

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

5 August 2020

Imagion Biosystems Phase I study update: Submission for ethics approval filed

MELBOURNE — Imagion Biosystems (ASX: IBX), a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to provide an update with regard to its plans to undertake a Phase I study of its first MagSense™ product for the detection of HER2 metastatic breast cancer.

The company has completed preparations of the requisite materials for a Human Research Ethic Committee (HREC) review and has submitted its Phase I study for HREC review and approval. The HREC review and approval process provides an independent review of scientific and ethical considerations of proposed human research in Australia. Given the normal review cycle for Phase I studies, the Company expects the review process to be consistent with its plans to start the study in Q4, noting that approval is not guaranteed and may require additional information or dialog with the Committee.

Additionally, the Company has confirmed three study sites, two in Melbourne and one in Sydney, plan to participate in the study. Additional sites are being consider and will be added to the study, if possible, to maximize the opportunity for enrolment of qualified subjects in a timely manner.

"We believe our regulatory and clinical team has put together a strong and compelling study and look forward to engaging with the HREC to gain approval," said Bob Proulx, Executive Chairman of Imagion Biosystems. "We are mindful of the ongoing risk arising from the COVID-19 pandemic. The potential disruption to hospital systems and their ability to treat cancer patients and undertake clinical studies continues to be high on our watch list. However, we do note that, presently under the current restrictions, Australian patients are allowed to travel for medical reasons and that cancer treatment is considered not only an essential service but crucial to delivering better health outcomes. In the meantime, we will continue to make ready and keep investors informed as near the planned start of the study and as we learn more from our clinical sites."

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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 detect cancer and other diseases earlier and with higher specificity than is currently possible. Imagion Biosystems listed on the Australian Securities Exchange (ASX) in June 2017.

For further information please visit www.imagionbiosystems.com

Authorisation & Additional information

This announcement was authorised by the Robert Proulx, Executive Chair of Imagion Biosystems Limited

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