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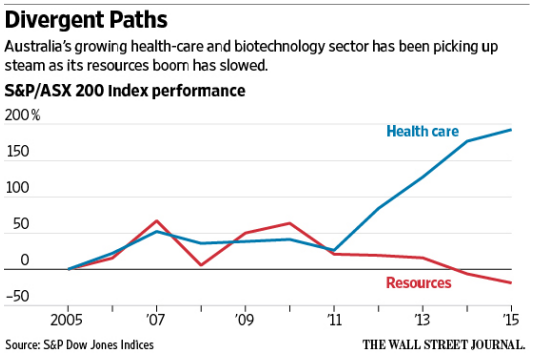
On behalf of the members of the BioMelbourne Network, I am writing in support of the impact the R&D Tax Initiative has on fostering and strengthening the health innovation ecosystem in Australia. This highly successful policy programme has helped many Australian biotechnology and medical technology businesses to undertake additional R&D activities and to successfully create innovative health care products for the global export market.

The BioMelbourne Network membership is representative of the diversity of companies undertaking R&D in Australia's health innovation ecosystem, including pharmaceuticals, biotechnology, medical devices and diagnostics, digital health, engineering and advanced manufacturing. Our members include both private and publicly listed companies prominent within the local and global healthcare sectors. The ultimate commercial success of these businesses will typically be built upon a strong foundation of research and development.

In order to add value to the current review of the R&D Tax Incentive, the BioMelbourne Network surveyed business members to gain additional evidence and commentary to support and inform the work of the Review Panel. The findings of the "BioMelbourne Network Member Survey 2016: The role of the R&D Tax Incentive in the health innovation ecosystem" are attached here and we would be happy to provide further information and discuss our findings with the panel.

Australia's biotechnology sector is internationally positioned for growth

Australia was ranked 4th in the world for biotechnology innovation in 2015, as measured by the Scientific American Worldview Scorecard. This is ranking was sustained for the second year in a row, after jumping to 4th position in 2014 from 7th position in 2013. As Australia transitions away from a mining and resources economy, Australia's biotech market is undergoing resurgence (See Figure) with market capitalisation reaching an all-time high due to recent growth. 2015 was a record year for capital raising, according to data collected by Biotech Daily, $1,152.7 million was raised in 2015, more than double the six-year annual average of $511.7 million.



Growth in the biotechnology sector has occurred, in part, due to the support provided by Government programmes such as the R&D Tax Incentive. This momentum provides Australia with an extraordinary opportunity to transform our economy, and it is critical that any changes in the policy landscape do not reduce the ability or disincentive companies to undertake additional R&D activity in Australia.

The BioMelbourne Network has already made contributions to the 2014 Senate Inquiry into Australia's Innovation System and the 2014 Inquiry into Tax and Superannuation Laws Amendment (2014 Measures No. 5) Bill with recommendations directly regarding the R&D Tax Incentive.

However I would like to take the opportunity to re-iterate our top 5 key points:

- R&D Tax Incentive provides significant support that enables businesses to undertake, develop and extend their R&D activities that would not be possible in the absence of the R&D Tax Incentive.
- The result of the R&D Incentive is that Australian companies retain their ownership of intellectual property of significantly greater value and across multiple programs than would have been the case if they did not have access to this programme.
- The R&D tax incentive is a significant factor in maintaining Australia's competitiveness as a preferred location for R&D activities, such as pre-clinical testing and clinical trials. Biotechnology and medical technology are global industries, and Australia must compete to retain the R&D activity of local companies, as well as attracting international R&D activity into Australia.
- The R&D Tax Incentive provides spillover benefits into the health system by providing Australians with access to early stage therapeutics, diagnostics and medical devices during clinical trials.
- In order to incentivise innovation and R&D it is critical to maintain a stable supportive policy environment to provide businesses with a consistent framework in which make strategic decisions around R&D activity.

Recommendation: Maintain a consistent and supportive policy environment that incentivises R&D and innovation by avoiding any unnecessary changes to the R&D Tax Incentive that would be detrimental to the R&D activities of biotechnology and medical technology companies in Australia.

Australia has a huge opportunity to build from our strong foundation of health and medical research and globally competitive R&D capabilities to lead the global transformation of healthcare. Our spirited biotech and medtech entrepreneurs are engaged in R&D, innovation and commercialisation activities that seek to transform Australia's ideas and discoveries into valuable products and services that benefit patients and create better health. Alterations to the R&D tax initiative could create a barrier to achieving this vision for the future of Australia. I will leave you with to reflect on the responses of BioMelbourne Network members to the survey questions, and would be happy to discuss this matter with you further.

With best regards,

Dr Krystal Evans
Chief Executive Officer
BioMelbourne Network

BioMelbourne Network
Progressing BioIndustry

BioMelbourne Network Member Survey 2016
The role of the R&D Tax Incentive in the health innovation ecosystem

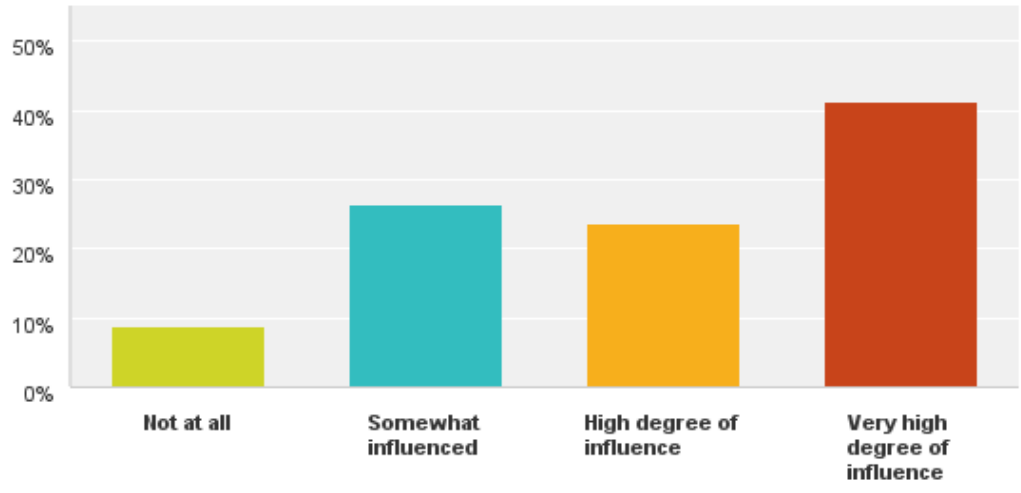
The BioMelbourne Network membership is representative of the diversity of R&D companies in Australia's health innovation ecosystem, including pharmaceuticals, biotechnology, medical devices and diagnostics, digital health, engineering and advanced manufacturing. Our members include both private and publicly listed companies prominent within the local and global healthcare sectors. The ultimate commercial success of these businesses will typically be built upon a strong foundation of research and development. This survey was completed by 35 members, and while this is a small sample size, it provides insight into the impact the R&D Tax Incentive has on the health innovation ecosystem in Australia.

> The R & D tax incentive encourages the conduct of R & D within Australia, creating jobs. Encouraging the conduct of Research and Development within Australia allows further value to be added to IP, which hopefully leads to increased value recognition in the future. All of which contributes to the Australian economy through the tax system via employment taxes and taxes on investment returns.
> - Tony Di Pietro, Chief Financial Officer, Sienna Cancer Diagnostics

The R&D Tax Incentive has a very high degree of influence on businesses R&D activities and decision making

The R&D Tax Incentive plays a significant role in the R&D activities and R&D decision making in our member companies, with 41% of companies rating the program as having a "very high degree of influence" on R&D activities and decision making, and 24% rating the program as having a "high degree of influence".

To what degree does the R&D Tax Incentive influence your R&D activities and decision making?

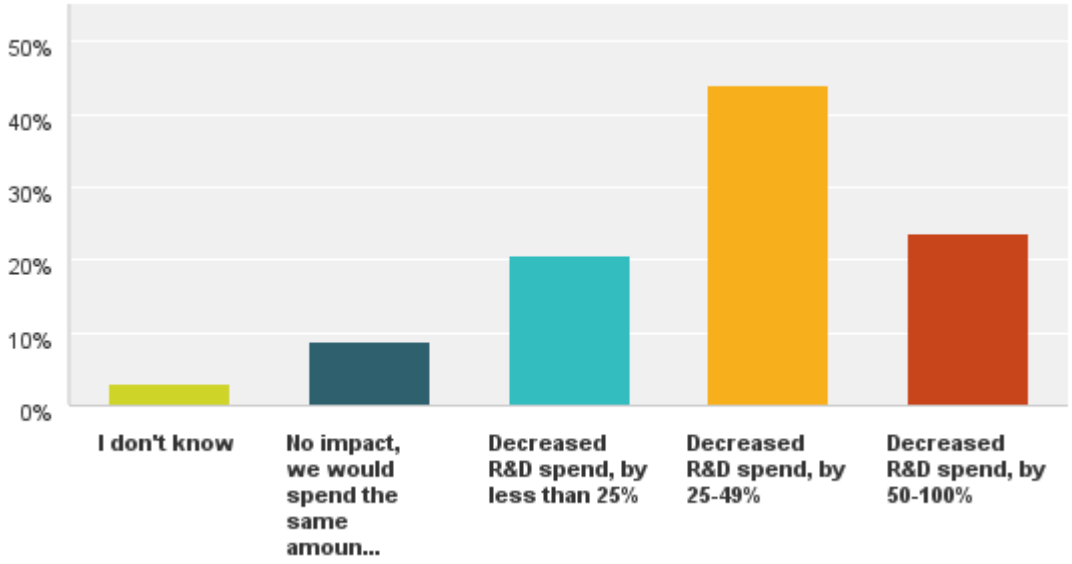


"The R&D tax incentive is pivotal in managing cash flows and deciding which projects can be undertaken, there is also some consideration as to whether activities can be conducted in Australia where possible"
- Kathy Harrison, General Manager Dimerix

The R&D Tax Incentive is critical for retaining high value R&D activity, capability and jobs in Australia

To measure the significance of the R&D tax incentive to R&D expenditure by business, we asked companies to estimate the impact on their R&D activities and employment in the absence of the program.

In the absence of an R&D Tax Incentive, what would be the impact on your R&D spend?



88% of companies said that they would reduce their R&D spend in the absence of an R&D Tax Incentive. 44% of companies indicated their R&D spend would decrease by up to 50% and 24% indicated that the absence of the R&D Tax Incentive would decrease their R&D spend by between 50-100%.

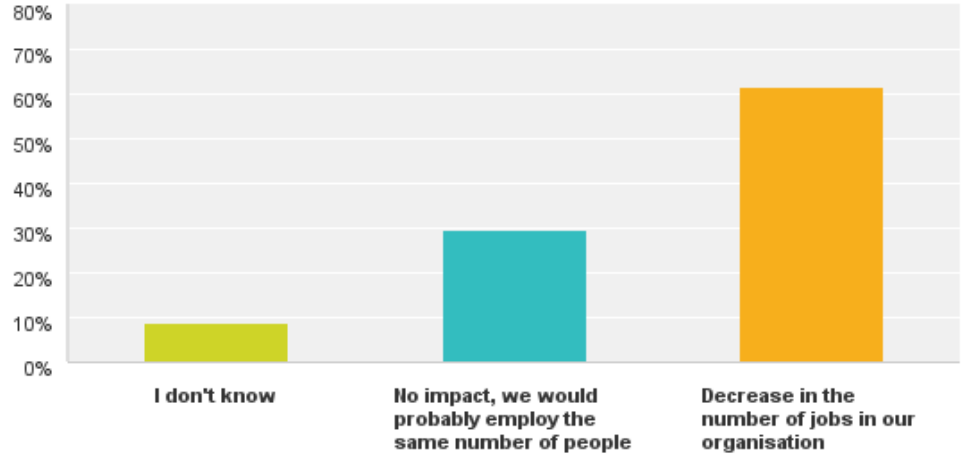
Significantly, several companies indicated that in the absence of an R&D tax incentive they would spend the same amount on R&D, but would no longer conduct their R&D activities Australia.

- We would move more research to Canada with positive government tax incentives for R/D and clinical
- To put it simply, in its absence, it is very likely that our R&D investment would not occur in Australia at all.
- We would look at moving most to the US as we could leverage NIH and other grant funding bodies

"I work with biotech companies in Australia and the US, and the R&D incentive creates an economic driver to perform R&D and clinical trials here in Australia. I estimate that companies that I work with have spent $10M on Australian R&D over the past 5 years - this could easily have been done in the US"
– Biomelbourne Network Member

The impact of this decreased R&D spend would be felt in FTE terms, with 62% of companies indicating that there would be a decrease in the number of people employed in their organisation in the absence of the R&D Tax Incentive. When asked to quantify the jobs lost, companies estimated that they would reduce their headcount by up to 30% in the absence of an R&D tax incentive.

In the absence of an R&D Tax Incentive, what would be the impact on the number of people you employ (FTE)?



Member Comments:

- "We would immediately shed our entire Australian R&D team. At this time that's 6 PhD engineers, but if the credits continue this will be 10-15 research staff by years end"
- "I would estimate around 10% to 20% decrease in employees and we would stop all collaborations which impacts employment at research institutes across Australia"
- "At least $500,000 (a couple of FTEs) would be lost per annum"

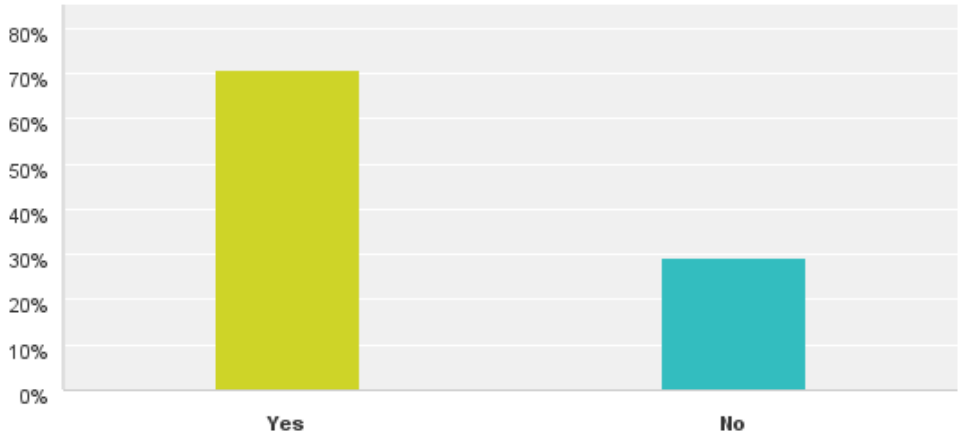
"We have created our new business and attracted investment because the R&D tax incentive gives us a chance to access the right skills and expertise here in Australia, create new IP with potential commercialisation and keep/create jobs here. Without it, our project would simply not have happened" – BioMelbourne Network Member

These survey outcomes illustrate the critical role of the R&D Tax Incentive in supporting R&D activities and employment in R&D intensive businesses in the biotechnology and medical technology sector. The market opportunity for healthcare innovation is global, and the R&D Tax Incentive plays a critical role in securing R&D activities in Australia to capture a greater share of the value of innovation, by building capability and creating high-value jobs for skilled innovators.

The level of R&D collaboration is high in the biotechnology and medical technology sector

Whilst the overall level of collaboration with publically funded research organisations (PFROs) is considered to be low across all Australian businesses, this not the experience of those businesses engaged in the health innovation sector. Collaboration between businesses and publically funded research agencies is high in the biotechnology and medical technology sectors. When considering R&D activities undertaken in FY15 (July 2014 - June 2015), 71% of companies indicated that projects had involved R&D collaboration with universities, medical research institutes and the CSIRO.

Did any of the projects registered under the programme involve collaboration with a publically funded research agency ?

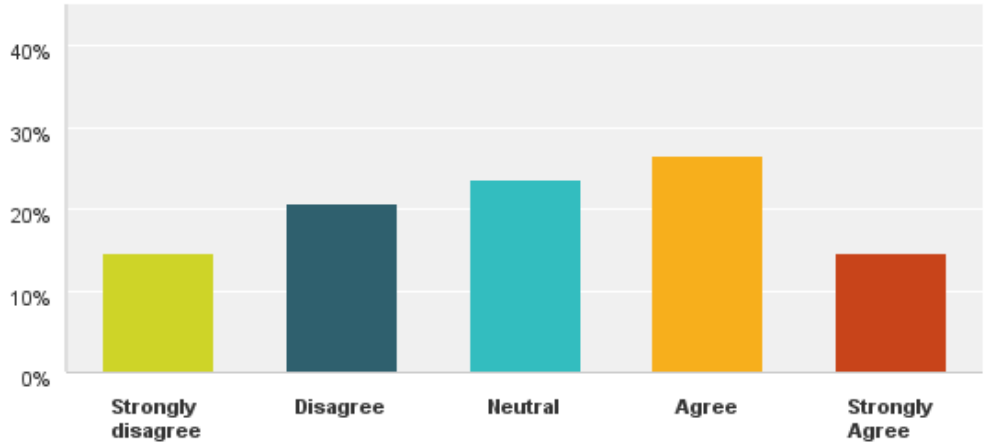


When asked to quantify this activity, 30% of companies indicated that collaborative projects represented up to 50% of their R&D spend. This demonstrates that innovation intense companies in the biotechnology and medical technology sector are actively engaged in significant R&D collaboration with academia.

The R&D Tax Incentive may not be an effective tool to incentivise collaboration with publically funded research organisations

With the majority of companies accessing the R&D Tax Incentive already involved in significant collaboration with research organisations, it suggests that there are already strong incentives in place for businesses to collaborate with publically funded research organisations, where it makes sense for both parties. There was a complex range of responses to the proposed use of the R&D Tax Incentive as an effective mechanism to increase the level of collaboration with PFROs. Many companies indicated that they would require further detail of proposed changes to fully commit to a position. When surveyed, 36% either disagreed or strongly disagreed, 24% remained neutral and 42% either agreed or strongly agreed. This uncertainly would lie with the detail and where the program would be changed.

Do you think that changes to the R&D Tax Incentive would be an effective way to increase the level of collaboration with publically funded research agencies?



Member Comments:

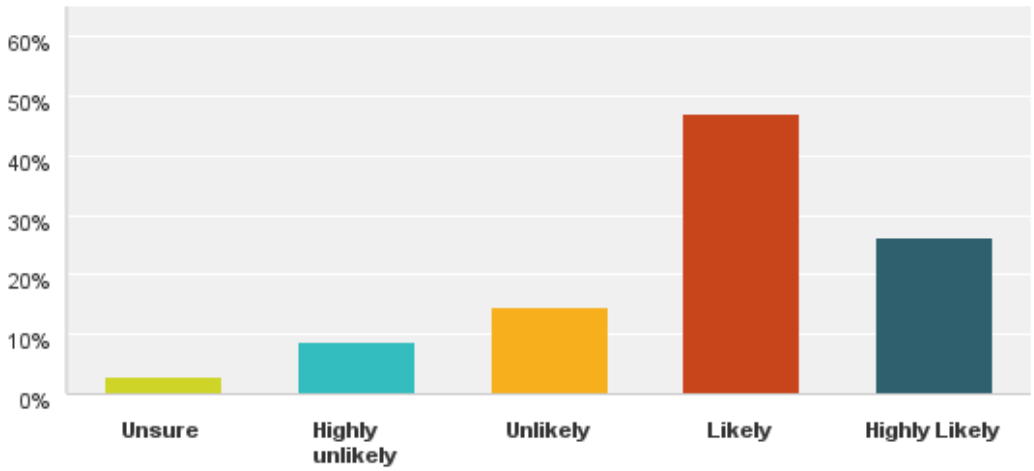
- We would make this decision based on the merits of the collaboration partner
- Agree but wouldn't want to restrict the incentive to such collaborations only
- Depends what the changes were. Strongly agree that cutting the incentive will directly affect funds flowing into public research agencies.

Companies stressed that a major driver for collaboration is the value that partners bring to the relationship, and that business decisions to collaborate on R&D are often based on the merits of the partner, rather than the tax benefits. However, it should be noted that the R&D Tax Incentive does create additional value for collaborations by offsetting costs while reducing the risk hurdle, which deepens the level of collaboration involvement.

"We don't collaborate because the R&D Tax Incentive makes it cheaper, we collaborate because partners could add value. If there's no potential for value, then the R&D Tax Incentive doesn't change things" - Dr Erol Harvey, CEO MiniFab

This is reflected in the view that 73% of companies indicated that they would be likely or highly likely to increase their level of collaboration with PFRO if there was additional incentive in the R&D Tax Incentive for R&D spend with PFROs.

How likely would you be to increase your level of collaboration if there was additional incentive in the R&D Tax Incentive programme for R&D spend with those agencies?



The major barriers to collaboration would not be addressed by changes to the R&D Tax Incentive

When considering whether the R&D Tax Incentive would be an effective tool to increase the level of collaboration between industry and research organisations, we sought to identify the barriers that businesses experience when approaching collaboration.

The top five barriers identified by companies were:

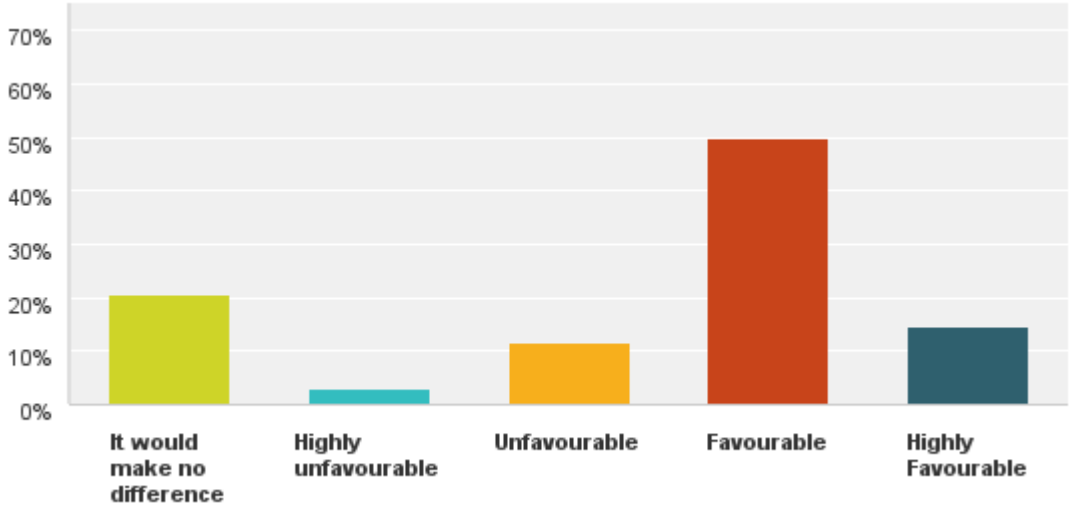
- issues and potential conflicts around intellectual property (55%)
- the cost or value for R&D spend (44%)
- Long timelines and orientation of publically funded research (38%)
- Lack of understanding about expectations of R&D outcomes (38%)
- The administrative burden imposed by research organisations (32%)

It is not clear whether changes to the R&D Tax Incentive would act to overcome these identified barriers, and whether the risk of changes to existing policy settings would outweigh any potential gains, given the high level of collaboration that already exists in the sector.

Quarterly payments would accelerate R&D activity

It has been suggested that pre-registration of programme activities may increase the integrity of the R&D Tax Incentive; however this would increase the administrative "red tape" for businesses. When asked to consider the administration of the R&D Tax Incentive program, 64% of companies viewed the requirement to complete a pre-registration of R&D activities as either favourable or highly favourable if it meant quarterly payments were made available. Quarterly payments assist with cash flow and accelerate the R&D capacity by allowing businesses to re-invest into their R&D programs sooner, increasing agility and ability adapt to the changing global healthcare landscape. Being able to access funds sooner would have a very positive impact for start-ups, high growth potential SMEs and entrepreneurs in the sector, as they cross the "commercialisation chasm".

How would you view the requirement to complete a pre-registration of your R&D activities if it meant quarterly payments were made available?



"I think that quarterly payments would make it very attractive to early stage medtech companies performing research in Australia. Helps immensely with cashflow at early stage of funding"
– Matt Godden Australia Healthcare Solutions

The concerns expressed by businesses who viewed this proposal as unfavourable were centred around increased administrative burden associated with pre-registration. Comments made indicated that some companies felt that the cost of any increased administrative burden would offset the benefit of receiving payments more frequently.

Member Comments:

- Pre-registration would be administratively burdensome
- Only worthwhile if there is a benefit, otherwise it is just another administrative cost burden.
- Business and startup activities should be flexible....we need to pivot quickly. We can pre-register, but don't want to 'administrate' the programs

Conclusions:

The R&D Tax Incentive provides significant support that enables our members to develop and extend their R&D activities and retain R&D capability here in Australia. The consistent and continued Federal Government support in this manner is critical in maintaining and growing high-value innovation jobs and exports of Australian health innovation products and services. The R&D tax incentive is particularly critical for start-ups, spin-outs and SMEs who are in tax loss, as the cash refund has allowed these entrepreneurial enterprises to maintain consistent R&D programs for longer. This results in a broader, more robust R&D pipeline, advanced products for advanced manufacturing and increased employment opportunities for highly skilled STEM professionals. The result of the R&D incentive is that Australian companies retain ownership of intellectual property of significantly greater value and across multiple programs than would have been the case if they did not have access to this initiative.

For the biotechnology and medical technology sectors, the R&D Tax Incentive is performing at a high level of effectiveness and integrity, while achieving the intended policy outcomes of encouraging additional R&D expenditure in Australia. If material changes were made to the R&D Tax Incentive program there is a substantial risk that this would be to the determinant of high-intensity R&D businesses working in the biotechnology and medical technology sector. It is our view that if any revisions are to be considered, businesses in the biotechnology and medical technology sectors should be closely consulted to ensure there are no unintended policy outcomes for this high-performance sector. As Australia transitions toward an innovation-led knowledge economy, it is critical to maintain support for high-growth potential businesses that foster the growth of our health innovation ecosystem.

It is our recommendation that the R&D Tax Incentive be maintained, without material changes.