

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

26 February 2020

Business Update: Manufacturing commences

MELBOURNE – Imagion Biosystems Limited (ASX: IBX) (the **Company**), a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to provide an update on progress towards its key business objective of initiating its first study for HER2 metastatic breast cancer in human subjects this year.

The primary operational focus for the past quarter has been on ensuring the readiness of its contract-manufacturing partners to begin the manufacturing of the nanoparticle formulation to be used in the study. The company is pleased to report it has purchased equipment and supplies and has completed the necessary vendor qualifications and audits to confirm compliance with GMP (Good Manufacturing Practice), required for the manufacturing of medical devices and pharmaceutical products used in human clinical studies.

With these steps complete, the company will now commence manufacturing.

"Patient safety is of paramount importance for all human studies," said Bob Proulx, Executive Chairman of Imagion Biosystems. "With this being the first time our nanoparticle product is to be used in a human study, we have taken great care in our preparations to ensure we could move forward with confidence into manufacturing and achieve the exacting standards required of GMP manufacturing processes."

While manufacturing proceeds, the Company will continue working on the other key areas needed to support initiating the study later this year when manufacturing is complete. This includes establishing clinical sites and preparing the sites for enrolment of subjects, and receiving the necessary regulatory authorization, for example an Investigational Device Exemption (IDE) from the US FDA.

Dialogue with the FDA continues as previously advised, and is in line with expectations at this stage of the process.

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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.

This Announcement has been approved by the Disclosure Committee of Imagion Biosystems Limited

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