IMAGION BIOSYSTEMS LIMITED

(ASX**: IBX**)

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Imagion Biosystems initiates regulatory communications for first-in-human study

MELBOURNE — Imagion Biosystems Limited (ASX: IBX) (the **Company**), a company dedicated to improving healthcare through the earlier detection of cancer, has filed a Pre-Submission with the U.S. Food and Drug Administration (FDA), the first step in gaining approval to commence its first-in-human study.

The communication with the FDA's Center for Devices and Radiological Health (CDRH) follows from the recent notification that the Company's MagSense System and Test for staging HER2 breast cancer have been designated as a "Breakthrough Device".

Based on FDA's previous guidance, the Company has filed a Pre-Submission with the agency in anticipation of filing for an investigational device exemption (IDE), a U.S. regulatory requirement for human studies with medical devices. In the submission, the Company has requested a "sprint" discussion, a facility within the Breakthrough Device program intended to expedite communication.

"The recent Breakthrough Device designation by the FDA has been very timely, allowing us to request an expedited review of our submission" said Bob Proulx, Executive Chairman. "While the designation does not change the compliance requirements, we expect it will improve the speed with which we receive feedback from the agency and reduce the risk of disruptions to our plans for undertaking a first-in-human study."

Following a brief review of the Pre-Submission by the FDA, the Company will be able to schedule a meeting wherein both the reviewers within the agency and the Company can address specific questions related to the IDE.

On July 18th the Company announced the Breakthrough Device designation for the MagSense System and Test for staging HER2 breast cancer. To qualify for Breakthrough Device status a product must be considered to "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions".

The company's early feasibility, first-in-human study is a critical milestone in the development of the company's non-radioactive imaging technology which provides a non-surgical solution to identify the progression or stage of HER2 breast cancer metastases. Operationally, the company is focused on the manufacturing of nanoparticles to be used in the study, and contracting the clinical site, in preparation for commencement of the study.

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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

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