Company Announcement

IMAGION BIOSYSTEMS LIMITED
ASX: IBX

8 September 2025

Phase 2 HER2 Clinical Trial Manufacturing Commenced, WSU Imaging Optimisation Program Underway

Highlights:

- **Dr Nina Webster appointed as IBX Non-Executive Director, bringing significant clinical development expertise and corporate experience to the IBX Board ahead of HER2 Breast cancer Phase 2 clinical trial, on schedule to commence by end of 2025**
- **Major milestone met with the commencement of the MagSense® HER2 clinical supply manufacturing for the Phase 2 clinical trial**
- **IBX, Siemens and Wayne State University (WSU) artificial intelligence Imaging Protocol Optimisation collaboration has commenced**
- **Initial results from the WSU led AI Imaging Protocol collaboration anticipated to be received during September 2025**
- **The WSU collaboration bolsters the existing agreement the Company has with Siemens Healthineers, the world's leading manufacturer of MRI equipment**
- **Ongoing engagement between FDA and IBX supports planned IND filing H2 2025**
- **Funding secured through successful $3.5m fundraising led by CPS Capital in August 2025, settlement to complete late September following shareholder General Meeting**

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 shareholders with a progress update regarding the Company's business and MagSense® HER2 Breast Cancer diagnostic imaging program, supporting the planned Phase 2 Clinical Trial expected to commence towards the end of 2025.

MagSense® HER2 Manufacturing Update – Major Milestone

A significant milestone has been achieved by the Company, with the commencement of manufacturing of the MagSense® HER2 imaging agent by Imagion's US based contract manufacturer which is expected to be completed by end of September 2025. Analytical testing of the drug product to support use in the planned Phase 2 clinical trial will be completed shortly thereafter.

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"Progress towards our IND submission and the Phase 2 clinical trial initiation remains our primary focus," ***said Bob Proulx, Imagion Executive Chairman****. "Establishing the appropriate manufacturing processes and analytical testing methods are critical in the product development process. If not done correctly at this stage it can delay future trials and regulatory authorisation. By developing robust manufacturing processes now, Imagion can ensure that the appropriate methods are in place and avoid any future delays in the development program as we work towards potential commercialisation."*

IND Update

The Company has continued its formal communications with the US Food and Drug Administration (FDA) following on from the positive feedback in July 2025 regarding its plans to submit an Investigation New Drug (IND) application. Preparation of the IND application is underway with submission anticipated in Q4 2025, subject to completion of the analytical testing by the contract manufacturer.

Dr Nina Webster – New Strategic Board Appointment

As announced on September 1, Dr Nina Webster has joined the IBX Board of Directors as a Non-Executive Director. Nina's extensive experience in the Australian listed biotech space and successful career in drug development and commercialisation will be a welcome addition to the IBX leadership team as the Company continues to mature and develop the MagSense® technology.

Wayne State University Collaboration – Imaging Protocol Optimisation Commenced

As recently announced, the Company has entered into a collaborative service agreement with MRI experts at Wayne State University (WSU) to develop optimised imaging protocols for use with the MagSense® HER2 imaging agent. The Company is pleased to report that work on the project has already begun and the outcomes are expected to be ready for inclusion in the Company's IND application.

With the support of Siemens Healthineers, under an existing collaboration agreement Imagion has with the world leader in MRI systems, it is anticipated that the protocols now being developed by WSU will be implemented at each of the clinical sites of the Phase 2 study. The quantitative imaging techniques that have been pioneered by the researchers at WSU could significantly improve the diagnostic utility of the Company's molecular MRI technology and set the stage for the development of AI diagnostic tools using the Phase 2 study data.

Authorisation & Additional Information

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

— ENDS —

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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 visualisation 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.