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AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Industry Position Survey April 2012

Biotechnology





The Biotechnology Industry Position Survey provides us with a comprehensive annual industry snapshot, direct from the industry’s leaders, based on experience, business knowledge and political insights.

Dr Anna Lavelle
CEO AusBiotech Ltd



We are proud to support the Australian biotechnology industry with this survey. The survey is an important tool to understand the issues and assist in laying a foundation to secure greater support for the industry.

Michael Cunningham
National Head of Life Sciences
Grant Thornton Australia Ltd

Contents

Key findings of the survey	02	Demographics	10
Background	03	Survey participants	11
Survey findings - Sentiment	04	About AusBiotech	12
Survey findings - Funding	06	About Grant Thornton	13
Survey findings - Government policy	08		

Key findings of the survey

Welcome to the annual Biotechnology Industry Position Survey. This research has been conducted as part of both AusBiotech and Grant Thornton's ongoing commitment to the biotechnology industry.

- The bullish sentiment reported in 2011 continues with 82% (75%: 2011) of respondents expecting their business to grow in the coming year, while 68% characterised 2011 as a good or excellent year, up from 56%.
- The expansionary approach to employment which emerged during 2009 persists with a majority of companies indicating they will increase staffing numbers in the coming year. The new positions will be predominately in 'sales and marketing', 'scientists and clinical trial staff'.
- Despite 54% of respondents raising capital during 2011, funding remains a significant industry issue with 34% indicating they have less than 12 months cash on hand at current burn rates. 46% intend to raise capital in the coming year and a further 20% are undecided.
- The Australian operating environment (economic and public policy) remains a concern, with only 24% of respondents identifying the environment as conducive to growing a biotechnology company, while 38% felt the environment was neutral and 38% thought it was working against the growth of companies.
- The passage of the Research and Development (R&D) Tax Incentive legislation was a significant event with the majority (65%) of companies indicating they are confident it will have a positive impact on their business. This is particularly significant as the delay to its passage through Parliament was a major area of frustration last year. Despite the Tax Incentive's significantly changed provisions and the first claiming cycle already being well underway, 53% of companies had not yet sought professional advice.
- The majority of responding companies (62%) are manufacturing, 46% of the overall respondents are manufacturing in Australia and a further 34% are manufacturing overseas. There is a crossover of 18% of companies manufacturing both overseas and in Australia.
- Collectively the responding companies plan to spend at least \$610 million on research and development in 2012.

Background

At a glance

AusBiotech's representation and promotion of the biotechnology industry continues to influence on critical issues.

While input on public policy is a year-round and core part of AusBiotech's work, it's vital to formally seek views from the industry to get a comprehensive, updated picture of the Australian biotechnology industry from its leaders.

The annual Biotechnology Industry Position Survey, proudly supported by Grant Thornton, sought the views of CEOs on the operating environment, the industry, and how their companies are faring.

The results enable evidence-based statements about the magnitude of issues and trends and what should be done in response to them.

At any given time there are a raft of biotech-related issues and developments, where policy is vital to the industry's progression and future.

Industry snap shot

Australia continues to be a leading location for biotechnology in the Asia-Pacific region and the world, with the Australian biotech industry ranked the fifth most innovative in the world, by *Scientific American World View* magazine (July 2011). With more than 400 biotechnology companies and 600 medtech companies, the Australian biotechnology industry has performed strongly despite an unpredictable economic market.

The industry is characterised by many small to medium private and public companies. There are currently in-excess of 100 ASX-listed life sciences companies: almost 40 in medtech and more than 60 in biotechnology.

The Australian industry has received a major boost with the 2011 passing of the R&D Tax Incentive legislation. This will inject significant new funds for innovative biotechnology companies and deliver spill-over benefits for the community from biotechnologies.

The survey

The survey results provide an independent perspective of the impact of the current economic and regulatory environment on the biotechnology industry.

Issues investigated include:

- Sentiment
- Funding
- Government policy

AusBiotech and Grant Thornton would like to express appreciation to those who participated in the survey in support of the industry.



Survey findings - Sentiment

A number of good news items and sizeable deals in the Australian biotechnology industry have kept spirits high amid and despite the economic gloom that has gripped the world.

Amongst the recent highlights, Acrux paid a \$100 million special dividend to its shareholders, after receiving its milestone payments from Axiron licensee Eli Lilly & Co. This dividend is without precedent in Australian biotech. TB diagnostics company, Cellestis was acquired by Dutch firm Qiagen for \$370 million.

Less than a week into the New Year, Bionomics was able to announce a collaboration, research, and licensing agreement with US-based Ironwood Pharmaceuticals, potentially worth up to US\$345 million, to develop and commercialise its anti-anxiety compound, BNC210.

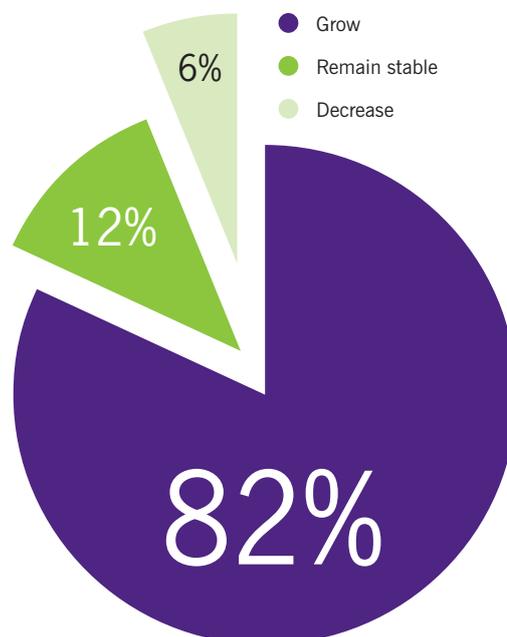
The annual capital raising figures for the industry (BioShares 30 Dec 2011), saw \$630 million raised in 2011, a 14% increase on 2010 when \$554 million was raised. Notable capital raisings were made by Pharmaxis, Starpharma and Phosphagenics.

Optimistic outlook

Optimism grew stronger with 82% (75%: 2011) of respondents expect their business to grow in the coming year.

This continues the positive sentiment of respondents when reflecting on 2011. 68% of respondents identified 2011 (56%: 2010) as a good or excellent year.

During 2012 do you expect your business to grow, remain stable or decrease?



Expansionary employment strategies

Despite a recent spate of high-profile redundancies in the broader Australian economy, the overall employment conditions remain strong. Expansionary sentiment from the 2010 and 2011 surveys continued into 2012 with 58% of companies expecting to increase staff numbers. The new positions will be in ‘sales and marketing,’ and ‘scientists and clinical trial staff’.

Economic and public policy environment

The Australian operating environment (economic and public policy) remains a concern, with only 24% of respondents identifying the environment as conducive to growing a biotechnology company and 38% indicating the environment was working against the industry. Despite this poor result, this is an improvement on the previous year when 13% felt the environment was conducive to growth and 52% felt it was working against the industry.

Research and Development tax incentive

The passage of the R&D Tax Incentive was well received with 65% of respondents expecting it to have a positive impact on their business.

Despite the significantly changed provisions and the first claiming cycle being well underway, 53% of companies had not yet sought professional advice. Of those companies, 50% plan to get advice soon, 39% feel they don’t need it and 11% were undecided.

Collectively the responding companies plan to spend at least \$610 million on research and development in 2012. To put this into context, the national budget for medical research for the NHMRC’s (National Health and Medical Research Centre) Medical Research Endowment Account Australia’s largest source of public medical research funding, is almost \$750 million in 2011-12¹.

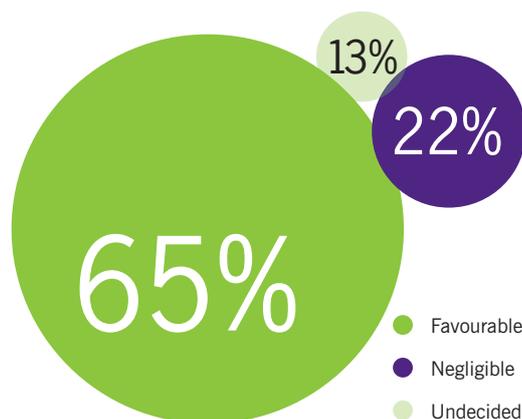
Employment intentions?



How would you describe the Australian operating environment?



Impact of the R&D tax legislation?



¹ Source: BioShares Edition 439 (30 Dec 2011)

Survey findings - Funding

High profile commercial deals and industry returns provided significant momentum as we entered 2011. The reality was a year full of extreme financial turbulence and market volatility.

From an overall market perspective capital raised from IPOs was significantly lower than the previous year despite a relatively good March quarter. The second half of 2011 was littered with aborted floats. The vast majority of new listings ended the year below listing price.

However on a more positive note, the respective listings and raisings of international companies Bioniche Life Sciences (raising \$12.5 million) and GI Dynamics (raising \$80 million) provide further evidence of Australia's ever-increasing international biotechnology presence.

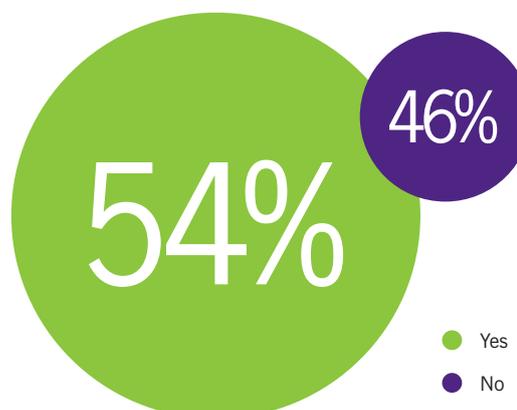
The industry also provided two of the top four best performing S&P/ASX 200 companies; Sigma Pharmaceuticals (1st) and Mesoblast (4th).

Sources of funding

Our previous survey reported that 24% of companies were holding less than 12 months cash and 58% were planning to raise capital during 2011. We are pleased to report, that despite what ultimately turned out to be a very difficult year, 54% of respondents were able to raise capital.

The majority of funding was raised via the issuance of equity. Other sources of funding such as debt instruments and government grants and concessions were also significant.

Did you raise capital during 2011?

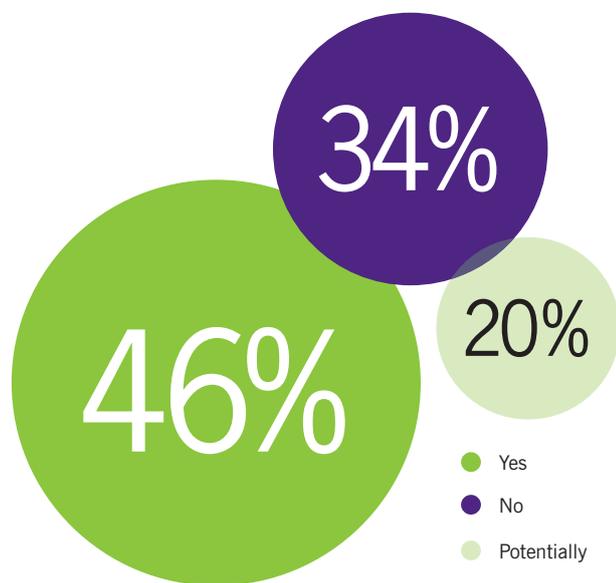


Funding requirements

The appetite and competition for capital in 2012 will again be high with 34% of respondents indicating they have less than 12 months cash and 46% anticipating raising capital during the current year.

Whilst there is no escaping the significant macro risks still prevalent, the industry appears well placed to leverage the benefits associated with a maturing profile.

Do you plan on raising capital during 2012?



Survey findings - Government policy

Federal concerns

CEOs were asked which issues concern them most at a federal level and to name the thing they want most from the Federal Government, to assist the industry. Among the major industry concerns and desired assistance, the themes of note were:

- Incentives for investment;
- A greater quanta of targeted funding support; and
- Predictability in relation to policy and programs.

Incentives for investment

Access to capital remains the biggest issue for the biotechnology industry. While programs such as the R&D Tax Incentive, the Innovation Investment Fund (IIF) and Commercialisation Australia (CA) grants all assist, there remains a gap in terms of incentives for investors.



Provide tax incentives for investors in biotechnology to hold their investment for 12+ months.

The industry (and innovation more generally) would benefit greatly from incentives for investors in the form of tax breaks. An incentive for investors in innovation-based companies to hold their investment for a minimum period would have a beneficial impact.

The Australian industry is also keen to emulate a new UK Government initiative, known as the Patent Box. It provides a preferential regime for profits arising from patents, allowing companies to apply a 10% corporation tax rate to profits attributed to UK patents.

The Patent Box is expected to encourage companies to locate high-value jobs and activity

associated with the development, manufacture and exploitation of patents in the UK – and enhance the UK's competitiveness globally.

Greater quanta of targeted funding support

Almost four years after the demise of the Commercial Ready program, the industry is still seeking a replacement that would provide access to adequate-sized grants for commercialisation activities and clinical trials.

Despite the recent improved provisions for CA grants, industry CEOs feel “the quanta applied to CA grants is still too small for fast outcomes,” and needs to be raised to a more realistic level, such as \$5 million.



Lack of a consistent and appropriate grant and assistance program specific for the biotech sector.



Bring back a co-investment scheme similar to the axed Commercial Ready.

More predictability

A major theme in CEOs' comments was the notion of stability, certainty and a plea to keep support programs, and keep them predictable. Respondents asked for the maintenance of current policies, as the changing of “goal posts” is disruptive, and disables companies from making reliable forecasts.



Uncertainty around policy is disruptive and hinders fund-raising strategy.



More certainty. More transparency. Longer term policy horizons.

Employee remuneration

The majority of respondents use share options and shares in addition to cash to remunerate their employees. Only 16% of companies remunerated with cash alone.

Not surprisingly, the tax treatment of share options and shares was repeatedly cited as a barrier to biotechnology companies in competing for and retaining highly-skilled talent.

Manufacturing

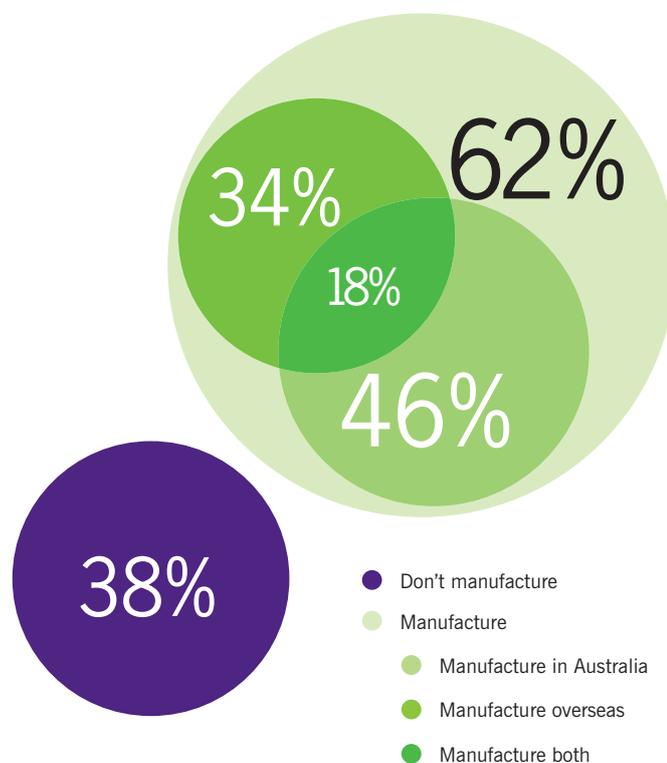
The majority of responding companies (62%) are manufacturing. 46% of overall respondents are manufacturing in Australia and 34% are manufacturing overseas. There is a crossover of 18% where companies manufacture both overseas and in Australia.

AusBiotech believes there is a serious lack of understanding, at a policy level, about the contribution that biotechnology and medical device companies are making and can further make to manufacturing in Australia, or what their needs or barriers are – and in what ways they differ from the manufacturers of commoditised items, such as cars.

Biotechnology is one of the so-called ‘sunrise industries’ and fits neatly with the Government’s desire to move to advanced manufacturing, providing high value-added products, with highly-skilled labour and global production chains, for niche markets.

AusBiotech sees an opportunity for manufacturers of medicines, medical devices and diagnostics to become the rule not the exception. Policy must support a future manufacturing industry that will provide highly-skilled jobs and excellent returns to the economy.

Do you manufacture and if so where?



Demographics

About the survey

This is the second joint Biotechnology Industry Position Survey by AusBiotech and Grant Thornton. The survey was conducted via mail and email during January 2012. It was open to all ASX-listed life sciences companies and AusBiotech member biotechnology companies, including unlisted companies.

Issues explored by the Biotechnology Industry Position Survey were identified by AusBiotech and Grant Thornton's Life Sciences team. Enquiries regarding this survey may be directed to:

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Analysis of respondents

Companies were asked to submit information regarding their financial status, issues impacting their business, their current outlook and expected plans for the future.

Responses were received from 50 companies; the major identified area of business was Therapeutics (56%) with medical devices and diagnostics representing 26% and 20% respectively.

For additional copies of the survey, please contact AusBiotech www.ausbiotech.org or Grant Thornton at www.grantthornton.com.au

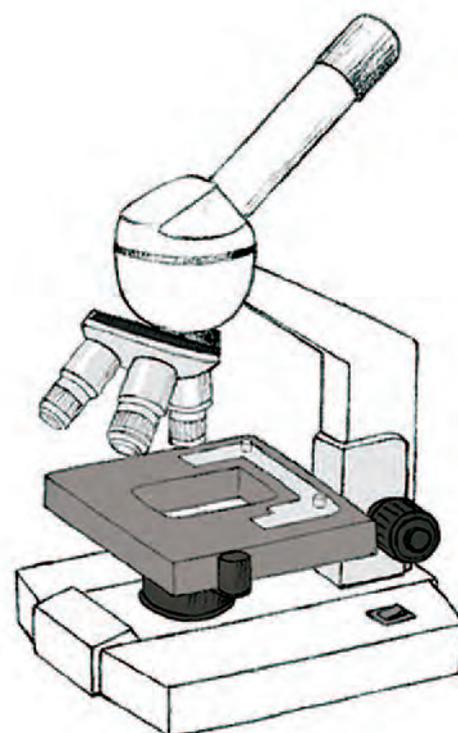


Survey participants

Sincere thanks goes to the following participations, who agreed to be named.

- Acrux
- AIMEDICS
- AMGEN
- ASDM
- AstraZeneca
- Atomo Diagnostics
- BioDiem
- Bioplatforms Australia
- Bluechiip
- Broadvector
- Cellmid
- Cell Therapies
- Clinical Genomics
- CSL
- Cyclopharm
- Devro
- Genera Biosystems
- Genetic Technologies
- Given Imaging
- GlaxoSmithKline
- Grey Innovation
- Hatchtech
- Hunter Immunology
- Immune System Therapeutics
- ImpediMed
- iNova Pharmaceuticals
- Invetech
- Lipotek
- Minomic International
- MyGene
- Neural Diagnostics
- Photonz Corporation
- PolyActiva
- Prana Biotechnology
- Progen Pharmaceuticals
- Shire Australia
- Sienna Cancer Diagnostics
- Tissue Therapies
- Viralytics

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



About AusBiotech

AusBiotech is Australia's biotechnology industry organisation, which represents 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.

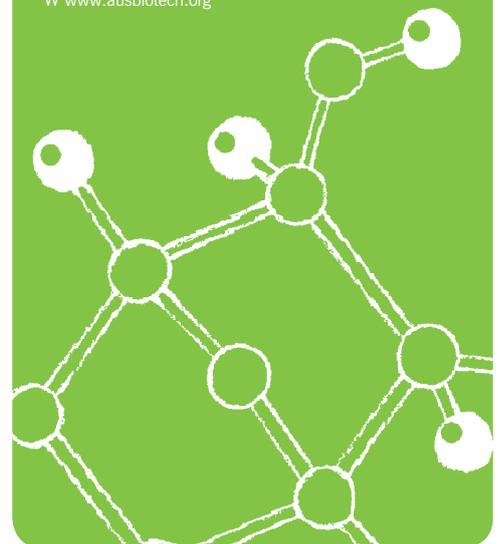
AusBiotech is a not-for-profit organisation, which has representation in each Australian state and in various special interest sectors. Active state committees and advisory groups provide a national network to support members and promote the commercialisation of Australian bioscience in the global marketplace.

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, individual and student members from Australia and overseas.

If you want to know more, please contact AusBiotech's national office...

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