THE KEY TO MED-TECH SICCES

With government grants of up to \$1m on offer, and exciting collaborative projects between industry and academia occurring, innovative biomedical devices and technologies are being developed, built and commercialised in Australia for the global market. By Carole Goldsmith.

Australia's industry growth centre for the med-tech, biotech and pharmaceuticals sector, MTPConnect is offering BioMedTech Horizons (BMTH) grants of up to \$1m to support development and commercialisation of cutting-edge new medical technologies. The BMTH program forms part of the Federal Government's Medical Research Future Fund and is administered by MTPConnect.

"Following a highly competitive Round 2, we have Round 3 of BMTH opening later this year," says Dr Dan Grant, CEO and MD of MTPConnect. "These grants can provide eligible SMEs (small and medium-sized enterprises) with up to \$1m of funding over a two-year period to progress medical technologies and devices through to proof-of-concept stage. This is a fully funded grant program that encourages, but does not require, matching funding by the applicant."

The proof-of-concept stage is the point where the idea for a new device is technologically feasible and it has the potential to secure further venture capital to assist in its commercialisation. Dr Grant adds that the BMTH four-year program has a total budget of \$45m with an expected program end in June 2022. Grant recipient projects in Round 1, completed in 2018, included: Indee Labs' microfluidic gene delivery device for immune cell modification and optimisation for clinical use; and Monash Vision Group's wireless Brain Machine Interface that offers the potential to bypass damage to nerves and neural pathways restoring function to affected areas of the brain.



Dr Dan Grant, CEO and Managing Director of MTP Connect.

With an extensive background in industry and university research, Dr Grant has been at the helm with MTPConnect for just over 12 months: "We have been very busy the past year working closely with companies, universities, state governments, Federal Government and industry organisations like AusBiotech and the Medical Technology Association of Australia (MTAA). This June we saw our largest ever Australian delegation at the Bio International Convention in Philadelphia, with well over 300 Australian companies and organisations participating."

MTPConnect has also grown rapidly in the past 12 months, expanding to 15 employees with a national presence encompassing offices in Melbourne, Sydney, Perth and Brisbane, as well as supporting projects and activities across the country.

When asked what med-tech companies need to do to grow and enter the global economy, Dr Grant cites the example of chimeric antigen receptor (CAR) T-cell therapy lab/manufacturing as an area providing enormous export opportunities for the Asian market. According to the Leukemia and Lymphoma Society's website, CAR T-cells identify cancer cells in a patient's body with the target antigens and kill them. The T cells are genetically engineered in the lab/manufacturing facility to find and kill the patient's cancer cells.

"Med-tech SMEs need to interact and learn from larger medtech manufacturers. Where disruption (such as advanced manufacturing and artificial intelligence) is occurring, Australian medical companies need to get involved."

BioFab3D@ACMD - Advanced bio-fabrication

One of MTPConnect's 2016 Project Fund recipients is BioFab3D@ ACMD, a robotics and biomedical engineering centre based at St Vincent's Hospital Melbourne. Having commenced just two years ago, BioFab3D today is abuzz with research and discovery. MTPConnect provided \$1.1m in support with matching industry funding from St Vincent's Hospital (lead applicant) as well as from Stryker Australia and the Universities of Melbourne, Wollongong, RMIT and Swinburne.

Equipped with advanced bio-fabrication technology such as 3D bioprinters and tissue bioreactors, BioFab3D is a collaboration between St Vincent's Hospital and the four participant universities: Melbourne, Wollongong, RMIT and Swinburne. On a walk through the facility, Centre Manager Dr Cathal O'Connell explains how PhD students and graduates from those institutions are working on bio-research projects at the BioFab3D labs.

"The BioFab3D centre brings researchers and clinicians together to develop and produce replacement body parts" He points to a high-end bioprinter, on which live cells can be printed to make artificial tissues. "It allows us to 3D print different types of cells as well as hard and soft material, allowing us to mimic the structure of bone and cartilage."

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Biopen and knee defect model. Image courtesy of BioFab3D



The BioFab3D centre brings researchers and clinicians together to develop and produce replacement body parts. Image courtesy of BioFab3D.

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Elsewhere in the tour, O'Connell points out of the window to a brick building in the grounds of St Vincent's Hospital: "That's the site of the proposed 11-storey Aikenhead Centre for Medical Discovery (ACMD), and BioFab is a stand-alone facility of it. Both Federal and State government funding has been allocated for ACMD with its estimated completion in the next five years."

One of BioFab3D's flagships projects, the BioPen is on display at the entrance to the centre, above a model of a knee joint. The BioPen is a hand-held device for printing stem cells in surgery.

"We have performed a short-term animal trial in sheep which showed promising results in repairing cartilage," says Dr O'Connell. "Now we want to see if our new treatment can lead to long-term repair, so we're about to start a year-long sheep trial. This project is moving fast. That (display) version has now been superseded by two updated prototypes."

Dr O'Connell explains that injury or even just normal 'wear and tear' can cause damage to knee cartilage, which the human body can't repair. This can lead to painful osteoarthritis and there are currently no effective treatments, except a knee replacement. The BioPen is designed to produce new cartilage in the patient's knee.

"We take the stem cells from a small pad of fat in the patient's knee joint and load them into the pen," says Dr O'Connell. "Then we use the BioPen to print out the patient's stem cells into the defect. If we can fill in this hole with the patient's stem cells and that can repair the cartilage, we might prevent osteoarthritis from ever developing."



BioFab3D is based at St Vincent's Hospital Melbourne.

According to an Arthritis Australia report, osteoarthritis is costing our healthcare system around \$2bn a year, says Dr O'Connell: "We have a \$900,000 grant from the MTPConnect BMTH fund for two years to develop the proof of concept and to bring the BioPen device to commercialisation."

The BioPen has been jointly developed by the University of Wollongong and St Vincent's Hospital. The project is led by the hospital's Director of Orthopaedics, Professor Peter Choong, along with Professor Gordon Wallace, Director of the ARC Centre of Excellence for Electromaterials Science (ACES), and Professor Simon Moulton from Swinburne University.

Also on display at BioFab is a waving robotic hand - another one of its flagship projects. The researchers working on the project include engineers, biologists and a trainee orthopaedic surgeon. Dr O'Connell says that the goal is to create a robotic hand that can be controlled by the patient's mind.

"The robotic hand comes with a special microchip which is inserted in the patient's limb," he explains. "So the goal is for the patient's cells to be growing on the tip of the microchip and their brain can control the hand. Although research is moving very fast on this project, it's a very ambitious project that could take 10 years to develop."

Trajan - University links drive global success

The story of Trajan Scientific and Medical started in 2011, with an idea generated around the home kitchen table between co-founders Stephen and Angela Tomisich, to develop a scientific and medical technology business to enrich well-being and benefit people. Both Stephen and Angela have scientific qualifications and had corporate backgrounds prior to starting Trajan.

Eight years later, Trajan's operations now span six manufacturing sites. It has a team of 450 staff worldwide, including senior leaders in their field and a deep technology pipeline poised for large-scale global commercialisation. The company's finances have grown steadily based on consolidation and growth of acquired businesses, with a current forward plan to 2022 that targets revenue to reach around \$150m.

"One of the drivers for Trajan is our collaborative business model, working with universities such as the Universities of Tasmania. Adelaide, Latrobe and Melbourne on projects," says Stephen, now Trajan's Group CEO. "One example of this is our on-site collaboration with the University of Adelaide as an R&D hub for innovative technologies and new devices for the global scientific and medical equipment markets. The Trajan Nutrition laboratories and joint venture partners are based at the South Australian Hospital Medical Research Institute. Trajan also has business-to-business commercial agreements with companies worldwide."



Trajan Scientific and Medical co-founder and Group CEO Stephen Tomisich with the hemaPEN device.

Given that Trajan was founded on the vision of being able to translate science to deliver human impact, Stephen adds: "Another reason that Trajan has grown so rapidly is that we have been acquiring companies. Over the past eight years, we have acquired six businesses in analytical and clinical science and invested in their production, R&D and infrastructure, resulting in strong organic growth."

Trajan's production facilities are located at its global headquarters in Ringwood, Victoria, plus in Penang, Malaysia, and at four sites across the USA. The Ringwood site is also the company's global R&D centre, while its commercial and distribution hubs in the UK, USA and Japan enable Trajan to service and supply its customers worldwide.

The Victorian Government has provided financial support for Trajan's expansion of the Ringwood manufacturing site. Stephen says that the expansion has already commenced: "We are acquiring new manufacturing equipment and building new custom-designed equipment in-house for our own use. With the expansion, Ringwood staff numbers are rising from 240 to 280."

Trajan's hemaPEN device, manufactured at the Ringwood facility, is expected to be registered by both the Australian Therapeutic Goods Administration (TGA) and the European Medicines Agency (EMEA) by the end of 2019, and by the US Food & Drug Administration (US FDA) early next year. The hemaPEN provides a minimally invasive and convenient sampling procedure for collecting four identical dried blood spot focused samples. Stephen advises proudly that the device came out of a university collaboration.

"In 2014, we set up an industry Australian Research Council Training Centre university collaboration (with the Universities of Tasmania, South Australia and Latrobe), in which we were the sole industry



The hemaPEN is manufactured at Trajan's facility in Ringwood, Victoria.

partner," Stephen explains. "The ARC provided \$2.1m towards the cost of the \$5.2m project. We had 10 work themes and recruited 10 PhD candidates and a team of post docs (nine of whom were from overseas) to work on the research projects.

"Each of the researchers spent 12 months on our site in Ringwood, being mentored, both academically and commercially. Because we were the only industry partner, we invested far beyond our commitment, removed barriers to progress, and achieved almost 50% yield of new products and technology - hemaPEN being one of them. We hear of other ARCs with multiple industry partners that achieve much lower translation rates."

According to Stephen, Trajan's micro biopsy device can sample 400 to 600 skin surface cells for a broad range of applications, including screening for melanoma: "Trajan worked in partnership with UniQuest and the University of South Australia in its development and production. We are in the final stages of confirming the business and IP arrangements, which will see Trajan as the exclusive commercial and production supply partner."

Meanwhile, in a four-way collaborative partnership, Trajan has also brought to market a fully automated powder-dispensing work platform. Stephen notes: "In the field of drug discovery, as our first customer put it, this is a game-changer."

So what's next for Trajan?

"We will achieve the next series of potential acquisitions, the effective commercialisation of new technologies and the continued refinement of global infrastructure," says Stephen. "All of this is aimed at benefitting people's health." AMT

www.mtpconnect.org.au www.biofab3d.org www.trajanscimed.com

