



AusBiotech submission in response to the *National Reconstruction Fund* consultation paper

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Introduction

AusBiotech welcomes the opportunity to submit a response to the Department of Industry, Science and Resources' consultation paper on Australia's National Reconstruction Fund (NRF).

Biotechnology is widely recognised as a 'game-changer' and foundation stone of our future. It is anticipated that biotechnology will underpin our economy and provide solutions to disease, climate change, fuel alternatives and food security – in addition to improving our quality of life.

Already globally-recognised for the strength of its research and talent, the Australian biotechnology industry's vision is to become a global leader, with a mature and vibrant ecosystem, increased local and global standing, and being an even greater positive contributor to the Australian economy.

This vision comes from a strong position: there are already more than 2,654 organisations in the Australian life sciences ecosystem, of which there 192 life sciences companies are listed on the ASX and represent a market capitalisation of approximately \$233 Billion (~\$170B in 2019). In addition, Australia's clinical trials sector contributes to the economy around \$1.4 billion per annum, including \$1.1 billion industry-sponsored trials.

Australia has a substantial life sciences and biotechnology sector, which is consistently ranked as one of the top countries for biotechnology innovation globally when adjusted for population. Industry employs almost 100,000 Australians and consists of more than 1,425 biotechnology and medical technology companies. Around 80 per cent of these industry companies are classified as small to medium enterprises (SMEs) and are working to commercialise their research, with an important number developing new and novel technologies – the majority of which are pre-revenue.

As outlined in the [Biotechnology Blueprint](#), the decadal strategy written by the Australian biotechnology industry, for the Australian biotechnology industry, Australia is home to a world-class medical and health research ecosystem, however, access to capital to feed the need for commercialisation, clinical development and growth remains key amid an expanding industry, and the diversity of investment sources is a pressing issue. If the technologies cannot be commercialised, then they cannot reach the ultimate beneficiaries: the Australian community. This is why the establishment of the NRF is so important.

Australia's industry is well placed to participate in the global growth but will need to develop a balanced community of companies at all stages/sizes. This will require that capital, and more of it, from a diversified and well-educated investor base is available for quality opportunities, and that the business environment is as attractive as possible compared to international competitors. This is why the NRF's design is critical.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences industry, which includes biotherapeutics, medical technology (devices and diagnostics) and digital health, and agricultural biotechnology sectors.

This submission represents AusBiotech members actively engaged in delivering social and economic benefits to Australia through the commercialisation of biotechnologies and medical technologies, and therefore relevant and interested in the [medical science, critical technologies, and advanced manufacturing priorities](#) outlined in the draft NRF consultation. Comments have been considered and formed in response to these priority areas, and have been framed around the Department's feedback questions, as requested in the consultation paper.

We are pleased to see medical science and medical, advanced manufacturing recognised in the Fund, as they are both fundamentals of biotechnology.

It is important to note that the development of bio/medical technology differs from traditional business and other non-medical technology in both its development challenges and in its potentially world-changing technologies.

Its main unique characteristics include being highly regulated, usually requiring expensive and extensive clinical trial data before any product can be approved, and having longer than usual development times. It typically can take 7 – 15 years and up to \$2.5 billion to bring one bio/medical product from early research to market, with little or no revenue.

Policy settings and initiatives, such as government investment, are critical to the future of this industry and ensuring the promise and potential benefits of biotechnology for Australia can be realised. The entire ecosystem needs to work in synergy to ensure our stability and competitiveness in a global environment.

Key recommendations

On behalf of its members representing the Australian life sciences industry, AusBiotech appreciates the opportunity to welcome the National Reconstruction Fund and to provide commentary on how to best shape its design to achieve its purpose. Key recommendations include:

1. The biotechnology sector has unique characteristics, and needs to be treated as such. The sector operates within their unique market forces, and offers unique social and economic returns/offers, and it is critical that these are reflected within the design of the NRF.
2. **Patient capital** is necessary for sustainable growth opportunities – with investments beginning at a minimum of 10 years. Providing genuinely patient and risk-tolerant capital enables a great opportunity to co-invest and partner with these companies, to support their growth and accelerate progression through the commercialisation pathway to reach market, and to succeed in co-investing in the economy of today and tomorrow.
3. **To support and foster end-to-end ecosystem development**, the NRF should consider companies of all sizes: small, medium and large. Currently, incentives and structural supports along the pipeline are patchy, inconsistent and uncoordinated. There is a valuable opportunity for the NRF to support the development and growth of a balanced community of companies at all stages/sizes in their commercialisation journey.
4. Co-investment assessment criteria must be broader than the rate of return; **success should be measured through a set of balanced financial and non-financial objectives** (such as patient outcomes and skills and learning development) that outline impact metrics.
5. To enable crowding-in of investment into Australian life sciences, industry encourages the Government to consider designing the National Reconstruction Fund into a **'fund of funds'** where greater private and public investment into the sector can be pulled into/added, for example, superannuation funds. This could create a mechanism to both attract and build (diversify) investments, as well as to overcome key skills gaps that the sector is currently facing.
6. NRF Board **representation includes expertise specific to medical sciences**. This could be through a high-level appointment, or through a dedicated advisory group, thereby maximising the contribution of industry knowledge and skills.

Priority areas

1. What types of projects or investments should the Government direct the NRF to focus on, or not invest in, within each of the seven priority areas to achieve the NRF's purpose?

The investment of \$1.5 billion for medical manufacturing, \$1 billion for critical technologies, and \$1 billion for advanced manufacturing is welcomed by Australia's biotechnology industry. Leveraging our opportunity in medical science is worthy of investment.

The 'market failure' is in Australia's venture capital, meaning that many of our companies need to go overseas for capital and this in turn undermines our ecosystem. There are many worthy companies, developing great technologies, that struggle to access capital. This would be a key benefit that the NRF could provide for Australia's future.

Equally the nation-wide structural set up of advanced manufacturing in sectors of the future, such as gene and cell therapies, is a worthwhile public-good activity that will seed an economically-buoyant future as well as access to life-changing therapies.

It is noted that medical science is outlined in the consultation paper as "... such as medical devices, personal protective equipment, medicines and vaccines", and we recommend amending this. The definition of medical science needs to be broadened to include all important and critical new technologies, such as gene and cell therapies, digital technologies, and diagnostics. It is recommended that the NRF looks to an already-legislated definition, such as the Government's definition of therapeutic goods as shown Section 3(1) of the Therapeutic Goods Administration Act 1989.

Aligning the definition will enable the intended recipients to access the Fund with confidence. For example, Australia has many companies working in medical diagnostics with the potential of growing to become the next 'SpeeDx' – the successful home-grown medical diagnostics company, whose founders won the 2022 Prime Minister's Prize for Innovation for its ground-breaking work in antimicrobial resistance testing.

Conversely, we would not want to see the Fund's purpose being undermined, and becoming a channel to subsidise traditional manufacturing, where it has already proven there is no sustainability model, and where Australia does not have, and will never have, a competitive advantage.

2. How should industry 'transformation' and 'diversification' be defined and measured for each of the seven priority areas?

Transformation can be thought of as industry maturation.

The vast majority of Australia's biomedical companies are small, early-stage, pre-revenue and pre-clinical. The industry has a shared desire to support the growth, depth and maturation of the industry by helping small companies transform into medium-sized, and medium-sized companies to develop and transform into large companies. Workforce is the backbone of the industry, and development and acquisition will equip Australia for its future in biomedical science.

The number of small, medium and large size companies is an indicator of the industry's sustainability, stability and depth of the industry, and the industry's job market. Tracking Australia's ability to transform and grow companies is a measure of its vibrancy. As such, transformation would be evidenced through the growth in company maturity and (employee) size.

With considered assessment, the NRF can support the transformation, scaling and growth of a balanced community of Australian biotechnology companies at all stages and sizes of the company life cycle, which can then in turn enable greater access to broader sources of funding and investment.

3. How should 'value add' be defined and measured in relation to relevant priority areas?

Biotechnology offers exceptional 'return', extending beyond the economic returns to also deliver social and health outcomes for Australia and Australians. Therefore, 'value add' should be considered and measured accordingly for the sector that is considered a foundation stone for our future.

For example, financial and non-financial outcomes are seen through Australia's clinical trials sector, which contributes to the economy around \$1.4 billion per annum, including industry-sponsored clinical trials accounting for almost one-third of all clinical trials and over \$1 billion expenditure each year. Around half of Australian biotech companies are undertaking clinical trials, and the world continues to consider Australia a destination of choice; this investment makes a valuable contribution to R&D, patients and the Australian economy. As such, around 95,000 Australians had early access to innovative technologies by participating in clinical trials in 2019 alone.

Capital is globally-mobile, and therefore the level of investment backing Australian-based intellectual property is a strong indicator of 'value add' to a company, as well as the industry's position as a global leader. As such, tracking the overall capital raised would be a beneficial measurement of value. This could incorporate capital raised and/or co-invested through private, public and government means, as well as the amount and origin location of Australian versus foreign capital investment. The amount of capital raised is a leading indicator of future growth and a measure of support for industry.

Together with a 'scorecard' of financial metrics that go beyond the dollar-per-product, non-financial objectives outlining impact metrics would be constructive. Non-financial objectives could include health economics such as patient outcomes; and skills and learning development for industry and healthcare talent.

Sovereign capability infers not only a degree of Australian-based manufacturing capability and associated domestic supply chains, but also the appropriate research and development facilities and a skilled, experienced workforce.

It is recommended that the way 'value add' be defined and measured enable home-grown biotechnology companies, as well as global companies seeking to strategically deploy its capital, to expand their local workforces as this return on investment would deliver vital skills and training for the future workforce of Australia and offer a competitive advantage over countries such as the USA, Canada, and the UK.

As one measure tends to skew outcomes, a balanced set of objectives and metrics will best contribute to achieving the outcomes sought by the NRF.

4. How much detail should be provided on each of the priority areas? How should greater detail and the need for flexibility be balanced?

Leveraging existing and legislated TGA definitions will not only create an inclusive Fund that targets its intended recipients and encompasses all regulated medical science technologies, it will also result in the need for less guidance developed in some areas.

Investment needs and opportunities

5. What are the opportunities for value-add, growth and diversification in each of the priority areas?

Biotechnology is unique and offers significant benefits. However, the industry is young. The vast majority of ‘medical science’ companies developing therapeutics, diagnostics, devices, vaccines and other technologies in Australia are in the very early stages and are small and medium enterprises (more than 80 percent), the majority of which are pre-revenue, pre-market and on a journey of commercialisation.

As an industry, biotechnology can be characterised by long and costly product development cycles – for example, it can take around 15 years and up to \$2.5 billion to bring one biopharmaceutical from research to market. Medical devices typically take a shorter time to reach patients, but also require significant investment attraction during long periods of no revenue.

Fostering end-to-end ecosystem development is welcomed, and should be considered as the NRF assesses investing into projects to ensure that co-investment opportunities are cognisant of where (stage/phase) in the development pipeline the NRF is supporting. Currently, incentives and structural supports along the pipeline are patchy, inconsistent and uncoordinated and there is a valuable opportunity for the NRF to consider supporting companies that are earlier in their journey, together with those companies that are more mature/progressed in their commercialisation pathway. This offers a spectrum of diversity and growth opportunities, and will also lower the overall risk profile of the ‘medical science’ portfolio.

Greater understanding is sought on how the NRF intends to ‘weigh’ manufacturing in its assessment. While the Fund’s purpose is to *“add value and develop capability ... to create high quality, sustainable industries and jobs”*, as an IP-based industry, revenue-generation for the biotech sector requires manufacturing. The real value of the NRF lies in its potential to foster end-to-end ecosystem development (adding value and developing capability), and industry seeks to understand assessment weighting, as it would not want to risk the Fund’s purpose being undermined, and becoming a channel to simply subsidise the traditional manufacturing sector and therefore competing against countries where we cannot compete for low cost high volume manufacturing.

The biotechnology industry is unique and distinctive by virtue of the way it uses the latest advances in biomedical science to deliver potentially life-changing and life-saving therapies, vaccines, diagnostics and devices that have application in markets around the world. It is intrinsically global, and Australia’s industry is strongly connected to the worldwide biotechnology sector through development partnerships and trade relationships.

This uniqueness cannot be overlooked. Working in a global market isn’t just about opportunity, but rather due to necessity too – while great economic and social impacts are present, unlike many other market segments in Australia, there is an insufficiently large-enough local market for most medical science products to focus only on Australia as its end market. As such, it is encouraged that the Fund notes this unique focus in its assessment criteria, and the global nature of the industry. Australia has world-leading biotechnology talent and research and development, and so it is these market pressures that drives Australian biotechnology companies to collaborate globally in their commercialisation pathways.

Patient capital is necessary for sustainable growth opportunities. Companies face continued challenges accessing private capital both at early (pre-clinical) and later stages (Phase II and

beyond), often leading them to seek inappropriate commercialisation strategies such as premature public listing on the ASX.

Due to this industry's unique nature (outlined above), the NRF's investment into biotechnology should be considered as diversifying the Fund's overall risk portfolio. Providing genuinely patient and risk-tolerant capital enables a great opportunity to co-invest and partner with these companies, to support their growth and accelerate progression through the commercialisation pathway to reach market, and to succeed in co-investing in the economy of today and tomorrow.

- 6. Workforce talent** is the backbone of the industry, and the development and acquisition will equip Australia for its future in biomedical science. The increasing convergence of technologies is having a positive outcome on patients and can reduce the cost of delivery, however, also results in a greater need for new skills and education. For example, data scientists, informaticians and machine learning engineers and all needed for the expanding industry that is being driven by a flourishing digital health sector.

- 7. What are the manufacturing capabilities needed to support each priority area?**

Though they are complex, building Australia's sovereign manufacturing capability for complex and advanced cell and gene therapies offers a multitude of opportunities. These include: offering equitable access to cutting-edge treatments for Australian patients and therefore reducing the burden of disease significantly, leading to better health outcomes for Australians and higher participation rates in the workforce; and creating a new highly skilled workforce now and for the future, thereby cumulatively impacting the economy on a large scale.

The potential of the cell and gene manufacturing sector is large, and Australia is well positioned to capture the high-value opportunities that exist now, and in the future. Despite the COVID-19 pandemic, 2020 saw US\$19.9 billion investment globally in advanced therapy developers. There is a robust pipeline of regenerative medicine products at various phases of clinical trials and the FDA predicted in 2019 that by 2025, 10 to 20 cell and gene therapy products will be approved each year in the USA.

Australia has an opportunity to harness and leverage a growing and active global cell and gene industry. If we get this right, success could be worth at least \$6 billion in annual revenue, 6,000 new jobs across the sector for Australia by 2035 and earlier access to ground-breaking therapies for Australian patients.

This includes the opportunity for Australia to be a regional hub in the Asia Pacific region providing world-leading manufacturing capabilities, as well as research, clinical trials, and translational know-how. The Alliance of Regenerative Medicines revealed in H2 2022 that the Asia Pacific region has taken in the lead in cell and gene clinical trials, accounting for the largest share (42 percent) of new trials during the first half of 2022.

To be a destination of choice for cell and gene manufacturing, Australia requires a nationally-coordinated approach, and a significant uplift in our capabilities and capacity in order to service the commercial opportunities available.

With some calling cell and gene therapies the most important discoveries of our future, the NRF is invited to support home-grown manufacturing by backing Australia's Cell and Gene Catalyst – a joint venture that is nationally implementing the [*Regenerative Medicines in Australia: A Strategic Roadmap for the Regenerative Medicines Sector*](#) as it seeks to mobilise resources, advance cell and gene medicines policy, build community engagement, establish shared measurement practices and support aligned activities.

8. What are other capabilities needed to support each priority area?

The key elements of sovereign capability that need addressing are defined as: manufacturing capability; access to talent; and access to the elements needed to develop a pre-clinical package, including onshore toxicology capability and quality assurance.

Workforce and skills are considered a key sector enabler underlying the ability to grow the Australian biotechnology industry.

The high-value talent backing our Australian biotechnology sector has increased and there are now approximately 263,000 people employed. The number of employees employed by industry has also expanded, increasing 21 per cent from 2019 to 2022. The biotechnology sector is atypical in its collaboration culture: with around 80 per cent of industry companies classified as small to medium enterprises, it is hugely reliant on the broader ecosystem to commercialise research – from funders/investors, through to a plethora of support services, to government bodies. A quickly-growing sector and workforce means that active support of skills training, acquisition and retention is a critical need (and measure) within the NRF assessment and success criteria, and for government more broadly.

Pre-clinical packages

Australian industry faces capability gaps in pre-clinical packages as Australia does not have the infrastructure nor skills required. As such, some home-grown companies are forced to look overseas to undertake their pre-clinical packages, after which they leverage their new networks to continue onto human clinical trials.

Australia needs to bridge its domestic toxicology capability by building a plan to remedy the barriers inhibiting the growth of companies - understanding the role of regulation, ethics and reputational impacts, quality assurance, facility access and availability, as well as funding and costs.

With the US Food and Drug Administration (FDA) no longer requiring new medicines to be tested in animals for approval, following legislation signed by President Joe Biden in late December 2022, the opportunity is available to Australia to address this now.

Bridging these gaps would deliver economic benefits: it would keep more R&D of home-grown biotech in Australia, create more jobs, and make Australian biotech even more attractive to investors. Replacing, reducing and refining (3Rs) is internationally recognised as the ethical and humane use of animals for scientific purposes, and would therefore fulfil greater ESG reporting opportunities. ESG is a continuing investment trend, with community and stakeholder expectations demanding conscious consideration of the impact of business operations, mitigatory actions, and a broader commitment to playing a positive role in the sustainability of the world. ESG performance is a competitive advantage for attracting and engaging employees, investors, and consumers. Addressing the capability gap in pre-clinical packages would support the creation of a more competitive/attractive investment environment for biotech companies.

9. What are the strategic priorities for supply chains / enabling inputs in each priority area?

n/a

10. What are the gaps in or barriers to private sector investment in each of the priority areas?

Australia's industry is well placed to participate in the global growth of biotechnology but will need to develop a balanced community of companies at all stages/sizes. This will require that capital, and more of it, from a diversified and well-educated investor base is available for quality opportunities, and that the business environment is as attractive as possible compared to international competitors.

A barrier to greater private sector investment is the number and access of biotech-literate fund managers in Australia. Due to the sector's unique characteristics, investors without experience in biotechnology investment tend to shy away from the sector due to the nature of its different risk profile and complex 'product'/science.

As identified in the *Biotechnology Blueprint* as one of the key objectives of 'creating a better connected and vibrant community that is able to consistently create and grow high-value biotech companies', growing the Australian pool of funders would support biotech companies in accessing more sources of funding and investment. Increasing the number/accessibility of fund managers with the appropriate skills and capabilities would therefore increase new opportunities for life science companies.

AusBiotech is committed to fostering relationships between life science companies and investors, and in response to industry's needs, has bolstered its investment programme. Together with world-class platforms to connect innovators with investors, it has developed a number of resources to assist Australian life science companies in working with investors and navigating the investment market.

Government could also play an important role in supporting the attraction of new investors and building investments from existing investors through the consideration of incentives (including long term tax or income incentives, management of capital losses) for angel and private investors to overcome different risk profile and time to market, and by building a partnership between industry and government to develop a capital-raising education programme.

11. How can the NRF help build or encourage stronger pathways for Australian developed innovation and research, and encourage additional private investment in priority areas?

Australia's biomedical researchers continue to prove their world-class capability by leading efforts to analyse the COVID-19 virus and develop a response, while hundreds of Australia's biotechnology companies play key roles in developing technologies to address unmet medical needs, heal, protect, repair, and improve health outcomes.

The financial return – or its weighting within the broader value-add metrics – may be dependent upon the investment's strategic importance to Australia. For example, should building sovereign capability for future pandemics be a priority, then it may be deemed that the financial return-on-investment may hold less 'weight' relative to other metrics; if an investment has less sovereign responsibility and, rather, is destined to be a commercially global product, then the return may require an increased number.

12. How could the NRF consider Government policy priorities in performing its investment function?

Governments have a responsibility to step in where there's market failure, and the NRF is one initiative to address the 'market failure' in Australia's venture capital that results in many of our companies needing to go overseas for capital, which in turn undermines our biotechnology ecosystem. There are many worthy companies developing great life-saving and life-enhancing technologies that struggle to access capital, and therefore the role of Government is to continue its existing support as well as creating new policy levers that enable the ongoing attractiveness of the sector relative to competing markets, and also to other sectors.

Throughout the design of the Fund and the allocation of funds, as a Federal initiative the NRF should focus on and advance Government's fundamental policy principles, such as Australia's economic development, including fostering competitive advantages, and the health and wellbeing of its jurisdictions.

Returns, financial instruments and working with other investors

13. What factors and considerations should inform the portfolio rate of return for the NRF?

Genuinely patient and risk-tolerant capital – with investments beginning at a minimum of 10 years – is required given the biotechnology industry’s unique and distinctive development period and market pressures/opportunities, as noted earlier in this submission. It is, therefore, pleasing to note that the NRF Board will aim to achieve its benchmark rate of return over the medium to long-term.

The consultation paper also notes that *“The Government’s intention is to set [the Benchmark rate of return] at a level that provides the NRF Board with the flexibility to appropriately manage risks and returns across the NRF portfolio, while also delivering on the NRF’s purpose.”*

A benchmark return rate would be logical, however, the rate should be considered sector by sector (thereby introducing a segmentation within the portfolio’s required rate of return) due to their unique market forces and their unique social and economic returns/offerings.

14. What factors and considerations should inform the setting of acceptable but not excessive level of risk? Should the acceptable level of risk differ between priority areas?

Similarly to the portfolio rate of return, the risk profile should also be considered sector by sector, rather than applying one standard to all priority areas.

By applying the same risk level to seven very different markets/priorities, then the NRF risks inadvertently overlooking an investment project, when a pure-play analysis would otherwise deem its risk level acceptable for investment within its own market segment. In contrast, should the risk level be targeted to its sector, it would offer the NRF portfolio diversity and therefore decreases the variance of the returns.

Biotherapeutics is known to be a high reward investment with a different risk profile from other sectors. Gaining regulatory approval for therapeutics has a cumulative probability of success of approximately 21 percent¹, which would be different than the development risk of other priority sectors’ outlined in the NRF’s scope. Therefore, a segmented approach to risk and the investment decisions between priority areas would be fitting in order to achieve the desired NRF outcomes.

Given the biotech industry’s unique social and economic outcomes and impact delivered, industry is also keen to understand how ‘purpose’ will factor into the risk profile of the investment mandate/how will these broader returns/benefits to Australian communities be weighted. For example, if companies stay on Australian soil to manufacture products, will it reduce the NRF’s equity stake or lower the return required?

15. What types of concessional offerings would be preferred if these were offered (for example, lower interest rates) and why?

The biotechnology industry is distinctive by virtue of the way it uses the latest advances in biomedical science in markets around the world.

While Australia enjoys a high international reputation for the quality of its research and clinical trials capability, its biotechnology industry is ‘coming of age’ with visibility on the global stage, having consistently ranked in the top countries globally for biotechnology innovation, when

¹ [Guide for Life Science Company Directors](#) (2013)

adjusted for population. However, there is undoubtedly intense competition for jobs and investment from other jurisdictions such as the US, UK, Singapore and China.

Should concessional offerings be offered, it is important that they are relevant to the type of investment class or loan, and – critically – they must be globally competitive. As noted above, biotechnology works within a global market and therefore has access to low-value loans in numerous countries.

16. What factors drive or constrain co-investment (for example, by industry, financial sector or domestic or offshore investors) and how should these be taken into account?

As demonstrated through the Victorian Government’s Science, Technology and Innovation Initiative (2000-2008), co-investment into the biotechnology ecosystem delivers substantial economic impact and jobs. From \$470 million of funded projects, the Initiative was estimated to increase gross state product by an additional \$1.1-1.7 billion, create an additional 1,400 FTEs, and generate cumulative real investment of an additional \$1.045 - \$1.232 billion over the period of 2000-2014². These impacts/factors are expected to continue delivering into the future thereby driving the social and economic returns to Australians.

The valuation methods for life sciences companies, and their assets, are quite different to other sectors. Life sciences’ assets are usually non-tangible; valuation of these assets is an important and highly specialised area, often requiring independent expert advice. Commercialisation potential can be difficult to apply a valuation to at its early stages.

There is a risk to the integrity of the NRF that inappropriate methods of valuations are used and therefore inappropriate valuations created, that will then constrain the co-investments for the company(ies)/impact the returns delivered to the NRF. It is recommended that once the initial assessment is undertaken via market comparable valuations, a specialist be engaged to conduct a more in-depth analysis.

17. What are the mechanisms and types of finance which will best attract co-investment from the private sector? How can the NRF best crowd-in investment?

To enable crowding-in of investment into Australian life sciences, industry encourages the Government to consider designing the National Reconstruction Fund into a ‘fund of funds’ where greater private and public investment into the sector can be pulled into/added, for example, superannuation funds. This could create a mechanism to both attract and build (diversify) investments, as well as to overcome key skills gaps that the sector is currently facing.

From an economic perspective, a ‘fund of funds’ could attract new investors and build investments from existing investors, and with its crowd-in potential, offer a further opportunity to keep home-grown assets (companies) – and the value they create – on shore, longer.

Despite the interest from superannuation funds, Australia is currently lacking the mechanism required for them to invest into life sciences companies. A ‘fund of funds’ could open this door. It would offer the ability to draw investors together to create a large investment pool of funds to disperse (which in turn offers large tranches with the investment flexibility that smaller funds do not have the benefit of); generate the scale of investment required by industry; and access to experienced investment assessors that is currently lacking in the biotechnology sector.

Delivering a mechanism for superannuation funds to become funders of biotechnology companies would crowd-in investment to create a fund of sufficient size to enable companies to

² Australian Council of Learned Academies (2020) *Stimulating the Science and Research Ecosystem Creates Jobs and Investment*. acola.org

access the funds required for phase-III-ready assets, and to redefine success to partner or sell later rather than currently after phase II.

From a skills and capability perspective, Australia has a gap in the number of biotech-literate fund managers; creating a pool of fund managers with the appropriate skills and capabilities would therefore increase new options and confidence for life sciences investment.

Due to the sector's unique characteristics, investors without experience in biotechnology investment tend to shy away from the sector due to the nature of its different risk profile and complex 'product'/science.

Those investors without previous experience in investing in biotechnology shy away due to the nature of the sector's different risk profile, no track record of personal success in the sector, and the complexity of its 'product'/science. Creating a pool of investors would mitigate these barriers by simultaneously creating a programme through which to up-skill teams without existing skills and capabilities (thereby diversifying the talent operating in this space), and overcome the risk of being isolated in an investment without co-investors. The need for upskilling was identified in the *Biotechnology Blueprint* as one of the key objectives needed in order to grow the Australian pool of funders.

The NRF also has an opportunity to work hand-in-glove with State-based investments, where mutual priorities are present - such as the Victorian State Government-funded \$2 billion Breakthrough Victoria and \$20 million Equity Investment Attraction Fund that provides funding in return for an equity stake; the NSW Government's \$703 million Future Economy Fund; Queensland Government's \$350 million Industry Partnership Program; and Western Australia's \$100 million Investment Attraction and New Industries Fund. These funds are supporting end-to-end ecosystem development.

Complementary reforms

18. What are the non-financial barriers preventing businesses from making the most of opportunities for value-add, growth and diversification in the priority areas?

Understanding of the unique characteristics of 'medical science', or biotech literacy, is a barrier for policy makers and investors, and ultimately to the development of new and novel technologies.

The life sciences sector is at the cutting edge of new and complex technologies, however, the unique characteristics of industry are often not considered when new ideas and approaches are brought to the 'policy table', potentially locking out key pathways of future success.

A simple example seen many times is a government programme or initiative seeking to support start-ups or SMEs, and requiring a company to be revenue-generating; whilst this would work for many sectors, it immediately and regrettably precludes the biotech sector, as a medical technology company typically takes around seven years to be in this stage of development, and biotherapeutics approximately 15-20 years.

This education barrier is key and can be overcome in a number of ways.

For the NRF, it is recommended that NRF Board representation includes expertise specific to medical sciences. This could be through a high-level appointment, or through a dedicated advisory group, thereby maximising the contribution of industry knowledge and skills.

As Australia's only national peak industry body for biotechnology companies, AusBiotech would be pleased to draw on its membership and provide industry contribution to support Government efforts in its decision-making processes and to improve biotech literacy.

In addition, to foster the growth and development of the next generation of policy champions and leaders within government decision making and policy roles that are relevant to the Australian biotechnology sector, it is recommended that an education and information programme is developed to support Parliamentarians and government employees.

The establishment of an Australian biotechnology workforce programme would nurture emerging leaders across the industry for the future and would stand ready to assist and work effectively with the Australian Government to deliver for Australian biotech while aiming to lift the biotechnology 'literacy' levels amongst policymakers and decision makers.

19. Are there non-financial mechanisms that could support priority areas and the objectives of the NRF?

The life sciences sector is at the cutting edge of new and complex technologies, however, the role of the industry is often not considered when new and innovative ideas and approaches are brought to the 'policy table', potentially locking out key pathways of future success. While Australian academic institutes are widely celebrated and consulted by government, the Australian biotechnology industry is under-represented as part of the policy and decision-making process. For the NRF to be successful, it requires broad experience and expertise represented at the highest levels.

It is recommended that together with the detailed guidance proposed, including via a statement of expectations, representation through expertise specific to medical sciences is present on the NRF Board. This could be addressed through a high-level appointment, or through a dedicated advisory group, thereby maximising the contribution of industry knowledge and skills.

With over 2,654 organisations employing over 260,000 people across a broad and diverse sector that is working across the biotechnology pipeline, having appropriate representation with a rich and invaluable practical understanding, and a lived appreciation for the realities facing Australia's biotechnology ecosystem is crucial to cultivating and nurturing talent and companies into the future, and to accelerating the scaling and growth of Australian biotechnology companies by expanding access to funding.

As Australia's only national peak industry body for biotechnology companies, AusBiotech would be pleased to draw on its membership and provide industry contribution to support Government efforts in its decision-making processes and to improve biotech literacy.

20. How could the NRF work alongside other complementary reforms to best deliver on the Government's policy priorities?

Procurement: Australian innovation and manufacturing are two sides of the same coin, and supporting Australian medical science companies through the expansion of domestic market volume is a beneficial non-financial mechanism worth considering.

Expanded market volume, a necessity in any package of support, must come from a genuine commitment by state and federal governments to source and procure locally made products, materials, and services, creating economies of scale, and helping to deliver a necessary precursor to global competitiveness.

A good example of this in motion is the Moderna agreement that will see onshore manufacturing of life-saving mRNA vaccines. A partnership between Federal Government, State

Government, and industry through a 10-year agreement offers surety of supply, meaning it is easier to get broader investment, and creates local jobs.

Health procurement policy needs to be harmonised, and reframed so that research value is seen in both clinical (health and social), and economic and commercial outcomes. For example, rather than procurement prioritising only the lowest dollar-per-product figure, it should also consider how manufacturing in Australia offers additional value and capability development as it creates high quality, sustainable industries and jobs, as well as improving patient outcomes.

This non-financial mechanism would work hand-in-glove with other initiatives, including the NRF, and support sovereign manufacturing into the future.

End-to-end incentives: In a globally mobile industry such as biotechnology, a strong and supportive policy environment is essential to attracting new investment and intellectual capital and retaining the value that has and can be created by companies and their investment.

Our R&D Tax Incentive (RDTI) supports additional R&D, is world class, and is creating the value and spillover benefits for our sector that were intended. However, to incentivise Australia's revenue-generating biotechnology industry to locate its high-value jobs, manufacturing, exports and economic benefits in Australia, rather than sending the benefits of innovation to more competitive jurisdictions, industry has been advocating for an Australian patent box for many years. This incentive would dovetail with the RDTI, offer sound, long-term structural policy that will benefit the country, complement the NRF, and assist in global competitiveness.

21. To what extent are other levers required to support the objectives of the NRF (for example, skills, trade, supply chains)?

Visas to attract the best and brightest

As a highly-skilled industry, the ability to attract the best and brightest from wherever they may be is imperative to growing and sustaining a successful, vibrant, and world-class biotechnology ecosystem.

The complexity in Australia's visa application processes has tended to discourage talent and expertise from relocating to Australia. This complexity, coupled with a lack of understanding of Australia's visa system, has acted as a barrier to attracting new talent and meeting skills shortages across the sector, creating little opportunity to tap into expertise without having to overcome obstructive red tape.

To remove the challenges around intra-company transfers and recruitment from overseas parent/sister companies, industry seeks to work with the Department of Immigration to enhance the accessibility of the 'Sub-class 188, Business Innovation and Investment (Provisional) visa' by introducing a stream to allow greater intra-company-based personnel exchanges for employees of companies with operations in Australia, or partnerships with Australian based companies.

Operationalising this policy lever would not only create an ongoing attractiveness of the biotech sector relative to competing markets and also to other sectors, but it would also support the NRF's explicit purpose of *adding value and developing capability*, and could be tracked through the 'value add' metrics outlined in the consultation questions above, as increasing the number of high-quality medium and large companies will attract talented and skilled people to the local industry by providing career paths and opportunities, as well as on-the-job-training in management and industry-specific skills.

Developing and retaining the best and brightest

Building domestic capability in research and development, manufacturing and a skilled workforce not only addresses Australia's sovereign risk, but will also drive innovation and increase Australia's global competitiveness in the biotechnology.

To increase the level of Australian self-reliance, including the development and retention of a skilled and experienced workforce, industry recommends that the Government consider an appropriate support model for Australian start-up or scale-up companies looking to disrupt supply chains, establish new capabilities and/or services to those undertaking manufacturing, research and/or development. This would include creating a "pull forward" of new growth areas, establishing kick-off investment funding and support for training and skills development, and/or with incentives to build and retain companies in Australia with IP held locally.

There is an opportunity for Australia to be a regional hub in the Asia Pacific region known for leading research, clinical trials, translational know-how and manufacturing capabilities. However, unlocking these opportunities requires a significant uplift in our capabilities. To make a difference, particularly in cell and gene technologies, ongoing and increased government investment in domestic manufacturing capability through additional post-graduate training for the current workforce and undergraduate training for future workforce is required. To build a job-ready workforce, current university degrees need to include industry knowledge, or a suite of courses be introduced, including regulatory affairs, good manufacturing practice (GMP), and quality control.

22. How does the NRF, with other private and Government settings, drive the right ecosystems for sustainable industry growth?

The biotechnology and life sciences sectors have enjoyed bipartisan, solid support from governments over many years, including Federal and State governments. Industry continues to welcome and appreciate this support and it is considered that such ongoing support will be critical to the successful implementation of the Blueprint.

As the voice of Australia's biotechnology industry, AusBiotech has led the development of the *Biotechnology Blueprint* (Blueprint), and it builds upon AusBiotech's existing knowledge from its more than 37 years operating as an industry leader, and comprises of the contribution of almost 350 individuals and organisations, all working to realise the potential of biotechnology in our society.

Delivering the Blueprint's shared vision for the Australian biotechnology ecosystem will deliver benefits and returns to all Australians. Achieving that vision will require a partnership between governments and industry to create greater investment and funding opportunities, local infrastructure, translatable public sector science, workforce development, and the urgent sovereign capability Australia needs.

To this end, the Blueprint makes a series of strategic recommendations, some to government, others to the Australian biotechnology sector, which work simultaneously towards achieving that vision.

Read the *Biotechnology Blueprint* here: www.ausbiotech.org/policy-advocacy/biotech-blueprint