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AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

INDUSTRY POSITION SURVEY JUNE 2014

Biotechnology

Foreword

The Australian biotechnology industry is now in its third decade. Predictions that 2013 would be a good year for the local market were realised with the Australian sector following the United States' positive lead.

Excitement from this positive year must be tempered, however, as many of the gains were made by the smaller, more speculative players. Biotech stocks rose on average by 53% in 2013 [Bioscience Managers] but the weighted index (which accounts for market capitalisation), increased by a very positive – albeit much smaller – 14% [Bioshares Small-Mid Cap Index]. This is a strong, much needed endorsement that the industry is growing after some difficult years.

The industry's contribution to the Australian economy is growing. Spending on medical and scientific research in Australia is estimated to be in the range of $9 billion per annum and the medical industry is now Australia's largest manufacturing exporter of elaborately-transformed goods. It is imperative that government policy and the investment community continue to support this industry, which delivers high-tech jobs, exports, and life-enhancing products.

The continued support from both political parties for innovative industries in Australia is welcome. However, in the context of the broader volatile policy environment, the removal of two of the core support programs in the past year and the repetitive threats to a third program are taking their toll.

The Government's continued attention to cost saving, coupled with the lack of focus on investing in the future commercialisation of our world-class research, means there is much to be done to ensure public policy allows Australia to capitalise on the current opportunity.

The 2014 Biotechnology Industry Position Survey found the industry to be largely neutral towards the current public policy environment despite the change of government. Only 22% expressed the view that the change of government will be positive for the biotechnology industry. It is important to note that these metrics were captured before the 2014-15 Federal Budget ('the Budget') (13 May 2014) was announced. All three major support programs for biotechnology were impacted by the Budget, with the abolition of both Innovation Investment Fund (IIF) and Commercialisation Australia (CA), and an unexpected cut to the R&D Tax Incentive.

Dr Anna Lavelle
CEO, AusBiotech

"Significant and on-going change in the public policy environment and consistent threats to industry support programs are proving the greatest issue for biotechnology companies at present."

Michael Cunningham
National Head of Life Sciences,
Grant Thornton

"Whilst capital markets more broadly remain challenging, the last year saw a renewed focus on the Australian biotech sector."

Foreword

The recent Budget provides the industry with new pressures and hopes. For example the announced establishment of the Medical Research Future Fund (MRFF), should it be passed by Parliament, would make it the biggest medical research fund of its kind in the world and is welcomed as a great nation-building investment for Australia. However the removal of commercialisation support, along with the lack of detail on a translational aspect for the fund, has left the biotech sector wondering if and how the commercialisation of research will be realised going forward.

Australia already has a recognised issue in translating our world-class research into cures and treatment, products and services. With the support for commercialisation that has been removed in this Budget (CA and IIF to cease), the level of difficulty in translating research help that reaches patients just got a whole lot harder.

Add to this the reduction to the R&D Tax Incentive, which is expected to be neutralised by the 1.5% reduction to the corporate tax rate (1 July 2015). An expectation that fails to take account of the impact on the many pre-revenue companies that are in tax loss (and therefore don't pay corporate tax). For them, this is a permanent, further and damaging reduction to the support available for R&D as they will not get any benefit from the planned corporate tax reduction.

As this report goes to publication, the Industry is awaiting an 'innovation statement' from the Government that takes account of the National Industry Investment and Competitiveness Agenda and the Tax White Paper, as well as further details on the MRFF and a new Entrepreneurs' Infrastructure Program (EIP) that is currently under development.

Key findings

Life sciences companies have reported a clear shift to overseas manufacturing, with 54% now manufacturing their products overseas. This is up substantially from the 36% recorded in 2013. The trend for companies manufacturing has seen a slight rise from last year in the quantity of companies, with 73% of surveyed companies now manufacturing – 44% in Australia and 54% overseas (a cross over of companies manufacturing in both Australia and overseas is 25%).

Industry outlook for the coming year is bullish with 81% of respondents expecting their business to grow. This is the most optimistic result recorded in the four years we have been conducting this survey. The flow-on impact to the employment market is expected to be strong: 70% of companies intend to hire more people, and only 4% plan to reduce their headcount.

The R&D Tax Incentive was very well received by the industry when it was introduced. Many companies have acknowledged its key role in their development in achieving new value inflection points and milestones. Not surprisingly, its in-tact preservation remains the number one public policy issue within the industry.

The number of companies identifying the Australian operating environment (economic conditions and public policy) as conducive to growing a biotechnology company improved significantly this year, up to 38% (from 16%:2012 and 24%:2013). This is likely driven by a combination of factors: improving investor sentiment and capital markets, cash support flowing back to industry from the R&D Tax Incentive scheme, and the change in government.

Respondents remain cautiously optimistic regarding the change of government. A significant majority are opting for a 'wait and see' approach. When asked "do you think the Coalition Government will be better for the biotechnology industry?", 70% responded "maybe". This is hardly a ringing endorsement for the impact of the Coalition Government on the sector. Importantly, only 9% felt it would have an adverse impact.

Positive shifts in investor sentiment both locally and internationally have translated into an improved funding position for many respondents. The number of companies holding less than 12 months' cash decreased to 22% this year (37%:2013). Interestingly only 33% of respondents were definitely planning on raising capital in the coming year, while a further 17% flagged fund raising as a consideration.

Sentiment

Year of momentum

Expectations at the start of 2014 were positive with a significantly improved view of the local operating environment (economic conditions and public policy). Respondents who felt it was conducive to growing a biotechnology business increased from 16% in 2013 to 35% in 2014. This appears to be driven by the flow of support from the R&D Tax Incentive, improving share market conditions, and strong industry fundamentals. However, the vast majority of respondents were yet to form a view as to the impact of the federal government change from Labor to the Coalition.

The industry has sobered recently, due to unfavourable announcements in the recent Budget and the associated unfortunate cluster of bad news from a regulatory perspective.

Growth

As we entered 2013, anticipation of a positive year was high. 73% of respondents expected to grow their business. Companies reporting that they had a good or excellent year remained similar to previous year (58%:2013 and 55%:2012). Companies characterising the previous year as average or poor also remained fairly consistent (41%:2013 and 25%:2012).

This reaffirms that whilst the market generated some very strong returns, conditions remain difficult for many, especially those with earlier stage or more pioneering technologies. Nevertheless, at the time of the survey the growth outlook for companies exhibited a small increase, up to 79% (73%:2013).

ASX listing

No respondent listed on the ASX flagged an intention to delist. This provides a strong indication that the local environment is able to provide a sufficient mechanism to raise funds locally and internationally.

IPO activity has remained sparse. A burst of IPOs in the US has seen much speculation that Australia would follow suit. When 2014 commenced, sentiment was up-beat, with *The Age* and *Sydney Morning Herald* (4 Jan 14) reporting that "biotech has finally boomed". The article reported the numerous and diverse successes of 2013, which included a string of IPO activity, four to nine-fold surges in share prices for a number of companies, high profile investors turning their attention to biotech and a steady flow of capital raisings that totalled $739.1 million (Biotech Daily, 2 Jan 14), the highest amount since 2007. However, the first quarter of 2014 saw only one IPO occur in Australia; a dual listing.

Employment outlook remains robust

The survey showed a strengthening in hiring intentions with the industry overall optimistic for growth. This is the strongest position for employment that the industry has seen since the record high in 2010. Collectively, the survey respondents plan to hire 208 new people.

Of those specified, the majority of the roles will be in sales and marketing, research and management.

Regarding staff levels, do you expect to...?

R&D Tax Incentive

The perception of the R&D Tax Incentive continued to strengthen with 54% (41%:2013) identifying it as having a positive impact. When asked to comment on the public policy environment, the common theme from respondents was, at a minimum, to leave the current incentive arrangements alone and if there was to be any change, it should be to raise the threshold for the refundable component from $20 million to $50 million.

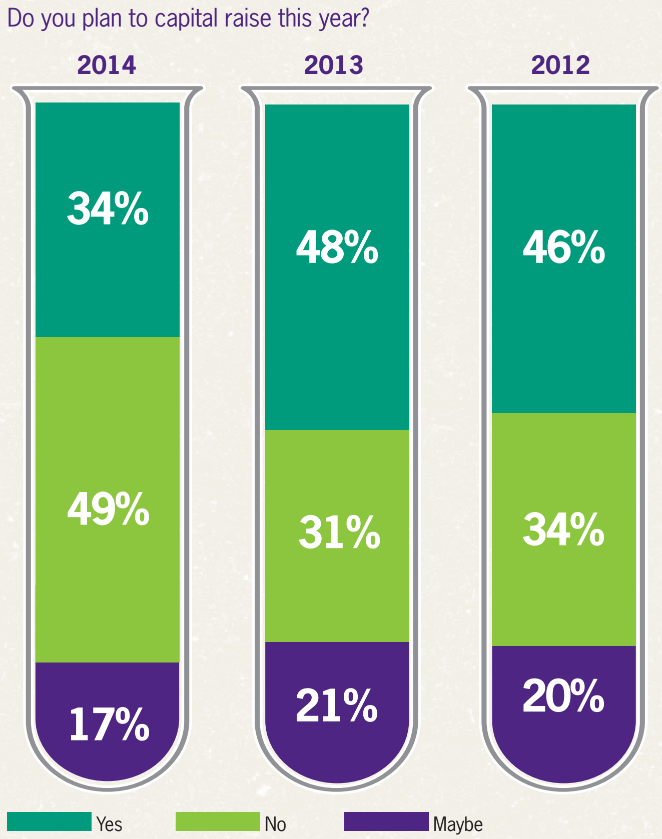
An unexpected and unwelcome change was made to the R&D Tax Incentive in the 2014-15 Federal Budget. More information on the potential impact is provided in the 'Government policy' section of this report.

> 'The R&D Tax Incentive arrangements are an essential source of funding, and we would encourage the government to resist any temptation to water it down, and in fact further strengthening the current arrangements would be a significant positive step.'

Funding

Availability of funding
2013 was without doubt a strong year for the biotechnology sector with underlying market indices both locally and overseas generating strong returns.

This ensured that funding pressures were largely met, as seen in the correlation between the proportion of parties flagging their intention to raise capital in 2012 survey and those who did raise capital during the course of 2013 (46% respectively).



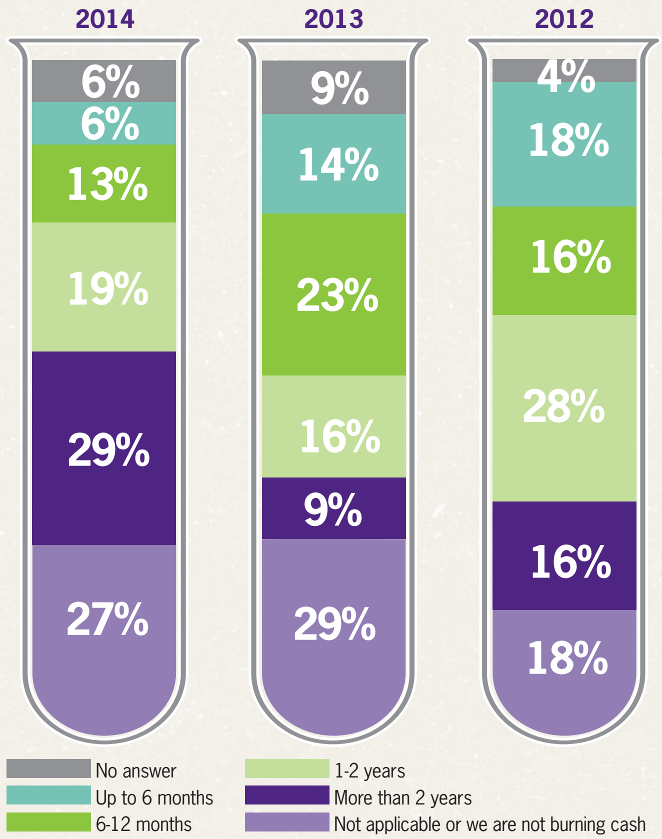
The competition for capital appears to have eased, with 34% of respondents (48%:2013) intending to raise capital. This is a significant decrease from the prior year's survey, possibly reflecting the easing of immediate funding pressures. The percentage of companies with less than two years of cash on hand has improved significantly to 38% (53%:2013) and the number of companies with more than two years' cash has more than tripled to 29% (9%:2013). This echoes the successful results from capital raising intentions in the prior year.

Of the 22 companies that raised capital in 2013, an overwhelming 81% did so by issuing equity, in the forms of equity issue, convertible notes or rights issue. Of those, the dominant purpose of the capital was intended to fund research and development programs.

While funds raised last year were predominantly from Australia, this year has already seen capital raisings in excess of $30 million from US cornerstone investors. For example Benitec, Spinifex and Nexvet are amongst those raising capital from the US .

For those seeking to raise capital in 2014 (34%), the dominant purpose was to fund research, development and commercialisation programs.

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



Government policy

A time of change

The past year has been dominated by the 2013 Federal Election, both in the lead-up to the event and the post-Election change of government, and the resulting change in policies and ideology. The period may be characterised as volatile in policy terms and has presented a very unpredictable policy environment, especially around the Coalition Government's first budget, which has now been delivered.

Optimism that the newly-elected Coalition Government would be more business-oriented, was tempered by the Coalition's focus on returning the budget to surplus. This resulted in intense scrutiny of expenditure, especially industry assistance, and its subsequent reduction.

As Australia's window of mining construction-driven prosperity begins to close, and car manufacturing phases out, building Australia's capacity as a technologically innovative country is vital for our economic future. Sympathetic policy settings are critical to aid the structural transformation of the Australia economy toward high-tech, knowledge-based industries, which have the capacity to generate a globally-competitive economy, higher exports and sustainable, high-skilled jobs.

Australia has a strong comparative advantage in 'high tech, high cost, low volume' manufacturing of elaborately-transformed goods such as medical devices and bio-pharmaceuticals, and a burgeoning biotechnology and life sciences industry that is globally impressive by any comparative measure.

Manufacturing

73% of the companies surveyed are manufacturing – 44% in Australia and 54% overseas. The trend for manufacturing has seen a slight rise from last year in the number of companies, with a clear shift to more companies manufacturing overseas (54%), up from the 36% recorded in 2013.

If Australia is serious about retaining advanced manufacturing, policy settings should be designed to provide incentives for innovative companies and high-tech manufacturing in order to keep us internationally competitive and able to attract and retain business, and the resulting jobs and exports.

It's all about tax reform for international competitiveness

AusBiotech has been advocating for tax incentives as an asset for innovation and business, with four pillars:

- Retain the Research & Development (R&D) Tax Incentive – a top priority for the life sciences industry
- Introduce the AIM Incentive, a 'patent box'-style incentive to keep home-grown intellectual property (IP) once it reaches commercialisation, as well as associated manufacturing, in Australia
- Introduce fiscal incentives for investors in pre-revenue and start-up companies
- Restore the Employee Share Scheme (ESS) to its pre-2009 form, specifically tax shares or options upon realisation of a gain, rather than upon issue.

This policy position was developed with feedback from the survey (this year and past years) and further discussed and moulded in CEO focus groups held in April 2014.

When asked what issue most concerns them at a Federal policy level, the majority of survey respondents were concerned that the government might tamper with the R&D Tax Incentive: a concern that has been realised in the 2014-15 Federal Budget. Respondents were also predominantly concerned with policies in relation to employee options and share schemes and manufacturing support.

> "Uncertainty over R&D Tax Incentive for small enterprises creates a difficult environment to attract investors or research partners."
>
> "Our company would not be here today if it weren't for the R&D Tax Incentive."

The dominant answers on the 'wish list' for the Federal Government in the Budget were:

- Certainty, stability and predictability
- Transparency and an articulated plan for industry support
- Retain current industry incentives (these were subsequently removed or reduced in the Budget)
- Retention and consistency in the R&D Tax Incentive and an up-lift to the $20 million threshold to $50 million.

> "Get health spend focused on value, not price…"
>
> "It is more often than not, easier to leave the country within this [the early commercialisation] period."
>
> "It is not just the financial benefit [of the R&D Tax Incentive], it is the signal it sends on the importance of R&D to investors, here and overseas."

Unfortunately, the 2014-15 Federal Budget delivered a round of cuts for biotechnology, including a reduction to the benefit of the R&D Tax Incentive and abolition of the Innovation Investment Fund (IIF) and Commercialisation Australia (CA). This was compounded by no resolution or repair for Employee Share Schemes (ESS).

ESS has proven to be a major issue for biotechnology companies, especially start-ups, since damaging changes were made in 2009. The will to repair ESS appears to be supported by both sides of government and yet there was, disappointingly, no move to fix this measure which would have had a small budgetary impact and large benefit for small and medium-sized companies.

The Budget included measures to save $620 million over four years by reducing the rate of the R&D Tax Incentive by 1.5 percentage points. The Government said that, consistent with its commitment to cut the company tax rate from 1 July 2015, the relative value of the Incentive will be preserved by reducing the rates of the refundable and non-refundable offsets by 1.5 percentage points, effective from 1 July 2014.

But the devil is in the detail. The timing means that the R&D Tax Incentive cut will occur one year earlier than the reduction to the company tax rate (from 1 July 2014), when the refundable R&D tax offset will be set at 43.5% and the non-refundable tax offset set at 38.5%. It also fails to take account of the impact on the many pre-revenue biotechnology companies that are in tax-loss (and therefore don't pay corporate tax). For them, it is a damaging reduction to the support available as they will not get any benefit from the planned corporate tax reduction.The industry, still recovering from the damage caused by the sudden removal of the Commercial Ready program by the previous Labor Government in 2008 and followed by the GFC, has clawed its way back. The ability to retain and sustain the industry since this time has been largely credited to the three-pronged support from the R&D Tax Incentive, commercialisation support via CA, and venture capital support via the IIF.

While AusBiotech has been advocating for greater support for investment in innovation and new industries, and therefore extensions to the CA and IIF programs to make them more meaningful, the industry fears the decisions announced in the 2014-15 Federal Budget may seriously damage Australia's hard-won innovation momentum.

Amongst the hopeful news in the Budget was the announced establishment of the Medical Research Future Fund (MRFF). Should it be passed by the Parliament, the fund would be the biggest medical research fund of its kind in the world. If the commercialisation and translational aspects can be addressed, the MRFF is a great nation-building investment for Australia.

However, the removal of commercialisation support will make translating Australia's world-class research into cures and treatment, products and services more difficult. AusBiotech is urging the Government to consider the dedication of a portion of the MRFF proceeds to the translation of research, in-line with the McKeon Review recommendations.

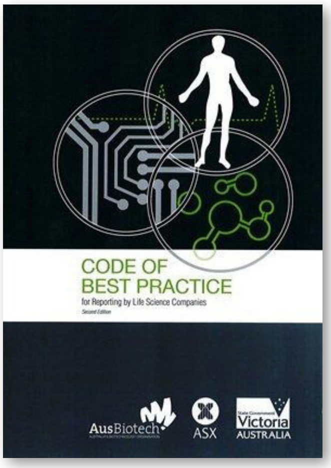
A key element of the report was the strengthening of commercial pathways to ensure the translation of research outcomes into health and economic benefits for the Australian community, and recommends funding "address the twin 'valleys of death' in commercialising research" and called for the establishment of a Translational Biotech Fund.

The McKeon review recommendations were made while CA and IIF existed. The removal of the remaining support for commercialisation, means that there is now an even greater need for the Translational Biotech Fund, if we are to see benefits flow from the MRFF to real treatments and cures.

Attracting investment

Businesses in the biotechnology industry have a unique business model. Many are small and require long-term investment during their pre-revenue phase, making them less attractive for institutional and other investors who don't have specific knowledge of the sector. One of the important ways to address information quality and asymmetry, thus improving investor confidence, is to utilise guidelines that are recognised by the ASX.

Since the last survey, AusBiotech has revised and published the *Code of Best Practice for Life Science Companies* (Ed 2) ('the Code') to support boards of biotechnology companies in governance and disclosure, which in turn supports the attraction of investment. The Code was developed and revised in consultation with the Australian Stock Exchange (ASX) with the support of the Victorian government.



Amongst the ASX-listed companies responding to the survey, 63% were using the Code to signal best practice governance to investors. The usage was up from 2013 when 52% were using the Code (Ed 1).

Copies of the Code can be accessed via the AusBiotech website (www.ausbiotech.org/biotechboards). A companion document to the Code has also been developed by AusBiotech, which outlines guidance on governance for directors of life sciences companies.

Methodology

This is the fourth Biotechnology Industry Position Survey conducted by AusBiotech and Grant Thornton. The survey was conducted via mail and email during February and March 2014 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.

Issues were identified by AusBiotech and Grant Thornton's Life Sciences team.

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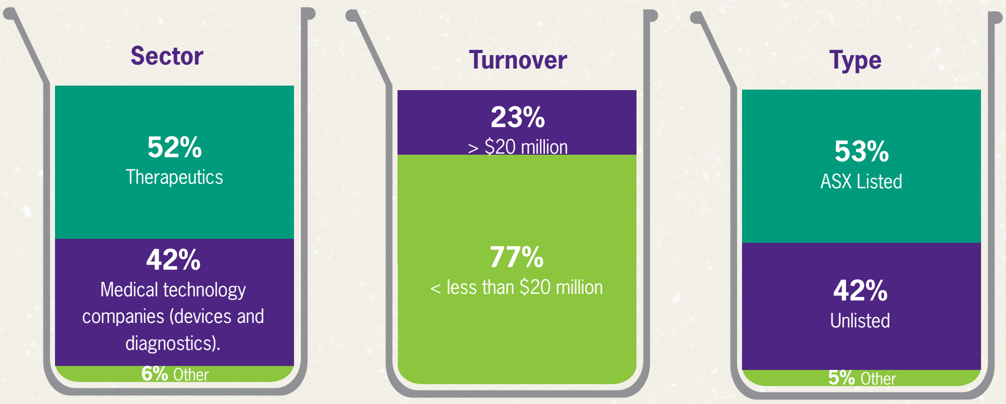
Analysis of respondents

Responses were received from 48 companies. As a sample, 36 of the 48 responding companies will collectively spend $132 million on R&D this year.



AusBiotech and Grant Thornton appreciate those who participated in the survey in support of the industry and thank the following companies that agreed to be named.

- AdAlta
- Advent Pharmaceuticals
- affinity BIO
- Alchemia
- Alere
- AMEC Australia, Bioprocess & Controlled Environments
- Anatomics
- Ascend Biopharma
- AstraZeneca
- Atcor Medical
- Avita Medical
- Benitec Biopharma
- BIASSEX
- Biodiem
- Bioplatforms Australia
- Bristol-Myers Squibb
- Clarity Pharmaceuticals
- Cook Medical
- CSL
- Epichem
- Horten Medical
- IDT Australia
- Imugene
- Innate Immunotherapeutics
- Johnson & Johnson Medical
- Marinova
- Minomic
- Neuren Pharmaceuticals
- Novogen
- Omnigon
- OncoSil Medical
- Osprey Medical
- Pharmaxis
- Shire Australia
- Sienna Cancer Diagnostics
- Stryker
- UCB Australia
- Universal Biosensors
- V-Patch Medical Systems

AusBiotech and Grant Thornton also wish to thank the remaining survey participants who did not wish to be named here.

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 industries in biotechnology.

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 more than 25 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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