

International collaboration and partnerships are moving our life sciences sector forward, as BIO 2024 showcases Australian life sciences innovation globally.

Carole Goldsmith reports.

This June, the life sciences industry association AusBiotech partnered with MTPConnect, Australia's innovation accelerator for the life sciences sector, and led an Australian delegation of over 500 life sciences professionals and government representatives to the BIO 2024 International Convention in San Diego, USA. This is the world's largest and most comprehensive annual biotechnology and business partnering event. Held from June 3 to 6, BIO 2024 represents the whole biotech ecosystem, with more than 18,500 industry leaders attending from across the globe. This year, the Australian delegation was the largest group to attend this convention.

"The Federal Government has designated medical science as a national priority area for Australia," MTPConnect CEO Stuart Dignam says. "We have had fantastic support from the Federal Department of Industry Science and Resources, CSIRO and the NSW, VIC, WA, SA, and QLD State Governments."

"Our role at BIO 2024 was to bring everyone in the Australian delegation together. We created the BIO 2024 Australian Pavilion to showcase Australian life sciences companies at this global business event," says Dignam.

A Memorandum of Understanding (MoU) was signed on 4 June at BIO 2024 by Dignam and Biocom California Chief Executive Officer Joe Panetta to support the growth of life sciences companies. The Hon. Ed Husic MP, Minister for Industry and Science, who led Australia's presence at BIO 2024, was also at the Pavilion for the occasion. The agreement sees the two organisations working together on collaborative programs and events, providing key connections and in-market support, exchanging information on key issues and trends, and support for investment and trade missions between Australia and USA.

"The US is the world's biggest pharmaceutical and medtech market and Australia's largest two-way investment partner," advises Dignam. "This agreement with Biocom California will help open up new markets, plus commercial and collaboration opportunities for Australia's life science start-ups, SMEs and researchers."

MTPConnect also organised a US company tour for interested Australian delegates to attend ahead of the BIO 2024 week. "International markets are a priority for us and the biotech sector," says Dignam. Delegates visited life sciences companies in San

Diego including global science and technology leaders: J&J Innovation, Illumina, Novartis, and Truvian Sciences.

\$180m invested in 200 life sciences projects

MTPConnect operates accelerator programs to support cutting-edge medical technology, biotechnology, and pharmaceutical innovation. Since its inception, around \$180m has been invested in 200 projects. Founded in 2015 by the Australian Government, MTPConnect is a not-for-profit organisation established to assist in Australia's vibrant medical product sector growth.

"Medical science manufacturing is a focus for the Federal Government's National Reconstruction Fund," advises Dignam. "We take a holistic view of manufacturing as you have R&D at the beginning, through to product development and small runs manufacturing. You then have the safety, regulatory and efficacy approvals through the Therapeutic Goods Administration (TGA) and then you need to get the product launched and it goes to market. You cannot manufacture a medical product that has not been developed properly."



“We also need skilled people to deliver R&D and manufacturing programs. Our Researcher Exchange and Development within Industry (REDI) initiative is successfully developing Australia’s life sciences sector workforce.” Over the past four years, REDI has delivered training, mentoring and industry placements to more than 8,400 participants across Australia. The program has provided researchers with a diverse range of industry experiences and delivered 48 targeted training programs in skills like Good Manufacturing Practice (GMP) and Quality Management Systems (QMS). It has also provided innovation training for clinician entrepreneurs including nurses, allied health professionals and doctors. In May, MTPConnect was selected as an Industry Partner Organisation to support start-ups and small to medium enterprises under the Australian Government’s Industry Growth Program.

Most recently, it launched a joint AI accelerator with the Advanced Robotics for Manufacturing (ARM) Hub to help biomedical companies harness the power of data and artificial intelligence. Successful participants will receive up to \$50,000 in matched funding, upskilling in the use of AI and data analytics, access to affordable data management infrastructure, and help in developing a tech-ready workforce.

“Last year, we wrapped up the projects funded through our WA Life Sciences Innovation Hub voucher scheme, providing a major boost to medical products manufacturing in WA,” says Dignam. “Five WA-based companies were awarded a total of \$450,000 to accelerate their advanced manufacturing capabilities. Matched by the businesses’ total \$600,000 contribution, this initiative saw more than \$1m invested to accelerate WA innovation projects requiring advanced manufacturing capabilities, driving job creation and economic growth.” When Dignam first joined MTPConnect in 2019 to lead corporate communications, the organisation had six staff, working out of an office at Monash University in Melbourne. Five years on, the organisation has grown to handle the increased demand for its funding programs and services, with staff located at its head office in Melbourne and state hubs in Perth, Adelaide, Brisbane, and Sydney. “We have a terrific MTPConnect team across Australia and we invite life sciences companies to contact us to discover more about what we have on offer,” says Dignam.

Additive Surgical

Adelaide spinal implant manufacturer Additive Surgical CEO and Co-founder, Gibran Maher says that MTPConnect does a fantastic job in championing the growth of the Australian med-tech sector. “The MTPConnect, Adelaide intermediary program is based locally, close to us at Kent Town, an inner Adelaide suburb,” said Maher. “It works with companies, universities, medical research institutes, health professionals and funders, to strategically build capacity, connection, and opportunity.”

Additive Surgical is the first Australian company to manufacture “off the shelf” 3D printed titanium novel spinal implant technologies. “The core products we manufacture are spinal fusion cage devices,” Maher advises. “These are mainly used for spinal degenerative and deformity correction. One titanium implant replaces the worn disc and restores the spine’s height and balance.”

Established in 2020, the company is located at Colab.Tech in Kent Town. “We have created a med-tech hub here as Additive Surgical is co-located with five other companies on-site: Actis Medical, Evolution Surgical, BFF Surgical, Civitas Medical and Atlas Orthopaedics. Flinders University is our primary academic collaborator.”

“We are also working very closely with Flinders University’s Medical Device Partnering Program and its Medical Device Research Institute, which also have a presence at the Colab.Tech hub,” says Maher. “We provide important internships and employment pathways for Biomedical engineering graduates. Currently, we have a Flinders University Biomedical Engineering Masters student and a PhD student engaging with us on projects.”

Additive Surgical has been manufacturing spinal implants for the past five months and is already exporting to the NZ markets. We have been working closely with a group of Australian and NZ spine surgeons and our engineers to design and develop new implants.

“It is easier to enter export markets than to sell our products in Australia,” says Maher. “Unfortunately to supply into Australia, the pathway through the TGA Conformity Assessment, is lengthy and expensive compared to export markets, which makes launching locally difficult.”

Continued on next page

Continued from previous page

The TGA's site reports that conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device (including IVD medical devices) complies with the Essential Principles which set out safety and performance requirements. "Commercially we will launch in many markets before we can launch in the Australian market. This is where I believe that local medical device manufacturers need some policy support from our regulator to fast-track local med-tech manufacturing innovations."

Additive Surgical supplies its medical products to global distributors. As well as the spinal implants, the company is also developing foot and ankle implants, CMF (cranio-maxillofacial) implants and other implants. It uses GE Additive Concept Laser M2 Series 5 machines to manufacture its spinal implants. Maher says that these machines have reliable systems and provide fine resolution and detail.

When asked if there are other companies in Australia or globally making spinal implants, Maher responds: "3DMorphic is manufacturing patient specific spinal implants in Sydney. The team there are very talented and has pioneered patient-specific technology which is fantastic for the Australian spine manufacturing ecosystem. Globally there are several manufacturers in the spinal implant space."

Additive Surgical is a partner with Tsunami Medical in Italy, one of the global leaders in innovative spinal implant technology. "Tsunami Medical has some of the best spinal implant intellectual property (IP) globally and we are working closely with them complementing each other's skill sets," Maher says. "The global market presence that Tsunami Medical has achieved is worthy of applause and Additive Surgical is continually upskilling and learning from its staff with their decades of global experience."

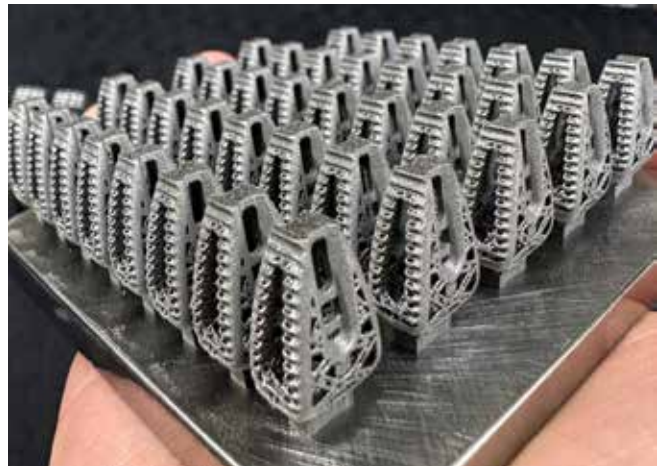
This July, Additive Surgical announced a partnership with UK company Osteotec. Maher advises that his company is working with Osteotec to manufacture a range of off-the-shelf spinal implants for the UK market: "Different markets have different philosophies around spine operations and Additive Surgical is partnering with leading distributors globally to address these specific market needs and taking a clinician centric approach to manufacturing spine technology."

Ongoing clinical refinement for innovative new medical implants

Additive Surgical continues in its clinical research stage for new innovative medical implants developed through its quality and regulatory system. "We are further developing some of our core products and proceeding with a range specific to certain regions. Being an SME, we must capitalise on our fast-moving and agile nature." When asked if the company receives Federal or State Government grants to help develop implant prototypes, Maher responds: "No, we have not received any grants or funding from the government to develop our products. The turn-around of some of the available grants presents some challenges.

"We are moving as quickly as possible to get more products to market and some of the grants can take up to 12 months to receive an outcome on, which makes aligning the grant with the needs of the business very difficult. We are 100% private industry driven and funded and what we are doing is truly unique."

The US International Trade Administration reports that around 85% of Australian medical devices and diagnostics are imported, while nearly all medical technology products manufactured in Australia are exported. The three major suppliers of medical imports are the United States, China, and Germany. The United States is the largest supplier of medical products, accounting for 31% of Australia's imports.



"Australia is consistently in the top five countries in the world for IP generation," says Maher. "This is fantastic and we punch above our weight. However, we fail to translate this strength into commercialisation. Often our IP ends up overseas, only for Australia to then import med tech products back into Australia that were based on Australian IP."

"However, Australia is invariably in the bottom three countries in the OECD for commercialisation translation of IP, depending on which report and measure you look at. The take-home message is that Australia is great at R&D and IP generation, however, it fails dismally at translating this to local manufacturing and exporting high-value med tech products. If there were regulatory support and streamlined pathways from our regulator for Australian-manufactured medical devices, this would provide significant benefits to local med-tech manufacturers. If the TGA approval could gain reciprocity approvals in other countries, this would assist sovereign capability."

Many other OECD countries have comprehensive policies and pathways for local IP to be manufactured, launched, and reimbursed in their local market first, providing an ideal platform for export growth. "Our company's future is to keep moving onwards and upwards. We are working with global clinicians to invent new medical devices and bring these to market."

Work-life balance is also essential to Maher, and he admits that it is tough managing the balance of family and business. "However, one of the lessons that I have learnt in business, is that although I travel about 50% of the year, when I am with my family, I need to be fully engaged and present. Doing projects with my sons like a recent tree house we built together is such a fulfilling part of the life I prioritise." **AMT** additive-surgical.com mtpconnect.org.au

Portable sensor tech

Queensland-designed tech could help turn the tide on ovarian cancer.

It is a challenging disease to spot and claims the lives of 1,000 women every year. Still, researchers at the Australian Institute for Bioengineering and Nanotechnology (AIBN) are hoping to turn the tide against ovarian cancer with a device that can detect it as early as possible. Over the next five years, AIBN nanodiagnostics specialist Dr. Mostafa Kamal Masud will use a \$750,000 Next Generation Cancer Research Fellowship from Cancer Council Queensland to develop a low-cost, benchtop device that picks up the earliest indicators of ovarian cancer in a patient's blood, while also precisely monitoring the disease through treatment.

Detecting ovarian cancer early is crucial for patient survival but extremely difficult given symptoms are often vague and resemble other illnesses, and current screening tests are ineffective.

This means of the 1800 or so Australian women who are diagnosed with ovarian cancer each year, 70% have already reached an advanced stage of the disease. Dr. Masud said he hopes to improve the odds with new portable sensor technology that steers patients towards preventative care options as soon as possible.

"The testing methods for ovarian cancer that do exist are quite expensive and tedious, which makes screening very tricky," Dr. Masud said. "And, of course, the longer something like this is left undiagnosed, the more serious the problem becomes. "That is why many people diagnosed with ovarian cancer have already reached a point where it has spread to other parts of their body."

Through his five-year fellowship, awarded through the National Health and Medical Research Council's Investigator scheme, Dr. Masud will develop novel mesoporous nanostructures capable

of automatically isolating, purifying, and simultaneously detecting cancer biomarkers in a patient's blood. Dr. Masud said this biosensor technology would be designed as a compact, portable, and simple device to be operated out of a GP's office.

This will make it suitable for communities that might not have the technicians and equipment that are usually required to amplify cancer biomarkers and interpret the data. The project is also a deeply personal one for Dr. Masud, following the untimely loss of his aunt to ovarian cancer, and the loss of his grandmother to colon cancer due to late-stage detection.

"I have seen how cancer affects people and their families, and their strength and stories of hope inspire me," he said. "This motivates me to work on finding solutions for this tough disease."

Cancer Council Queensland chief executive officer Andrew Donne said he was proud that the Next Generation Cancer Research Fellowships program has enabled researchers like Dr. Masud.

"Replacing the ACCR grants scheme, these fellowships fund early-career cancer researchers – like Dr. Mostafa Kamal Masud – who are on the frontline of clinical innovations in cancer detection and treatment," Donne said.

"Thanks to our generous donors, Cancer Council Queensland is proud to fund local researchers like Dr. Masud, who will go on to make global breakthroughs. With their innovative approaches and deep personal commitment to improving patient outcomes, these recipients represent the future of cancer research, and we are proud to provide the necessary funds to support their life-saving work."

uq.edu.au

Experience the flexibility of an ERP system that understands the unique needs of your manufacturing business.