

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

10 July 2025

Imagion Receives Positive Feedback from FDA for HER2 Breast Cancer Phase 2 Clinical Trial

Imagion Biosystems (ASX: IBX) (**Company** or **Imagion**), a company dedicated to improving healthcare outcomes through the early detection of cancer utilising its proprietary MagSense® HER2 imaging technology, is pleased to provide shareholders with an update regarding the Company's planned Phase 2 HER2 Breast Cancer clinical trial to be conducted in the U.S.

As previously advised in Company ASX releases, the IBX clinical team has been in communication with the U.S. Food and Drug Administration (FDA) regarding plans to submit an Investigational New Drug (IND) application for its MagSense® HER2 imaging agent. The Company can now confirm it has recently received formal written feedback from the FDA which included positive feedback and constructive input regarding the study plan and outcomes. This is part of the formal review process for FDA approved clinical trials, and the Company will be meeting with the FDA in person in the coming week to complete this process, ahead of the formal IND submission.

"I'm very pleased with the trajectory of our communications with the FDA", said Bob Proulx, Executive Chairman. "We view the feedback from the FDA as very encouraging and can now confidently press forward with the formal submission and plans for undertaking the Phase 2 clinical study knowing we are in good shape regarding the regulatory path."

The company expects to file the Investigational New Drug (IND) application for the Phase 2 study in the third quarter of the 2025 calendar year.

Authorisation & Additional Information

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

— ENDS —

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://imaginationbiosystems.com/investor-hub/>

Imagion Biosystems Limited

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