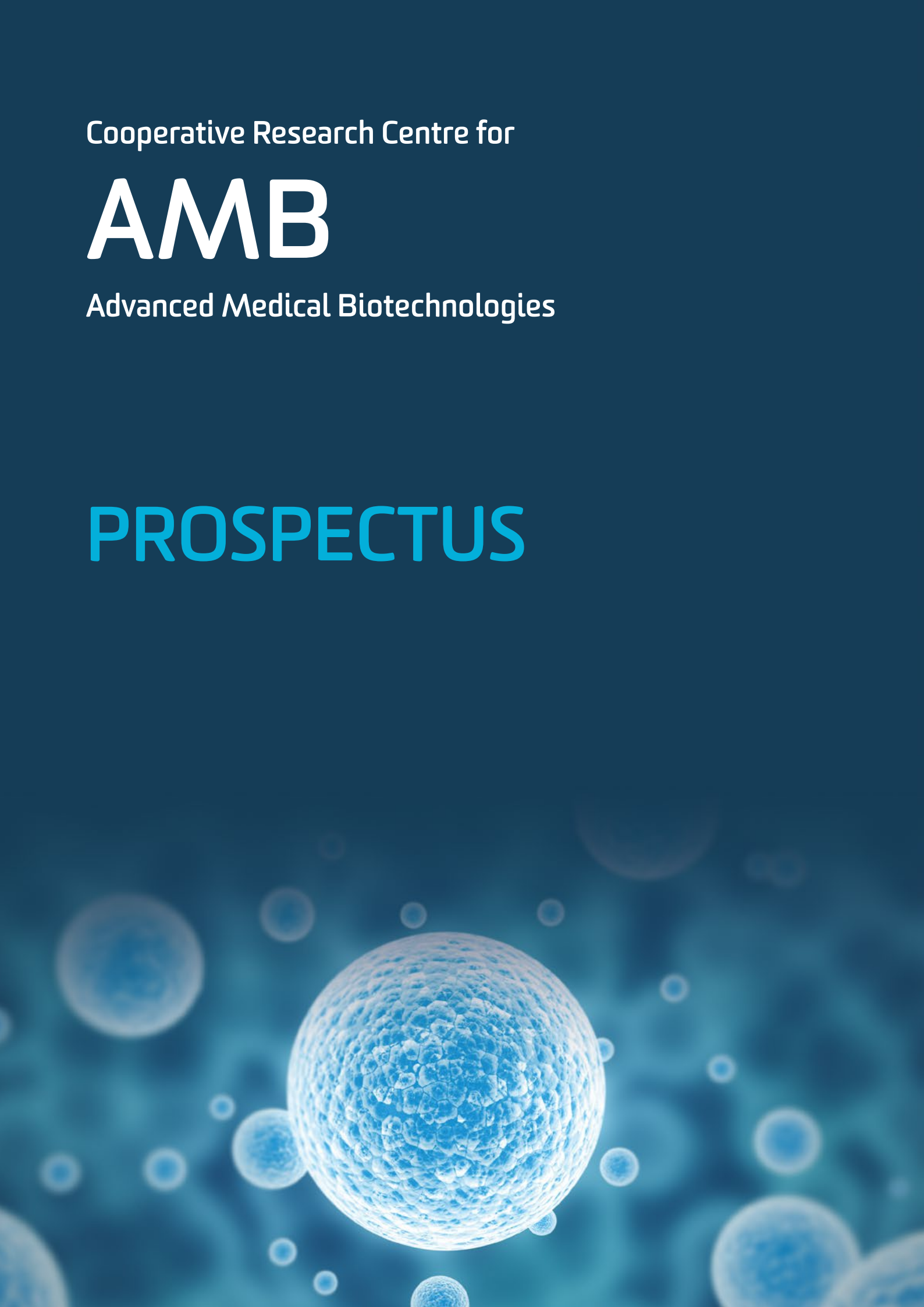
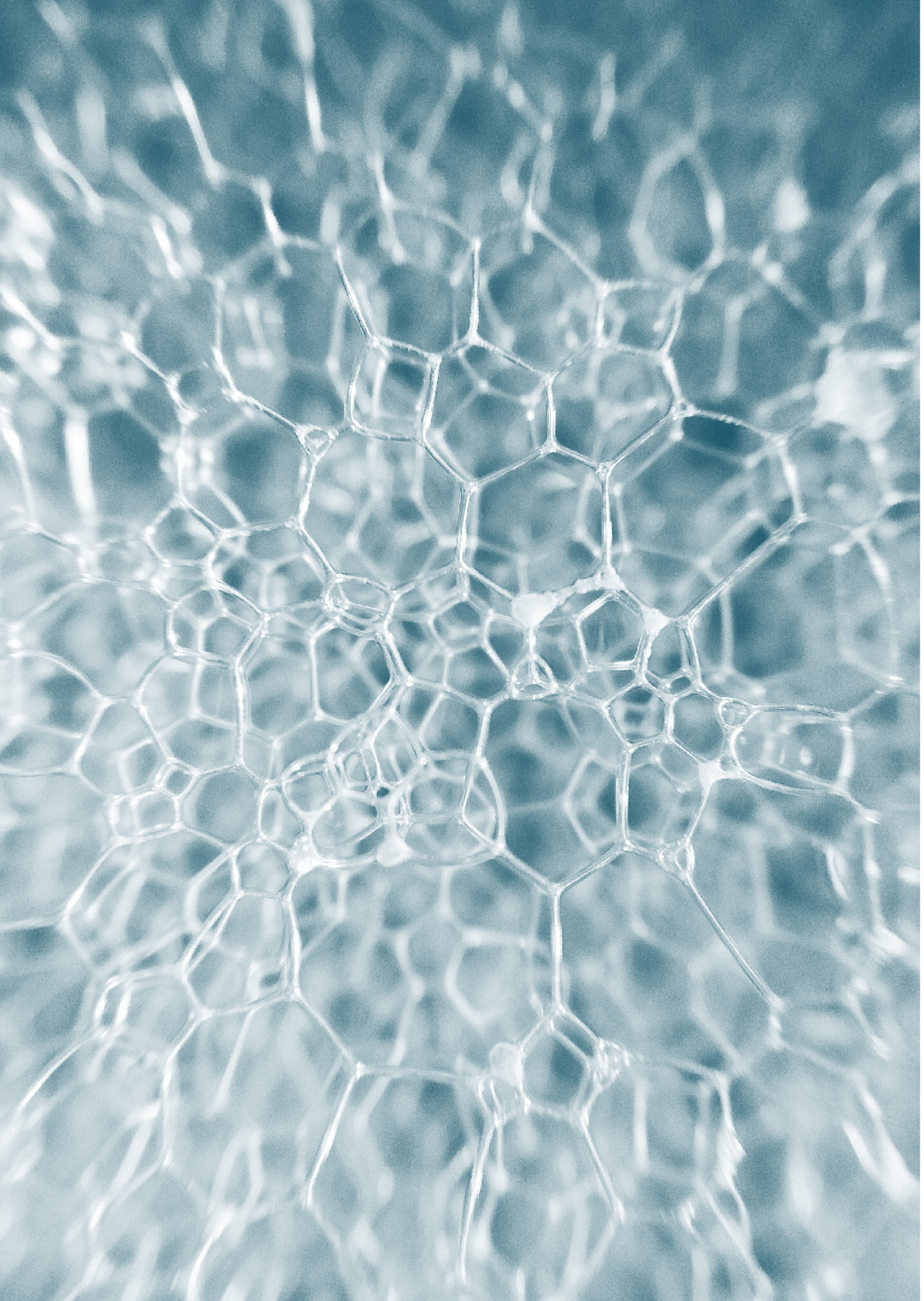
Cooperative Research Centre for

AMB

Advanced Medical Biotechnologies

PROSPECTUS





The proposed Advanced Medical Biotechnologies (AMB) CRC will provide a comprehensive multidisciplinary approach to addressing known key roadblocks along the product development pipeline that are impeding Australian SMEs in getting their medical therapeutic products to the market.

GOAL

The Goal of the AMB is to support companies in the medical bio-technology sector by assembling a collaborative network across industry and researchers to support a fully integrated product development capability spanning from research proof-of-concept to early-clinical stage.

STRATEGY

To provide new technologies and capabilities for advanced manufacturing of products and tailored clinical services to support companies in developing their products all the way to clinical trial stage within Australia.

VALUE PROPOSITION FOR MTP COMPANIES

Acceleration of your product development will be achieved through:

- **Access to a fully vertically-integrated product development pipeline capability that will expedite your product development from post-research POC to early-clinical stage**
- **Access to leveraged (1:1) funding and tax incentives for industry-led, milestone-driven R&D and tech-transfer projects tailored to solving your specific problems and needs**
- **Improved access to local GMP manufacturing and fill and finish facilities; clinical support services; regulatory and commercial advice and tailored, industry-ready workforce training programs.**

The Medical Technology and Pharmaceutical (MTP) Sector

GLOBAL PERSPECTIVE

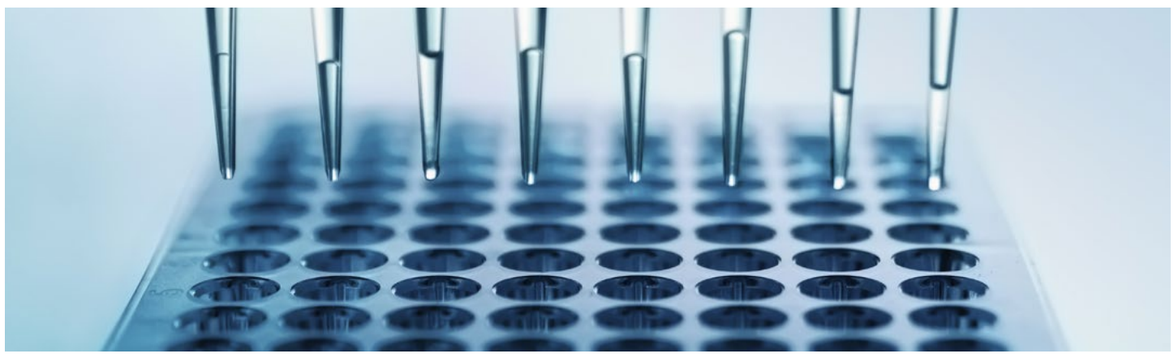
- The growth in our ageing population will require increased health care, presenting major opportunities for the MTP industry.
- Global health care spending is projected to grow by more than 5% pa, creating an urgent need for new technologies, goods and services to reduce health costs and improve patient care.
- The world market for pharmaceutical sales for 2015-16 exceeded $1.2T where the market for Contract Research Organisations in the MTP sector is estimated to grow to $50B p/a in 2019 (11% growth p/a).
- Innovation driven by advancements in technology will stimulate the development of new products.

AUSTRALIAN PERSPECTIVE

- Around 100 medical technology, biotechnology and pharmaceutical companies are listed on the ASX, with a market capitalisation of $85B.
- Australia has an enormous economic opportunity to develop and manufacture high-value vaccines and therapeutics that will shape the future of healthcare. We are in an excellent position to capitalize on this growing world market given our favorable regulatory system, recognition as an attractive location for human clinical trials and our close proximity to emerging markets in Asia.

ROADBLOCKS FOR SUCCESS

- Despite Australia being recognized as a world leader in MTP research, we have not been very effective in translating R&D into commercial outcomes. Our manufacture and commercialisation of MTP products remains below par and thus we rely on off-shore capabilities and on importation of most health products.
- Specifically, timely access to advanced GMP manufacturing capability and capacity, preclinical testing, clinical trial expertise and are inadequate, significantly impeding the international competitiveness of Australian SMEs.
- Thus, our early stage deals lose the additional value that would otherwise have been added by local/Australian commercialisation for the global pharma market.



OPPORTUNITIES

- Australia's MTP Industry is poised on the brink of opportunity as noted in Deloitte's 2015 industry review:

  https://www2.deloitte.com/au/en/pages/economics/articles/medical-technology-industry-workforce-skills-review.html

  These include:

  - ◊ Australia's ageing population will require increased health care, presenting a large opportunity for the MTP industry.
  - ◊ Developing Asian economies will demand better health care, providing new export markets.
  - ◊ Innovation driven by advancements in technology will provide opportunities to create and develop new products.
  - ◊ Complex global regulatory requirements and processes can be met in Australia.

- If we can more effectively connect the existing networks of start-ups, medium-sized businesses, large multinationals, hospitals, service providers, universities, research organisations and facilities we can improve our national capability to more effectively translate cutting-edge research and technology into commercial products.

ALIGNMENT WITH NATIONAL PRIORITIES

The 2016 National Research Infrastructure Roadmap identified Therapeutic Development as a priority area to address our future needs, fulfil national interests and build on our existing national capabilities. This complements the National Science and Research Priorities and is aligned with the Medical Therapeutics and Pharmaceutical Industry Growth Centre (MTPConnect).

ALIGNMENT WITH MTPCONNECT

MTPConnect has developed a Sector Competitiveness Plan that identifies critical future needs and priorities for the sector including the need to:

- Accelerate industry initiatives aimed at enhancing competitiveness and productivity, in particular those that have the strongest impact on supporting SMEs.
- Increase coordination across the sector to link industry, public and private research organisations to State and Australian Government initiatives, reduce duplication and identify opportunities for alignment.

While Australia is well positioned to build on investments in medical research and has some of the elements required for the product development flow for new medical therapies, there are significant gaps in capability, capacity and coordination. Industry consultations have identified clear needs around translating therapeutic developments in Australia including:

- Production facilities to make appropriate quality candidates for pre-clinical and clinical testing.
- The ability to design and undertake high quality, ethical clinical trials to test product candidates.

The Cooperative Research Centres (CRC) Program

The Cooperative Research Centres (CRC) Program The CRC Program is an Australian Government initiative that brings together researchers and industry with the aim of focusing research and development that improves the effective translation of research into commercial products.

The CRC Program objective of improving the competitiveness, productivity and sustainability of Australian industries will be achieved by encouraging collaboration between industry and research organisations that will improve R&D capacity within SMEs and facilitate the up-take of research outputs by industry through:

- Undertaking industry-led collaborative research to solve industry-identified problems and deliver outcomes consistent with Government Priorities.
- Implementing an industry-focused education and training program. This includes a PhD program that complements the research program and training of industry-ready highly-skilled employees.

CRC Selection Criteria with AMB responses

THE FIRST STAGE OF THE CRC APPLICATION PROCESS IS THE LODGEMENT OF AN EXPRESSION OF INTEREST THAT ADDRESSES 6 KEY SELECTION CRITERIA.

1

Industry outcomes (30%): What are the industry problems to be solved?

Consultation with Industry identified the following problems:

- Lack of advanced manufacturing capability for high-value medicines for global markets.
- Lack of GMP pilot manufacturing capability and capacity for pre-clinical and early-human clinical studies – forces overseas outsourcing.
- Lack of commercial scale GMP bioprocessing capacity and sterile fill-finish.
- Poor access to support services that improve transition from pre- to early-clinical trials.
- Poor access to regulatory advice, clinical trial assistance and commercialization issues.
- Low level of local highly-skilled, industry-ready workforce, forcing overseas recruitment.

2

Proposed research activities (30%): How will the problems be solved?

The proposed AMB CRC Programs are designed to address the product development gaps identified by the MTP Connect Sector Competitiveness Plan (Dec 2016). The AMB CRC will support **a large-scale and multi-disciplinary approach** to address key roadblocks along the product development pipeline. The AMB Programs are strategically designed to provide a continuous flow from advanced bioprocessing technologies and GMP manufacturing to pre- and early-clinical trial testing of products with the **overall aim of reducing the time to market.**

Program 1: Advanced Technologies for Manufacturing: Developing novel platform technology systems for advanced manufacturing of biomedical products.

Program 2: GMP Manufacturing: Establish highly efficient and flexible GMP manufacturing capability and capacity for biomedical products for domestic and export markets by coordinating existing infrastructure.

Program 3: Product Transition to Early-Clinical Trials: Provide National capability and capacity to accelerate the transition of biomedical products to market through improved access to clinical assessments and regulatory advice.

Program 4: Workforce Training and Education: Support training of an industry-ready workforce across all areas from post research POC to early-clinical stage.

Appendix 1 provides more detailed Program information.

3

Governance and management capability (10%): A skills-based Board with expertise in business, commercial and project management will provide oversight of the CRC's direction, activities and performance. The Board will oversee the appointment of a CEO with deep industry understanding and Programs will be managed by industry experts and R&D leaders.

4

Education and training programme (10%): How will the CRC build capacity and capability in industry and R&D sectors?

AMB will support the training of an industry-ready scientific and technical workforce that is capable and experienced in all areas from post research POC to early-clinical stage, including regulatory, clinical trial and commercial expertise.

5

Value for money (10%): Why should the Government invest?

Value proposition: Growth of the Australian biomedical industry will lead to:

- Growth in GDP through increased export of locally manufactured high-value technology and finished goods for international and regional Asian markets.
- Provision of tailored training for a highly-skilled and industry-ready Australia workforce across the full R&D and life science business spectrum.
- Enhanced national self-reliance for product supply and health care security.

6

National benefits (10%): How is the CRC aligned with Government Priorities?

- Generation of high-value jobs associated with advanced manufacturing, pre-clinical development and clinical trial services.
- Future growth of smaller Australian SMEs into larger, more stable and successful companies that are internationally competitive.
- The MTPConnect 2016 Sector Competitiveness Plan identified gaps along the product development pipeline that impede the growth and competitiveness of Australian bio-medical SMEs and listed priority areas that are needed to support the future growth of smaller companies into larger, more stable and successful companies.
- The AMB CRC is fully aligned with these MTP priorities and will focus on supporting SMEs in crossing the "valley of death" of the product development pipeline spanning post research POC to early-clinical stage testing of products.

AMB CRC Participation

The AMB CRC will provide an opportunity to partner with other segments of the industry and research community to improve the delivery of breakthrough advancements in the bio-medical product market. There are two ways to get involved in the CRC; become a core participant or a supporting participant. Flexible investment and tailored participation agreements will be developed to ensure that the CRC's business model meets the partner's needs.

1. **Core participants** will commit cash and in-kind investment over the term of the CRC. They have an opportunity to shape the CRC's business model, including;
    - Governance and operational structure.
    - R&D programs, strategy and key milestones.
    - Legal and fiscal structures.
    - Intellectual property and commercialisation agreements.
    - Smaller SME's may be able to form a single "amalgamated" participant.
2. **Supporting participants** commit a lower level of funding that may be made on a per-project basis. Flexible terms can be tailored to suit particular business requirements and situations.

AMB CRC CO-INVESTMENT PROPOSAL

- The CRC's resources will include cash and in-kind commitments made by the participants.
- The total value of these commitments will determine the amount of public co-investment provided by the CRC grant.
- We will seek approximately $30M of Government cash funding over the term of the CRC, which must be matched by participant cash contributions.

PROPOSED GOVERNANCE

- The AMB CRC will be an incorporated company limited by guarantee with an independent, skills-based Board of Directors that will provide oversight of the CRC's direction, activities and performance.
- Participants will be represented on a Participants Committee.
- Participants will also have a board member assigned as their liaison in order to have direct links to CRC management and its Board.
- The company will be a 'for-profit' company as no net tax is likely to be payable provided all income is expended on research, training and related activities.
- This will enable direct benefits to participants and can allow flexible IP and licensing arrangements.

PROPOSED TERM

- The proposed AMB CRC will be a public-private venture.
- Participants will decide the length of funding to be requested.
- Typically, the term is 7-10 years.

PROPOSED IP AND COMMERCIALISATION PRINCIPLES

The AMB CRC will offer flexible IP and commercialization agreements. In general, IP resulting from AMB CRC funded projects will be owned by the AMB CRC company and beneficially owned according to the project shares defined in individual Project Agreements. Companies sponsoring a project will have first rights to commercialise IP developed in that project.

CRC Application Timeline

Preliminary Stage (Jan-Dec 2017)

- Engagement with potential partners (industry, research and government)
- Workshop and meetings to identify key industry problems
- Agree on AMB focus and develop proposed Program areas
- Develop AMB value concepts

Stage 1 (Jan-July 2018) - develop expression of interest

- Engagement with potential partners
- Gather in-principal participant commitments
- Lodge expression of interest

Stage 2 (Aug-Nov 2018) - full business case and interviews

- Workshops to finalise the programs and initial projects
- Develop business plan and value proposition - cover all selection criteria
- Develop CRC Centre agreement, management team, Board structure and members and Program Managers
- Develop IP and commercialisation agreements
- Identify Interview Team, undertake mock interview for feedback
- Final Interviews in November

Announcement (Q1 2019) with CRC starting operations in July 2019

Appendix 1: Detailed Program Structure

The proposed AMB Programs are strategically designed to support a pipeline from advanced bio-processing technologies and GMP manufacturing to early-clinical trial testing of products.

The Program structure is designed to:
Address key aspects of the mid-way points of the product development pipeline from research proof-of-concept through to early clinical trials (TRL 3-7).

- Provide a continuous flow for product development where the AMB's value to companies is clearly relevant including: tailored processes for unique products; access to facilities and/or technologies; pre to early clinical trial capabilities; a broad range of advice; workforce training; reducing the need to outsource overseas.
- Individual projects can be tailored to progress a company's specific product along the development pathway.

Program 1: Advanced Technologies for Manufacturing (TRL 3-5)
Objective: Develop novel platform technology systems for generic cell-based production of biologicals including viruses, antibodies, biosimilars and other proteins.
Outcomes:

- Modification of existing cell lines for enhanced vaccine, antibody and protein production that are of broad use for advanced manufacturing, including continuous bioprocessing.
- Development of modified eggs for enhanced production of live vaccine viruses.
- Development of IP for novel cell lines and egg and manufacturing processes.

Program 2: GMP Manufacturing: (TRL 4-6/7)
Objective: Establish highly efficient and flexible GMP manufacturing capability for biomedical products for domestic and export markets by coordinating existing infrastructure.
Outcomes:

- Advanced GMP biological manufacturing facilities with fill and finish capability.
- Training in working under QA/GLP/GMP conditions.
- Reducing the need to outsource overseas.
- Provide fee-for-service income for partners.
- GMP manufacturing that is affordable, scalable and flexible.

Program 3: Product Transition to Early-Clinical Trials: (TRL 4-6/7)
Objective: Provide National capability and capacity to improve the transition of biomedical products to market through provision of clinical assessments and regulatory advice.
Outcomes:

- Establishment of a networked regional facility for comprehensive pre-clinical testing in a range of animal models and in vitro systems, focusing on increasing the quality and reliability of experiments and trials.
- Provide GMP/sterile fill material for first-in-human clinical trials.
- Predictive organs-on-a-chip that reduce reliance on animal trials.
- Generate fee-for-service income from interactions with CROs and CMOs.
- Implementation of new methods to support clinical and non-clinical trials for new biomedical products and increased capacity for local clinical trial management.

Program 4: Workforce Training and Education:
Objective: Support training of an industry-ready workforce that is capable and experienced in all areas from post research POC to early-clinical stage. This will enhance the commercial success of existing SMEs and underpin newly emerging companies in the MTP sector.
Outcomes:

- Industry-focused courses for bio-technology and workplace training (internationally).
- Expanded highly-skilled workforce and create high-value jobs.
- Increased access to clinical trial experts and managers through training of physicians.
- Increased attractiveness for new and expanded biotech and clinical trial businesses.
- Provide support for startups.

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