

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

13 August 2025

Imagion Initiates Collaboration with Wayne State University to Develop Advanced Molecular Imaging Capabilities to Enable Al Cancer Diagnostics

Imagion Biosystems (ASX: IBX) (**Company** or **Imagion**), a company dedicated to improving healthcare outcomes through the early detection of cancer utilizing its proprietary MagSense® imaging technology, is pleased to announce it has entered a collaborative service agreement with industry leading MRI experts at the Wayne State University School of Medicine (WSU).

This new collaboration bolsters the existing agreement the Company has with Siemens Healthineers, the world's leading manufacturer of MRI equipment.

Key objectives of the WSU/IBX collaborative service agreement include:

- ➤ Determining the lowest concentration (dose) of the MagSense® imaging agent that could achieve the needed detection sensitivity for clinical utility;
- Establishing Magnetic Resonance Imaging (MRI) sequences and protocols that are optimized for MagSense® molecular imaging agents;
- Collaborating with Imagion and Siemens to transfer the optimized protocols to clinical sites for use in the planned MagSense® HER2 Phase 2 study; and
- Employing quantitative imaging techniques that could yield AI compatible image data and improve and democratize diagnostic accuracy.

WSU's Dr. Mark Haacke and Dr. Sagar Bush have pioneered the use of MRI in quantitative imaging and have had a long-standing relationship with Siemens. Equipped with Siemens' top-of-the-line scanners, WSU will focus on quantitative imaging techniques compatible with Siemens and other commercially available MRI scanners. By combining advanced quantitative imaging with the MagSense® imaging agents the Company aims to enable AI-based interpretation and to deliver more accurate and precise data for cancer detection and patient care.

The Company, with the support of Siemens, plans to use the optimized sequences developed by WSU in the upcoming Phase 2 clinical study of the company's HER2 breast cancer imaging agent.

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"We are very excited to have the collaboration and support of Dr. Haacke's group," said Ward Detwiler, Chief Business Officer of Imagion Biosystems. "Dr. Haacke literally wrote the book on MRI, which anyone in the MRI space will recognize as required reading. Combining their knowledge and expertise in quantitative MRI, with the specificity of our targeted MagSense® imaging agents, we believe we can significantly improve the diagnostic utility of the images by introducing quantitative data to enable precise, AI-based detection."

Quantitative MRI Pioneer Dr Mark Haacke

Dr. Haacke has been a pioneer in the field of quantitative MRI for decades, and the collaboration with his team will lay the foundation for future automated analysis of MagSense® images using AI. By implementing quantitative MR imaging techniques, the specific signature of MagSense® imaging agents will be uniquely detectable in affected tissue. Applying advanced post-processing techniques and AI interpretation to these images, MagSense® has the potential to enable not only automatic detection and differentiation of normal vs. cancerous tissue, but also enable improved staging, tracking, and treatment monitoring.

"Imagion's MagSense® imaging agents are a very exciting development for the medical imaging field as it finally brings molecular specificity to MRI," said Haacke. "I have spent decades developing quantitative, high-resolution imaging to identify new biomarkers and explore disease etiology. Working with Imagion is a natural extension of that work, adding increased specificity to the already high resolution and sensitivity of MRI and powering the future of AI based diagnostics."

WSU, Siemens and Imagion Collaborations – Advancing AI Enabled Quantitative Molecular Imaging

Conventional MRI, while producing excellent images of soft tissue, is qualitative by nature, relying on subjective interpretation by radiologists to make a diagnostic determination based on differences in contrast of the various tissues. As a result, imaging findings still require confirmatory biopsies in order to achieve diagnostic certainty. This presents particular challenges in the analysis of small lesions or in the early stages of disease progression. This lack of specificity is a fundamental hurdle for radiologic AI models, which are limited in their diagnostic capability due to the subjectivity of the training data and the accuracy of the readers' interpretation.

Quantitative imaging, on the other hand, provides specific information about tissue characteristics on a pixel-by-pixel basis. These imaging techniques can measure precise amounts of elements such as iron, water, calcium or fat in a given region of interest. Combining quantitative MRI sequences with the MagSense® imaging agent may solve one of the key barriers holding back AI diagnostics, as the unique quantitative signature of MagSense® particles bound to cancer cells can automatically be differentiated from healthy tissue. This holds the potential to not only enable earlier and more accurate diagnosis of cancer but also removes bias between readers and expands access beyond the walls of specialized academic medical centers. Incorporating these quantitative sequences into the MagSense® Phase 2 study will help accelerate the development of AI diagnostics by providing early training data to help refine AI models.

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Authorization & Additional Information

This announcement was authorized by the Board of Imagion Biosystems Limited.

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About Imagion Biosystems

Imagion Biosystems is developing a new non-radioactive and precision diagnostic molecular imaging technology. Combining biotechnology and nanotechnology, the Company aims to detect cancer and other diseases earlier and with higher specificity than is currently possible.

For more information, visit https://imagionbiosystems.com/investor-hub/

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About the MagSense® Imaging Agent Technology

MagSense® technology is a new class of MRI imaging agents that improves cancer detection compared to conventional imaging technologies by adding molecular specificity without using radioactivity. MagSense® agents will be the first imaging technology to use targeted magnetic nanoparticles to tag and detect cancers allowing for visualization using MRI. This new class of imaging agents does not use ionizing radiation or radioactive tracers and improves how medical imaging can be used compared to conventional imaging methods which only identify a region of interest using anatomical or morphological features but cannot differentiate benign tumors from malignant cancer. Imagion has developed MagSense® imaging agents for three different types of cancer. The lead product has completed a Phase 1 study for the detection of nodal metastases in HER2 breast cancer and is now being advanced to a Phase 2 study. Two additional agents for prostate cancer and ovarian cancer are ready for IND-enabling studies before advancing to Phase 1 studies.

About Dr. E. Mark Haacke

Dr. E. Mark Haacke, PhD, is the Co-Director of the MR Research Facility at Wayne State University, a Professor of Radiology and Biomedical Engineering at Wayne State University, a Professor of Radiology at Loma Linda University in California, and a Professor of Physics at Case Western Reserve University in Cleveland, Ohio. Dr. Haacke is an original pioneer of the MR angiographic imaging, fast imaging and cardiovascular imaging, and has developed a powerful new method for imaging veins, micro-hemorrhaging and iron called Susceptibility Weighted Imaging (SWI). This work has been extended to quantifying iron content using the technology quantitative susceptibility mapping (QMS). He has focused on studying the role of magnetic field variations in the human body and applying the results to clinical translational research.

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About Dr. Sagar Bush

Sagar Buch, PhD is an Assistant Professor (Research) with the Department of Neurology at Wayne State University, School of Medicine. Dr. Buch has more than 10 years of experience implementing advanced magnetic resonance imaging (MRI) quantitative techniques. Dr. Buch's background and expertise has been in MRI physics, development and optimization of MR-based protocols for quantitative imaging such as quantitative susceptibility mapping (QSM). He is experienced in MR angiography/venography, susceptibility weighted imaging (SWI) and signal processing for studying the cerebral microvasculature with an eye toward their effects in normal aging, as well as in neurodegenerative and neurovascular diseases.



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