Company Announcement

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

14 November 2024

Corporate Update – IND for MagSense® HER2 Phase 2 Study To Commence

- **$3.0m capital raising led by CPS Capital to complete in early December**
- **Filing of IND for MagSense® HER2 Phase 2 Study Immediate Priority - plans to commence Phase 2 Study in CYH2 2025**
- **Dr. Susan Harvey to join team as Medical Affairs Advisor**
- **Investor Webinar scheduled for Wednesday, 27 November at 9:00am (AEDT)**

Imagion Biosystems Limited (ASX: IBX) (**Company** or **Imagion**), a company dedicated to improving healthcare through the early detection of cancer, is pleased to provide this business update for shareholders and the markets.

As announced on 10 October 2024, the Company received $3.0m firm commitments for the placement of ordinary shares in IBX. The Company has completed Tranche 1 of the placement, raising $0.11m (before costs), with Tranche 2 of the placement ($2.89m) due to be completed and settled following the General Meeting of shareholders on 9 December 2024. These funds will be used to advance the clinical development of the Company's MagSense® molecular MRI imaging technology, as well as general operating expenses.

"We are very grateful for the show of support from Australian investors and CPS Capital clients," said Executive Chairman Bob Proulx. "For the majority of 2024 we have had limited ability to advance our business. These funds give us the ability to immediately resume our work to bring our novel molecular imaging technology closer to commercialization."

Priority Program – IND Submission for Phase 2 Study of MagSense® HER2 imaging agent

Pending closure of the placement, the Company plans to prioritize pursuing the filing an Investigational New Drug (IND) application with the US FDA to undertake a Phase 2 study for its MagSense® HER2 imaging agent. See further detail below regarding why the Phase 2 study is important for Imagion. Over the next several months, the Company, with its advisors and contractors, will be focused the following key activities in support of the IND with the aim of beginning the Phase 2 study in the second half of 2025, pending securing appropriate funding for completion of the study.

- Commencing manufacturing a new batch of the MagSense® HER2 imaging agent;
- Selecting the lead investigators for the Phase 2 study;
- Finalizing the study design; and
- Initiating site selection through a Contract Research Organization (CRO).

Appointment of leading Medical Affairs Advisor

The Company is also pleased to announce that Dr. Susan Harvey has joined Imagion in the capacity of Medical Affairs Advisor. Dr. Harvey recently retired from her role as VP of Medical Affairs at Hologic, a world-leader in mammography and women's health. A radiologist by training, she previously served as Director of Breast Imaging at the Johns Hopkins School of Medicine. Dr. Harvey is also a co-founder of the non-profit organization, Cure Women's Cancer (https://www.curingwomenscancer.org).

"Being able to attract the support of someone like Dr. Harvey, I believe is a real testament to the potential of our first-in-class technology," said Bob Proulx. "With her extensive experience in breast imaging in women's health she appreciates what our MagSense® molecular imaging technology could do to improve radiological assessment and disease detection. We are very excited to have her participation and input into our program."

MagSense® Pipeline Advanced – Prostate and Ovarian Cancer

The Company also plans to use a certain portion of the funds for the other MagSense® imaging agents in its pipeline, one targeting prostate cancer and another for ovarian cancer. Both of these imaging agents have completed the majority of the preclinical research needed and are poised to advance to the IND-enabling studies necessary before human clinical investigations are undertaken. Both are aimed at achieving earlier and better detection of cancers that represent large market opportunities where MRI is currently underserved.

"Advancing our prostate and ovarian cancer imaging agents will open up significant new market and partnering opportunities for the company," says Proulx. "Demonstrating that we have a robust platform to improve diagnostic accuracy compared to existing imaging modalities, will significantly strengthen our value proposition."

Investor Webinar

The Company invites existing shareholders to participate in an Investor Webinar in advance of the upcoming General Meeting.

Highlights of the Webinar include:

- An update on our business plan and key milestones
- Explanation of and reasons for the resolutions proposed for shareholder approval
- Q&A session with our leadership team

Date & Time: Wednesday, 27 November 2024 at 9:00am (AEDT)

Registration Link: https://vistra.zoom.us/webinar/register/WN_LR3iv03TTYuUEdIEF_Yfw

Key Background Information on MagSense®

Why is the MagSense® HER2 Imaging Agent Phase 2 Study important?

Each year, over 5.9M American women undergo high-risk screening for breast cancer, with roughly 45,000 receiving a HER2+ diagnosis. The Phase 2 study is a critical step towards bringing the MagSense® HER2 Imaging Agent (MSH2IA) to this patient population. In the successfully completed Phase 1 study, radiologists ascertained that MSH2IA produced a readily identifiable change in contrast to differentiate between suspicious and non-involved nodes. For Phase 2 the primary goal is to optimize the dose of the imaging agent and the imaging protocol and schedule. Typically, Phase 2 studies represent a significant milestone for biotech companies such as Imagion, since success in Phase 2 establishes the path to success in the more extensive Phase 3 study required to demonstrate the diagnostic performance in a larger and more diverse patient population and compared to existing diagnostic techniques. Each step through clinical investigation establishes improves the likelihood of achieving regulatory clearance and commercialization.

Additionally, beyond addressing HER2+ breast cancer staging, successful completion of these milestones for MSH2IA provides proof that the MagSense® molecular imaging platform is extendable to additional indications such as prostate and ovarian cancers, with an estimated 1,000,000 and 900,000 annual patients in the U.S., respectively.

Why is testing for nodal metastases important?
Of the four breast cancer subtypes, 10% to 20% are Human Epidermal Growth Factor Receptor 2 positive (HER2+). A HER2+ classification has significant prognostic and predictive implications for the patient because the HER2-positive subtype is considered an aggressive phenotype with a high rate of recurrence and metastasis.

After a new cancer diagnosis, nodal staging, which involves a combination of clinical assessment and radiographic imaging, is performed. Precise nodal staging is an essential component in the management of patients with breast cancer, as treatments depend on patient specific characteristics of the primary tumor, nodal status, and evaluation for distant metastatic disease. Although regional nodal assessment is crucial, there are variable practice patterns and imaging modalities employed based on available resources and institutional experience. The most commonly employed method is ultrasound with pooled diagnostic sensitivity and specificity of 49% to 87%, and 55% to 97%, respectively. Although ultrasound has the advantages of convenience, patient comfort, and decreased cost compared to MRI, its utility depends on the experience of the operator, which accounts for the wide variability in sensitivity and specificity. Ultrasound is also limited in its ability to scan for the extent of the locoregional disease. Therefore, given the significance of accurate nodal assessment, improving radiographic assessment still represent an important medical opportunity.

A noninvasive and molecularly targeted, tumor-specific approach that serves as contrast enhancement to the well accepted imaging modality, such as MRI, will add value to existing ways of nodal staging as well as contribute to the evolving practice of surgical de-escalation and subsequent clinical decision making.

Authorisation & Additional information

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

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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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