

IMAGION BIOSYSTEMS LIMITED

ASX: IBX

30 August 2023

Imagion Biosystems 1H2023 Half-Year Results

1H2023 Highlights:

- **Achieved enrolment target for Phase I study of MagSense® HER2 breast cancer detection; imaging results corroborated by independent panel of radiologists**
- **Announced plan to advance MagSense® HER2 program to US IND application**
- **Expanded collaboration with Siemens Healthineers to support clinical investigations of the MagSense® imaging agent technology**
- **Appointed Dr. Isaac Bright as CEO**
- **Opened non-renounceable entitlement offer to raise \$2.4 million (completed fully subscribed in July 2023)**
- **Secured a \$15 million funding facility with Mercer Street Global Opportunity Fund, LLC**

MELBOURNE - Imagion Biosystems (ASX: IBX), a company dedicated to improving healthcare through the early detection of cancer, today released its Appendix 4D and Half-Year Financial Report for the half-year ended 30 June 2023.

"We are delighted with the progress the Company has made during the half-year, particularly pleasing is how our MagSense® HER2 breast cancer imaging technology is progressing and with having achieved our enrolment target for the Phase 1 study," commented the Company's recently appointed CEO, Dr. Isaac Bright. "Our clinical data to-date supports our vision that our targeted nanoparticle technology has the potential to change how MRI can be used to specifically detect cancer."

Dr. Bright continues, "Strategically, we are poised to capitalize on the optionality that partnerships and corporate development initiatives may create. For decades, leadership in our sector has been achieved through successful execution of collaborations - whereby complementary competencies and assets enable new tools, interventions, and therapies that improve patient outcomes. As the first-mover introducing molecular imaging to MRI, we do not take our charge lightly and intend to expand prospects for improved clinical decision-making that benefits our partners and patients."

Imagion Biosystems Limited

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1H2023 Highlights

In February 2023, the Company announced that an independent blinded review by a panel of expert breast cancer radiologists corroborated the Company's previously reported positive findings from its MagSense® HER2 breast cancer phase 1 study.

Subsequently in June 2023, the Company reported that its MagSense® HER2 imaging agent Phase 1 study (IBI10103) achieved its enrolment target with 13 patients enrolled, meeting the original goal of 10-15 patients. The Company noted its intention to close the study by 31 July 2023.

This was a great achievement for the Company in its first clinical study with the MagSense® HER2 imaging agent being well-tolerated and having shown no safety concerns in this study. The Phase 1 study has been instrumental in revealing the potential clinical utility of the MagSense® HER2 Imaging Agent and confirms that the Company's targeted nanoparticle technology has the potential to expand MRI utilization with molecular specificity in the detection of cancer.

The confirmation by the panel of independent radiologists that cancer detection could be achieved when using the MagSense® imaging agent with MRI provides for a reduction in risk in the Company's future clinical studies. This reduction in risk and the ability to utilise the MagSense® imaging agent with a large installed base of MRIs throughout the world has the potential to be more attractive for strategic partners and provides an increased likelihood for the Company to achieve commercial success sooner.

Results of the study will be published in due course and the Company will use the data in support of an Investigational New Drug (IND) application submission to the US FDA expected late this year or the beginning of 2024.

Also in June, the Company extended its collaboration agreement with Siemens Healthineers for an additional two years, in anticipation of the Company extending clinical programs to the USA post the IND filing. The collaboration allows Siemens to provide expertise to the Company as they work together with the Company's clinical advisors and investigators to optimize the Magnetic Resonance Imaging (MRI) protocols in anticipation of the Company's MagSense® clinical studies and provide technical support to clinical sites.

Dr. Isaac Bright was appointed as CEO of the Company in June. Dr. Bright brings over 20 years of experience as a health industry executive and venture capitalist in medical technology, biopharmaceuticals, and oncology-based molecular diagnostics. This represents an exciting new phase for the Company and Dr. Bright's track record in strategic partnering, financing, and M&A are well suited to support the Company's vision and drive the next chapter in the Company's growth. Dr. Bright's appointment followed the retirement of Bob Proulx as CEO, with Mr. Proulx remaining as Chairman of the Board.

Financing

During the quarter the Company announced an entitlement offer seeking to raise up to \$2.4 million as well as a funding facility of up to \$15 million with Mercer Street Global Opportunity Fund, LLC (Mercer). The entitlement offer, which closed on 14 April 2023, provided funds of \$413k (before costs) from existing shareholders. The shortfall of \$1.97 million was placed in full in July 2023.



The funding facility with Mercer initially provided an investment of \$2.5 million in convertible securities, which was received during the quarter. A further \$1.0 million was subsequently invested in August 2023.

The decision to enter into the funding agreement was taken to assist in providing liquidity for the Company as it advances its clinical development towards an IND filing given this required significant investment. The Company is utilising its positive relationship with Mercer to provide another avenue of liquidity. This liquidity is in addition to the capital markets and prior to the ability to find any strategic commercial partners. In making this decision the Company is cognisant of the depressed capital markets, particularly in relation to microcap and pre-revenue companies, in Australia and to a lesser extent the US. At this stage, the Company has no intention to fully utilise the Mercer facility but is pleased to have this facility as part of its overall capital requirements.

Financial Position

The Company's cash balance stood at \$0.5 million at the end of June 2023, down from \$4.4 million at 31 December 2022. Cash was boosted by \$1.0 million in Q3 2023 with a subsequent issuance of convertible securities to Mercer and will be further boosted in Q3 2023 by the expected receipt of \$3.5 million in research & development tax incentives from the Australian Taxation Office in respect of its 2022 research & development costs.

— ENDS —

About Imagion Biosystems

Established in 2017 and headquartered in the San Diego, California, US, Imagion Biosystems is an ASX-listed company dedicated to developing innovative medical imaging technologies for various cancer types. Imagion Biosystems is advancing clinical development of its MagSense® platform technology to revolutionize cancer diagnosis, introducing molecular imaging to MRI. The Company's lead program has demonstrated its innovative technology embodied in MagSense® HER2 Imaging Agent (MSH2IA) is safe and well-tolerated in patients with diagnosed HER2+ breast cancer. Imagion Biosystems' MagSense® pipeline includes prostate cancer, ovarian cancer, and brain cancer programs advancing towards clinical development.

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

Imagion Biosystems Interactive Investor Hub

Engage with us directly by asking questions, watching video summaries, and seeing what other shareholders have to say about this and past announcements at our Investor Hub:

<https://investorhub.imagionbiosystems.com/>

Authorisation & Additional information

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

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