BioMelbourne Network Submission to

The New Research & Development Tax Incentive

1st October 2009

General Manager

Business Tax Division

The Treasury

PARKES ACT

Dear Sir / Madam,

This submission is made on behalf of the membership of the BioMelbourne Network, a not for profit industry association, based in Victoria.

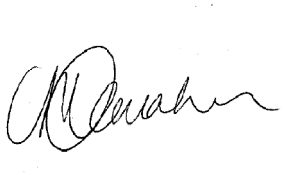
The role of the BioMelbourne Network is to facilitate a well connected network that supports and promotes collaboration and the dissemination of information for the benefit of the 175 member organisations that make up the Network and more broadly, play a leadership role in progressing BioIndustry in Victoria.

This submission was developed following a consultation process, held on the 1st October 2009 in Melbourne , involving 9 representative organisations from within the BioMelbourne Network, kindly facilitated by Ernst & Young (also a member of the BioMelbourne Network). The companies involved in the consultation were:

- Sienna Diagnostics
- Biota
- CNS Bio
- Pharma Bank
- Hospira
- GlaxoSmithKline
- AW Stephen and Associates
- Avexa
- Nucleus Network
- Ernst & Young

Thankyou for the opportunity to make a submission.

Regards,



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Overview

The BioMelbourne Network strongly supports the introduction of the proposed research and development (R&D) tax incentive scheme and applauds the Government for both recognising and then prioritising this important reform.

For some sectors, the R&D tax incentive proposal, released for discussion on the 18th September 2009, will have a fairly dramatic impact, for others less so. The BioMelbourne Network sees the introduction of this scheme as having a vastly positive effect on the majority of the biotechnology industry in Australia which has matured significantly over the past five years.

The Victorian biotechnology sector has more than delivered on expectations. Analysis of basic market indicators of success confirm the sector is gaining in strength. The market capitalization of Victoria's listed biotech companies at 30 June 2009 was $22.5 billion* almost three times that at the same time in 2002, despite the severely depressed economic conditions. The PricewaterhouseCoopers BioForum Index is down only 0.7% compared to a fall of 26% for the All ordinaries for the 2008/09 financial year. R&D expenditure (public and private) within the sector is estimated to be more than $555 million in 2007/08* and will continue to grow as product pipelines advance closer to the market into larger, more sophisticated multinational clinical and field trials, demanding a much larger commitment of funding. For the biotechnology sector – cash will always be king and the great enabler.

The 45% refundable credit for SME's, particularly for biotech's with a group turnover of less than $20m (which is most of the biotechnology sector), is a very positive step. The removal of the annual R&D expenditure cap (set at $2m for 09/10) is considered a major win for biotech. The 40% non-refundable credit for larger groups (equivalent to the 133% R&D Tax Concession) is also positive. Foreign-owned R&D will now qualify in full for the 40% R&D Tax credit, therefore no longer just supporting incremental expenditure, which, to some extent, covers the loss of P3.

Discussion & comments

Each of the principles were discussed by the consultation group of representatives with few raising any serious objection or concern. The majority represent a positive development for the biotechnology industry in Australia.

Eligibility of R&D activity

Recommendation 1: Definitions of terminology are necessary as soon as possible to give biotech's greater confidence in committing to expenditure and potentially is raising funds.

If the legislation is enacted for the commencement of the 2010 /11 financial year and the credit is not paid to SME's for another year – that's a very long time in biotech, particularly small biotech. Therefore we need as much certainty as possible regarding program definitions as soon as possible so biotech companies can work more effectively in managing cash flows and being able to progress with a higher degree of confidence that funds that are being committed are very likely to be refunded in future. Having a high degree of confidence in the definition of innovation and technical risk and what is 'core' and what is 'support' R&D may also give biotech a greater degree of confidence and some leverage in fund raising. The definitions of eligible and ineligible R&D activities for P3 were seen as potentially providing useful guidance in this regard.

Further guidance by offering sanitized AusIndustry reviews would be a useful learning resource.

Recommendation 2: Claims that need to meet the requirement of innovation and high levels of technical risk should refer to (i) project objectives (outcomes) to assess the innovation associated with the project and (ii) methodology (activities) to appreciate the level of technical risk associated with the project.

On the definition of 'innovation and high levels of technical risk', biotech's by nature try to minimize technical risk as much as possible therefore this in itself may be detrimental to the understanding of what might constitute a technical risk for the purposes of the R&D Tax Credit. It is important that the assessment of claims is made on projects as a whole, or at least to ensure in the assessment of claims that the project objectives and methodology, particularly relating to innovation and technical risk, be considered and rated very highly. Breaking up the business of a clinical trial or pre-clinical activity into separate process parts may not be seen as particularly innovative and many pre-clinical activities may not constitute a technical risk in itself. But the project as a whole would certainly be viewed as innovative and of high technical risk.

On the whole, biotechnology as an industry sector is likely to meet the assessment criteria as such a large part of our operational business is considered innovative and of reasonably high levels of uncertainty.

Design question 1 – Exceptions to the general rule that R&D must be conducted in Australia

Recommendation 3: Specific and agreed pre-clinical activities and advanced clinical trial and field trials, undertaken by an Australian owned company, required by a recognized regulatory body (such as the FDA), that can only be conducted overseas should be exempt from the 10% cap on overseas R&D expenditure, and if not eligible in full, should attract some level of agreed refund. Alternatively, Innovation Australia should be provided with the discretion to approve greater than 10% expenditure on R&D activities overseas.

To be eligible for the refund, at least 90% of the R&D activity must be conducted in Australia (with the remaining amount of up to 10% requiring pre-approval to be conducted overseas). This poses a significant disadvantage for the biotechnology sector.

In the pre-clinical stages of development, few activities are able to be undertaken in Australia as certain facilities and expertise is rare and simply not available in this country. For example primate tests – no primate facility exists in Australia. Many chemistry and toxicology studies are not available in Australia therefore a large proportion of pre-clinical work in this area must be carried out overseas. If companies can show that certain pre-clinical R&D activity is unable to be conducted in Australia, and that the only option is for companies to take this work offshore, these activities should be considered for an exemption from the restriction on overseas activities.

Phase III trials are also generally not carried out in Australia, other than maybe 3-5 sites. International regulatory bodies such as the Food and Drug Administration in the United States demand multi-centre trials in a number of different countries around the world. This ensures a reasonable spread of ethnic populations to adequately test new drugs. Phase II and Phase III trials are a major R&D expense for Australian biotech companies, certainly the most significant financial commitment of the development pathway. For example, a number of Victorian companies who have product in Phase III trials this year have been required by international regulatory bodies to establish trials in numerous countries at various sites. Typically only 3-4 sites in Australia were included in the Phase III trial protocol. Therefore under the proposed tax credit system, expenditure relating to only the 3-4 Australian sites would be deemed eligible (probably representing less than 5% of the total R&D costs for the trial) plus a small portion of the overseas related activities if pre-approval from the government was gained.

For some Australian companies, undertaking clinical trials in populations that are not available in Australia is often required. For example, a company may be developing a drug for a relatively localized tropical disease. Some patients may exist in Australia, though not enough for a clinical trial. Other companies may need certain ethnic populations that are not readily available in Australia.

Therefore, as biotech companies and their products mature into advanced trials and are required by regulatory bodies to undertake research and development activities overseas, the degree of support from the R&D tax incentive scheme may be relatively low at a time in which the company will be committed to the highest R&D expenses.

Creating a list of exempt international pre-clinical activities would offer a significant advantage to early start up biotech's which have little available funds and limited ability to attract capital from other sources. Pre-clinical activities are generally very expensive and biotech's need to minimize risk by choosing preclinical partners carefully.

Extending a partial exemption to Phase II and Phase III trials undertaken by Australian-owned companies in overseas trial sites, would demonstrate valuable confidence and support to the more mature sector of the industry and potentially encourage further private investment in these companies.

Recommendation 4: The 10% cap on overseas R&D expenditure as part of the total eligible expenditure amount should be subject to self assessment and not require pre-approval from Innovation Australia.

The group noted the challenge of being able to identify activities that will need to be conducted overseas in sufficient time so as to seek pre-approval.

The group considered that funding of overseas R&D has to be balanced by IP requirements. It was agreed that you cannot have a situation whereby the Australian R&D Tax Credit funds work where the IP is held overseas and the work is also undertaken overseas. There probably needs to be restrictions on these provisions such that:

- if the IP is held overseas, only Australian-based R&D activities may be claimed; or
- if the IP is held in Australia, some overseas R&D activities may be claimed, as discussed above.

Design Question 2 – Expenditure that is currently deductible at 100%

Considered that this expenditure should still be deductible under R&D provisions as it provides a safety net for companies. Some of the expenditure may be not otherwise deductible under general principles.

Design Question 3 – Payments to associated entities

Generally considered that the Australian Tax Office should rely on existing anti-avoidance provisions.

Design Question 4 – Supporting activities

Supporting activities need to be clearly defined. The group suggested that 'core' could be defined and then refer to 'supporting' as a fraction of this, similar to the percentages of salary costs used for 'supporting' activities or overhead costs for grant purposes. Generally, the group considered that the proposals in relation to production related supporting activities do not overly affect the pharma/biotech industry.

Design Question 5 – Excluded activities list

This related to Attachment C of the Consultation Paper – activities listed as considered to be excluded from core R&D. This list, though somewhat unrelated, was not considered a disadvantage to the biotech sector. The group generally considered it was probably best to leave it alone rather than try to redefine it, although the P3 list of ineligible activities was considered quite useful and potentially of use if activities were added to the exclusion list.

Design Question 6 – Software development

The treatment of R&D software was considered to have a low impact on biotechnology as the sector generally considers the use of software to be supportive rather than a core development activity.

Other questions and comments

The concept and definition of 'turnover' for biotech's was considered somewhat 'grey'. One-off licensing fees or an unexpected windfall or an extraordinary payout (as a result of litigation not pursued nor considered revenue) may or may not reasonably be considered turnover. The group also suggested the definition of 'turnover' be aligned with the SME definition, therefore increasing to $50 million instead of $20 million and potentially be indexed on an annual or biannual basis.

The timing of the credit/ payment and notification is very important to the biotech sector, particularly for small companies. For smaller SME's a quarterly reporting / claim schedule would be an advantage. If credits / payment could be preapproved in a quarterly online registration of claims system, biotechs would be able to manage cash flow and investment with a significantly more confident manner, thereby potentially attracting further private investment and being able to move projects more quickly through the various stages of research and development.

Matters not raised in the consultation paper

The consultation group sought clarity on the impact of the R&D tax credit on franking credits and the impact of the application on the claw back rules.