South Australian Productivity Commission Inquiry into Health and Medical Research in South Australia – Draft Report released 2 September 2020

Translation and Commercialisation
Submission from the University of Adelaide, 16 October 2020

This submission focuses on *Chapter 8: Translation and Commercialisation* and is presented on behalf of the University of Adelaide by Dr Stephen Rodda, Executive Director Innovation and Commercial Partners.

The Commission is to be commended for the considerable work invested in the production of its draft report.

The draft report outlines a generalised process for translation and commercialisation of Health and Medical Research (HMR) outcomes. Furthermore, the Commission rightly highlights the observed barriers to translation and commercialisation through that process, principally:

- The need to improve linkages between fundamental research and clinical practice;
- Lack of transparency in collaboration nor structured Intellectual Property (IP) principles and ownership;
- Access to capital;
- Commercialisation skills, and
- Industry-led research and development.

This submission aims to outline and contextualise these barriers as part of the wider HMR system and to propose new initiatives that could be further considered by the Commission.

1. BACKGROUND

In 2019 the University of Adelaide created the Innovation and Commercial Partners Branch as a new approach to coordinating commercial activity and commercial strategy across the institution; and to reaffirm the University's commitment to industry engagement and commercialisation of research outcomes.

Our Commercialisation team works directly with research leaders to identify outcomes of research with commercial potential and to work to develop and implement IP and commercialisation strategies.

If one defines commercialisation as the process of development and delivery of new products and service to the market, then universities themselves do not commercialise the outcomes of research. As such, much of the effort expended by university commercialisation offices is on identifying companies and investors external to the university that have the capability and capacity to drive the commercialisation process.

While commercial terms for access to the intellectual property will often include the payment of royalties as a percentage of sales back to the university, this financial return is often single percentage points, reflecting the early stage of development of such technologies, and the risk/reward taken by commercial partners and investors to back the opportunity through completion of pre-clinical development and clinical trials before it is approved for commercialisation.

Universities benefit more broadly from additional research income secured for further research on the technology (through grants or contracts with companies and consultancy arrangements with inventors) and, importantly, from brand/profile/reputational benefits from being linked to the successful commercial outcome originating from the university.

Rarely, if ever, is an outcome of research directly commercialisable without further investment into the development of the new product or service. As such, it is the commercial partners and investors that take on the financial risk and technical risk, amongst others, to deliver these new products and services to market. The aggregation of these risks means that success is never guaranteed and consequently much time and effort can be invested in commercialisation of research outcomes that never make it to market as a new product or service.

The Commercialisation team have a modest budget to fund protection of IP and as such they work through a rigorous due diligence process to help inform decisions about which projects receive support and those that don't. In addition to this we also have a modest proof-of-concept fund that we use to invest in projects with the goal of achieving technical milestones (proof of principle, demonstrator, prototype, or the like) that ultimately validates the commercial potential of the research outcome and reduces technical risk; making it more attractive for a commercial partner or investor to take the opportunity forward.

Funding for IP protection and the proof-of-concept fund both represent a direct investment by the University to support this activity, where industry and investors are not yet ready and, thus, to support the successful translation of research outcomes. By the very nature of a university's business, this funding is limited and is required to service opportunities across the breadth of research activity at the University, not only HMR.

We work to leverage this investment with other funding sources to drive as much value creation as possible. However, due to the limited nature of this funding, and sources to seek leverage, there are many opportunities that, with further work, investment and time, could be developed into commercialisation outcomes but simply do not progress.

In recent years the University of Adelaide has contributed over $3M to promising early-stage technologies from our Commercial Accelerator proof of concept fund, in addition to IP costs, and we have also leveraged this investment to secure millions more from venture capital, angel investors and commercially-focused support programs provided by Government.

A great example of what can be achieved is exemplified by our recent award of $1.3M under the Biomedical Translation Bridge Program for development of a novel vaccine for Zika Virus. The Commercialisation team worked with the research team to develop both a technical and commercial development plan, which included IP and funding strategies. Investing in the development of this project has supported the team to secure a commercial partner and a successful outcome to fund further development of the technology.

Since launching the Innovation and Commercial Partners Branch, we have seen a pleasing trend in performance under our new strategic approach over the first year, which includes:

- Providing over 20 education and training sessions.
- Over 60% increase in the number of new patent filings.
- Doubling the number of new technologies licensed.
- Doubling in our non-plant breeder rights royalty income.
- Working to support five new spinout companies based on University IP.
- Working with our portfolio of companies to secure over $17M in new capital.

The University has 43 active HMR technology licences to commercial partners (since 2007). Of these, 25 have been in the last five years. 59 HMR technologies have been disclosed to the University over the last five years, with 23 progressing to patent.

The University has also assisted with the establishment of eight other start-up companies (non-equity holding) to commercialise University HMR IP:

- ART Lab Solutions – media solutions to produce cattle IVF embryos.
- Carina Biotech – broad-spectrum CAR-T therapy to treat solid cancers.
- GPN Vaccines Pty Ltd – Pneumococcal vaccine.
- MiniProbes Pty Ltd – mini camera for brain surgery.
- OncoDx Pty Ltd – cancer diagnostic.
- Pentamer – cancer diagnostic.
- Trajan Nutrition Pty Ltd – Omega 3 and other nutrition tests.
- Eustralis Pharmaceuticals Pty Ltd – treat brain injury.
- ICMStem Cells - IVF media for human reproduction.
- ZeroScar – antimicrobial post-surgical coating.

2. PROCESS

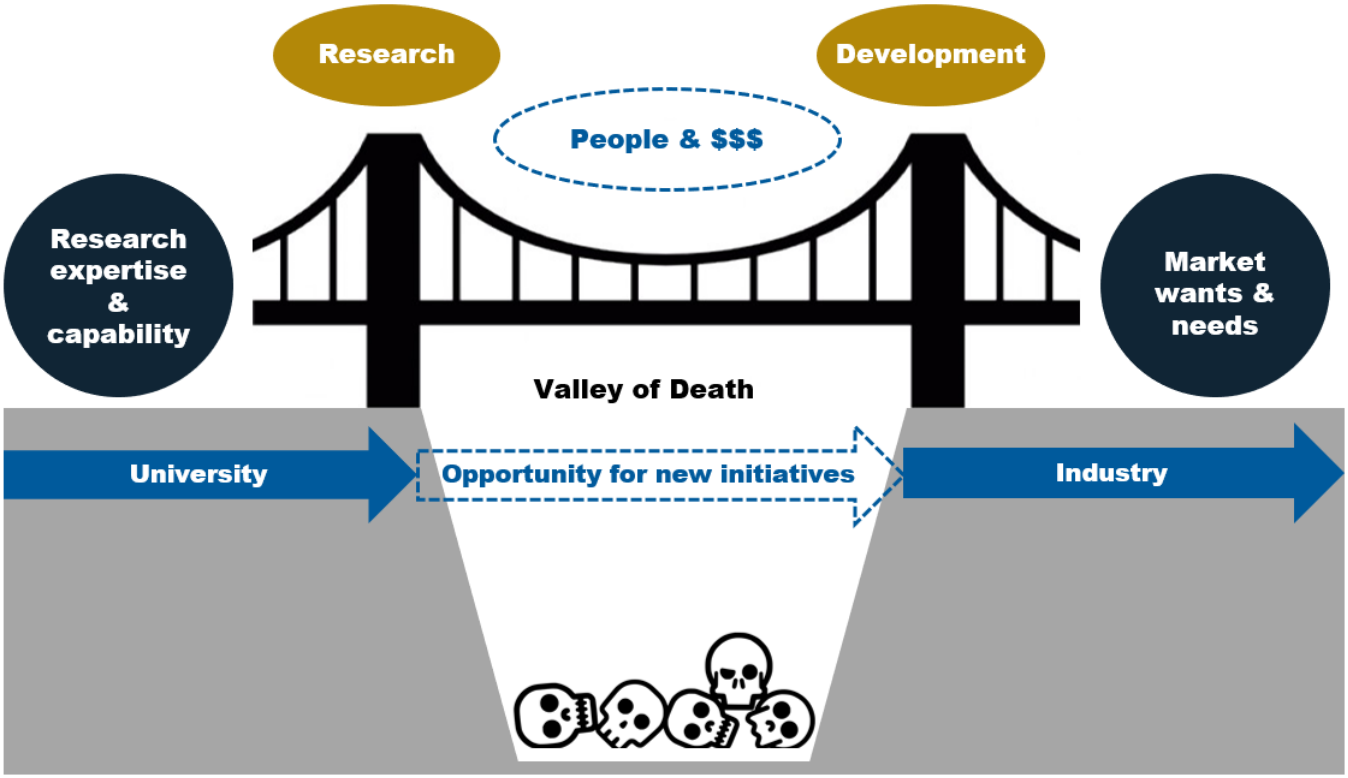
Commercialisation of new technologies from the health and medical sector can be a long and complicated process. It is well documented that the timeframe to go from 'bench to bedside', that is from the initial breakthrough in a research laboratory to a new therapeutic being approved by regulators and available to the

health care system can take between 10 to 15 years. There are also many reports highlighting the average cost of developing and launching new therapeutics to exceed an investment of well over US$800M – some reports put this cost at over US$1B.

If we take this from the 'bench' starting point, funding support is typically led by national competitive grants schemes such as the NHMRC and MRFF. There is also a strong level of support from various charities and not-for-for profits across the State and the nation.

This work will often yield interesting research outcomes that could have utility as new diagnostics, therapeutics or medical devices. The reality is that initial funding will enable research leaders to achieve 'proof of concept' or demonstration that, in *in vitro* or rodent animal models, the new discovery has clinical potential.

The challenge is funding the next step which is to demonstrate the efficacy of the new discovery in large animal models or first in human clinical trials. From a technology development perspective achieving this de-risks the



new discovery enormously.

However, this is also the point at which many new discoveries will fail where they cannot be scaled-up in manufacture and/or they fail to demonstrate efficacy as expected. This is often referred to as one of the 'valleys of death' in commercialisation as depicted in the diagram above.

Funding to bridge this 'valley of death' is extremely limited in Australia as this work does not look to make new discoveries and it is also not taking a new product to market – it is a critical step in validation. It is high risk and complex for companies to take projects on at this stage and venture investors are reluctant to fund this work due to the failure rate and, as such, the market does not support this step. It is and continues to be a gap in the system.

3. OPPORTUNITY FOR NEW INITIATIVES

The commission's draft report highlighted that SA does not have a program or initiative that directly supports HMR translation and goes further to highlight such examples from NSW, VIC and QLD initiatives. Further examples such as BioCurate and QEDDI are also referenced.

While the University invests in IP and proof of concept funds across the institution, the level of funding available limits the number of projects that can be supported to the 'development' phase.

The point at which traditional funding sources can progress research will only get them so far along the technology readiness scale (TRL), which is often far too early for equity investors. As such, there is a considerable gap that could be addressed through a revised grant funding initiative that is government led.

In the past, the SA Government supported Bio Innovation SA (BioSA) as a dedicated granting body to support growth of the biotech industry in SA and HRM commercialisation from the state's research institutions. This model was highlighted in our initial response to the Commission, and was also discussed in some detail as part of a follow-up round-table discussion with the Commission. In addition to grant funding, BioSA also had a team of dedicated Business Development professionals that worked effectively as intermediaries between research institutions and companies/investors to support and facilitate outcomes.

The funding that BioSA administered was specifically targeted at this 'valley of death' with the aim of supporting new technologies from SA to be 'investor ready', that is developed to the point where commercial partners or Venture Capital funds would be able to invest in further development to take these technologies to market. BioSA also provided grant funding directly into all three of the state's major research active universities to help support a greater number of patent filings.

Filing more patents, together with greater access to development funding helped to build a pipeline of significance. This led to new companies being created, and national and international companies attracted to the state for partnerships and access to the IP and research expertise in our universities.

We acknowledge and commend the existing investment by the state in the Research Commercialisation Start-up Fund, however, this funding is limited, is positioned to support all industry sectors (not targeted at HMR) and is not readily available to universities to bridge the 'valley of death'. Company structures are required to receive grants.

Overall, what is lacking is funding at scale to support more new research breakthroughs in the health and medical sector of SA, to get further down the development path to definitive clinical efficacy. Access to such funding would see more new research breakthroughs developed locally, reach the point of further investment by companies and/or investors to commercialise these outcomes and deliver new products to market.

In previous reviews of the state's ability to translate research outcomes from universities it has been proposed that a 'single commercialisation office', or the like, would be the solution. This is not the case. The creation and capturing of new IP is not the bottle neck, and trying to centralise this process would be overly complex in creating unintended legal complexities for the root cause of what we are trying to solve as a challenge in the state.

As rightly highlighted by the Commission in the draft report, access to capital and commercialisation skills are barriers. The BioSA model provided access to both.

There is merit in exploring a BioSA-like initiative that helps to provide these much-needed funds and access to 'matchmaking' Business Development support to advance and progress the outcomes of HMR in SA beyond what is possible (and funded by other means) at universities to the point where it becomes feasible for commercial partners and investors to take them on for further development.

The aim of such a renewed approach could be to:

- Make available greater proof-of-concept funding to the HMR sector in the state;
- Provide a greater opportunity to leverage university funded proof of concept funds;
- Attract and leverage investment into SA from interstate and overseas;
- Create a pipeline of technologies that could be commercialised through creation of new start-up companies and attract national and international companies to the state;
- Seed a broader local industry and provide an investable pipeline of opportunities for the SAVCF, MRCF and other HMR-focused investment VC funds;
- Provide experienced staff that can undertake 'independent' due diligence on projects to assess their commercial merit;

- Provide experienced staff to support 'matchmaking' for companies and investors from around the world to learn about SA developed technologies. This team of staff would;
    - develop a broad overview of the state's HMR outcomes;
    - identify opportunities for collaboration and joint commercialisation of IP; and
    - overtime, lift the level of experienced managers to run this process who will go on to lead new companies and investment funds in the state.

4. PRIVATE INVESTMENT OPPORTUNITIES

Further to this is access to investment capital. There is considerable interest from high-net worth individuals and family offices to invest in technology development. However, there is currently no platform or mechanism for them to do so in a sophisticated or coordinated manner. This opportunity goes beyond the current 'angel investor' activity in the state, where an opportunity exists to create a fund of scale for this purpose with support from Government and larger institutional investors.

5. BRIDGING FUNDAMENTAL RESEARCH WITH CLINICIANS AND THE CLINIC

A key element to successful HMR commercialisation is the involvement of clinicians (either through leadership or early engagement). Clinicians are on the 'front lines', they see first-hand the pain points for better patient care and outcomes. They know that if certain therapeutics, diagnostics, devices or procedures were in place or available, better outcomes would be achieved for patients and the healthcare system. From a commercial perspective, clinicians are the 'voice of the customer'. They highlight the unmet market need for where research programs can help to create new technologies and approaches.

Coordination and collaboration across Adelaide BioMed City (ABMC) will provide the opportunity to bring fundamental research closer to the clinic so that research programs can be directly informed through this level of input from the 'market'.

Investors realise the importance of this input and HMR related fund managers engage often and early with clinicians in the due diligence process to seek this market input.

6. STRUCTURAL AND PROCESS COMPLEXITIES

Clinical researchers can often have multiple appointments and affiliations. This can cause complexity in determining inventorship and ownership of IP.

In 2017, the University of Adelaide and AusHealth developed the 'Lite' agreement to establish a fair and equitable agreement to address IP ownership, benefit and future contribution. This agreement should be rolled out more broadly.

Greater coordination and alignment across the LHNs under a similar structure could be expected to make the process of dealing with IP rights across multiple employers more straightforward and transparent.

7. LINKING RESEARCH EXCELLENCE AND CLINICAL RESEARCH IMPACT

This submission aligns with and supports the broader proposal made by the University of Adelaide for the options presented by the Commission in the draft report.

Linking research excellence and clinical research impact is vital and underpins the investment and strategic initiatives being led by the University through the ICP Branch to support greater translation and commercialisation outcomes.

We thank the Commission for their time in considering this submission and would be pleased to work with the Commission to explore or further develop new initiatives to achieve greater outcomes for HMR translation and commercialisation.