



IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

24 February 2022

Imagion Biosystems 2021 Full-Year Results

2021 Highlights:

- **Enrolment for the Phase I HER2 Breast Cancer Study commenced with multiple patients completing the study**
- **Initiation of research for prostate cancer imaging with Monash University**
- **Collaboration with Patrys Limited in relation to new cancer imaging agents**
- **Joint Development Agreement established with Global Cancer Technology to develop nanoparticle-based treatment of breast cancer**
- **Secured new premises enabling increased R&D and manufacturing capabilities**
- **Received \$2.6 million in R&D tax incentives**
- **Raised over \$4.7 million from exercise of IBXO options**

MELBOURNE - Imagion Biosystems (ASX: IBX), a company dedicated to improving healthcare through the early detection of cancer, today released its Appendix 4E and Annual Report for the year ended 31 December 2021.

Executive Chairman and CEO Bob Proulx said, "FY2021 marked our transition to becoming a clinical stage company with the commencement of our MagSense® HER2 breast cancer study - a first-in-human investigative study of our proprietary molecular magnetic nanoparticle-based imaging technology. This Phase 1 study is our initial clinical investigation into the safety and tolerability of the MagSense® HER2 nanoparticles and their ability to reach tumour cells that may have metastasized to the lymph nodes. The study will also provide initial important information on the potential effectiveness of two imaging modalities to detect the MagSense® imaging agent, before we commit resources to larger studies for regulatory approval. While the pandemic significantly impacted us from achieving our goal of completing the study in 2021, we made significant progress securing four clinical sites across Victoria, New South Wales, and Queensland in Australia and finishing the year with multiple patients having completed the study."

2021 Highlights

During 2021, Imagion has continued to make progress in relation to the MagSense® HER2 breast cancer Phase 1 study for the detection and staging of HER2 metastatic breast cancer. The first patient was enrolled into the study in May 2021 with additional patients enrolling as new study sites were activated. In addition to the initial screening site at Monash Health (Victoria) three screening sites were added during the year including the Austin Hospital (Victoria), the Royal Brisbane Women's Hospital (Queensland) and Lake Macquarie Private Hospital (New South Wales).

Further progress was made during the year in relation to expanding the MagSense® product pipeline for other indications including commencing a preclinical research project between Imagion and researchers at Monash University's Biomedicine Discovery Institute with the aim of providing early proof of concept demonstration of MagSense® nanoparticles as a potential prostate cancer imaging agent. In addition, a collaborative research project with Patrys Limited (ASX:PAB) is investigating use of a Patrys antibody with Imagion MagSense® nanoparticles with the aim of improving brain tumor imaging and diagnosis.

A \$2.6 million R&D tax incentive was received by the Company in relation to 2020 R&D activities. This was higher than the \$2.2 million received in the prior year and reflected increased R&D spend leading up to the commencement of the Phase I HER2 Breast Cancer Study in December 2020.

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The Company announced that it had entered into a Joint Development Agreement with Global Cancer Technology (GCT), to develop GCT's novel nanoscintillator technology for the treatment of breast cancer, leveraging Imagion's nanoparticle expertise. Scintillating nanocrystals are nontoxic minerals and rare earth elements that emit photons (light) when activated by a low dose of gamma radiation. Photocleavable linkers release a drug payload when exposed to the small burst of light from the scintillating photons. Employing nanocrystals to deliver a drug payload enables a controlled release of the therapeutic agent. This next generation approach, known as x-ray induced photodynamic therapy, has the potential to deliver a more localized and effective dose of drug product to treat cancers and improve the utility of low dose radiation for the treatment of solid tumours. Under the terms of the Agreement, Imagion will be paid for certain R&D services while gaining an ownership interest in the GCT nanoscintillator product being developed.

Imagion employed Dr Yalia Jayalakshmi as Chief Development Officer during August 2021. Dr Jayalakshmi comes to Imagion with experience in clinical development spanning pharmaceuticals, devices, nanoparticle delivery and diagnostic imaging products in oncology, ophthalmology and other therapeutic areas.

In December 2021 the Company announced that it had received the full allotment of funds available from the exercise of all 94,708,863 IBXO listed options raising over \$4.7 million since the options listed in November 2019.

The fit-out at the new San Diego R&D facility was largely completed in the fourth quarter with the Company taking occupancy early in the new year. This new facility significantly expands our internal nanoparticle research & development capabilities, provides additional manufacturing capacity to support our clinical programs and can be leveraged to generate revenue through third party commercial relationships.

Financial Position

Imagion's cash balance stood at \$13.4 million at end of December 2021, up from \$13.2 million at December 2020. Cash was boosted by the receipt of \$5.5 million from the exercise of options in 2021 as well as \$2.6 million in research & development tax incentives from the Australian Taxation Office in respect of its 2020 research & development costs.

Operating cash outflows increased by 10% to \$5.1 million in 2021 mainly due to an increase in staffing and administrative expenses as the company has expanded organisational capability during 2021.

Overall, the Company's net loss was \$6.0 million. This represents a \$0.7 million (or 12.3%) increase compared to the prior year, with the increased income from research & development tax incentives being offset by an increase in staff, and other general and administrative expenses.

As Imagion's MagSense® HER2 breast cancer Phase 1 study progresses and the Company advances its development pipeline, the Company is budgeting for research and development expenditures and staffing costs to increase in 2022

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About Imagion Biosystems

Imagion Biosystems is developing a new non-radioactive and safe diagnostic imaging technology. Combining biotechnology and nanotechnology the Company aims to provide non-invasive detection of cancer and other diseases with higher specificity than is currently possible. Imagion Biosystems listed on the Australian Securities Exchange (ASX) in June 2017.

Authorisation & Additional Information

This Announcement was authorised by the Board of Directors of Imagion Biosystems Limited



For further information please visit www.imagionbiosystems.com

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