IMAGION BIOSYSTEMS LIMITED

ASX: IBX

15 July 2025

Imagion MagSense Breast Cancer Program Phase 2 Clinical Trial Update

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 further update regarding the Company's proprietary MagSense® HER2 Breast Cancer diagnostic imaging program, and recent progress towards commencing its Phase 2 clinical trial in 2025.

Regulatory Update – FDA Meeting held for HER2 Breast Cancer Clinical Trial

As disclosed on July 10th, the Company had received a written response from the U.S. Food and Drug Administration (FDA or the Agency) regarding the Company's plans to undertake a Phase 2 trial of the MagSense® HER2 imaging agent in the U.S. As forecast in the release, the Company and its clinical team attended a videoconference with FDA reviewers. The Company's clinical team that attended the FDA meeting was led by Executive Chairman Bob Proulx, Chief Business Officer Ward Detwiler and Medical Affairs Advisor, Dr Susan Harvey.

The purpose of the meeting was for the Agency to seek detailed responses from the Company, and the Company to receive clarification in relation to the written feedback provided on the structuring and operation of the planned HER2 Breast Cancer Phase 2 clinical trial.

The Company is pleased to report that no issues were identified that could negatively impact the Company's current plans and that the dialog included input regarding future clinical and commercial development considerations. This positive outcome of the FDA meeting paves the way for the Company to file the Investigational New Drug (IND) application for the Phase 2 study in the third quarter of the 2025 calendar year.

"Our clinical team was pleased and very encouraged with the level of engagement we had with the reviewers," said Bob Proulx, Executive Chairman. "We view the fact that senior Agency staff participated on the call as a sign that the Agency is interested in what we are doing, our plans for the Phase 2 trial in the U.S. and the potential impact our technology may have on breast cancer diagnosis and staging."

Manufacturing Update

Based on the recent communications and feedback from the FDA the Company will move to fast track the manufacturing of the MagSense® HER2 Imaging Agent for the proposed Phase 2 trial.

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

Final steps of manufacturing and testing are in process and expected to be completed in the third quarter of 2025.

IND Application Submission Update

The Company post this FDA meeting will immediately action plans to submit the Investigational New Drug (IND) application to the FDA in the third quarter of 2025. Dr. William Dooley, a surgical oncologist at the University of Oklahoma Health Sciences College of Medicine, will serve as the Principal Investigator for the multi-site open label study.

"Throughout my career, I have been involved with numerous clinical trials seeking to bring knowledge of biological responses and resistance to neoadjuvant treatments prior to surgery," says Dr. William Dooley. "This new approach offers the potential ability to image these responses following pre-surgical treatment, which is particularly important for guiding decision making and improving patient outcomes."

About Dr. William Dooley

William C. Dooley, MD, FACS, is a Professor in the Department of Surgery at the University of Oklahoma. He is a board certified by the American Board of Surgery. He received his medical degree at Vanderbilt and completed surgical training at the Johns Hopkins Hospital. He did his surgical oncology training at Oxford University and at Johns Hopkins before joining the Hopkins faculty.

He developed and directed the Johns Hopkins Breast Center which became an award-winning model for cancer care. Upon arrival in Oklahoma he worked to transform the outreach and breast cancer treatment of under-served and disparity populations and transformed the OU Breast Institute into the first National Accreditation Program for Breast Centers-certified breast center in Oklahoma.

His involvement in setting higher standards for cancer care have led to national and international recognitions. He serves on the Commission on Cancer, which sets and monitors national quality standards for cancer care and is a member of the Society of Surgical Oncology, the American Society of Breast Surgeons, the Fellowship of American College of Surgeons and the Society of University Surgeons.

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.

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

For more information, visit https://imagionbiosystems.com/investor-hub/

Media & Investor Relations:
Email: info@imagionbio.com
AU: +61 3 9692 7222