Company Announcement

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

7 October 2025

Imagion Biosystems HER2 Breast Cancer Program Update

Key Highlights:

- **Manufacturing of the MagSense® HER2 Breast Cancer Imaging Agent for the Phase 2 clinical trial has been completed – major milestone achieved**
- **IBX, Siemens and Wayne State University (WSU) artificial intelligence imaging protocol optimisation collaboration progressing with results to be included in IND submission**
- **The WSU study aims to improve particle visualisation at lower dosage while introducing quantitative techniques for future AI development**
- **New collaboration with WSU bolsters the existing agreement the Company has with Siemens Healthineers, the world's leading manufacturer of MRI equipment**
- **Program remains on track for FDA Investigational New Drug application H2 2025**
- **Completion of AU$3.5m placement provides essential resources for the Company to submit its IND application to the US 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® imaging technology, is pleased to provide the markets with an update on the Company's Phase 2 Clinical Trial HER2 Breast Cancer program.

MagSense® HER2 Clinical Supply Manufacturing Completed

The Company is pleased to report that the contract manufacturer has completed production of the drug candidate and is now completing the required analytical testing ahead of release for use in the planned Phase 2 clinical study. Results of the testing ensure its quality, safety, and suitability for patient use, and are an essential part of the Company's Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA).

"*We are very happy with the recent progress of our contract manufacturer in completing the new batch of the MagSense® imaging agent*," said Executive Chairman, Bob Proulx. "*Once testing is complete, we anticipate submitting the IND application, which we believe will be in order based on our previous communications with the FDA*."

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Wayne State University Collaboration – Imaging Protocol Optimisation

Additionally, the previously announced collaboration with WSU to develop optimised protocols for the MagSense® imaging agent is also progressing well. Based on current timelines, the Company anticipates this protocol work to be completed in the coming weeks to support the proposed IND filing timelines in H2 2025. Further updates will be forthcoming as appropriate when results are available to the Company from WSU.

Completion of $3.5m Capital Raising

As announced on September 24th 2025, IBX shareholders approved the second tranche of an AU$3.5M capital raise. The funds will be used to commence the planned HER2 Breast Cancer Phase 2 Clinical Trial as well as preclinical studies for the prostate cancer and ovarian cancer programs. Key objectives for the HER2 Phase 2 program include:

- ✓ **The completion of drug manufacturing of the imaging agent for the study;**
- ✓ **Submission of an Investigational New Drug (IND) application with the Food and Drug Administration (FDA);**
- ✓ **Development of new Intellectual Property related to molecular MRI; and**
- ✓ **The initiation of the clinical trial and completion of the first patient cohort.**

No expected impact on IND submission from US Federal Government Shutdown

The Company notes that the U.S. federal government shut down is not expected to impact the planned Phase 2 Clinical Trial IND application submission. The Company will monitor any protracted closure of the FDA and any future impact on the proposed approval timelines, alongside investigating alternative pathways in advancing its clinical programs, including the HER2 Breast Cancer Phase 2 Clinical Trial.

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://imagionbiosystems.com/investor-hub/

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