3 October 2006

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

Dear Dr Kates

Re: Productivity Commission: Science and Innovation Study

It was good to speak to you today regarding a submission by Biota to the abovementioned study. Biota welcomes the opportunity to contribute to this important review.

Background

Biota is a leading antiviral drug development company based in Melbourne, Australia. Biota was established in 1985.

Biota's development program has produced a number of innovative products which have been commercialised and marketed by licensees or partners.

These products include:

- Zanamivir; the first in-class neuraminidase inhibitor for the treatment and prophylaxis of influenza, initially launched in 1999 and marketed as Relenza™ by GlaxoSmithKline. 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.

- FLU OIA® and FLU OIA A/B®; rapid influenza diagnostic tests which were commercialised and subsequently marketed by Inverness Medical as part of their BioStar product range.

Biota also has key partnerships with:

- 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).

In 2006, Biota commenced a phase Ib clinical trial of its human rhinovirus (HRV) drug for the prevention and treatment of one of the major causes of the common cold which is also thought to be a major cause of exacerbations in patients with chronic obstructive pulmonary disease and asthma.

The Company's research pipeline also extends beyond respiratory diseases, including early stage research targeting the hepatitis C virus (HCV).

Clearly Biota has evolved from a one product company to a maturing biotechnology company with a growing drug pipeline. The Company has established in-house expertise in areas including drug discovery, virology, medicinal chemistry, drug delivery, toxicology, health economics, strategic marketing and clinical trial management. Such a skill base is quite unique in the Australian biotechnology sector. Further validation of Biota's international science and drug development standing is the award to the Company of two US National Institute of Health Grants worth over US$14m (~A$19m) to develop our long acting neuraminidase inhibitor for the treatment of influenza.

Biota firmly believes that continued innovation is a key driver for sustainable growth of our business. Reflecting Biota's commitment to innovation is its spend of $26m in 2005/06 on research and development activities, predominantly occurring in Australia. Through its R&D expenditure, Biota supports local research institutions, manufacturers, clinical centres and consultants. The level of R&D expenditure is planned to increase in the ensuing years. Currently Biota also employs 45 full time staff and envisages future increases in staff levels.

Federal Funding Initiatives – Recommendations for the future

The Federal Government recognises that funding innovation is not a cost, but an investment in our future. They have had a pivotal role as a catalyst for driving the innovation process through research grants, venture capital initiatives, industry assistance grants and R&D tax concessions. Biota has benefited from several of these schemes. It would be useful if these initiatives could assist Biota in its stated growth strategy of progressing certain of its proprietary drugs further down the clinical development path to capture more value before partnering. Obviously, such clinical trials are expensive. For example, it is not unreasonable for a Phase II clinical trial to cost between US$20-40m. Currently there is no incentive for Biota to conduct these clinical trials in Australia. We feel that there is a mechanism by which this could be achieved (see below).

We propose that all qualifying expenditure under the R&D tax concession provisions be rebated for all companies through the tax credit process.

Many companies invest significant resources in innovation that qualify for beneficial treatment under the R&D tax concession rules. However, only tax payable companies and some small loss making companies can access the tax benefits associated with this expenditure on innovation. As such, there appears to

be a significant inequity in the manner in which expenditure on innovation is treated by the Australian tax system.

Where a company is engaged in cutting edge, world's first innovation such as drug development, it can take 12-15 years to develop each new drug product and can cost US$800m. Investment in research is often significant (year on year) and it is typically many years before a company is able to profit from its investment in innovation and emerge from accumulated losses. As such, there are many highly innovative companies that are unable to access the benefits of the R&D tax concession for many years, due to the fact that they are neither profitable (ie taxable) and are outside the 'tax offset' definition of a small company. This inability to access the benefits of investment in innovation (through the R&D tax concession) impedes the cashflow of true R&D companies and has a significant and detrimental impact on a number of companies crucial to the success of the Australian biomedical industry. The very companies who are disadvantaged by the inequity of the R&D tax concession are often the same companies who have developed Australian based capability and are continually increasing this capability in order for Australia to compete on the global stage.

For many innovative companies such as Biota, valuable resources are therefore locked up in a pool of tax losses that can only be accessed when a company becomes profitable. This can take many years and access can not be guaranteed, as expenditure can be lost if a company cannot meet strict ownership and same business rules. Indeed, tax losses are usually lost when a company is acquired, which may be necessary in order to obtain the funding needed in order to advance the research and development. The result is that many innovative companies can not access the benefits of the R&D tax concession when they most need it (during the capital intensive development phase) and gain access to the benefits of the concession when they least need it (often after they have commercialised the innovation and are profitable). This scenario may account for the increasing number of companies who are unable to fund the ongoing research needed to produce innovative results and goes some way to explaining why so many companies are unable to take innovation through to commercialisation.

As such, the application of the R&D concession to truly innovative companies is actually counter the spirit of innovation, where high risk takers are penalised and those engaged in low level, low risk innovation gain access are the prime beneficiaries of one of Australia's primary funding mechanism for research and development.

We also have a number of other suggestions that we would welcome the opportunity to share with you at a later date if you deem this helpful. In the meantime, please contact me should you require any additional information.

Yours sincerely

Leigh B Farrell, PhD FAICD
Vice President Business Development