

Biotechnology

INDUSTRY POSITION SURVEY MAY 2015



Partnering with





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Foreword

The Australian biotechnology industry is a key global player, currently ranked fourth in the world among industrialised nations for biotechnology innovation.

Australia's biotechnology industry is ranked well on several measures in the Scientific American rankings: Adjusted for our relatively small population, our ASX-listed companies rank third globally for the highest revenues and for the highest capitalisation.

The modern world is beset with issues of grave significance – from climate change, cleansing waste streams, food production and quality, alternative fuel developments, through to the ills experienced by ageing populations, increasing incidence of serious infections resistant to antibiotics and increasing prevalence of tragic diseases like Alzheimer's. Australia is not quarantined from these challenges and innovation is the tool by which we can seek to redress solutions and build ourselves a knowledge-based economy.

Individuals today are part of an active revolution, which has taken the building blocks of biology and applied them to a wide range of important problems. In the developed world and for many in the developing world, people are touched by or reliant on biotechnologies – although perhaps not aware of the term or the revolution it represents. Biotechnology is one of the most innovative sectors in the world, enabling many industries.

Taking the annual pulse of Australia's biotechnology industry has revealed some key themes, perhaps none so stark as the need for local companies to work globally and, sadly, fight to keep their operations in Australia as the international environment gets more competitive and Australia's policy environment fails to adequately respond.

As Australia's window of mining-driven prosperity begins to close, it is widely acknowledged that building Australia's capacity as a technologically innovative country is vital for our economic future. We largely agree that high-tech industries generate globally competitive economies and sustainable, high-skilled jobs.

Times have changed since Australia perceived itself as an industrialised country or simply a mine. We now prefer to think of ourselves as a smart country, where we compete on a world stage in the knowledge economy.

Australia has a strong comparative advantage in medical research and the calibre of its researchers, in its ability to specialise in 'high tech, high cost, low volume' manufacturing to elaborately-transformed goods such as medical devices and biopharmaceuticals, and a burgeoning biotechnology industry that is globally impressive by any comparative measure.

Everyone wants to be healthy and productive, and to remain so throughout our lifespans. Community expectations of healthcare are very high around the globe, driven by a rapidly-growing middle class. Asia, in particular, has demand growing along side increasing affluence.

With these strong global drivers, investment in biotechnology seems future-proofed. While venture capital is scarce when compared globally, the right technologies are continuing to attract funding and licensing deals. For example, most recently US biotech giant Celgene bought a US\$59.5 million stake in Australian-based Mesoblast.

Despite some high profile company disappointments during the past year, respondents to the annual biotech survey were the most positive they have been regarding how their companies performed with 69% reporting a good or excellent year. This is our second highest result and 10% above the prior year.

The positivity extended to the industry outlook for the coming year with 84% of respondents expecting their business to grow. This is the most optimistic result recorded in the five years we have been conducting the survey.

The Federal Government in releasing its Industry Innovation and Competitiveness Agenda (October 2014) identified five areas in which Australia is globally competitive, and which the Government plans to support into the future. Three were in the biotechnology sector: medical technology and biopharmaceuticals, agriculture and food, and advanced manufacturing. AusBiotech has long advocated for such support, and is confident of the industry's ability to continue attracting new investors.

Foreword cont.

In the past three years, the industry had undergone a perceptible phase change: several small companies that had formerly struggled to survive, and were probably listed much earlier than they should have, evolved into serious, dynamic middle-sized companies. Good product pipelines helped them make good deals, usually with international partners, to take their products into clinical trials.

The strong fundamentals of the industry are underpinning the march forward and this is despite a difficult policy environment.

The number of companies identifying the Australian operating environment (economic conditions and public policy) as conducive to growing a biotechnology company reversed the gains noted in the previous survey to 35% with a return to 16% (16%: 2013 and 24%: 2012). 39% of respondents felt the operating environment was working against the growth of biotech businesses.

The funding landscape which improved dramatically in the previous survey now returns to levels more comparable to the earlier surveys with the number of companies looking to raise funds at 48% up from 34%, and the number of companies with less than one year's cash increased significantly from 18.8% to 34%.

Tax continues to be a top-of-mind issue for the Industry, which has welcomed changes to Employees Share Scheme, and the abandonment of the 1.5% cut from the R&D Tax Incentive are amongst the good news that will buoy the industry. The first move toward third party conformity assessment of medical devices was widely acknowledged as a win for common sense.

Tax incentives that level the 'playing field' or compete with other countries are the most wanted item. The R&D Tax Incentive continues to be named as the comparative advantage for Australia, while the industry pleads for a tax incentive to keep our IP and manufacturing via the Australian Innovation and Manufacturing (AIM) Incentive.

At a time when the global market for biopharmaceuticals, medical devices and vaccines is booming, Australia's biopharmaceutical exports have declined by more than 30% since they peaked at around \$4.3 billion in 2012.

Biopharmaceutical exports had grown to more than \$4 billion annually, substantially greater than either the wine and automotive industries, which have always had a high public profile, but the latest ABS figures show Australia's biopharmaceutical exports declined by 18% to \$2.9 billion in 2014, compared to \$3.6 billion in the year before.

The industry shows a rise in companies manufacturing to 70% from last year when 62% were manufacturing. The rise is driven by companies manufacturing in Australia, now 53% up from 37.5% last year.



Dr Anna Lavelle
CEO, AusBiotech

"Cell therapies, specialised medical devices and other advanced manufacturing is precisely the sort of activity that Australia should excel in. We have all the ingredients of a comparative advantage - a highly-skilled workforce, world-class infrastructure, a good regulatory system and a healthy regard for IP - except we do not yet have a globally competitive tax environment."



Michael Cunningham
National Head of Life Sciences,
Grant Thornton

"Now is the time for this industry to take its rightful place as a leading Australian industry. This will only happen if the industry is allowed to operate in an environment which supports innovation and encourages biotechnology companies to operate in Australia."

Key findings

1 Sentiment strong despite business environment

Respondents to the annual biotech survey were the most positive they have been regarding how their companies performed with 69% reporting a good or excellent year. This is our second highest result since data collection began in 2011 and 10% above the prior year. In the year ahead 84% expect to grow, up from 79% last year.

2 Improved policy is all about tax reform

In an open question on what public policy issue most concerns companies at a Federal level, un-prompted, 19 out of 49 companies said tax. For the most part companies were concerned about possible tampering with the much-loved R&D Tax Incentive. Other responses were concerned with a patent box tax incentive for Australia and restoration of the Employee Share Scheme provisions. When asked about the policy environment, an example of indicative responses: "Only positive is R&D tax refund" and "conducive only due to R&D tax incentive".

3 Cash is the life-blood of the industry

The competition for capital has returned to the similar levels reported in 2013 and 2012 when almost half of the responding companies reported that they were intending to seek funding in the coming 12 months.

The percentage of companies with less than one year of cash increased significantly to 34% from 18.8% in 2014 to reach level just below that of 2013 (37.5%). With the prior year being a particularly strong period for capital raisings it is not surprising given the typical raising is for funding of 12 to 24 months that this result has weakened, and returned to levels similar to 2012 (34%). Companies with more than two years' cash dropped from 29.3% to 18%.

4 A tough and unsupportive environment

The number of companies identifying the Australian operating environment (economic conditions and public policy) as conducive to growing a biotechnology company fell dramatically to 16%, reversing the gains noted in the previous survey when 35% called the environment conducive (16%: 2013 and 24%: 2012). A hard-to-ignore 39% of respondents felt the operating environment was working against the growth of biotech businesses, up from 27% last year. The key and most repeated issues are tax, regulation, red tape and access to patient investors.

Contribution to the economy and value of the industry

48% of respondent companies are exporting. Of these, 17 companies reported an estimated value, which totals **\$158.270 million.**

The combined market cap of 47 responding companies is \$21.63 billion.

55 companies employ 4,929 people.

46 of the responding companies reported their R&D spend for 2014 at a total of **\$889.603 million.**

The Australian biotech industry will create **at least 239 new jobs in 2015.**

41 companies had a combined spend of \$22.35 million to manage their patent portfolio.

70% of companies manufacture: 52% manufacture in Australia & 43% manufacture overseas, 25% manufacture both in Australia & overseas.

Business sentiment in the industry

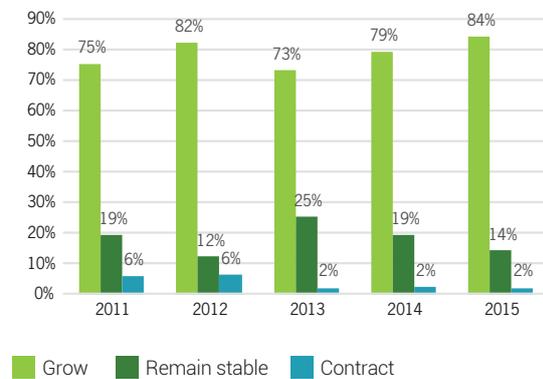
Bump or road block?

Business sentiment is strong despite the view of the environment. With significant international momentum and a strong finish to 2014, 69% of companies reported the year past had been a good or excellent year for them, compared to 58% in the year before. The vast majority, 84% of respondents, are expecting to grow this year, up from 79% the previous year and only 2% expecting their business to contract.

However, 2014 was not without its challenges with a number of higher profile industry participants disappointing for a variety of reasons. Nevertheless in a true sign of the local industries ever-increasing strength and resilience, a number of good news stories emerged and are poised to provide the company specific news that industries must deliver in order to remain relevant and at the forefront of investor and stakeholder attention. This is not to say we have written off those who experienced less favourable years but merely flag it to provide context.

As those of us who have operated in the industry for any significant duration know; with Australia's abundance of world-class talent and industry support and a dash of fighting spirit many of those who underperformed have already taken important steps to remediate and rebound. It is therefore no surprise that the outlook for 2015 is the most positive it has been in the five years of the survey.

In 2015, do you expect your business to ...?



Of concern is the significant shift in sentiment regarding the Australian operating environment with those identifying it as conducive to growing a biotech business halving from the prior year, with the result only marginally above the lows reported the federally tumultuous 2013; the last year of the minority Federal Labor Government.

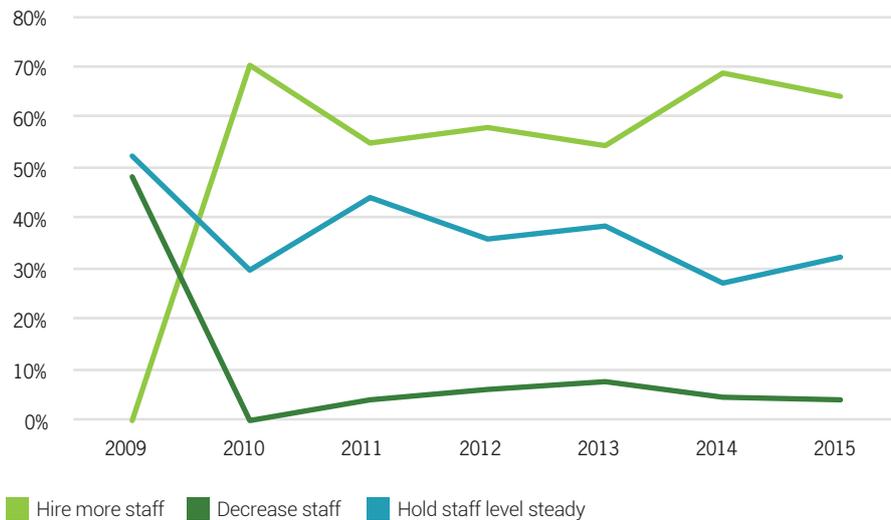
"The federal government has significantly underwhelmed the industry during its first 12 months. Recent positive news regarding employee share arrangements should assist in swinging the pendulum back, nevertheless much work needs to be done."

Michael Cunningham

Employment outlook stable and expansionary

The employment outlook remains strong with the intention to hire staff above 60% for the second year running. *While there was a slight drop in the percentage of companies planning to hire staff (64% down from 69% last year), the majority of companies are hiring, with 36 companies to provide 239 new jobs in 2015.* We have seen a shift however regarding the nature of the hiring with a significant move towards scientists and clinical trial staff, which almost doubled to 80 from 41 jobs in the same vocation last year. Recruitment to sales and marketing jobs remained strong at 33 new positions, as did advanced manufacturing/production jobs (30 in 2015, up from 3 in 2014).

Regarding staffing levels, do you expect to:



Financing, investment, listing & costs

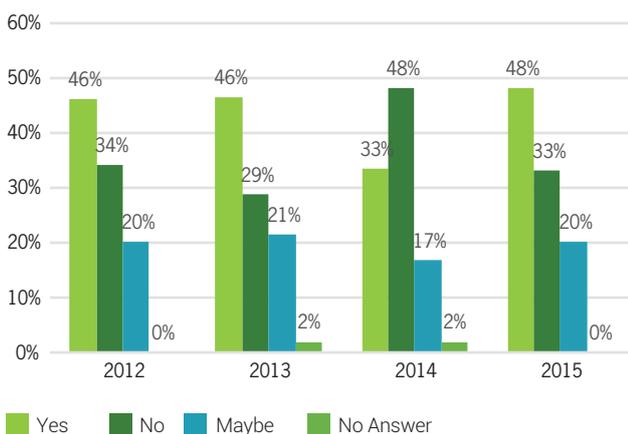
Availability of funding

The biotechnology sector at an international level, driven by the continued momentum (last year, NASDAQ's biotech index outperformed the broader market by 60%) from the United States capital markets with an excess of 70 Biotechnology (102 healthcare) IPOs during 2014 provided a strong backdrop for the local Australian market.

The local market provided some mixed results, with a number of high-profile companies stumbling through a combination of issues both within and outside of their control.

The good news stories were not without prominence, which combined with the international landscape and a weakening Australian dollar will ensure foreign capital providers continue to keep a watchful eye on the Australian biotechnology sector and will provide continued resilience.

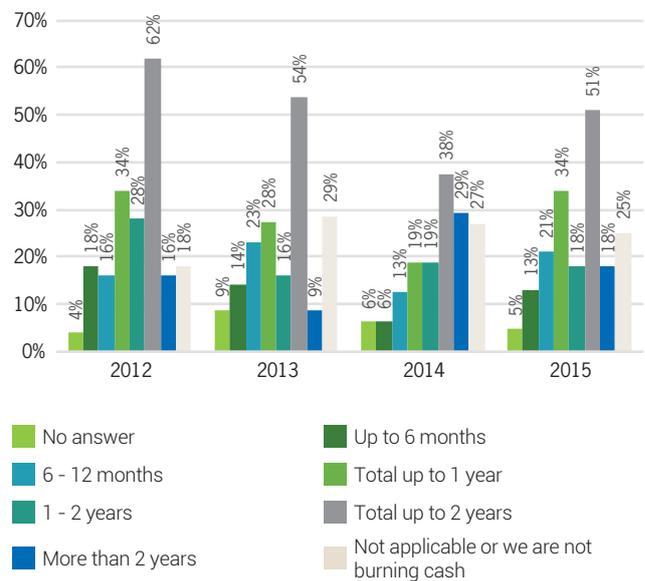
Do you plan to raise capital this year?



The competition for capital has returned to the similar levels reported in 2013 and 2012, with over 45% of companies intending to seek funding in the coming 12 months.

The percentage of companies with less than one year of cash increased significantly to 34% from 18.8% in 2014 to reach a level just below that of 2013 (37.5%). With the prior year being a particularly strong period for capital raisings it is not surprising given the typical raising is for funding of 12 to 24 months that this result has weakened, and returned to levels similar to 2012 (34%). Companies with more than two years' cash dropped from 29.3% to 18%.

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



"Compliance costs and a comparably small VC market continue to limit in a relative sense the funding options of junior biotechnology companies."

Michael Cunningham

Government policy

Building a world-class innovation ecosystem

The annual survey of the biotechnology industry has revealed some key themes in relation to government policy. While none are unexpected, or even new, the four strongest themes are:

- Tax reform for international competitiveness;
- Access to capital for commercialisation;
- How to support the life sciences industry to take its rightful place in the economy as an industry of the future;
- Development of innovation and advanced manufacturing.

It is perhaps obvious to say that all-of-the-above are interrelated, but they have so much overlap with one another that they might even be viewed as perspectives of the same issue – policy to support the development of a world-class innovation ecosystem.

Biotechnology is a core element of our future, both in social and in economic terms, globally and for Australia. The mapping of the human genome marked the opening up of a whole new world of bioscience and of its potential to underpin innovative and knowledge-based economies and industries. Australia, recently ranked fourth in the world for its biotechnology achievement and has the opportunity to exploit its strength by investing in a sustainable ecosystem – or to waste the momentum it has built.

AusBiotech has gone on the public record numerous times about the critical role public policy plays in the development of the biotechnology industry: by incentivising desirable behaviours/choices to build Australia's innovation ecosystem in a global context, such as providing globally competitive tax policy and in providing support where the ecosystem currently has gaping holes.

Australia has for some years realised the positioning of innovation as central to jobs, productivity and a thriving economy.

In Australia, the economy needs to diversify from mining, car manufacturing and agriculture. While they are or have been essential parts of our economy, we need to understand and build on the key industries of the future; the industries that will employ our educated young people, create wealth and jobs and deliver products and services to a waiting community. Biotechnology not only performs all these functions, but it also assists the mining and agricultural sectors. Biotechnology-based products epitomize advanced manufacturing, an area where we have a comparative global advantage.

The Reserve Bank of Australia has recognised for some time that the structure of the Australian economy is moving from its historical agriculture, mining and industrial base to more of a services base ('Structural Change in the Australian Economy', 2010) and we now prefer to think of ourselves as a smart country, where we compete on a world stage in the knowledge economy. Australia has expertise in all of the areas of biotechnology flagged above, which could and should be leveraged to our economy's advantage.

"As Australia comes to grips with the need for a "plan B" to sustain the economy after the mining boom fades, it is widely acknowledged that building Australia's capacity as a technologically innovative country is vital for our economic future. Encouraging entrepreneurship and innovation policy is the key."

Dr Anna Lavelle

Tax reform for international competitiveness

Local companies are 'born global' and at the moment are fighting to keep their operations in Australia as the international environment gets increasingly competitive and Australia's policy environment fails to adequately respond.

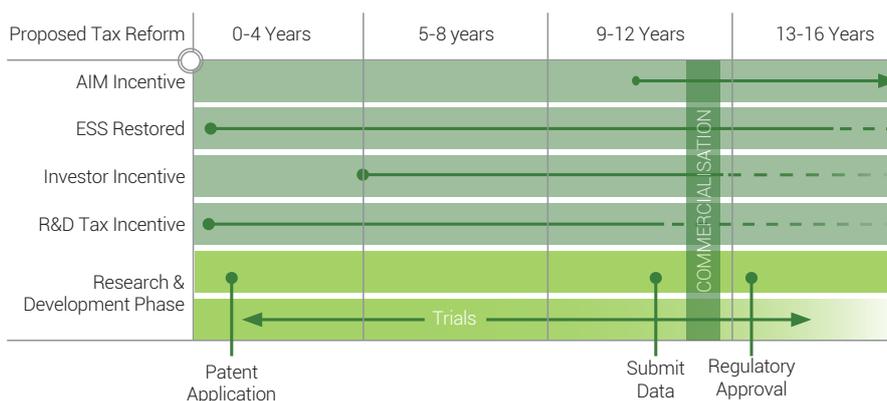
AusBiotech is leading the industry's call for further tax reform in Australia, which will provide a supportive environment throughout the life-cycle of a company. Incentives for innovative companies and high-tech manufacturing will support Australia's future and keep us internationally competitive by attracting and retaining business, and the resulting jobs and exports.

AusBiotech advocates making tax incentives an asset for innovation and business, with four pillars:

- Retain the R&D Tax Incentive, and lift the \$20 million cap for the refundable component to \$50 million in line with the Cutler recommendations of 2008;
- Introduce the Australian Innovation & Manufacturing (AIM) Incentive, to incentivise the monetisation of IP, and in turn innovation, and retain the associated benefits once it reaches commercialisation;
- Introduce fiscal incentives for investors in pre-revenue and start-up companies, to encourage 'patient' venture capital; and
- Restore the Employee Share Scheme to its pre-2009 form, for ASX-listed, pre-revenue companies up to 15 years of age.

"As R&D and patent box incentives become more common around the world, a number of governments have demonstrated that to stay competitive, it is necessary to offer a competing tax and business environment. Ten percent of something will be better for Australia than 30% (corporate tax rate) of nothing, which is what we have when companies take their IP elsewhere."

Dr Anna Lavelle



It's imperative that Australia takes action to remain competitive and relevant on the world stage, especially, when other economies including the UK and Singapore are already reaping the benefits of their tax regimes and some Australian companies are moving operations to these nations to develop IP that originated in Australia. Maximising Australian innovation and reinvigorating the manufacturing sector in Australia largely depends on the existing R&D Tax Incentive being complemented with a tax regime that can secure Australia's competitiveness for the future.

Access to capital for commercialisation

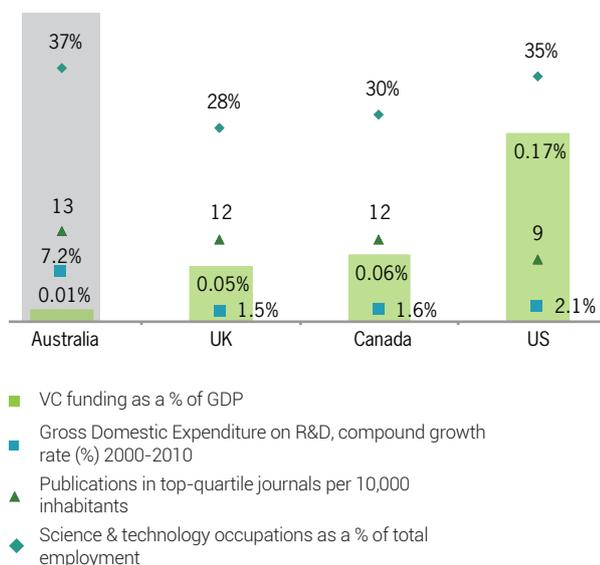
The quote from one survey respondent that “without capital, innovation will die” sums up a critical issue for Australia. Australia’s research output is substantial, and its research and innovation indicators are highly competitive compared to other advanced economies (see graph below).

Only a small fraction of the opportunities afforded by Australia’s substantial pipeline of research and innovation are being supported with venture capital. This indicates substantial scope for increased outcomes from investment and returns from further support for commercialisation.

Australia’s innovation industries are in need of a more competitive tax regime to ‘match’ major trading blocks in Europe, US and Asia, and other public policy support to offset the lack of venture capital available and a model for funding the gap between basic research and private equity, for translation of our research.

The comments above about tax reform are critical in this context.

VC funding vs research and innovation metrics



Source: AVCAL Venture Capital Fact Sheet, April 2015

Australia is also in need of a program to replace and improve on the now lost Innovation Investment Fund and Commercialisation Australia, both of which were critical supports and criticised only for their lack of quanta and tranche size. The Accelerating Commercialisation stream of the Entrepreneurs’ Infrastructure Program that has replaced Commercialisation Australia, while well intentioned, is lacking in size and therefore in its capability and focus.

Support the life sciences industry to take its rightful place in the economy as an industry of the future

With the right policy settings for innovation, Australia’s biotechnology industry has the capacity to be a major contributor to our economy as well as our lives. From the development of valuable intellectual property, spinning out start-up companies to advanced manufacturing, Australia has strengths in its life sciences industry that can and will provide treatments, devices, diagnostics, solutions to enhance and extend out lives as well as high-skilled jobs and economic prosperity. The question is whether Australia will get the benefit or will the exodus continue to other countries.

The Federal Government in releasing its Industry Innovation and Competiveness Agenda (October 2014) identified five areas in which Australia is globally competitive, and which the Government plans to support into the future. Three were in the biotechnology sector: medical technology and biopharmaceuticals, agriculture and food, and advanced manufacturing. AusBiotech has long advocated for such support, and is confident of the industry’s ability to continue attracting new investors if policy settings, especially tax settings, are right.

Other nations are making sizeable investments to support innovative new businesses and economic activity, while Australia is at a very real risk of falling behind these countries who are working hard to give their innovation enterprises the boost needed to stimulate economic growth and that are more supportive.

As Australia faces an economic transition to a knowledge economy, the Abbott Government has an immediate challenge to think differently about the development of future industries and jobs for future generations of Australians.

Development of innovation and advanced manufacturing

With strong global drivers, investment in biotechnology seems future-proofed. While venture capital is scarce when compared globally, the right technologies are continuing to attract funding and licensing deals. However innovation and manufacturing are two sides of the same coin and while our manufacturing is attracted overseas, so is the IP that is being developed and manufactured. Many companies, including Australia's largest biotechnology companies, keep their manufacturing and IP in the same location. If the manufacturing moves outside Australia, the IP moves overseas too.

Manufacturing is one of the major sources of innovation in Australia. While the sector makes up just 8% of the economy, it is responsible for a quarter of all investment in R&D. A constant push-pull operates, whereby innovation in product design encourages innovation in manufacturing processes, and vice versa. For this reason, the Harvard Business School and many others advise against the separation of R&D and manufacturing.

"We have an opportunity to position and develop Australia as a high tech manufacturer of medical devices, pharmaceuticals and cell therapies. And the above-proposed Australian Innovation and Manufacturing Incentive is an essential component."

Dr Anna Lavelle

Eleven things CEOs would like policy makers to know about biotech - Themes from our CEO roundtables

- 1 Australian biotech companies are doing great work.
- 2 New technologies need new thinking and systems.
- 3 We can do what we do anywhere in the world: IP is extremely portable.
- 4 Manufacturing goes where the IP goes and IP goes where there are positive tax structures.
- 5 Innovation will die without access to capital and Australia's on-going lack of VC makes other programs even more important.
- 6 Company CEOs don't want to rely on government any more than government wants to be relied upon.
- 7 R&D Tax Incentive is the one bright spot and should not be weakened.
- 8 Offering comparative tax incentives is a no-brainer. Why do we want to be the biotech supermarket of the world?
- 9 Companies can and will move offshore if nothing improves.
- 10 Australia could be the world leader in regenerative cell manufacturing (but Japan will beat us with their 70% reimbursement offer.)
- 11 If the R&D Tax incentive keeps getting cut back, we will lose our clinical trials too.

Methodology

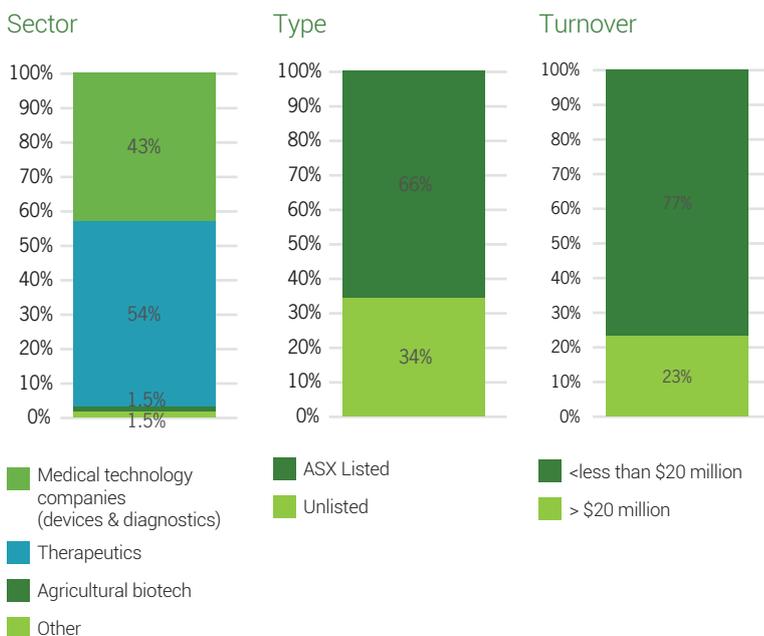
This is the fifth Biotechnology Industry Position Survey conducted by AusBiotech and supported by Grant Thornton. The survey was conducted via mail/email during February 2015 and was followed by roundtable focus groups in April 2014. The survey was open to all ASX-listed and unlisted biotechnology companies, including AusBiotech members.

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 56 companies, of which 7 were anonymous



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 Limited	Innate Immunotherapeutics Limited
Analytica Ltd	Johnson & Johnson Medical
Anteo Diagnostics Ltd	LCT
Avita Medical Ltd	Mariposa Health Limited
Benitec Biopharma Ltd	Minomic International Ltd
BioDiem Ltd	Nanosonics Ltd
Bioplatforms Australia Ltd	Narhex Australia
Biotron Limited	Nexvet Biopharma plc
Biovite Australia Pty Ltd	Novogen Limited
Blue Curve Pty Ltd	NuSep Holdings Ltd
Brandwood Biomedical Pty Ltd	Patrys Limited
Bristol-Myers Squibb	Phosphagenics Limited
Cell Therapies Pty Ltd	Reproductive Health Science Ltd
Cellmid Ltd	ResMed Ltd
Circadian Technologies Ltd	Shire plc
Cook Medical	Simavita Ltd
CTX CRC Ltd (Cancer Therapeutics CRC)	Specialised Therapeutics Australia (STA)
Dimerix Bioscience Limited	Starpharma Holdings Limited
dorsaVi Ltd	SUDA Ltd
Elanco	Tissue Therapies Ltd
Elastagen Pty Ltd	TRAJAN Scientific and Medical
Fischer	Uscom Limited
IDT Australia Ltd	

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.

If you want to know more, please contact us...

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About Grant Thornton

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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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