

ASX ANNOUNCEMENT | 14 September 2026

Imagion Biosystems Resumes MagSense® Nanoparticle Manufacturing Capabilities

Key Highlights:

- Master Service Agreement with key CDMO in place
- Manufacturing capabilities aligned with U.S. FDA product quality requirements
- Strengthens IBX's core competencies and supports strategic business plan

Imagion Biosystems (ASX: IBX) (**Company** or **Imagion**), a company dedicated to improving healthcare outcomes through early and more accurate detection of cancers, is pleased to provide an update on product manufacturing aligned to support current product development needs and potential commercialisation of the MagSense® technology.

Following from the U.S. Food and Drug Administration's (FDA) clearance of the company's Investigational New Drug (IND) application (see announcement 1 June 2026) for MagSense® in HER2 breast cancer, the company has entered into a Master Service Agreement with nanoComposix, a specialty nanoparticle Contract Development and Manufacturing Organisation (CDMO), to resume nanoparticle manufacturing capabilities. Under the terms of the Agreement, Imagion will provide the company's proprietary nanoparticle synthesis equipment, software and procedures for manufacturing the core particles to nanoComposix (a Fortis Life Sciences company) to manufacture pharmaceutical grade material under the company's direction.

Partnering with the CDMO is a key business initiative that will keep the company's operational costs low, avoiding fixed costs of investing in a manufacturing facility and staffing, while still allowing for the development of the technology towards potential commercialisation. By developing robust manufacturing processes early, Imagion can ensure that the appropriate specifications and shelf-life of the product are well characterised at the time of submitting a potential New Drug Application (NDA), thus helping to avoid delays in the marketing authorisation process. Additionally, since the core nanoparticle is the base component of all MagSense® imaging agents, implementing this program now positions the company well and will likely add value to any potential partnering transaction.

"Establishing robust nanoparticle production capabilities is extremely important for our future," said Ward Detwiler, President of Imagion's US operations. "The core particles are a key component of our proprietary MagSense® technology and, therefore, essential to the long-term success of our business. We're very pleased to be partnering with nanoComposix at this time to support our business initiatives."

The CDMO had previously demonstrated its capabilities, having supported production of the MagSense® HER2 imaging agent for both the successfully completed Phase 1 study and the investigational product planned for use in the pending Phase 1b/2 study. nanoComposix's ability to make the MagSense® nanoparticles under Good Manufacturing Practice (GMP) quality controls ensures pharmaceutical grade material and aims to align with the U.S. FDA's product quality requirements.

Initially, the CDMO will focus on establishing a robust manufacturing protocol to meet the regulatory requirements for the MagSense® drug product and to supply material for any additional MagSense® HER2 investigational product that might be needed for the planned Phase 2 clinical trial. The nanoparticle production capabilities will also support research and development needs for the prostate and ovarian cancer programs as and when those programs are advanced with the availability of funds.

About the MagSense® Imaging Agent Technology

MagSense® technology is a new class of MRI imaging agents that aims to improve 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 potentially tag and detect cancers allowing for visualisation using MRI. This new class of imaging agents does not use ionising radiation or radioactive tracers and aims to improve how medical imaging can be used compared to conventional imaging methods which cannot differentiate benign tumours from malignant cancer. Imagion has developed MagSense® imaging agents for potential use in three different types of cancer. The lead product has successfully completed a Phase 1 study for the detection of nodal metastases (spread) in HER2+ breast cancer and is now advancing into the planned Phase 1b/2 study. The MagSense® technology platform has the potential to expand into two additional indications, being prostate cancer and ovarian cancer.

Authorisation & Additional Information

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

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About Imagion Biosystems

Imagion Biosystems (ASX: IBX) is a clinical-stage, medical imaging company dedicated to transforming how cancer is diagnosed and treated. The company produced and is developing clinical applications for MagSense®, a first-of-its-class MRI imaging agent that aims to enable clinicians to detect cancer earlier and with greater precision. Advancing molecular MRI, the company is using non-radioactive, bio-safe magnetic nanoparticles to potentially improve



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diagnostic certainty for a broad range of applications, including HER2+ breast cancer, prostate cancers and ovarian cancers. For more information, visit imagionbiosystems.com.

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