

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

29 May 2025

Imagion AGM Business Update

MELBOURNE – Imagion Biosystems (Company, ASX: IBX), a company dedicated to improving healthcare outcomes through the early detection of cancer, is pleased to provide shareholders with a general business update in advance of its Annual General Meeting.

As previously noted, the main focus of the company's business has been the continued development of the MagSense® HER2 Imaging Agent which is intended to be used in the assessment of axillary nodal disease in patients diagnosed with HER2+ breast cancer. Manufacturing of the imaging agent drug is expected to commence in June and be completed in July, with the company still planning to be filing its Investigational New Drug (IND) application for a Phase 2 study with the U.S. Food and Drug Administration (FDA) in the third quarter of 2025.

Other key updates associated with the IND milestone include:

- The Company has recently been in communication with the FDA regarding the planned application and is expecting to receive feedback in mid-July before making the final submission;
- A Principal Investigator for the study has been identified; and
- Optimization of the MRI protocols is expected to commence in June in collaboration with Siemens and experts from Wayne State University.

Commenting on the Company's progress, Executive Chairman, Bob Proulx said, "Whilst progressing our business plan in the most cost-effective way, I am very pleased with the progress we have been making and that we remain on track to advance our MagSense® HER2 product to the next phase of clinical testing. As we have continued to reach out to clinicians and prospective partners in the imaging markets, it is clear that there is an unmet need and that our first-of-its-kind molecular MRI technology is addressing a gap that should result in significant value creation for the company."

"Whilst the majority of the Company's business activities have focused on developments of the HER2 breast cancer program, the company is pleased to report that Dr. Kayat-Bittencourt, Vice Chair of Innovation at University Hospitals and an Associate Professor of Radiology at Case Western Reserve University has been engaged as clinical advisor for the Company's prostate cancer program. Dr. Kayat-Bittencourt is a leader in the field of prostate cancer research using multiparametric MRI (mpMRI), with over 45 peer-reviewed publications and 110 conference abstracts. Previously IBX had reported strong preclinical evidence for the MagSense® PSMA imaging agent that was under development for the detection of prostate cancer but has limited activities on this product based on funds available."

Imagion Biosystems Limited

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“As we approach having the breast cancer program move to Phase 2 clinical trial, we are anticipating restarting the prostate and ovarian cancer programs. Working with Dr. Kayat-Bittencourt gives us the chance to have input into the clinical development program from one of the world’s leading prostate cancer imaging experts.”

— 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/>

Authorization & Additional information

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

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