23 October 2009

General Manager
Business Tax Division
The Treasury
Langton Crescent
PARKES ACT 2600

Dear Sir/Madam,

Submission on new R&D Tax Incentive

Please find the attached submission from the Medical Research Commercialisation Fund (MRCF) and the Association of Australian Medical Research Institutes (AAMRI) with our feedback on the new research and development tax incentive Consultation Paper of September 2009.

Yours sincerely,

Dr Chris Nave
Principal Executive
MRCF

Managing Director
Brandon Capital Partners

Prof Robert Graham
Chairman
AAMRI

Director
Victor Chang Cardiac Research Institute

MRCF and AAMRI Submission on R&D Tax Incentive Scheme

Introduction

The Medical Research Commercialisation Fund (MRCF) is a dedicated early-stage, proof-of-concept and pre-seed investment fund for medical discoveries emanating from twenty seven of Australia's leading medical research institutes and their related research hospitals. The Association of Australian Medical Research Institutes (AAMRI) represents thirty seven independent, not for profit medical research institutes across Australia.

The MRCF and AAMRI both welcome the Government's initiative to reform the existing R&D Tax Incentive. As stakeholders engaged in R&D and committed to the commercialisation of Australian medical research discoveries, we are broadly supportive of the proposed changes. Although AAMRI members are not-for-profit entities that enjoy tax-exempt status, AAMRI, along with the MRCF, are interested in ensuring that the new reforms create an environment that is supportive of health and medical research and its translation into improved patient treatments. Under some of the provisions outlined in the Treasury Consultation paper, *The New Research And Development Tax Incentive*, September 2009, it is not clear to us that commercial entities engaged in medical / life science R&D will be able to reap the full benefit of the new initiatives. This submission is in response to the September 2009 Consultation Paper and its intention is to provide input regarding several aspects of the proposed new tax incentive, particularly where they impact the medical research/life science R&D sector, and to address relevant questions raised in the Consultation paper.

Principle 1 and Design Question 1

Tax exempt entities:

As outlined in the Consultation paper, the new refundable R&D Tax Credit will be open to companies with up to 50% ownership (increased from 25%) by tax-exempt entities, such as medical research institutes. However, many early stage, high tech, R&D based start-ups may still not be eligible for the R&D tax credit in their formative pre-seed and seed stages even though the ownership threshold for exempt entities has been increased to 50%. In most medical research institute or university start-ups, the exempt entity (institute or university) often owns far greater than 50% of the equity after the first (seed) round of investment. Furthermore, these start ups are not eligible for "public support" through other programs (e.g. from the ARC, NHMRC). We believe that there is a strong case for removing this ownership threshold for start-ups 'spun out' of Australian Medical Research Institutes and other Publicly Funded Research Agencies. This exemption could be conditional on the turnover of the start-up being less than $1 million to make sure it was targeted at very early stage R&D start-ups.

A second point for consideration is that most of the early stage venture funds that currently support the Commercialisation of Australian Intellectual Property by investing in new start-up companies (e.g. MRCF, Trans Tasman Commercialisation Fund, Stone Ridge Ventures and Uniseed) are structured as unit trusts. This structure means that these funds are unable to take a controlling (i.e. greater than 49%) equity stake in any of their start-up investees (as a >50% ownership by a trust in a company causes the trust to be taxed). Given that these funds are generally the first investors in new R&D based start-ups, this proposed limitation could impede early stage, technical innovation in Australia.

Recommendation:

- *That the ownership threshold for exempt entities is either abolished (or raised to say 80%) for R&D start-ups spun out of Australian Medical Research Institutes and other Publicly Funded Research Agencies, with the condition that the applicant has a turnover of less than $1 million.*
- *Alternatively, that this threshold is raised from 50% to 51% to facilitate investments made by early stage commercialisation/venture funds structured as unit trusts.*

Exceptions to the rule that eligible R&D must be carried out in Australia:

Under the existing R&D Tax Concession, pre-approval must be sought to claim up to the maximum of 10% of the costs of R&D conducted overseas in relation to a project. We understand that the R&D Tax Concession seeks to reward activity that is carried out in Australia. However, in the life science industry there are often situations whereby a specialised component of the R&D has to be conducted outside Australia, either because a particular test is not available in Australia or due to regulatory requirements. This is especially true of Phase II and Phase III clinical trials, where the international regulatory bodies (such as the FDA and EMEA) require trials to be conducted in multiple international jurisdictions prior to registration of the new product.

Recommendations:

- *The 10% cap is an automatic level and pre-approval is not required under the new program.*
- *Specific and agreed pre-clinical and clinical activities that can only be conducted overseas should be exempt from the 10% cap on overseas expenditure.*
- *Alternatively, Innovation Australia should be provided with the discretion to approve greater than 10% expenditure on activities overseas on a case by case basis.*
- *Alternatively, these activities might attract a refundable tax credit at a lower rate.*

Principle 3

Timing of R&D Tax refund:

The Paper proposes that start-ups can only access refunds after their tax assessment is completed. This presents start-up companies with a cash flow challenge, indeed they may not have the cash to be able to continue as viable entities long enough so as to claim their refund. If credits / payment could be preapproved quarterly, through an online application process, small start-ups would be able to manage cash flow and expenditure in a more confident manner.

Recommendation:

- *Small start-ups should be able to claim their R&D tax refunds on a quarterly basis, perhaps in conjunction with their BAS statement. This would be in line with the proposals set out in the Venturous Australia report, published in September 2008.*

Principles 5 & 6

Definitions of eligible core R&D activity:

It is important that the assessment of claims is made on projects as a whole. This would ensure that the project's overall objectives and methodology, particularly in relation to innovation and technical risk, are considered and rated according to the projects overall level of innovation and technical risk. For example, to prepare a new drug for testing in humans requires the completion of a suite of preclinical tests, at considerable cost to the company. Some of these tests are routine in nature, whilst some are more innovative and carry more risk. Nevertheless, the completion of all of the tests is necessary to progress the drug and therefore, when viewed in its entirety, the full preclinical program entails considerable innovation and technical risk.

The life science industry would appreciate having as much certainty as possible regarding program definitions as soon as possible, so as to effectively manage cash flows and be able to have a high degree of confidence that funds that are being invested in R&D are indeed eligible and in due course receive their R&D tax credit/refund.

Recommendations:

- *Claims that need to meet the requirement of innovation and high levels of technical risk should refer to (i) overall project objectives (outcomes) to assess the innovation associated with the entire project and (ii) methodology (activities) to appreciate the level of technical risk associated with the project.*
- *Confirmation as soon as possible that the current meanings of innovation and high levels of technical risk will remain unchanged.*
- *Alternatively, any revised definitions of terminology should be confirmed as soon as possible to give start ups greater confidence in committing to R&D expenditure.*

Principle 7 and Question 4

Definitions of eligible supporting R&D activity:

The consultation paper does, in Question 4, pose five options to limit the claiming of supporting R&D. All of these options would require the claimant to separately identify core versus supporting R&D which will be an additional (possibly significant) administrative burden for start-ups. If this principal is to be adopted then it must be done in a manner such that it is easy to implement.

In addition, the paper refers to the excluded activities list. The current list of excluded core R&D activities can still be claimed as supporting activities. The paper proposes to retain these exclusions and also entertains extending these exclusions to all R&D activities (i.e. these activities could be neither core nor supporting). If the proposed changes to the definition of core R&D ('innovation and high levels of technical risk') are adopted then we see no need to change the definition of supporting R&D activities.

Recommendations:

- *We believe that separating out core and supporting R&D activities will be an additional and significant burden for companies in claiming the R&D tax incentive and add a great deal of complexity to the process, and therefore we recommend that the distinction not be made where an applicant satisfies limits on turnover (e.g. >$1m annual turnover).*
- *Assuming one of the 5 options will be implemented, option (e), that supporting R&D attracts a lower rate of assistance (e.g. 30%) is the most practical and workable way of limiting the amount claimed as supporting R&D.*
- *There is no need to expand or change the definition of supporting R&D activities (in particular, to include those activities set out in the excluded activities list).*

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