



AusBiotech's Pre-Budget Submission
Federal Budget 2020-2021

Facilitating global development of the Australian life sciences industry

To
The Treasury
Australian Government
prebudgetsubs@treasury.gov.au

Prepared 24 August 2020

From:
AusBiotech Ltd
ABN 87 006 509 726
Level 3, 15 Queen St Melbourne VIC 3000
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org

2020 Federal Budget Submission Summary – facilitating global development of the Australian life sciences industry

Introduction

AusBiotech welcomes the opportunity to proffer its 2020-2021 Pre-Budget Submission. The recommendations in this submission will minimise and mitigate the impact of COVID-19 on jobs and businesses in the biotechnology industry, as well as facilitate the fastest recovery possible for the sector.

As the national representative body for one of Australia’s most innovative industries - the biotechnology or life sciences industry - AusBiotech is pleased to have the opportunity to comment.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology (devices and diagnostics), food technology and agricultural biotechnology sectors. With more than 1,852 organisations and 240,000 employees, Australia has a substantial life sciences ecosystem and one which is consistently ranked as one of the top for biotechnology innovation globally.

The biotechnology industry has the capability to address some of the precise issues that Australia is facing with the pandemic, including the need for strong R&D, biotherapeutics development, scale-up and manufacture and delivery of appropriate medicines and medical technologies to patients.

Investment in this sector is not only important for future jobs and growth but also can provide critical defence against some of the health impacts arising from this and future pandemics. This is not a “standing start”; Australia already has strong foundations upon which to grow, which as a smart nation we can leverage and accelerate.

To maximise the sector’s export and investment attraction potential – and its capacity to improve lives – AusBiotech urges the Government to focus on three key goals:

- Increasing Business Expenditure on R&D (BERD) and increasing the capability and resilience of manufacturing of local innovation
- Supporting developing small and medium sized companies
- Back the Biotech Blueprint: *a vision for biotech beyond COVID-19*

Life sciences delivers national benefits

Even before COVID-19, the life sciences industry was recognised as critically important to the health technology pipeline and the source of significant economic contribution to Australia in a post-mining boom era. It was growing strongly with 16 per cent growth in new company numbers and healthy employment growth. The most recent data available (2019) indicates that the biotechnology sector:

- Adds \$5 billion gross value every year to Australia’s economy;
- Employs over 240,000 Australians and encompasses 1,850 organisations of which 1,000 are life sciences companies developing new health technologies (of which 86 percent are SMEs, employing 65,000 people and pre-revenue);
- Attracts \$1.5 billion in R&D investment each year; and
- Attracts on average \$1 billion in venture capital each year.

In addition to the health and medical research opportunities, the sector also offers **new and significant economic opportunities for Australia**. There are opportunities related to achieving

excellence in new therapeutic and medical interventions, as well as opportunities related to our world-class infrastructure and capabilities. Australia is well-positioned to capitalise on these opportunities and increase our self-sufficiency and resilience. For example:

- By 2035 the global regenerative medicine market will reach \$120 billion, and capturing just five per cent would create 6,000 new jobs and \$6 billion in annual revenue. Australia was the first country to treat an industry-sponsored patient using ground-breaking CAR-T therapy outside North America, with the first therapy approved by the Australian regulator at the end of 2018.
- Every year \$1 billion is spent on clinical trials in Australia. These in themselves provide substantial economic benefits through inbound investment, job-creation, and skills development.

The biotechnology sector is unique, both in its development challenges and in its potentially world-changing technologies. It is based on intellectual property, is heavily R&D intensive, and is a globally-mobile industry. It is highly regulated, usually requiring rigorous clinical trial data before any product can be approved, and often has longer than usual development times. It can take 10 – 15 years and substantial investment (public and private).

In addition, the life sciences sector has stepped up and played a critical role in the global pandemic response. Commentators around the world are calling biotechnology's response to COVID-19, its 'finest hour' as it pivots to fast track COVID-19 vaccines, treatments, diagnostics and digital health solutions.

Around 70 percent of the more than 660 unique COVID-19 drug programmes underway are from small biotechnology companies, amongst them are Australian companies joining (and in some cases leading) the various collaborations.

However, despite their demonstrated resilience, like many others the biotechnology industry has been impacted by this pandemic and needs Government support.

Creating the right business environment for biotechnology and Australia to flourish

To commit financial resources into a long-term and resource-intensive activity such as R&D, life science businesses need to have confidence that changes are well-thought-out, transparent and evidence-based, and are implemented in a controlled, staged manner. Retrospective and/or 'kneejerk' policies, in particular, significantly erode that confidence.

Significant policy decisions should be evidence-based, transparent and consider industry input as policy necessarily evolves to adapt to changes in the business and economic environment.

Businesses need to be able to plan their economic, manufacturing and investment activities with confidence that the policy settings used to base these decisions on won't regularly and significantly change.

Government has an important role in projecting and conveying that confidence in this sector.

Increasing Business Expenditure on R&D (BERD) and increasing the capability and resilience of manufacturing of local innovation

Competition among peer nations for advanced manufacturing and R&D is intense and policymakers all over the world are actively using micro and macro-economic levers to compete for job-creating investments and skills. Even local R&D is still accessible to overseas companies in a globally competitive environment. Australia's focus on this aspect will be critical as all nations seek to supercharge their recoveries.

To encourage international and local companies to invest in R&D in Australia, we need: incentives that attract international investment; programmes to attract and retain talent onshore; tax regimes that incentivise the discovery, exploitation and value add of patentable intellectual property (IP), especially the advanced manufacturing of IP-based products.

The relationship between advanced manufacturing and a dynamic innovation culture is well documented. While comprising just eight per cent of the economy, manufacturing is one of the major sources of innovation in Australia, responsible for a quarter of all investment in R&D. Innovation and manufacturing are different sides of the same coin. A constant push-pull operates, whereby innovation in product design stimulates innovation in manufacturing processes, and vice versa.

Maximising the Australian manufacturing sector, as it relates to R&D, largely depends on the existing RDTI being complemented with a tax regime that can secure Australia's competitiveness for the future. As R&D incentives become more commonplace around the world, a number of governments have recognised that to stay competitive, they must also offer a competitive/compelling/an attractive tax and business environment.

There are two main recommendations to support BERD and manufacturing, and others AusBiotech considers worthy of inclusion in support:

1. The continuation of the Research and Development Tax Incentive (RDTI) gives the Australian life sciences sector a competitive edge in a climate of competition.

The stability of Australia's RDTI is continually identified as the most important tool for increasing business expenditure on R&D (BERD) in life sciences. It has been game-changing for this sector and certainty about its future will be key to the ongoing delivery of jobs and growth.

Without access to Australia's RDTI program, life science companies at the forefront of the global response to COVID-19 wouldn't be here today. The Australian life science sector has mobilised in the fight against COVID-19, which is testament to the value of the RDTI and that it is doing what it should. The industry should be recognised for its unique economic and social contributions, particularly in response to the current pandemic, and the changes should be abandoned.

Government support through the RDTI for this sector can provide a critical defence against some of the health impacts arising from this and future pandemics. Decade-long investment into the industry has prepared these companies to act swiftly in response to the pandemic, pivoting to fast track COVID-19 vaccines, treatments, diagnostics and digital health solutions.

Advantages of the RDTI for the sector include bridging pre-revenue stages of research and development, allowing Australia to compete internationally, and provision of a reliable backstop against share price fluctuations. Investors come on board knowing the rebate is available. It has

been game-changing for this sector and certainty about its future will be key to the ongoing delivery of jobs and growth.

2. An Innovation and Manufacturing Tax Regime would reward innovative Australian businesses that make profits from qualifying patents that enhance the international competitiveness of Australian innovation. Its purpose would be to encourage the commercialisation phase of innovation by providing an incentive to industry to locate high-value jobs associated with the development, manufacture and exploitation of IP in Australia. The incentive can also be used to attract overseas IP and associated benefits (such as jobs, skills, manufacturing) to Australia. While R&D incentives are designed to encourage activities that will result in innovation, this incentive is aimed at commercial activities, by providing tax relief on profit derived from qualifying patents.

3. Successful overseas initiatives worth considering to increase Australia's competitiveness include the Small Business Innovation Research programme in the United States – a competitive awards-based programme that reserves Federal funds to support growth-focused small business in priority areas. It has led to the creation of thousands of new firms, including many that are globally successful. It also enables rapid tech transfer of the type we are relying upon during the COVID-19 pandemic. This in itself provides desirable economic stimulus and uses public private partnerships as a vehicle to achieve outcomes. A 2018 study of the National Cancer Institute's SBIR program related \$26 billion in economic output, \$9.1 billion in sales, and over 100,000 new jobs to companies that were awarded Phase II grants between 1998 and 2010." Success of this programme has been linked to its longevity and consequent reliability for contributors, and its size; we recommend commensurate regard for certainty and size in an Australian version of this initiative.

(<https://itif.org/publications/2019/09/26/becomingamericas-seed-fund-why-nsfs-sbir-program-should-be-model-rest>).

4. Another notable programme from overseas is the UK's Enterprise Investment Scheme (EIS). The EIS helps smaller higher-risk trading companies to raise finance by offering a range of tax reliefs to investors who purchase new shares in those companies. This has enabled people to deploy their superannuation funds more readily into sectors like biotechnology, and been pivotal in reducing barrier to allow new money to be invested in the sector. Australia has enormous reserves of superannuation capital, a portion of which could be deployed if individuals were offered the right incentive. Of itself we consider such a programme would not be sufficient to increase BERD to competitive levels but could form an important component of appropriate policy architecture and we recommend considering a review of this program for its applicability.

Supporting developing small and medium sized companies

For small companies to progress into medium size companies, and medium sized companies into the next Cochlear, CSL or ResMed.

The lifeblood of the biotechnology industry is the investment of patient capital by knowledgeable investors into companies with strong intellectual property and sound management.

Whilst recent years have seen welcome growth in Australia's venture capital industry, the pools of genuinely patient and risk tolerant capital remain too shallow to sustain available growth opportunities.

There are also concerns about a lack of diversity in the local investor base. This has meant that companies are finding continued challenges accessing private capital both at later stages (Phase II and beyond) and at early stages (pre-clinical).

The ability to raise capital has been further impacted by the necessary travel bans that include incoming and outgoing international delegations

Although there are over 160 biotechnology firms listed on the ASX, the size distribution is heavily skewed with a handful of firms accounting for the vast bulk of the market capitalisation.

Many have argued that the large number of small listed firms on the ASX reflects the limited ability of companies to raise capital in private markets, due to its small size in Australia. Market participants also report that investor understanding of the industry, outside the larger firms, has not developed as rapidly as hoped.

Weighing heavily on investor sentiment has been the ongoing uncertainty and proposed reduction in support through the R&D Tax Incentive (RDTI). This measure should be continued, as it is the single largest policy or program that has a proven track record in the promotion of investment into business expenditure on R&D. SMEs rely on this measure in securing investment as well as retaining important value-generating research to be conducted in Australia rather than elsewhere.

To achieve growth of SMEs, increased access to capital should be bolstered via:

- Continuation of the RDTI;
- A second open round of the Biomedical Translation Fund, dedicated to addressing gaps in support particularly at proof-of-concept, pre-seed and seed stage so as to facilitate greater transfer of intellectual property from the publicly-funded research organisations;
- Increased funding of industry projects for translation and commercialisation activity through the MRFF, where industry R&D is aligned with MRFF priorities and includes process elements designed to increase industry requests and metrics to assess progress;
- Attract superannuation funds via an incentive that gives increased ability for fund members to deploy their capital into equities, for example akin to the Enterprise Investment Scheme noted above;
- Mix of positive incentives to differentially attract overseas capital;
- Incentives for overseas investors to preferentially locate research and manufacturing investment in Australia (particularly if R&D Tax Incentive is to be pared back).

Back the Biotech Blueprint: *a vision for biotech beyond COVID-19*

AusBiotech seeks support for the Biotech Blueprint: *a vision for biotech beyond COVID-19* – decadal framework that will articulate a shared vision and agreed actions to continue to grow and strengthen Australia's biotech sector through to 2030. Looking to the future, the plan will address research and development, investment, people and talent, and regulation for Australian biotechnology industry and discuss opportunities and barriers within the sector to achieve the best growth when delivering improved health and economic outcomes for all Australians. The sector is hungry for it; it is a powerful long-term approach to health technology development, and a potential accelerator to returning to a growth trajectory when we commence our recovery from the current crisis.

Summary and conclusion

The biotechnology industry can play a significant role in our country's economic future and healthcare.

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

It provides staggering new possibilities to improve – or salvage - our quality of life. For our part, Australia is well on its way to achieving this vision of a successful bio-economy. However, the sector is particularly sensitive to policy settings around investment attraction, research funding along the value creation 'pipeline', and the taxation environment, in the context of global enterprise where Australian comparative advantage is key.

Investment in this sector is not only important for future jobs and growth but also can provide critical defence against some of the health impacts arising from this and future pandemics. To capture the health and economic opportunities present, we seek policy settings that provide incentive to create and retain value in Australia.

In seeking the swiftest possible recovery post-COVID-19, AusBiotech recommends for Australia to:

- Preserve the RDTI in-tact;
- Implement an Innovation and Manufacturing Tax Regime;
- Increase funding of industry projects for translation and commercialisation activity;
- Back the Biotech Blueprint: *a vision for biotech beyond COVID-19*;
- Consider further levers in order to increase Business Expenditure on R&D (BERD) and to increase the capability and resilience of manufacturing of local innovation;
- Support the maturation of SMEs along the value chain, as the 'engine room' of the economy.