Biotechnology and Related Industries Leadership Group

Proposal for the Commonwealth Commercialization Institute

Overview

Architecture of the Commonwealth Commercialization Institute Key Roles of the Commonwealth Commercialization Institute 1. One Stop Information Shops (OASES)

- i) Business Mentoring Oasis
- ii) Beta-Testing, Market Testing and Clinical Trials Oasis
- iii) Grants and Funding Information Oasis

2. The Australian Intellectual Property Clearing House

3. Beta-Testing, Market-Testing and Clinical Trials Funds

Overview

The ad hoc Biotechnology and Related Industries Leadership Group proposes the following framework, aims and practical policies for the Rudd Government's Commonwealth Commercialization Institute.

The (BRIL) Group has discussed at length the range of possibilities as understood from Department of Innovation Industry Science and Research guidance and held two intensive seminars to arrive at the following proposals, along with further detailed cross-correspondence.

The Group includes representatives of AusBiotech CEO Dr Anna Lavelle and Glenn Cross, Bio-Melbourne Network chairman Dr John Raff and CEO Michelle Gallaher, Research Australia CEO Rebecca James and director of philanthropy Dr Noel Chambers, Chancellor of Monash University Dr Alan Finkel, GBS Venture Partners' Dr Joshua Funder and has taken advice from across the constituent groups of the sector including a range of biotechnology chief executive officers and other interested parties. The Group has been convened and chaired by Biotech Daily editor David Langsam

A number of models for commercialization have been discussed with some concentration on the perceived strengths of Israel's Office of Chief Scientist, which provides a range of measures including information services and grants designed to cater for a diversity of technologies.

Similarly the BRIL Group proposes a single unified system within the Commonwealth Commercialization Institute rather than a division into what may be arbitrarily-defined sectors. Much of what may be held under the umbrella of 'biotechnology', such as the innovative development of biomaterials, has great synergies with, and could potentially overlap, 21st Century 'manufacturing'. It was the Group's conclusion that information flows and methods of commercializing information technology, environmental technology and new manufacturing had much in common with biotechnology research and development. A clinical trial for one is beta-testing, markettesting and development for the others. The proposals which follow will create a viable and important cornerstone for the commercialization of new technologies in Australia.

Architecture of the Commonwealth Commercialization Institute

The challenge has been to create a single authority able to support the commercialization of both institutional and individual research taking inventions from the proof-of-concept stage in the field, workshop or laboratory to preparation for regulatory approval and the global market.

The BRIL Group was unanimous in supporting:

* a lean bureaucracy with a small secretariat and administration costs to be kept to a minimum;

* at arms length from Government;

* lead by successful start-up leader or a respected scientist, with appropriate managerial and commercial experience;

* supported by four advisory groups (biotechnology, information technology, environmental technology and new manufacturing);

* the pace of commercialization needs to be swift, so the decision-making process needs to be rapid and dexterous.

Key Roles of the Commonwealth Commercialization Institute:

1. One Stop Information Shops (OASES) for business development mentoring, clinical trials and grants availability.

The Oases will serve as fresh pools of information in the desert of research development's Valleys of Death. A place to go for those in need of assistance.

i) Business Mentoring OASIS

The biotechnology sector is well-connected and has regular meetings hosted by AusBiotech as well as excellent professional development courses, seminars and 'Bio-Breakfasts' convened by the Bio-Melbourne Network. While there is always room for improvement, these are good examples to assist other emerging industries in making the connections that will assist their work. The two organizations frequently bring small companies into contact with key players in the sector including specialist lawyers, intellectual property specialists, major developers (big pharma) and distributors, as well as regular discussions of industry-wide problems and their solutions.

Non-biotechnology examples of organizations that provide information and services include the Australian Institute for Commercialisation, Innovations Australia, Enterprise Connect, Comet and Innovic.

At a more individual level, direct mentoring programs can be developed so that innovative entrepreneurs can learn from already successful developers to avoid pitfalls and capitalize on the possibilities for the road ahead.

The Business Mentoring Oasis could also develop and broaden the Ausbiotech partnering program bringing scientific papers and abstracts across all disciplines to the relevant investors and product developers.

A key program to support emerging entrepreneurs, share best practice and establish long-term active mentoring relationships will be hosting business pitching contests. The Business Mentoring Oasis should host annual hightech business plan contests intended for tertiary students but open to any young person with good ideas to be judged by active investors and mentors in the relevant sector.

ii) Beta-Testing, Market Testing and Clinical Trials OASIS

Universities and research institutes have opened-up to commercial research and have ready-to-go infrastructure available to test materials, technologies and products. The Trials Oasis would identify resources in public and private sector institutions, provide linkage through a continuously revised database on the availability of laboratory space, Good Manufacturing Practice and Good Laboratory Practice facilities and programs along with the availability of facilities for testing and trials. One task of the Trials Oasis would be to establish strengths and weaknesses in Australia's facilities and arrange international cooperation agreements.

iii) Grants and Funding Information OASIS

The Grants Information Oasis will create a user-friendly database of all available and appropriate government, institutional and private grants from Australia and overseas that could be made available for the commercialization of innovation. Many researchers have difficulty finding grants and in some cases there are grants in existence that are under-utilized.

The Grants Information Oasis should be searchable by type of technology, stage of development and size of grant and include all relevant data on conditions and availability and provide assistance to companies to identify appropriate avenues for assistance.

The Grants Information Oasis will report to government and the community on the needs and gaps in the funding framework and record a corporate history of grants. The database will track a company or organization's grant history and outcomes, providing data for grant and funding discussions and policy.

2. The Australian Intellectual Property Clearing House

The Commonwealth Commercialization Institute will create and oversee but not administer an Intellectual Property Clearing House. The Intellectual Property Clearing House will be a key to positioning Australian innovation in the international market for commercialization.

All patents supported by public research funding would, once published, be registered with the clearing house, searchable online and actively sent to all relevant local and international groups, such as large corporate R&D groups, pharmaceutical companies, start-ups and venture capital groups.

Initial patent fees and expenses up to, but not beyond, the time of the auction and licence would be in part supported by the Commercialization Institute.

Patents, with an appropriate research exemption, would be available via auction beginning at a minimum royalty rate and financial investment in the technology with potential for equity holding to be recognized. Institutional commercialization groups and inventors would be able to promote the auction, as well as indicate a preference for partners, including spin-outs.

Proceeds from the auction and future royalty streams would be shared between the inventor, originating institution and the Commonwealth Commercialization Institute, to become self-funding over the long term.

The clearing house would rapidly expand the accessibility of Australian innovation to the most appropriate partners, enhance returns on our investment in research, facilitate local and international innovation linkages and prevent delay in the beneficial application of our ideas - the ultimate perishable goods.

3. Beta-Testing, Market-Testing and Clinical Trials Funds

A key to successful innovation is the timely funding of cutting edge programs. Israel's Office of Chief Scientist provides its grants in some cases with just three or four months from application to payment.

The pace of commercialization is critical and the speed of granting is as important an issue as the size and availability of grants.

The Group unanimously agreed that there would be no 'palliative care' for failing technologies and proposals for any grants would be closely scrutinized and objectively vetted. Only those proposals that are both innovative and have commercial potential will be considered for market testing, beta testing and/or clinical trials.

The BRIL Group believes that well-vetted and timely small grants of up to \$2 million can make significant differences to innovation outcomes. The Group is aware of some device and diagnostic companies that have needed less than \$1 million to complete essential testing for registration. Venture capital organizations use an approximate six-to-one leveraging scale for investments. The Group would expect that small Commonwealth Commercialization Institute grants would be the fulcrum to leverage sufficient funds for beta-testing, market-testing and early (phase I and phase II) clinical trials.

The direct grants available for the Commonwealth Commercialization Institute are expected to be required solely for early stage testing and trials, post proofof-concept and able to take the product or technology to pre-market development.

Any grant made available would carry a trail fee from successful commercial development back to the Institute of the order of magnitude to provide further funding for the Institute. As commercialized innovation demonstrates success, the Commercialization Institute will be able to encourage further success.

Signatories

Alevels	Rober James
Dr Anna Lavelle	Rebecca James
CEO	CEO
AusBiotech	Research Australia
Rauhn	John W Rff
Michelle Gallaher	Dr John Raff
CEO	Chairman
Bio-Melbourne Network	Bio-Melbourne Network
Alantinhee	J.V. France
Dr Alan Finkel	Dr Joshua Funder
Chancellor	Investor
Monash University	GBS Venture Partners
Nand Cal	Aunil 107-
Dr Noel Chambers	David Langsam
Director of Philanthropy	Editor
Research Australia	Biotech Daily

Melbourne, June 30, 2009