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

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3rd February 2010

Dear General Manager,

Submission: The New Research and Development Tax Incentive – Exposure Draft Legislation and Explanatory Materials

Re: R&D Tax Credit should include Clinical Research

Further to your request for submissions, we would like to make the submissions set out below to reflect our long-term experience in Australian innovation in the biomedical sector.

Background on GBS Ventures:
Founded in 1996, GBS invests in young businesses developing and commercialising biotechnology and healthcare products which, when combined with the right management and finance, make a significant difference to patients' lives and deliver financial returns for our investors. Our areas of particular interest and expertise include human healthcare, biotechnology product development and life science start-ups. In particular, recent investments have included biological or small molecule therapeutics, medical devices and diagnostics. GBS invests in private or public companies whether at start-up or later stages of company development. Our investors include major Australian superannuation funds. Our business, which focuses on the translation of Australian biotechnology innovation, relies heavily on the availability of high quality clinical trials in Australia and New Zealand in order to develop biotechnology and medical technology products for global markets.

Submissions:

- Clinical trials and clinical research are essential R&D for Australian biomedical innovation to reach global markets.
- GBS welcomed the proposed R&D tax offset to improve incentives for companies to undertake innovative commercial activities in Australia.
- Australia is already recognised as having high quality clinical care and clinical development opportunities which are pathways to global drug and device markets.
- Clinical research and development enhance healthcare quality and productivity with extensive economic spillovers at the same time as generating innovative new products.
- Clinical trials are the core R&D activity of biotech companies. Where those trials involve new agents or are applied to new diseases, there is high technical risk in order to determine if a new drug or device is safe in humans and effective to treat disease. The vast majority of

biomedical products fail during clinical development, whether undertaken by pharmaceutical companies and the biotech sector, clearly demonstrating the high non-linear technical risks involved in clinical research.

- Clinical trials are experimental, systematic and investigative. Discovery of research candidates and preclinical animal testing is a small and initial step in the R&D required to produce a new biotech product. First-in-human and first-in-patient clinical studies are essential clinical experiments required to understand safety, dosing and efficacy of a new product.
- If the R&D tax credit excludes clinical trials and only applies to laboratory research Australia will promote non-commercial research and leave a gap in funding and incentives for R&D which specifically addresses unmet medical needs.
- Australia's high quality healthcare and clinical research provides an effective and representative test market for the development of global healthcare products which are developed from Australian innovation. The number of Australian biomedical innovations which undergo clinical trials in Australia is a key measure of our national innovation systems' ability to translate local innovation into internationally competitive products. Furthermore, overseas pharmaceutical and device companies which conduct clinical development in Australia provide export service revenues as well as skills transfer and a global translational path for local innovations.
- A key issue for clinical trials and clinical research in Australia are recent suggestions to exclude most clinical research from the R&D tax credit. Any such proposal would severely limit the effectiveness of the biomedical innovation in Australia by:
    - Restricting public incentives to early stage, pre-clinical research
    - Reducing incentives to develop and test products which actually treat patients and improve healthcare outcomes
    - Reducing global development of biotech products in highly competitive local markets
    - Reducing "pull" signals from local markets for innovation and emphasizing "push" signals from early stage laboratory research, thereby increasing the risk profile of Australian innovation
- Every effort should be made to include first-in-human, first-in-patient and proof-of-concept clinical trials in eligible R&D for the purposes of the R&D tax credit. These are sometimes also described Phase 1 and Phase 2 trials.
- We suggest that government support biomedical innovation and industry by focusing much more heavily on clinical research. Funds to partially match private investment in the early stage clinical development of local biotechnology products would have a catalytic impact on and positive spillovers in the Australia healthcare and biotechnology sectors for the following reasons:
    - Patients involved in clinical research receive higher quality diagnosis, treatment and clinical care
    - Patients involved in clinical research receive access to new therapies which they would otherwise not be able to receive
    - Physicians and healthcare practitioners involved in early stage clinical research develop improved skills and capabilities to treat all patients
    - Clinical research generates high skill, high quality employment which is internationally competitive and sustainable
    - Clinical research is a significant service sector export industry
    - Supporting Australian companies' clinical research addresses some of the funding gap faced in the translation and product development of local innovation
    - Government support for clinical trials represents the most effective "pull" mechanism to enhance innovation as it relies on existing, high quality independent ethics and other regulatory approvals

- Initiating a clinical trial is the most effective way to enhance co-ordination of all the elements of preclinical development required for any specific new medical therapy

A suggested approach would be for the Australian government to either, by additional tax credit or matching funds, fund a significant portion of the costs of any first-in-man study for a locally developed new therapy and provide reduced but meaningful ongoing supplementary support for the costs of additional Ph 1 and Ph 2 studies for locally developed new therapies. Private investors would be required to meet the rest of the direct costs of the clinical studies as well as indirect corporate overheads and other costs. The matching funds would be justified as the most effective way to: enhance patient care; build capability in the sector; support an export services industry in clinical research; co-ordinate translational development by the local biomedical sector; and attract local and international investment in Australian clinical-stage biotechnology companies.

Yours sincerely on behalf of GBS Venture Partners

J.V. Funder