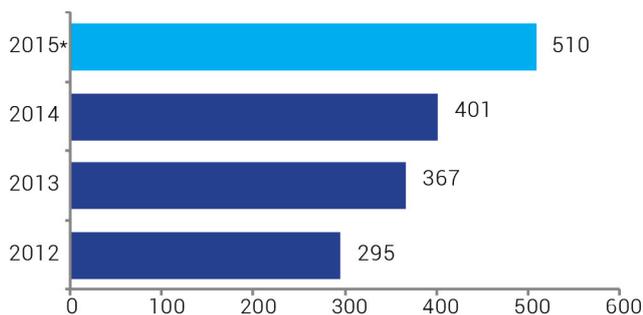


Source: Therapeutic Goods Administration, Half-Yearly Performance Reports, various years

\*From 2014, the reported figures include trials for mixed devices/medicines and mixed devices/biologics.

\*\*2015 data is only available for a half-year to June 2015 and was reported as 413. The amount shown is doubled, as an estimate.

### New clinical trial notifications that include a medical device



Source: Therapeutic Goods Administration, Half-Yearly Performance Reports, various years

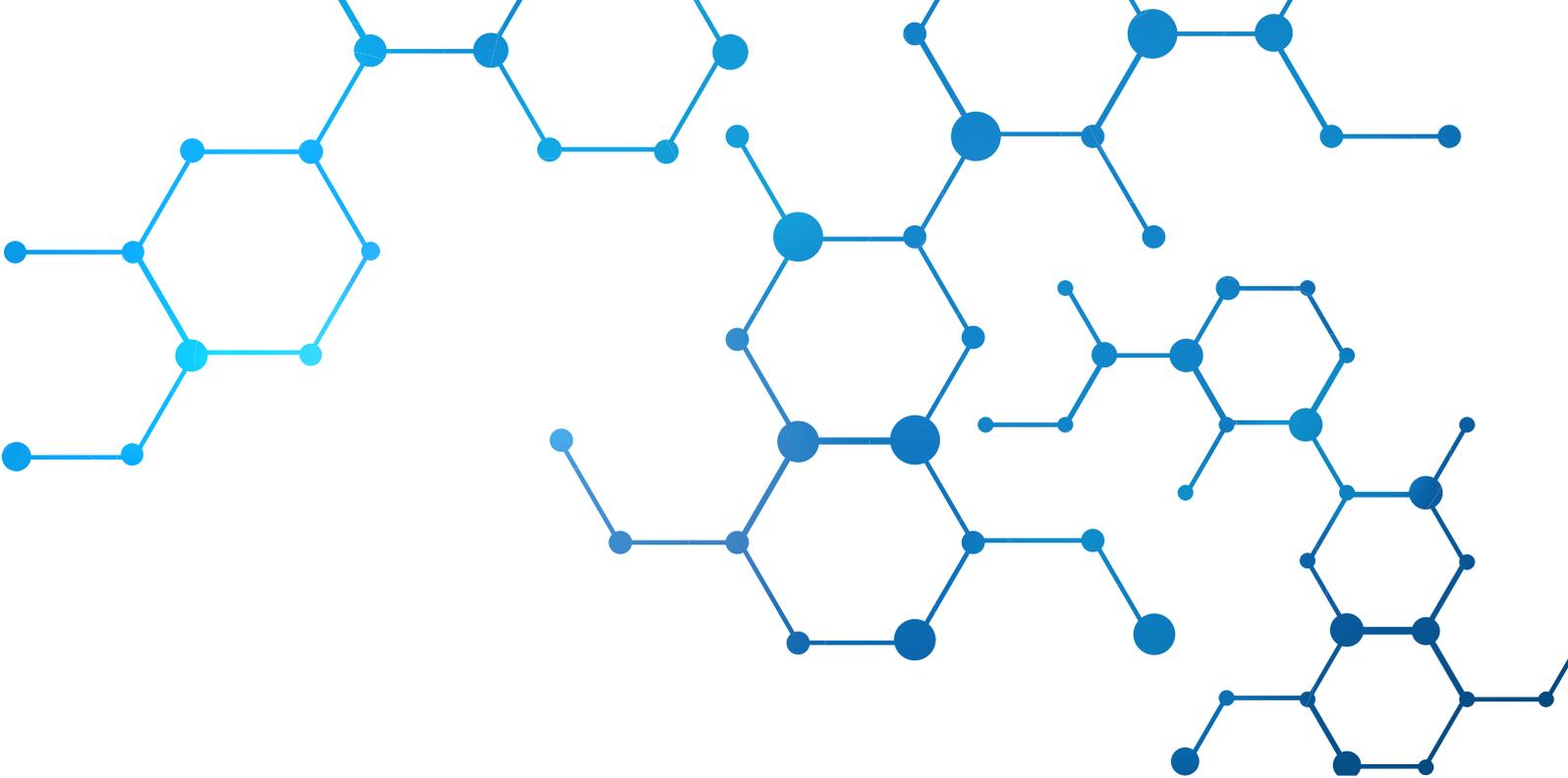
\*2015 data is only available for a half-year to June 2015 and was reported as 255. The amount shown is doubled, as an estimate.

CTs represent the most capital intensive stage of medicine and medical device development, and rightly they also represent the stage where the most value can be created for a biotechnology company and for patient pre-market. As indicated below, this annual survey of the biotechnology industry has revealed that of the 55 per cent of respondent companies conducted CTs in 2015; which when aggregated was worth approximately AUD \$ 34.413 million. The majority of Australian companies are engaged in Phase II (40 per cent) or Phase III (35 per cent) research.

### In which phase is the majority of your work?



The clinical trials section of this survey was supported by Novotech.



Given Australia's comparatively small population, one of the issues for an Australian biotechnology company in phase II or phase III CTs is location of where to conduct studies that require larger patient cohorts. Outside of Australia and New Zealand, most respondents indicated a preference for the US and Europe.

"This possibly reflects location of development partners and/or perceptions regarding regulatory acceptability of data. Nevertheless, a sizable proportion also indicated Asia as a location for their clinical development work, something US biotech firms have been engaging in for close to 10 years for their phase II and III CTs. Given the proximity of the region to Australia and other advantages, it will be interesting to see uptake of the Asian option in future surveys, particularly for later stage Australian biotech firms in the clinic."

Alek Safarian | CEO, Novotech

As Australia develops its CT ecosystem, including a broader, more sophisticated clinical research organisation (CRO) network and work to improve patient recruitment and study start up times, it has the opportunity to grow into providing increased, later-stage work here, for the benefit of all.

Facts and figures on the clinical development market in Australia:

- Oncology and cardiovascular disorders represent the largest number of clinical trials conducted in Australia. The oncology segment contributed around 37 per cent whereas the cardiovascular segment's contribution was estimated at 16 per cent in 2014.
- Although the overall number of CTs commenced in Australia rose slightly in 2014 as compared with the previous year, the number of early-stage phase I clinical trials increased by over 40 per cent.
- Despite the growth in phase I trials the majority of biotech and medtech SMEs are conducting phase II in Australia, phase III trials currently hold the largest market share in Australia. It is expected that high competition from other countries in APAC and Latin America for phase III CTs might cause a reduction in Australia's market share in coming years, however the trend of the phase I market suggests this segment is still growing.
- The Australian CRO market generated \$349.5 million revenue in 2014. The market is expected to reach \$615.9 million in 2019, growing at a CAGR of 12 per cent from 2014 to 2019.
- In Australia, the majority (~65 per cent) of the CTs are sponsored by private companies. A number of companies have collaborated with public institutions enabling trials to be conducted in public hospitals and universities/research institutes.
- As pharma and biotech companies continue to outsource services, there continues to be an opportunity for CROs that have the ability to support faster drug development. The country has more than 30 CRO providers, with the larger multinationals focusing on global trials, while smaller CROs work with local biotechnology companies.

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# Business sentiment in the industry

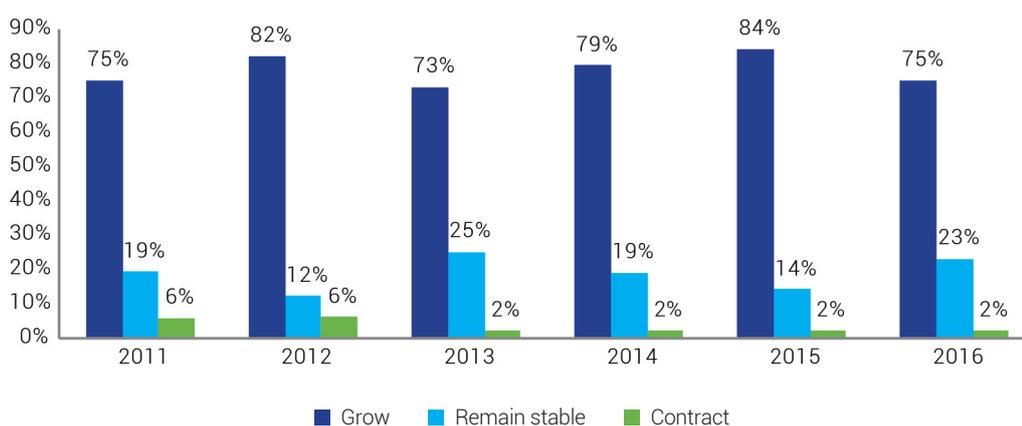
Only 60 per cent of Survey respondents said 2015 had been a 'good' or 'excellent' year, down from 69 per cent in 2014. However, 75 per cent said they expect 2016 to be a year of growth.

This positive 'forward looking' business sentiment reflects developments in the second half of 2015. The emergence of a potentially more positive policy environment has been complemented by very strong deal flow, headlined by Novartis' acquisition of Spinifex Pharmaceuticals for as much as AU\$1 billion and AstraZeneca's licensing agreement with Starpharma that could deliver over half a billion AUD.

In one of the more significant turnarounds in this year's Survey, 41 per cent of respondents said the environment in Australia (economic conditions and public policy) was now conducive to growing a biotechnology company, up from just 16 per cent last year and higher than the 35 per cent reported in 2014.

Importantly, while 75 per cent of respondents said they expect their business to grow in 2016, this was down from 84 per cent last year and still below 2013 levels, potentially highlighting the impact of policy and political instability.

## In 2016 do you expect your business to...?





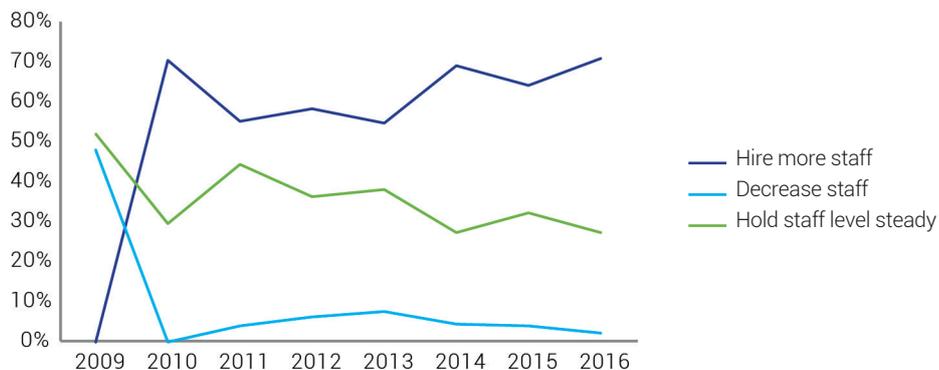
## Employment: intention to recruit continues to be strong

The outlook has strengthened in the past year, with over 70 per cent saying they expect to hire more staff in 2016, up from last year's 64 per cent and broadly in line with 2014 (69 per cent).

The majority of companies say they will recruit in 2016. Noting that the survey enquired about new positions, not recruiting to current roles, 30 companies indicated an intention to add a total of 218 new jobs, predominately in senior positions. In total, 46 companies employ 4,920 people (compared to 55 companies employing 4,929 people in 2015).

Last year's shift towards scientists and clinical trial staff has continued, with one company alone planning to add around 50 people to build its R&D and production capability. Thirty companies also indicated an intention to add business development capability in 2016, an important indicator of progress in translation.

### Regarding staffing levels, do you expect to



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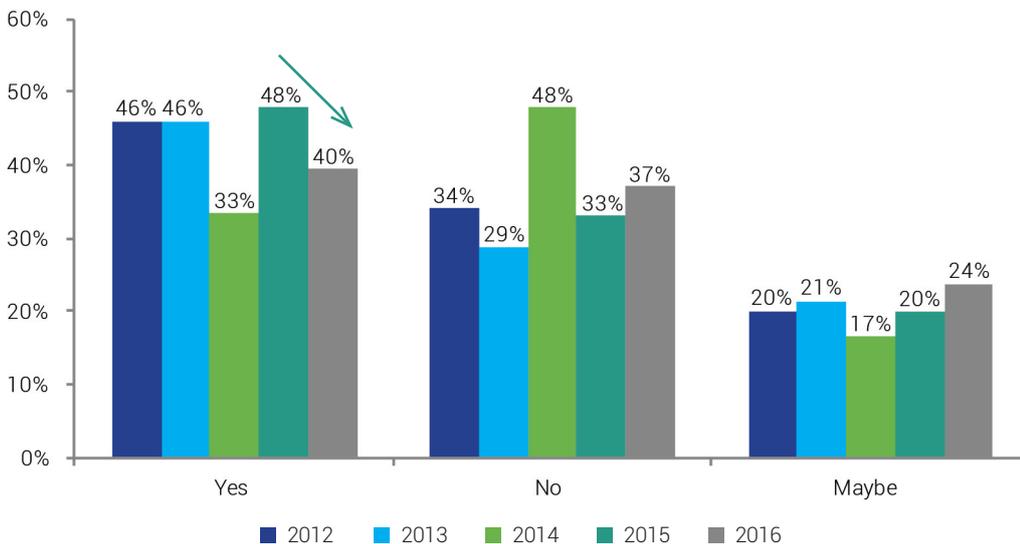
# Financing, investment, listing & costs

## Availability of funding

The past few years have seen some sizable transactions and acquisitions, in particular for large international pharmaceuticals and biotech companies. Expectations are that further transactions will take place as larger companies continue to seek to purchase biotech companies with a full product pipeline, and the lower Australian dollar is making companies attractive takeover targets foreign for buyers. While listing on the ASX remains a lucrative option, an increasing number of Australian biotech companies are considering a listing overseas.

The three 'Big Caps': Cochlear, CSL and ResMed were up 21.8 per cent in 2015 and similarly the Biotech Daily Index-40 exceeded 20 per cent, adding further momentum to the sector, which continues to attract more venture capital funds and interest. Some other major highlights in the sector included Sirtex Medical and Mayne Pharma, which soared off the back of a US-led growth strategy.

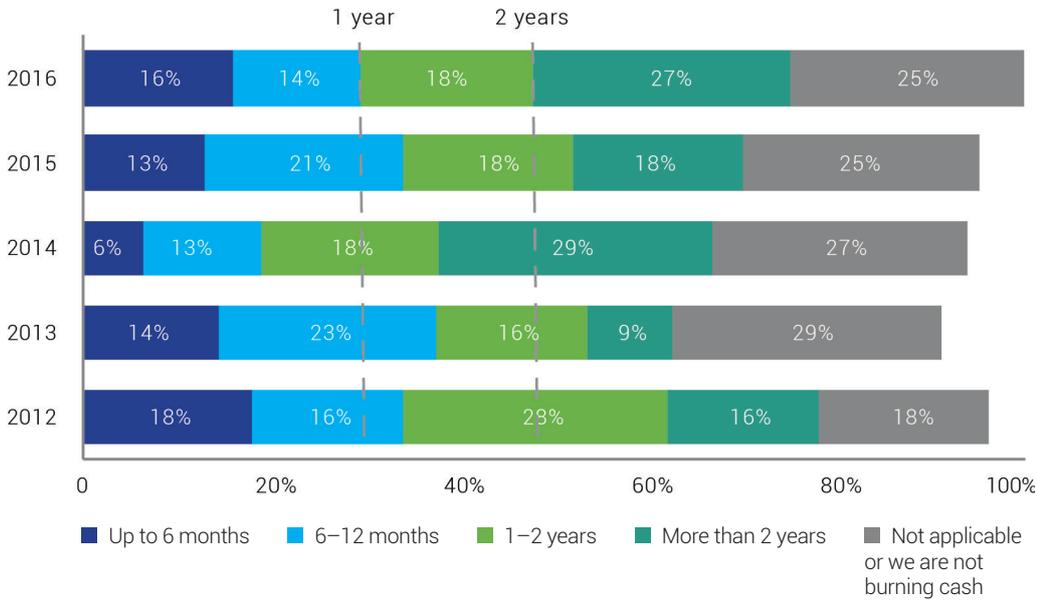
## Do you plan to raise capital this year?



Capital raising in 2015 exceeded \$1.14 billion, including Brandon Capital's Medical Research and Commercialisation Fund's raising of \$200 million. This compared to previous high of \$754 million in 2013 and a seven-year average of \$439 million a year. Of the companies surveyed, 57 per cent raised capital in the last 12 months, almost 10 per cent more than had been planned at the start of the year, which in part may explain the drop in the number of companies forecasting to raise capital in the next 12 months.

It is expected that revenues will continue to grow in the next 12 months, while profit margins remain tight. The percentage of companies with less than one year of cash decreased slightly to 30 per cent from 34 per cent in 2015. Consistent with the above expected capital raising outcomes of respondents, companies with more than two years' cash increased to 27 per cent, up from 18 per cent.

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



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# Government policy

The 2016 AusBiotech CEO Industry Position Survey of the biotechnology industry has revealed some key themes in relation to government policy. The themes coming out of the Survey are:

- Need for policy and political stability;
- Importance of the R&D Tax Incentive;
- Renewed focus on 'innovation' must materialise into positive reform; and
- The AIM Incentive.

Our sector operates at the intersection of a complex and inter-related ecosystem so the importance of government policy can never be understated.

The right policy settings are essential.

The biotechnology sector has been recognised as a strategic priority by successive governments. Its continued growth and success is clearly considered important as the Australian economy seeks to make a successful transition in a post-mining boom world.

This reality has been consistently identified by political leaders advocating and announcing policies designed to promote the further growth of our sector. Yet the same political leaders often make the mistake of adopting individual policy changes in isolation of the wider impact on our ecosystem.

The reality is that, while we have seen some positive recent developments, there is a risk the potential benefit will be undermined by other changes and continuing uncertainty on issues of strategic importance to our sector.

It is simply not possible to change or reform one related policy without potentially impacting the entire innovation ecosystem.

Government policies related to tax, intellectual property, education, direct government support for R&D and manufacturing, are inter-related, overlap, and each makes a contribution to the creation and maintenance of an environment conducive to the growth of our sector.

This year's Survey reveals a high level of understanding of this reality and an equally high level of engagement on the impact of policy.

AusBiotech recognises the importance of policy to the sector, the nature of our innovation ecosystem, and works to secure positive change through engagement with decision-makers and contributions to reviews and inquiries. Through direct advocacy and submissions, AusBiotech consistently highlights the critical contribution policy makes to the success of our sector, which will ultimately support the development of an enduring and globally competitive Australian innovation ecosystem.

## Need for policy and political stability

A successful innovation ecosystem requires the maintenance of a stable, supportive and consistent policy environment that encourages businesses to make decisions that attract investment and grow R&D activity.

The Survey has identified significant ongoing concern over the continued reviews and tweaking of policies and programmes designed to support the sector.

There is also concern over general political instability, something that is likely to be an enduring theme in 2016 given the Federal Election and all the uncertainty associated with that.

While 41 per cent of Survey respondents said the environment was conducive to growing a biotechnology company, up from 16 per cent last year and higher than the 35 per cent reported in 2013, the result could potentially be even higher if decision-makers commit to secure a stable and supportive policy environment.

The fact 23 per cent said the environment worked against growth of a biotech company suggests ongoing concern.

The current Federal Election represents a real opportunity for Australia's political leaders to commit to a stable operating environment for our sector.

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## Importance of the R&D Tax Incentive

The Survey shows leaders remain concerned and, according to one CEO, "genuinely fearful" over government's intentions in relation to R&D Tax Incentive, with 90 per cent saying program stability is 'very important' or 'important'.

Over 80 per cent say they are concerned about the current 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.

The review, which was originally announced last year to be conducted Treasury, evidence of uncertainty even in the conduct of the review, is creating concern across the sector.

AusBiotech has been a consistent advocate on the R&D Tax Incentive, arguing against changes that would reduce or dilute its benefit to the biotechnology sector.

A recent Australian Industry Report, produced by the Federal Government's own Office of the Chief Economist, also highlighted the benefits of the programme, pointing to evidence of significant knowledge spillover for local companies engaged in R&D.

The concern of our sector is legitimate given the Government's record on the R&D Tax Incentive. It has already imposed an expenditure claim threshold of \$100 million. It is also attempting to cut claims by 1.5 per cent. This proposal has so far failed to win parliamentary approval but remains government policy.

The roundtable discussions revealed specific concern over suggestions that the R&D Tax Incentive be used to incentivise collaboration. While the industry fully supports efforts for improved collaboration and understands the good intent of these proposals and comments, there is significant concern that this may undermine the programme, without producing the desired affect.

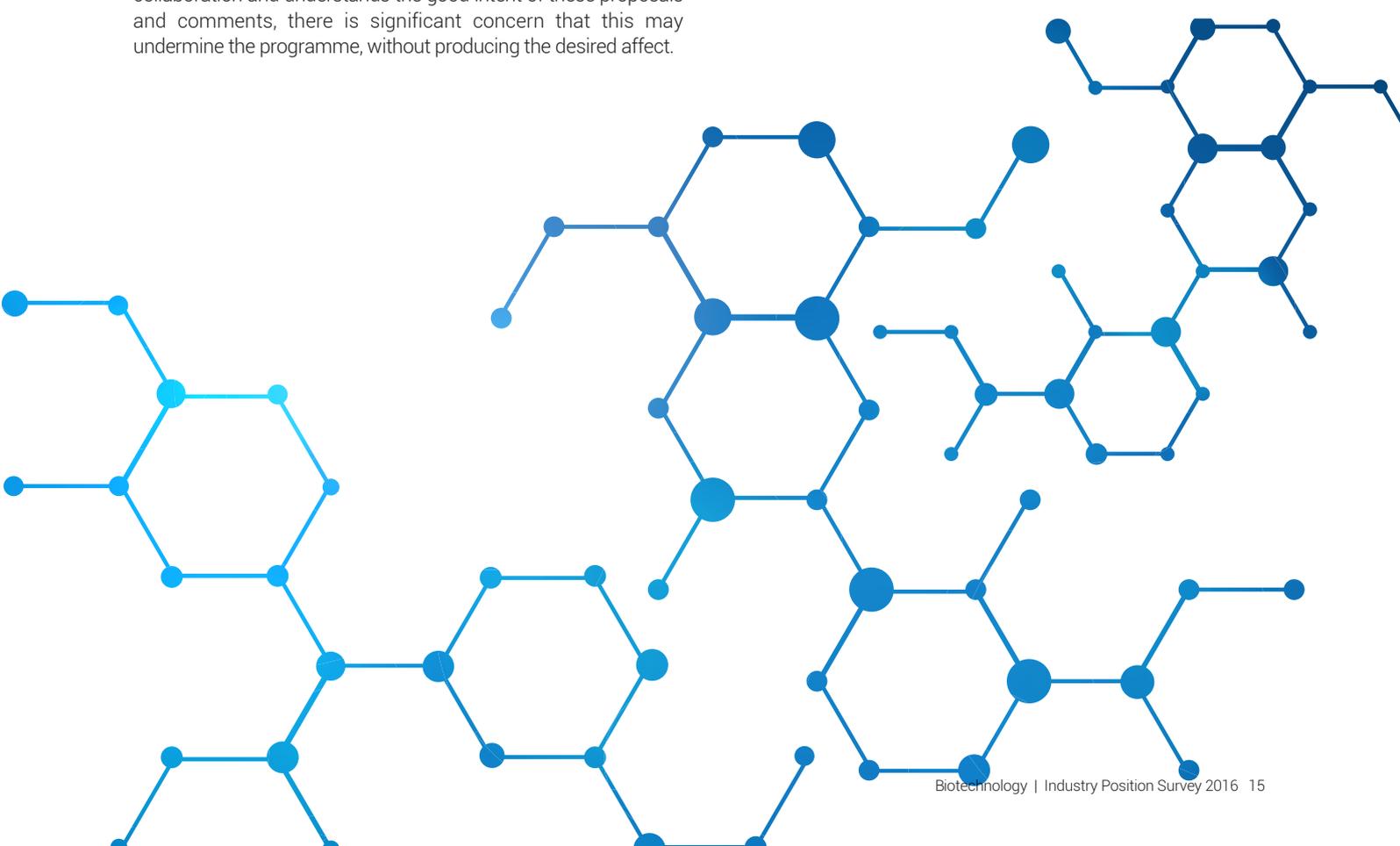
While it is generally agreed that better industry/academic collaboration is required, industry disagrees that the R&D Tax Incentive is the right 'tool' to achieve better performance in this regard and placing more restrictive rules on the program may in fact reduce its benefit and create other issues – thereby making the programme less effective.

As the majority of biotechnology companies' programmes are based on university research at their genesis or collaboration in research phases, the mechanics of what is being proposed is difficult to understand and would be complex – arguably impossible – to manage. For example, if industry is incentivised to work with a public sector partner and is motivated primarily by the incentive, phantom partnerships will eventuate. It will also make the R&D Tax Incentive more complex and increase compliance costs.

Funding already flows to the public sector from industry through contract R&D and this is a positive thing. However, the R&D Tax Incentive exists to "help more businesses do R&D and innovate" as it is recognised that the many and varied spillover benefits are desirable to our community. It appears to be counterproductive to use the incentive to achieve other outcomes, such as motivating collaboration for its own sake.

It is important that companies maintain freedom to partner on research as the need arises and with the most appropriate partner.

The ARC Linkages programme and CRCs already exist for the purpose of motivating collaboration and provide effective mechanisms. These should be examined for greater effectiveness or a grant or voucher system would be a more sensible mechanism for encouraging collaboration and get results as it will 'speak' directly to what is to be achieved – and without compromising the R&D Tax Incentive.



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## Renewed focus on 'innovation' must materialise into positive reform

The past year has seen an increasing political and policy focus on innovation.

The full benefit of this new direction is yet to materialise and we are looking for more action from government decision-makers.

Prime Minister Malcolm Turnbull announced the National Innovation and Science Agenda last December, including \$250 million for a Biomedical Translation Fund as the first investment from the \$20 billion Medical Research Future Fund.

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**Yet the fact remains that, in the same way each point in the biotechnology value chain overlaps, one policy cannot be seen as operating in isolation of another.**

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The success of biotechnology companies, many of which are pre-revenue, is dependent on a combination of factors, all of which are interdependent and directly related to government policy. It can be direct financial support in the form of grants, the tax treatment of employee share schemes and, of course, tax incentives for R&D. The point is that policy matters.

Survey respondents welcomed the renewed focus on innovation but expressed concern over the ongoing uncertainty in relation to the R&D Tax Incentive, specifically the latest review.

The review points to a policy confusion. Survey respondents did express frustration over the lack of understanding of our sector amongst key decision-makers in government.

While government tinkers with the vital R&D Tax Incentive programme, it announces the very positive Biotechnology Translation Fund. While it appoints an experienced biotechnology executive to lead its MTPConnect, it makes changes to the tax treatment of employee share schemes that largely exclude our sector.

The key point is that policy-makers must understand that the full benefit of positive individual policy reforms will be lost in the absence of support for the wider ecosystem.

## The AIM Incentive

Support for the proposed AIM Incentive has been spearheaded by AusBiotech as part of a collective effort by organisations representing companies that manufacture and export their products and expertise across the globe.

It would provide an offset against the tax payable on profits derived from the innovation and manufacture in Australia of qualifying patented Australian IP.

Qualifying IP profit would be taxed at the lower rate (10 per cent) with the standard corporate tax rate to be applied to other income.

The advantage of the AIM Incentive is that it requires no upfront government outlay, and is designed to stem the flow of manufacturing offshore whilst providing future jobs for Australians. It will be a competitive advantage for Australian innovators and manufacturers of patented products.

The Survey reveals that 80 per cent of respondents recognised the policy. It also enjoys strong support.



## 13 things company CEOs would like policy makers to know about biotech...themes from the CEO roundtables

- 1 Global competition is our reality now, but the window for maximising opportunities is closing.
- 2 Australia has lots of high quality innovation, and few drivers to develop products and reach the market.
- 3 Our companies are listing too early, seeking capital, and are then disadvantaged by being excluded from early stage incentives, like the Employee Share Scheme and new tax incentive for early stage investors.
- 4 Linking money to biotech and medtech developers is critical. How do we better link pools of money with the pool of ideas?
- 5 Smart ideas need smart money... investors and policy makers could benefit from better biotech literacy.
- 6 We need investors with patience, rather than short-term investment churn.
- 7 We need the R&D Tax Incentive left alone... it's working as it was intended, but constantly under threat.
- 8 We have been approached by foreign governments, who have a very good understanding of the Australian government support structures, and then blow you away with their offerings. We have been approached by Japan, Singapore, Switzerland and Germany in the last 12 months to relocate our business. They are offering a pathway to commercialisation.
- 9 We need some consistency of policy from the Federal and state governments to allow our sector to invest and grow.
- 10 We don't bother registering patents in Australia any more; we go straight to the US.
- 11 We all need collaboration to get to market; universities and others actually working together and leveraging of businesses to commercialise projects.
- 12 Concerned about the R&D Tax Incentive being co-opted with the notion that it may be used to improve collaboration. This is an unfounded experiment, which has the real potential to fail in its intent, while undermining the programme.
- 13 Building competence in the Australian industry is key. It's what is missing in the rhetoric on collaboration. More competent product developers are needed to be attracted and maintained here.

# Methodology

This is the sixth Biotechnology Industry Position Survey conducted by AusBiotech and supported by Grant Thornton. The survey was conducted via mail/email during February 2016, followed by roundtable focus groups in March and April 2016 and launched 30 May 2016. 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.

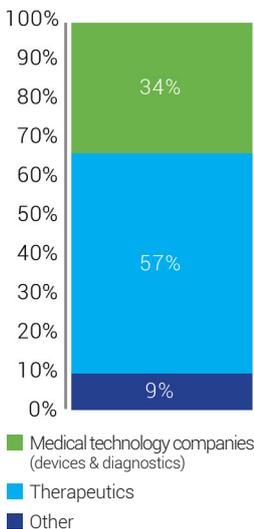
Companies were asked to submit information regarding their financial status, issues impacting their business, current outlook and plans for the future. This survey provides an independent perspective of the impact of the current economic and regulatory environment on the biotechnology industry.

Enquiries regarding this survey may be directed to AusBiotech (admin@ausbiotech.org/ 03 9828 1400)

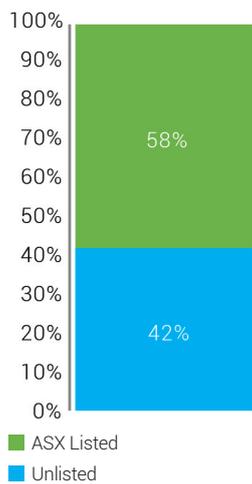
## Analysis of respondents

Responses were received from 44 companies. In addition over 60 companies participated in the roundtable discussions, held around the country.

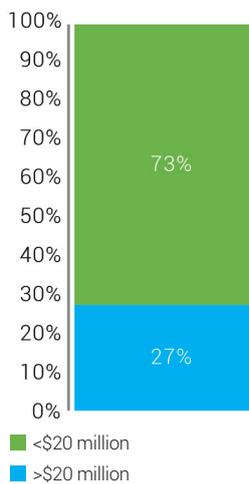
**Sector**



**Type**



**Turnover**



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

- Acrux
- Actinogen Medical
- AdAlta Pty Ltd
- Admedus Ltd
- Alcidion Group
- Alzhyne Pty Ltd
- Anteo Diagnostics Ltd
- BioDiem Ltd
- Bristol-Myers Squibb
- Cell Therapies Pty Ltd
- Cellmid Limited
- Clinical Genomics
- Clover Corporation limited
- Cook Medical
- CSL Limited
- Dimerix Bioscience
- Elastagen Pty Ltd
- Global Orthopaedic Technology
- HaemaLogiX Pty Ltd
- IDT Australia
- Innate Immunotherapeutics
- Invion Limited
- LBT Innovations Ltd
- Medical Developments International Limited
- Medtronic Australasia
- Minomic International Ltd
- Neuren
- Novotech
- OBJ Ltd
- Occurx
- Pharmaxis
- SMART Arm Pty Ltd
- Suda Ltd
- Trajan Scientific & Medical
- Vestech

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# 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, 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 almost 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.

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## About Grant Thornton

Grant Thornton is one of the world's leading organisations of independent assurance, tax and advisory firms. These firms help dynamic organisations unlock their potential for growth by providing meaningful, forward looking advice. Proactive teams, led by approachable partners in these firms, use insights, experience and instinct to understand complex issues for privately owned, publicly listed and public sector clients and help them to find solutions.

Grant Thornton Australia has more than 1,200 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.

More than 40,000 Grant Thornton people, across over 130 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.

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