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Dr Steven Kates
Commissioner
Science and Innovation Study
Productivity Commission
PO Box 80
Belconnen ACT 2616
Australia

Dear Dr Kates

Public Support for Science and Innovation

Biota welcomes the draft report issued by the Productivity Commission in November 2006. We feel that it represents overall a balanced and fair review of the impact of public support for science and innovation in Australia.

Key drivers identified by the Commission in justifying public support for R&D are:

1. ***Spillovers***, meaning returns that can not be captured by the innovator; and,
2. ***Additionality***, meaning eliciting private investments that would not have been otherwise made without public support.

A number of Federal initiatives have been important to Biota's journey from a fledgling company to becoming a profitable and sustainable biotechnology business. Biota has benefited from a number of Federal initiatives including R&D Start, ARC Linkage Grants and R&D Tax Concessions. The outcomes from these initiatives reinforce the role of government as a catalyst for science and innovation. The spillovers from Biota's presence in the Australian research community have been considerable with knowledge transfer occurring through R&D collaborations.

Biota has a rich history in collaborating with the Australian research community. The company has a number of long-standing relationships with universities, medical research institutes and the CSIRO. Spillovers from these collaborations occur through Biota staff transferring to the academic collaborator knowledge and skills in the drug development process that can be applied to their own research programs. For example, Biota has collaborations with organisations such as the St Vincent's Institute in Melbourne where Professor Michael Parker is head of Biota's Structural Biology Laboratory. This long standing collaboration has been extremely productive with numerous bidirectional spillovers occurring; these include upskilling of Biota's expertise in structural biology and the transfer of medicinal chemistry and clinical development skills from Biota.

Biota has had collaborations with CSIRO and the Victorian College of Pharmacy, in relation to the discovery of zanamivir, the drug subsequently licensed to GlaxoSmithKline and marketed as Relenza. Both organisations receive substantial income from Biota from these collaborations.

In addition to formal collaborations, Biota also has an extensive informal networks with the Australian academic and biotechnology sectors that result in a two-way spillover of knowledge sharing.

Indirect spillovers that flow from public funding of R&D in Biota are the migration of former Biota staff to senior management positions in other companies. For example, former Biota staff have become CEOs, company directors, chairmen and R&D managers in the biotechnology sector. Biota staff are very active at seminars and conferences in discussing its research programs and best practice for project managing drug development programs.

Biota has also been the industry partner with a number of universities on numerous grants such as GIRD and ARC Linkage Grants. This has resulted in spillovers with Biota transferring project management and drug development skill to the university partner. The university provide expertise and capabilities not resident in Biota. This work would not have been funded absent public support, providing good evidence of *additionality*. If this proof of concept work is successful, Biota would envisage funding additional development using its own working capital.

Biota was the recipient of two R&D Start Grants that enabled progression of two key R&D Programs that required additional investment above that which was possible using the company's working capital at the time.

- $3.2 million was awarded in 1998 to fund development of a lead compound to treat human rhinovirus infections,. At the time the grant was awarded, Biota did not have the capacity to fully fund this program. Without the R&D Start Grant Biota was considering abandoning this program. Biota has now funded in its own right two Phase I clinical trials in human subjects. The spillover of Biota's research has been a recognition and acceptance by the medical community of the importance of rhinoviral infections in patients with chronic respiratory diseases such as chronic obstructive pulmonary disease and asthma. Significantly the R&D Start Grant directly led to the establishment of in-house virology capabilities that were key to the initiation of our to respiratory syncytial virus anti-infectives program, contracting local drug manufacturer IDT for production of drug compounds and upskilling staff and local contract research organisation to run toxicology studies.

- $2.7 million was awarded in 2003 for lead optimisation and early pre-clinical development of compounds to treat respiratory syncytial virus infections. The data package generated under the R&D Start Grant was pivotal to Biota negotiating a US$112m Collaboration and Licensing Agreement with MedImmune, Inc. Again, it would not have been possible to generate the complete data package without this grant. Spillovers from this program have been considerable, including collaborations with the Monash University Centre for Development Candidate Optimisation that have enabled this group to hire and train additional staff that can be used on its other programs. In addition, CSIRO benefits directly from commercial payments under this agreement with MedImmune.

Biota has key partnerships with:

- GlaxoSmithKline: where it has a licence to zanamivir, the first-in-class neuraminidase inhibitor for the treatment and prevention of influenza that it markets as Relenza™. Relenza is used to treat seasonal influenza and is currently being stockpiled by various governments for defence against possible pandemic outbreaks of avian (bird) influenza.
- Boehringer Ingelheim International GmbH: where it has a licence and collaboration agreement to develop and commercialise Biota's novel nucleoside analogues, designed to treat hepatitis C virus (HCV) infections and potentially other diseases.
- MedImmune Inc: where it has a licence and collaboration agreement to develop Biota's lead compounds aimed at RSV (respiratory syncytial virus).
- Inverness Medical: Biota developed the influenza diagnostics FLU OIA® and FLU OIA A/B® influenza diagnostics, currently marketed as part of the BioStar range.
- Sankyo: for the development of second generation influenza antivirals (called LANI or long-acting inhaled neuraminidase inhibitors).

Biota has a solid product pipeline, with product royalty revenues positioning the company to become a profitable and sustainable business. Our group expenditure over the last few years has increased substantially as illustrated in the table below.

	$m
2006	26.3
2005	20.1
2004	16.2

The next growth phase of Biota will be capital intensive with the Company initiating new R&D programs, progressing certain programs further down the clinical path before partnering and acquiring or licensing new programs to expand its pipeline. Our R&D expenditure in 2007 could be in excess of $40 million.

An important consideration for our future growth will be government policy that recognises and supports innovation. Such policy will in part affect the timing, quantum and where this expenditure occurs. This expenditure will include advancement of our capital intensive clinical programs and commencement of new discovery programs. Given the high risk nature of drug development programs, in general, Australian companies do not have the capability (in particular, financial) to bring a drug to market without partnering with global pharmaceutical companies. The Government has an obligation that its prevailing policies initiatives in place support or do not impede this commercial objective.

Recommendations

1. Taxation Issues

(a) Consistency in access to the R&D tax benefit

It is important to provide certainty of benefit to companies investing in innovation. In particular, there should be uniformity in the treatment of claimants. In terms of promoting uniformity of treatment, we believe the tax offset incentive should be accessible to a wider range of companies, not just those companies deemed to be in 'start up' mode (e.g. companies with less than a $5 million turnover and less than $1 million in R&D expenditure).

Allowing a broader range of companies to access the tax offset would remove the disparity caused whereby some large investors in cutting edge R&D are unable to gain any timely benefit from the R&D provisions. At present, small loss making companies (eligible for the tax offset) and large profitable companies (via the R&D tax concession) are able to access real time tangible benefits from the R&D provision. In contrast, there are a group of companies such as Biota engaged in leading edge research and development, that are loss making and do not qualify for the tax offset due to the level of expenditure incurred in research and development being greater than $1 million). While such companies are able to claim the R&D tax concession and increase its losses, they are of relatively little value to the company, as it is often many years before such losses become available though the company becoming profitable..

By way of example, Biota could spend in excess of $40 million this financial year on leading edge research and development. In applying for the R&D Tax Concession, it incurs administrative time and expenses to capture the required data and lodge the necessary paperwork. The 'benefit' Biota gets out of the R&D tax concession is questionable as it is not profitable, therefore any R&D benefit is capitalised into a pool of tax losses that may take many years to realise..

This disparity in tax treatment has the potential to disadvantage those pre-profit organisations who are building critical mass in their research and development operations, the very type of enterprise the concession is targeted at.

(b) Same Business Test

There is merit in creating globally competitive companies in Australia. Consolidation of businesses is an accepted mechanism for companies to achieve critical mass and establish a competitive position. This is particularly relevant in the pharmaceutical/biotechnology industries.

When consolidation occurs, as the same business test is principally met, the tax losses of both the acquirer and acquired should be available to the combined entity. Losing the ability of the acquirer and acquired businesses to maintain tax losses serves to decrease the value of the business being acquired.

(c) Recognition of Licensing as an integral part of the drug development program

The current R&D rules seek to encourage expenditure on R&D activities within Australia, in an effort to enhance Australia in developing intellectual property and a commercial advantage within the global economy.

The commercial reality of drug development is that companies generally licence potential drugs (often in collaborative arrangements and often with overseas companies) to fund the expensive later stages of drug development.

There is a real opportunity to ensure that Australian companies are able to actively participate in such programs if the application of some specific provisions of the R&D concession were revised. Currently, if a company provides assistance with funding research associated with the development of any R&D undertaken by the research company, then this amount is ineligible as an R&D expense due to the 'guaranteed return' provisions. These provisions appear to be in place to ensure that no two companies claim for the same costs. However, in such circumstances, there is the potential for no one to claim the costs associated with the research, due to certain entities (i.e. where the funding company is a part of a trust or an overseas entity, etc). In such circumstances, in order to fund continual research, a research company can either accept funding (often at the expense of the ability to claim the R&D tax concession) or allow an investor company to take an equity position (with the potential of relinquishing control of the research). In terms of outcome, neither is a desirable position for the research company.

To overcome this potential influence on the behaviour of research and development companies, it is proposed an amendment to the R&D provisions could be considered in circumstances where an overseas entity contributes to the ongoing funding of research and development (and is provided with access to such research via a licensing argument) and all intellectual property continues to reside with the Australian company, the Australian company should be able to claim all eligible costs. Such an amendment would provide equity of access to the R&D concession to companies requiring funding for research and would serve to influence the behaviour of such companies by providing an alternative to relinquishing control of their research via foreign equity positions.

(c) Consistent rules for both the 25% and 75% concession

While eligibility to the 75% premium deduction is often viewed by the government as a significant incentive for businesses to continually increase its investment in innovation, the rules are so complex that, in some instances, group entities significantly increase R&D spend above the prior 3 year average, but do not have access to the 75% premium deduction (e.g. due to grouping provisions).

To provide certainty as to the level of concession available to companies, we propose amendments to the legislation to ensure a more consistent application across companies. Potential suggestions that would provide certainty of access to the concession (whilst influencing a company's R&D decision making) include:

- A standard 50% concession for all eligible R&D expenditure; or
- A static base level of expenditure could be set for each company (applicable for each year), with additional expenditure above a predetermined level eligible for the 75% premium. This would overcome the complexities associated with the use of the 3 year rolling average.

2. Procurement Issues

To successfully compete in the global marketplace it is important that local companies have a strong local base with strong local markets. This de-risks overseas expansion significantly. In framing conclusions, the Productivity Commission should recognise the current difficulty of Australian companies in getting therapeutic products listed on the Pharmaceutical Benefits Scheme at prices that recognise the R&D expense associated in bringing the product to market. Unfortunately, the current arrangement force Australian companies to enter high risk overseas markets in their initial launch phase to recover R&D costs.

It is imperative that Federal Health Department develops strategy in its procurement policy with Pharmaceutical Benefits Scheme that recognises Australian businesses developing therapeutic products in Australia.

Conclusion

We thank you for the opportunity to submit our suggestions. Should you have any queries, please do not hesitate to contact us. We would also be pleased to meet you to discuss our proposal.

Yours sincerely

Dr Leigh B Farrell
Vice President Business Development