Vanufacturers MONTHLY



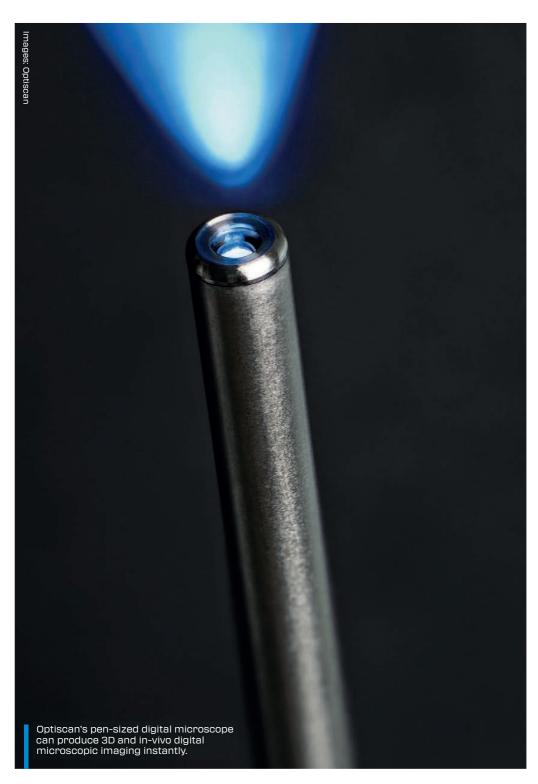
Medical Imaging Technology

Cover Series: RSM

Decision Maker: Premcar

Manufacturing an alternative to invasive diagnosis

Optiscan CEO Dr. Camile Farah delves into the company's technology and capabilities that have positioned it on the path to becoming a global leader in real-time digital microscopic imaging. *Jack Lloyd writes*.



ounded in 1994 by Peter Delaney and Martin
Harris, Optiscan is an Australian-based global
medical technology manufacturer that aims to
transform diagnostics and surgical decision-making
with live cellular imaging. The company's pen-sized
digital microscope – that is built upon proprietary
miniaturised technology – can produce 3D and invivo digital imaging instantly.

"As the manufacturer of the only fully integrated, miniaturised confocal laser endomicroscopy system, Optiscan enables real-time cellular imaging," said CEO and managing director of Optiscan Imaging, Dr. Camile Farah. "Our technology provides a high-resolution imaging solution that enhances precision and efficiency across a range of surgery, pathology, and preclinical settings."

By doing this, Optiscan technology can detect diseases earlier and improve patient outcomes by reducing the need for a traditionally complex and costly biopsy or slide-based pathology.

"This innovation is reshaping how tissue is examined in areas such as cancer detection, surgical guidance, and scientific research," said Farah. "While traditional methods require tissue biopsy, fixation, transportation, processing, and staining, Optiscan's technology digitally visualises living tissue at the single-cell level at point of care, enabling faster and more accurate decision-making."

It was the potential impact of the company's technology that, in 2021, attracted the attention of now CEO and managing director, Farah. Four years later, he continues to bring his experience – of over two decades in pathology, oncology, dentistry, medicine and medical research – to the company.

"Since 2021, I have worked with Optiscan to transform the company into a pioneer in digital health solutions, with a portfolio of hardware and software products," he said.

Covering all bases

Beginning as a research project at Monash University – where scientists discovered a way to shrink complex microscope components using optical fibre technology – Optiscan's suite of technology offerings has continued to evolve.

"This revolutionary technology has now been tailored and designed specifically for use in surgery,



pathology, life sciences and beyond," said Farah. With a variety of systems, Farah acknowledged the functionality and purpose of what each Optiscan product brings to different applications.

This begins with InVue, a surgical imaging device that uses sterile probes that were designed with a surgeon's input. It targets an array of surgical applications in operating rooms. This system provides clinicians with imaging of tissue during surgery to enable high-resolution cellular visualisation at the point of contact.

"InVue is designed to be used in a variety of surgeries such as breast as well as head and neck, with additional applications to be introduced as clinical evidence expands," said Farah.

Additionally, InVue is designed to enhance precision in tumour resection by allowing surgeons to assess margins in real time and reduce reliance on frozen sections.

"This capability minimises the need for revision surgeries by ensuring more complete tumour removal, ultimately improving surgical outcomes and efficiency," said Farah.

Next, Optiscan's pathology imaging device, InForm, is manufactured to image ex-vivo tissue samples in pathology labs, including fresh or fixed tissue. This model is a single probe type system, mounted on an articulating arm. It also has an inbuilt macro video camera for further guidance.

"The InForm enables faster, more efficient workflows for pathologists and lab technicians," said Farah. "It is designed to allow seamless adoption into digital pathology systems, eliminating traditional time-consuming processes."

Covering another vertical of the medical industry,

Optiscan's InVivage is the company's dental imaging device that features shorter probes tailored for oral use.

InVivage supports the early detection of oral cancer by providing high-resolution imaging of the oral mucosa

"This capability reduces unnecessary biopsies by allowing immediate assessment of suspicious tissue," said Farah. "It provides real-time, non-invasive imaging of oral tissues, allowing dentists and oral specialists to assess potential lesions instantly," said Farah. "It also enhances precision in oral surgery, ensuring clear margins during lesion excision."

Finally, the company's preclinical and life sciences research imaging device, ViewnVivo, provides imaging in live animal models and tissue samples. With a range of probes, contrast agents and dyes, Farah said this system provides flexibility for different research applications.

"It helps researchers study cellular dynamics, disease progression, and treatment responses in real time, making it particularly valuable in longitudinal cancer research, immunology, and drug development," he said.

These products combine to form a portfolio that Farah believes stands apart from any other microscopic imaging technology available today.

"It offers the highest imaging resolution – $0.55\mu m$ – among competing products and it's the only technology that can dynamically adjust the focal depth in real time, ensuring clearer and more precise images," he said.

Farah adds that there are more products and applications to come in the veterinary, gastrointestinal and robotic surgery domains.

Growing a capability to match such an ambition

Despite a clear evolution since the company's foundation, Optiscan has maintained a local production capability with all its instruments being manufactured and assembled at its headquarters in Melbourne. Victoria.

"We currently manufacture approximately 50 systems and associated probes per year, but we have established efficient manufacturing processes to scale our production numbers when required," said Farah.

At this facility, the company's production team consists of dedicated precision technicians, engineers, production managers and R&D engineers. Farah said these operations also see the use of components and advanced manufacturing equipment to ensure precise manufacturing.

"We source electronic boards, metal components, and other parts primarily from partner companies in Victoria," said Farah. "We utilise advanced equipment, including fibre splicers, laser welders, microscopes, curing ovens, optical power meters, and a range of custom-built instruments tailored for precision manufacturing."

Despite a growing sovereign presence, Optiscan is also expanding with manufacturing support, product development, and business development staff in multiple regions. Alongside staff scattered in Melbourne, Perth and Sydney, the company also has a regional office in Rochester, Minnesota, U.S and presence in Asia and Europe.

"Our Rochester office focuses on clinical and regulatory affairs, in addition to a business development manager working across North America," said Farah. "Also, our European presence

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is expanding, with an outsourced business development and sales operations team supporting market growth.

"In Asia, Optiscan works with key distribution partners to support adoption in China."

Ensuring quality is sustainable

To ensure the consistency of products that are breaking into a global audience, Farah said Optiscan has numerous quality assurance and control [QA QC] measures in place. This includes company positions that are dedicated to procurement, quality assurance, and regulation, and inspection processes at every stage of production.

"Our rigorous quality control measures – from incoming material inspection to in-process quality control and final product testing – ensure our products meet the highest industry standards, in compliance with ISO 13485 and FDA requirements," he said. "Our Corrective and Preventive Action [CAPA] system helps us address any potential issues, while Change Control Management ensures product updates maintain safety and efficiency."

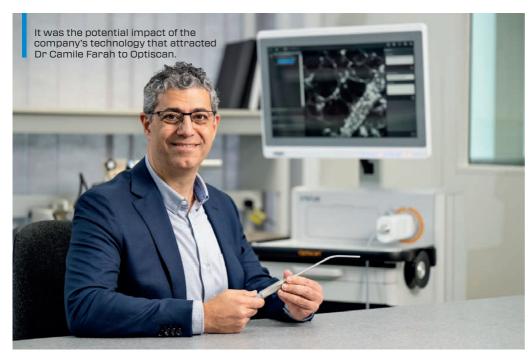
The company also monitors supplier performance, conducts internal audits, and embraces continuous improvement to maintain precision and reliability.

Yet, Farah said Optiscan are equally as committed to the safety and environmental sustainability of its products, represented through a sustainability model included in the company's environmental, social, and governance [ESG] principles.

Optiscan's digital pathology solutions reduce waste by providing a biopsy and slide-free alternative and by minimising transportation emissions that are associated with having to send physical samples to laboratories. The company also represents a commitment to sustainability by prioritising what Optiscan currently manufactures approximately 50 systems and associated probes per year.



Invue is Optiscan's surgical imaging device that is designed for use in operating rooms by clinicians.



Farah referred to as local procurement.

"We practice local procurement to lower our carbon footprint, power our manufacturing and on-site operations with renewable energy, and implement recycling initiatives to repurpose assembly parts for training purposes," he said.

Overcoming challenges to purse future innovation

Along the way to what now seems like a well-oiled machine, Optiscan, like any pioneering company, faced challenges. Despite this, Farah said that ultimately, "adaptability has been key". He said challenges that were tricky, but were ultimately overcome, ranged from finding specialised suppliers, to talent acquisition, to even regulatory affairs.

"Finding specialised suppliers has been difficult, so we've built strong partnerships and adjusted designs, when necessary. Talent acquisition has also been a challenge given how highly specialised our technology is. We've tackled this by investing in internal training and upskilling," he said. "On the regulatory front, shifting global standards demands continuous attention, and as an Australian company working across global time zones. We've refined our processes to stay aligned with overseas partners and regulators."

Farah said in the long run, these challenges have only helped the company to become more focused and resilient. For a company that has overcome challenges to develop such innovative technology, he said the response from the medical and research communities has been positive.

"They are excited by the ability to access live, highresolution microscopic imaging exactly when and where they need it," he said. "The enthusiasm we're seeing reflects the impact our technology could have on the future of medicine."

In the not-so-distant future, Farah said that Optiscan plans to unveil a solution catered specifically to veterinary medicine that will "bring the company's technology to a new and unique clinical field".

Longer term, Farah said that the company is also focused on further miniaturising its microscopes to be able to expand into endoscopic applications. It is also making great progress in AI-driven image analysis to enhance how people interpret imaging data.

"Later this year we will be unveiling our telepathology streaming software platform which



InForm is a pathology imaging device manufactured to image ex-vivo tissue samples, including fresh or fixed tissue.

allows remote viewing and consultations of images captured on our devices anywhere in the world," he said. "This will bring pathologists into the centre of the operating room and bridge the gap between surgery and pathology for better patient outcomes."

Moving forward, after five to ten years of further innovation and experimentation, Farah believes Optiscan will become a true global leader in real-time digital microscopic imaging.

Advantages of Optiscan technology

- Early detection and management of disease.
- Immediate clinical decision-making during diagnostic and surgical procedures.
- Non-invasive imaging, reducing the need for unnecessary biopsies.
- Improved patient outcomes in human and veterinary applications.
- Streamlined pathology workflows, replacing slide-based histology with digital imaging.
- Ethical, cost-effective, and high-quality longitudinal studies in animal research.
- Reduction in high cost of curative medicine and associated procedures.

"Our goal is to make our high-resolution, in vivo imaging platform a standard tool across clinical practice – revolutionising precision surgery and digital pathology," he said. "As adoption grows globally, we see Optiscan playing a key role in shaping the future of healthcare."

Applications of Optiscan technology

- Enabling real-time collaboration between clinicians and pathologists in hospitals and medical facilities.
- Supporting precision surgery with real-time tumour margin assessment for surgeons and oncologists.
- Enhancing digital pathology workflows with instant cellular analysis in pathology and diagnostic laboratories.
- Providing high-quality care for companion animals and the wider animal sector for veterinary practitioners.
- Providing high-resolution imaging for ethical and efficient animal studies advancing translational research with live-cell and in vivo imaging medical researchers.

