BioMelbourne Network Submission: Response to proposed changes to the R&D Tax Incentive

The BioMelbourne Network membership is representative of the diversity of R&D intensive companies in Australia's health innovation ecosystem, encompassing pharmaceuticals, biotechnology, medical technology, digital health, engineering and advanced medical manufacturing. Our members include both private and publicly listed companies prominent within the local and global healthcare sector, as well as start-ups and high growth potential SMEs. The ultimate commercial success of these innovation-led businesses will typically be built upon a strong foundation of research and development.

We strongly oppose Recommendation 3 as outlined in the Review of the R&D Tax Incentive Report; to introduce a cap in the order of $2 million on the annual cash refund payable under the R&D Tax Incentive.

To collect data on the impact of the recommendations on the sector we conducted a survey which was completed by 32 senior executives in the BioMelbourne Network membership from biotechnology and medical technology companies, representing the views of industry leaders. The results outline the **highly damaging and long-lasting negative outcomes that the proposed changes to the R&D Tax Incentive will have** on this strategically significant innovation-intensive industry.

Top 10 things that the proposed changes to the R&D Tax incentive will do to Australia's biotechnology, medical technology and pharmaceutical sector:

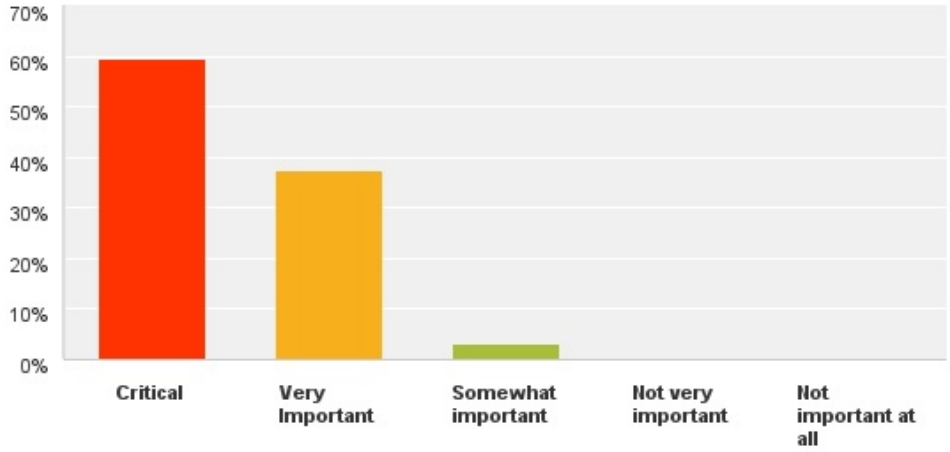
- Impact the majority of companies in the sector
- Reduce the level of R&D activity in Australia
- Result in direct job losses from medical technology and biotechnology companies
- Reduce the jobs out-sourced to the wider Australian innovation ecosystem
- Decrease the level of collaboration with publically funded research organisations
- Narrow R&D development pipelines due to loss of additionality
- Reduce Australia's global competitiveness as a location for R&D activity
- Drive clinical trial activity offshore
- Limit patient access to life-saving and life-enhancing therapies and technologies
- Undermine current sector growth strategies

> 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.
>
> - Chief Financial Officer, BioMelbourne Network Member

1. The R&D Tax Incentive is critical for the R&D activities of biotech and medtech companies.

The R&D Tax Incentive plays a critical role in supporting and extending the R&D activities in member companies. **97% of companies rated the R&D Tax Incentive as critical or very important to R&D activities.**

How important is the R&D Tax Incentive to the R&D activities of your company?



"We would have to down size our operations if the R&D Tax Incentive were to be changed or limited in any way"
– ASX Listed Medtech company

"The company could survive without the Incentive, but activities would be reduced and slowed"
– ASX Listed Biotech company

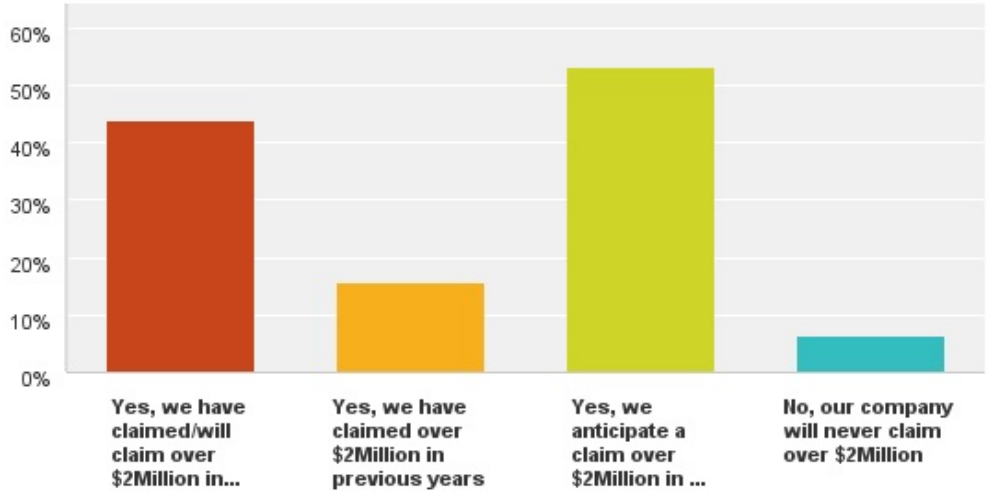
2. The proposed $2Million cap on the refundable R&D Tax Incentive will impact the majority of biotech and medtech companies

The changes to the R&D Tax Incentive will disproportionally impact companies in the innovation-intensive biotechnology, medical technology and pharmaceutical sector.

In a recent editorial (Australian Financial Review on 26 October) the authors of the R&D Tax Incentive Review Paper (Ferris, Finkel and Fraser) claim "It is estimated that fewer than 1 per cent of companies would experience reduced support". This is not the case for the biotechnology, medical technology and pharmaceutical sector where the majority of companies will be impacted by the proposed changes, either directly, or in the forecasted future.

45% of companies surveyed indicated that their R&D Tax Incentive refund claim would be over $2Million in FY16 (July 2015 - June 2016). This is consistent with historical data sets from R&D Tax consultants serving the sector who estimate 30-50% of companies will be effected (data not shown here).

Would the proposed $2Million cap on the refundable R&D Tax Incentive directly impact your business?



"The proposed $2 million cap on the Incentive would directly and negatively impact all corporate activities, including delaying R&D clinical development programs, necessitating additional fundraising activities (further delaying activities), resulting in a less competitive development program globally" – CEO ASX Listed Biotech Company

3. The proposed $2Million cap on the refundable R&D Tax Incentive will decrease the level of R&D activity in Australia

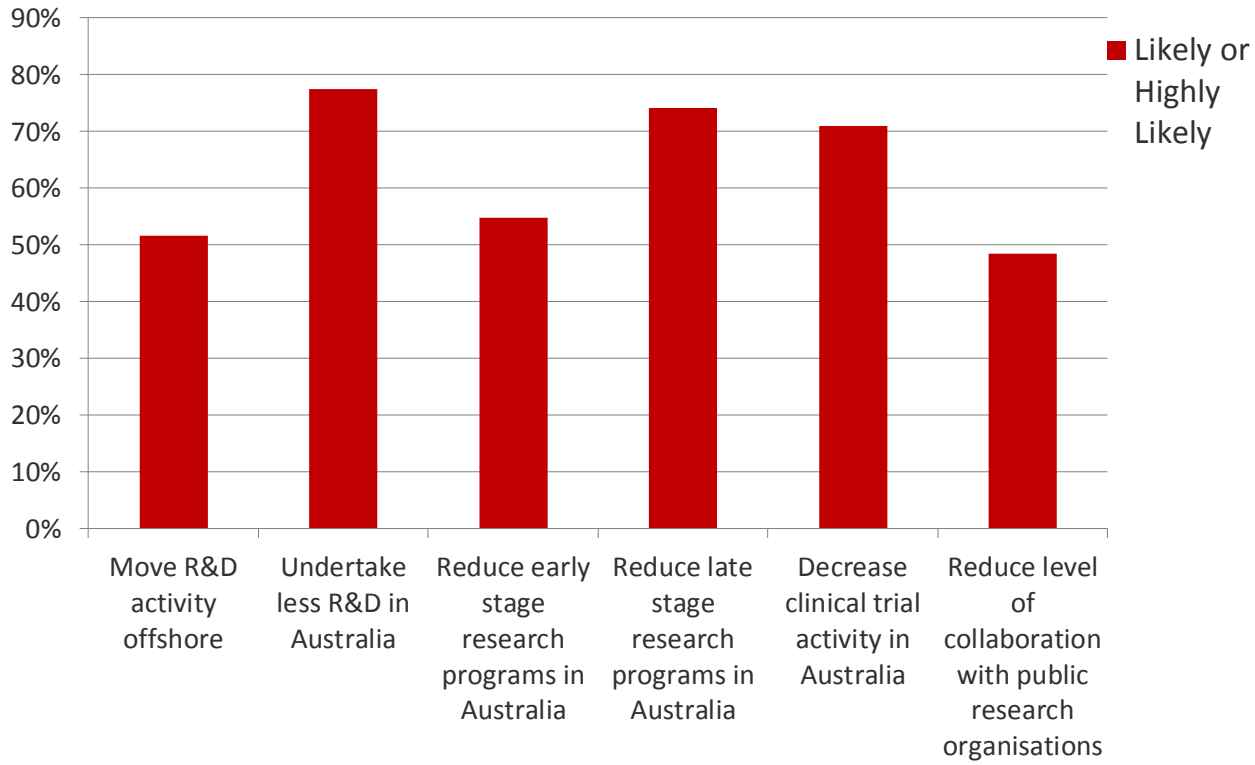
Recommendation 3 of the R&D Tax Incentive Review Paper proposes a $2Million cap on the refundable R&D Tax Incentive. This will damage Australia's innovation ecosystem, erode Australia's competitiveness as a global R&D location and reduce Australia's R&D intensity. The recommendation as outlined will drive jobs, economic growth, clinical trials and R&D activity offshore, away from Australia. The harm to Australia's dynamic, vibrant and growing innovation sector will have flow on effects for the investor landscape, clinical trials, patient access to novel treatments and therapies and reduce support for our most promising start-ups, entrepreneurs and high-potential growth stage companies.

To gauge the economic impact of the proposed $2Million cap, we asked **companies to indicate the impact of the cap on their R&D activities.** Based on likely or highly likely outcomes for companies:

- **77% would undertake less R&D activity in Australia**
- **71% would decrease their clinical trial activity in Australia**
- **55% would reduce early stage research programs in Australia**
- **74% would reduce late stage research programs in Australia**
- **52% would move R&D activity offshore**
- **48% of companies would reduce the level of collaboration with research organisations**

The impact of Recommendation 3 would be an overall loss of R&D Activity in Australia, either due to companies moving that activity overseas or being simply unable to progress their R&D pipeline.

If the proposed $2Million cap on the refundable R&D Tax Incentive was introduced, how likely would it be for your company to…



"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" – General Manager, ASX Listed Biotech

Our product development plans will be delayed and as such some of the R&D we have in our pipeline will need to be abolished. This will lead to the down sizing of our operations" – CFO, ASX Listed Medtech Company

4. Job losses will result from changes to the refundable R&D Tax Incentive

In contrast to the claim that the recommendations outlined would provide extra incentives for businesses to employ STEM graduates and PhD qualified researchers, our survey indicated that proposed changes would result in direct job losses across the sector.

- **More than one third of companies would incur direct job losses (38% surveyed)**
- **The resulting reduction in the workforce was estimated between 10-25% of employees**
- **Jobs lost would be high-value, high-skilled jobs, including PhD scientists, R&D technical specialists, clinical researchers, medical affairs, analytical chemists and engineers.**

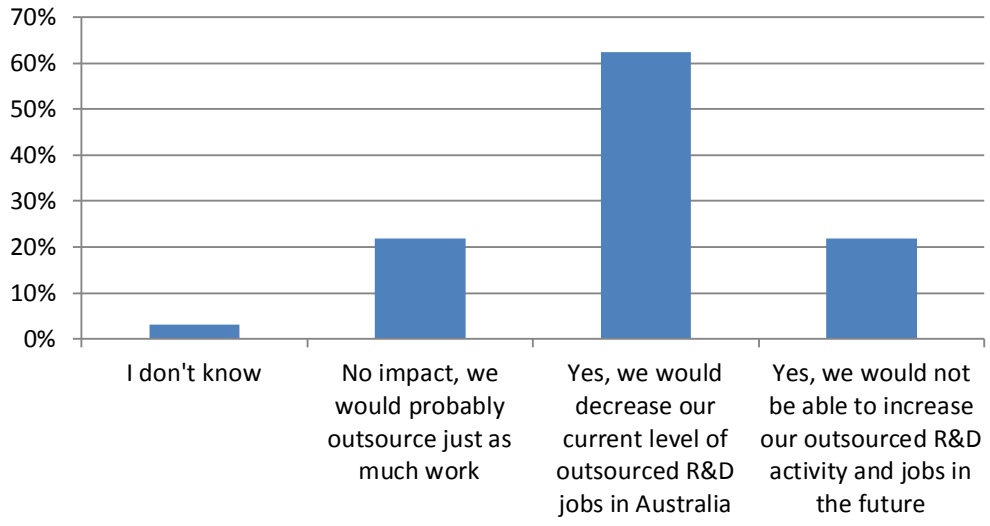
This would result in a significant de-skilling of the sector, with potential movement of highly qualified industry R&D specialists overseas to seek more stable and secure positions outside of Australia.

> "Between 10% to 20% of our work force may be lost. These principally include scientists and lead engineers" – CFO, ASX Listed Medtech Company

Many Australian biotechnology companies operate a lean "virtual" company structure, relying heavily on out-sourcing high skill roles to the wider innovation ecosystem. The high calibre, high quality Australian R&D service providers are an essential component of our innovation ecosystem, providing access to deep domain knowledge and expertise to assist biotech and medtech companies at specific points of their product development and commercialisation lifecycle.

85% of companies said that the $2Million cap would decrease their current or future outsourced R&D jobs to the wider sector.

Would the proposed $2Million cap on the refundable R&D Tax Incentive impact the number of people you engage in services external to your company?



- **63% of companies would decrease their current level of outsourced R&D jobs in Australia**
- **22% of companies would not be able to increase out-sourced R&D jobs in the future.**

The erosion of Australia's innovation ecosystem through direct and indirect job losses from the medical technology and biotechnology sector is a serious threat to the future of the industry.

5. There will be a loss of spillover benefits and additionality due to proposed changes to the R&D Tax Incentive

One third of companies indicated that additional spill-over benefits associated with their current R&D activity that would be lost due to the introduction of the cap on the R&D Tax incentive refund, including:

Impact on clinical trials will reduce patient access to new drugs, devices and therapies:

"For example, if clinical trial projects reduce in Australia due to the $2M capping, early access to possibly life-changing treatments may (will) be interrupted. Clinicians may miss out on advancing their skill-sets. Worse still, patients may miss out on new and possibly life-saving / life-extending treatments....is there a more ultimate price to pay??" - COO, Biotech company

Changes to the investment landscape:

"The R&D tax incentive provides private investors in the biotech space leverage for their investment. Investor appetite will be reduced in the biotech sector if there is a cap." - CEO, ASX-Listed Biotech

"If the proposed $2 million cap on the refundable R&D tax incentive was introduced, we will have to either slow down our development programs (thereby reducing our rate of expenditure) which will inevitably result in losing economics for our investors, and/or relocate some activities to more cost-effective jurisdictions, and/or raise more capital." – Senior Management, Unlisted Public Biotech

"Overseas investors recognise the cost effectiveness of investment in Australian R&D due to R&D Tax incentive - encouraging investment from sources that may otherwise choose to invest elsewhere." – CEO, ASX-Listed Biotech Company

Limiting company growth and reducing additionality:

"It also limits the growth of biotech companies and advancement to the clinic as during this stage companies are spending more than $4M/yr on R&D. Capping the refundable R&D tax at $2M provides no incentive to grow your company - but for expenses to remain at around $4m or less" - CEO, ASX-Listed Biotech

"The cap would limit the amount of money the company would be able to spend on new R&D initiatives and would significantly decrease the amount of money we currently invest in our R&D product portfolio." – COO, ASX-Listed Biotech

Reduced collaboration with publically funded research organisations:

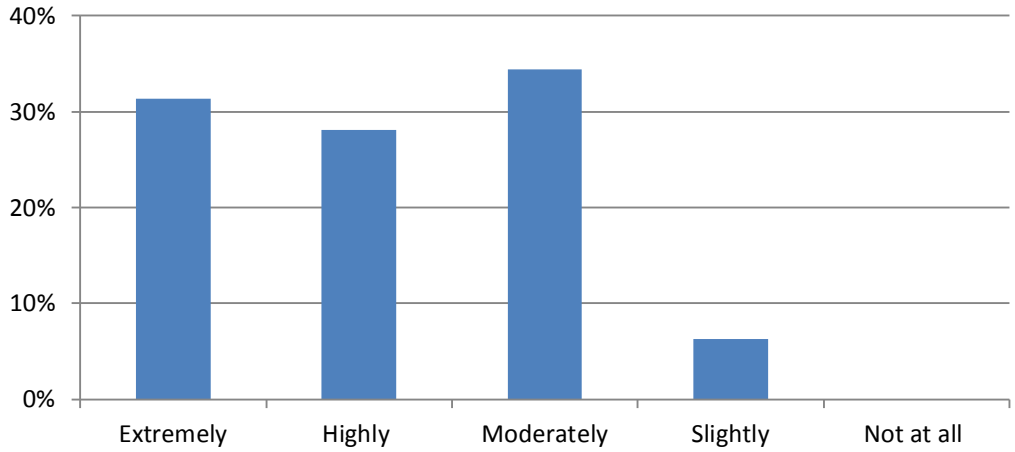
"Reduction of the (R&D Tax Incentive) program would reduce the benefit of the company funding and engaging with Research Organisations and Institutes in Australia to do R&D" – COO, ASX Listed Biotech

Impede Australia's transition to an innovation-led knowledge economy:

"Technology and Innovation is going to drive the Australian economy forward in the near-to-medium term now, with the downturn in the mining-resources sector. The Government has verbally stated that Technology and Innovation is key for our future. 'Talk' is one thing - we now need to see the 'Walk'. We have the expertise, we have the infrastructure, we now need the support to make this a reality, else R&D will go off-shore / remain offshore and Australia will be left behind in global economic terms. Not only would this be a missed opportunity, it would be an absolute shame and worse still, a disaster from an economic perspective" –COO, Biotech company

6. Quarterly payments of the refundable R&D Tax Incentive would be beneficial to businesses

How beneficial would it be to your business to have quarterly payment of the R&D Tax Incentive, rather than annual?



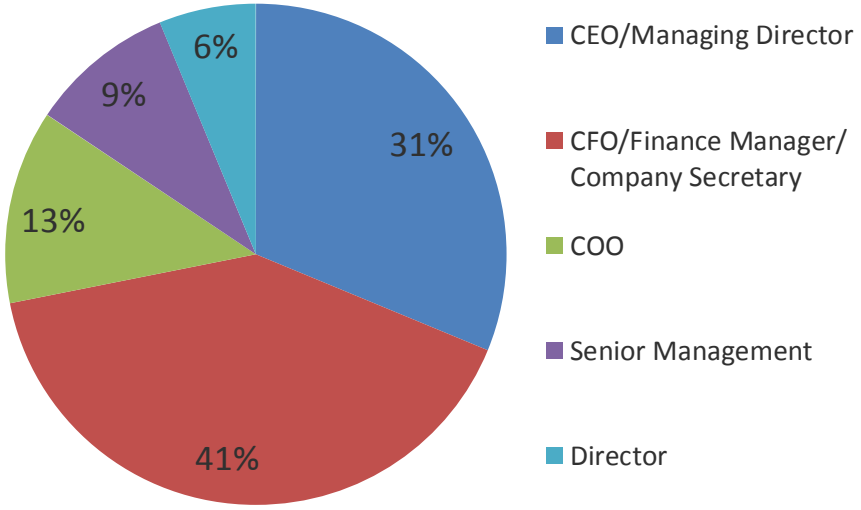
Quarterly payments would assist companies with cash flow and accelerate their R&D capacity through re-investment of funds into their R&D programs sooner, increasing agility and ability to adapt to the changing global healthcare landscape. Being able to access funds sooner would have a very positive impact for R&D intensive companies, particularly those in pre-revenue development stages.

"Quarterly payments would assist the company meet its financial commitments and not have to borrow money against our expected annual refund"
- COO, ASX-Listed Biotech

"During the start up phase quarterly payments would be critical as cash flow is of high importance. This however needs to be balanced with limited burden of paperwork"
– CEO, ASX Listed Biotech

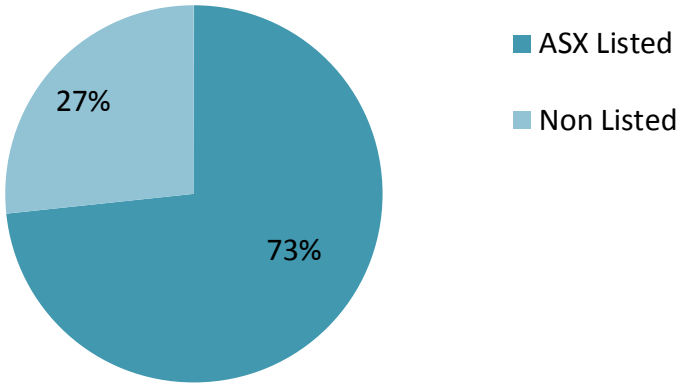
Profile of Survey Respondents (n=32)

Survey respondents were C-suite level executives, directors and senior management



73% of companies represented in the survey are ASX-Listed biotech and medtech companies.

Non-listed companies include public, private, start-ups and R&D services.



In summary:

The BioMelbourne Network is strongly opposed to a $2Million cap on the annual cash refund payable under the R&D Tax Incentive due to the damage it will cause to Australia's health innovation ecosystem. The ramifications of the changes will be far reaching, in terms of job loss, reduced economic growth and the loss of R&D activity, which will create long lasting negative consequences for the biotechnology, medical technology and pharmaceutical sector in Australia.

Considering the broader policy focus of the Turnbull Government's National Science and Innovation Agenda is to drive entrepreneurship and translate good ideas into great businesses, it makes no sense to propose changes that will limit the support for R&D in our most innovative companies.

"Medical Technologies and Pharmaceuticals" have been named as a priority Industry Growth Sector, but we have shown that the proposed changes to the R&D Tax Incentive will work directly against sector growth. The $2Million cap on the refundable Tax Incentive will decrease sector competitiveness and productivity, and erode the prosperity of Australia's medical technology and pharmaceutical industry.

Futhermore, there will be a damaging halo effect on the broader health ecosystem particularly around Australia's strengths in medical research and clinical trials. Australia's reputation as a world leader in developing cutting-edge treatments and technologies that change the lives of patients for the better is at risk. The recommendations as outlined will drive clinical trials and clinical translation research offshore, away from Australia. Recommendation 3 will reduce our ability to maintain Australia's standing as a world class, globally competitive and commercially attractive destination for international companies to relocate in order to perform clinical trials. This loss of global investment in clinical trials in Australia will significantly reduce patient access to emerging therapies and decrease Australia's competitiveness as we strive to remain at the forefront of global healthcare technology development.

We call for a "whole of government" approach to health and medical innovation and industry policy that fully considers the wide reaching impacts of the proposed changes to the R&D Tax Incentive. The results of the BioMelbourne Network member survey presented here reveals the likely negative consequences of implementing a $2Million cap on the refundable R&D Tax Incentive. This compelling data indicates that a more detailed analysis and considered consultation will be required to model the impact of any proposed recommendations on the biotechnology, medical technology and pharmaceutical sector to prevent job losses and a decline in sector growth.

The view of the BioMelbourne Network is that given the Industry Growth Centres are key pillars of the Government's industry and innovation strategy – under the National Innovation and Science Agenda – there should be consideration of the impact of the changes to the R&D Tax Incentive with respect to the priorities and vision for the Industry Growth Centres.

With regard to recommendation 3 we propose that companies engaged in R&D activities that are aligned with the priorities of the "Medical Technologies and Pharmaceuticals" Industry Growth Centre MTPConnect, be either:

(i) Exempt from the $2Million cap on the annual cash refund payable under the R&D Tax Incentive; or

(ii) Able to apply for an extension of the cap to a value up to $5-10Million for eligible R&D activity that aligns with strategic priorities of the Industry Growth Centre

We would be very happy to discuss these issues with the Department and the Minister further, on behalf of the members of the BioMelbourne Network.

The following paper outlines the BioMelbourne Network's position on the recommendations made in the R&D Tax Incentive Review Paper, as submitted through the DIIS online survey portal.

Recommendation 1

Retain the current definition of eligible activities and expenses under the law, but develop new guidance, including plain English summaries, case studies and public rulings, to give greater clarity to the scope of eligible activities and expenses (Section 4.1, p. 30).

BioMelbourne Network Position - **Agree**

Further Comments: That the new guidance and plain English summaries be developed in consultation with industry and technical experts. We suggest that this be conducted in consultation with the Industry Growth Centres, including MTPConnect, as well as peak industry bodies.

Recommendation 2

Introduce a collaboration premium of up to 20 per cent for the non-refundable tax offset to provide additional support for the collaborative element of R&D expenditures undertaken with publicly-funded research organisations. The premium would also apply to the cost of employing new Science, Technology, Engineering and Mathematics (STEM) PhD or equivalent graduates in their first three years of employment. If an R&D intensity threshold is introduced (see Recommendation 4), companies falling below the threshold should still be able to access both elements of the collaboration premium (Section 4.2, p. 35).

BioMelbourne Network Position - **Neither agree or disagree**

Further comments:

While we do not oppose this recommendation, we do not support it. BioMelbourne Network does not regard the R&D Tax Incentive as an effective mechanism to drive collaboration in the biotechnology, medical technology and pharmaceutical sector.

A major driver for collaboration our sector is the value that partners bring to the relationship. Business decisions to collaborate with academic partners on R&D are based predominately on the merits and capabilities of the partner, and financial incentives are often a lesser consideration for decision making. A collaboration bonus may create additional value for companies already engaged in collaborative activities by offsetting costs while reducing the risk hurdle. While this may deepen the level of collaboration involvement between two parties, it may not drive the establishment of new collaborative partnerships.

It is not clear why the collaboration premium is only available for the non-refundable tax offset. This discriminates against companies such as start-ups and high growth potential SMEs who are ideally placed to engage with public research sectors and employ STEM graduates. Choosing to exclude the collaboration premium from the refundable R&D Tax Incentive is an unnecessary distinction to make.

Recommendation 3

Introduce a cap in the order of $2 million on the annual cash refund payable under the R&D Tax Incentive, with remaining offsets to be treated as a non-refundable tax offset carried forward for use against future taxable income (Section 4.3, p. 37).

BioMelbourne Network Position - **Strongly Disagree**

Further comments: We strongly oppose Recommendation 3 and advise the Government not to adopt this recommendation. A cap on the annual cash refund payable under the R&D Tax Incentive will have a serious negative and long lasting impact on the level of R&D activity of biotechnology, medical technology and pharmaceutical companies in Australia. The impact of a cap on the R&D Tax Incentive will be that companies may not undertake additional R&D activity, slow or scale down their R&D programs or may choose to move their R&D activity overseas and reduce their overall R&D spend here in Australia. This will result in job losses and decreased R&D activity in Australia. This will have harmful spillover effects for the wider industry sector affecting advanced medical manufacturing, clinical trials and specialised R&D service providers, such as engineering and design. The overall impact of the cap will be to weaken and impede the growth of the innovation ecosystem here in Australia. The consequences of the proposed changes will put a handbrake on innovation. Less R&D activity in Australia. Less translation of medical research into medical products. Less opportunity to extend and expand the pipeline of discoveries that are being developed into the cures and therapies of the future. **We do not support Recommendation 3.**

Recommendation 4

Introduce an intensity threshold in the order of 1 to 2 per cent for recipients of the non-refundable component of the R&D Tax Incentive, such that only R&D expenditure in excess of the threshold attracts a benefit (Section 4.4, p. 39).

BioMelbourne Network Position – **Disagree**

Further comments:

While we understand the intention of this recommendation, we disagree with the position that that only R&D expenditure in excess of any introduced threshold attracts a benefit. If a company exceeds the intensity threshold, we recommend that the entirety of the R&D expenditure attract a benefit – as it demonstrates that the company is undertaking high-intensity R&D activity. This would encourage companies to strive to meet the threshold level as they would then be eligible to receive the full benefit. It would be harmful if a large company forecast that they may not reach the threshold in a given year, and in response, relocated their R&D activity off-shore to seek benefits in other jurisdictions. This would lead to an overall decrease in R&D activity for companies who may

not reach the threshold. Introduction of the intensity threshold would have to ensure that the threshold doesn't disadvantage those companies who have targeted and sustained R&D efforts in addition to a significant manufacturing and export activity in Australia. This is particularly relevant in for advanced manufacturing in areas of pharmaceuticals and medical technologies.

Recommendation 5

If an R&D intensity threshold is introduced, increase the expenditure threshold to $200 million so that large R&D-intensive companies retain an incentive to increase R&D in Australia (Section 4.4, p. 41).

BioMelbourne Network Position – **Neither agree nor disagree**

Further comments: An increased expenditure threshold may be beneficial to a few companies in the medical technology and pharmaceutical sector, however there is uncertainty as to whether this change will drive the desired policy outcome in terms of increasing additional R&D. Our position is that an increasing the expenditure threshold is not seen as a high priority if it comes at a cost of implementing recommendation 3 and 4 ($2Million cap on the R&D Tax Incentive refund and no benefits for costs below an intensity threshold)

Recommendation 6

That the Government investigate options for improving the administration of the R&D Tax Incentive (e.g. adopting a single application process; developing a single programme database; reviewing the two-agency delivery model; and streamlining compliance review and findings processes) and additional resourcing that may be required to implement such enhancements. To improve transparency, the Government should also publish the names of companies claiming the R&D Tax Incentive and the amounts of R&D expenditure claimed (Sections 5.1-5.5, p. 45).

BioMelbourne Network Position – **Agree**

Further comments: BioMelbourne Network would welcome the improvement of the administration and transparency of the R&D Tax Incentive and support the recommendation that this be investigated. However more detail and consultation would be required regarding the details of a single application process and changes to the two-agency delivery model, to ensure that there were no unintended consequences to the changes in terms of compliance and evaluation.

It was disappointing that quarterly payments were not supported in this recommendation. Quarterly payments would provide a further level of support for high intensity R&D-performing SMEs, addressing cash flow issues for eligible companies without an ongoing cost impact for the programme. We would strongly support a re-examination of the benefits of a quarterly payment process to enable start-ups and SMEs to fully leverage and accelerate the innovation outcomes supported by the R&D Tax Incentive.

This submission has been made in consultation with the members of the BioMelbourne Network and the Board of Directors and is submitted on behalf of our members by:

Dr Krystal Evans
Chief Executive Officer
BioMelbourne Network

Milton House, Level 2, 25 Flinders Lane
Melbourne Australia 3000
tel: 03 9667 8181
mobile: 0435 622 934
email: kjevans@biomelbourne.org
internet: www.biomelbourne.org