Company Announcement

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

1 December 2025

Positive Final Results of Wayne State Collaboration Drives Completion of Phase 2 Study Protocol for IND Submission to FDA in December

Key Highlights:

- **MagSense® HER2 Breast Cancer Investigational New Drug application remains on-track for FDA submission in December 2025**
- **Compelling results from the Wayne State collaboration strongly support the scientific rationale for the MagSense® Phase 2 trial design for HER2 breast cancer patients**
- **Strategic trial partners now in place, preparing for commencement of the Phase 2 clinical trial in early 2026**

Imagion Biosystems (ASX: IBX) (**Company** or **Imagion**), is dedicated to improving healthcare outcomes through the early detection of cancer utilising its proprietary MagSense® imaging technology on a variety of life-threatening cancer indications. The Board is pleased to provide shareholders with an important update on its progress towards commencing its MagSense® Phase 2 Clinical Trial for HER2 Breast Cancer in early 2026.

The Company has recently completed key operational milestones that will now enable it to complete its scheduled lodgment of an Investigational New Drug (IND) submission in December 2025 with the US Food and Drug Administration (FDA). Following the IND submission and review by the FDA, the Company is planning to commence its MagSense® Phase 2 HER2 Breast Cancer clinical trial at various hospitals in the USA during Q1 2026.

"I am thrilled with tremendous progress we've made recently towards completing the IND submission in December and preparation for our planned Phase 2 clinical trial in HER2 breast cancer early in the New Year," said Executive Chairman Bob Proulx. "Our recent progress marks a significant step forward in addressing a significant unmet need for this aggressive type of breast cancer. This progress reflects our commitment to creating shareholder value by delivering innovative solutions that can make a real difference for patients and their families."

Imagion Biosystems Limited
ASX: IBX ACN 616 305 027
Suite 2, Level 11 385 Bourke Street Melbourne VIC 3000
imagionbiosystems.com | investor@imagionbio.com

MagSense® Phase 2 Clinical Trial Design for HER2 Breast Cancer Finalised

Completion of the strategic collaboration with world leading MRI experts at Wayne State University (WSU), has delivered highly encouraging results that strengthen the foundation of the planned Phase 2 Clinical Trial. This breakthrough has enabled the Company to include a strong scientific rationale and justification for using a lower dose of the MagSense® HER2 Imaging Agent in the IND submission than was used in the previous Phase 1 study.

This is an important step for MagSense® HER2 Breast Cancer Phase 2 Clinical Trial as it addresses patient safety and trial efficiency. Additionally, the WSU researchers were able to establish optimised MRI sequences for the reduced imaging agent dose while still achieving the expected detection sensitivity needed for determining if the cancer has spread to the lymph nodes (known as nodal staging). The optimised MRI sequences will be deployed to the clinical investigative sites with the support of Siemens Healthineers under the Company's existing collaboration with the world's leading MRI provider.

The impact of the WSU program on the study design includes:

1. Reducing the dose of MagSense® HER2 Imaging Agent to one-third that used in the Phase 1 study. In the Phase 2 study, determining if a lower dose is effective will be an important step for clinical development as it impacts both patient safety and manufacturing/costs considerations.
2. Selection of optimised MRI sequences that could improve the clinical workflow and reduce scan times thereby reducing barriers to future commercial adoption.
3. Inclusion of quantitative imaging techniques that, when combined with the use of MagSense® molecular imaging agents, could lead to AI-ready imaging data and the implementation of AI diagnostic algorithms for the radiologists.

FDA Submission of IND for MagSense® HER2 Phase 2 Clinical Trial on Schedule for December

The clinical trial supply timeline for the MagSense® HER2 Imaging Agent remains on track to support the IND submission and the planned Phase 2 trial. The Company anticipates that the IND application will be submitted to the FDA during December 2025, and pending FDA acceptance of the IND, the Phase 2 study is expected to commence in early 2026.

These results from the WSU research program, together with the input from the study's principal investigator and study advisors have now been incorporated into a final Phase 2 study protocol for the final draft IND submission. Designed in three parts, the study plans to start with an initial cohort of subjects to collect additional safety data, as requested by the FDA. The reduced dosing regimen and optimised imaging protocol will then be evaluated in a second group of subjects before proceeding to a larger cohort of subjects to establish diagnostic performance.

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The MagSense® Phase 2 Clinical Trial for HER2 Breast Cancer is expected to be completed in 18-24 months upon commencement of the program, following acceptance of the IND by the FDA.

Strategic Trial Partners Selection Process Commenced

To ensure the planned Phase 2 study can initiate as quickly as possible following acceptance of the IND application by the US FDA, the Company has completed a rigorous vendor qualification process and is pleased to confirm that all USA based strategic trial partners required to manage the study have been selected. These experienced collaborators will play a crucial role in site identification and contracting with the clinical sites, supporting clinical investigators with participant recruitment, and overseeing the logistics and data analysis to ensure full compliance with Good Clinical Practices. This positions the Company in a strong position to commence its Phase 2 Clinical Trial launch in early 2026.

Authorisation & Additional Information

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

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About Imagion Biosystems

Imagion Biosystems (ASX: IBX) is a clinical-stage, medical imaging company dedicated to transforming how cancer is diagnosed and treated. The company produced and is developing clinical applications for MagSense®, a first-of-its-class MRI imaging agent that enables clinicians to detect cancer earlier and with greater precision. Advancing molecular MRI, the company is using non-radioactive, bio-safe magnetic nanoparticles to improve diagnostic certainty for a broad range of applications, including HER2+ breast cancer, prostate cancers, and ovarian cancers. For more information, visit imagionbiosystems.com.

Executive Chairman Contact Details

Bob Proulx
investor@imagionbio.com
AU: +61 3 9692 7222

Media Enquiries & Investor Relations:

Erich Boileau, Boileau & Co.
imagionbio@boileau.co
US : +1 (616) 786-4461