IMAGION BIOSYSTEMS LIMITED

(ASX**: IBX**)

25 October 2019

Imagion Biosystems Nanoparticle Manufacturing Update

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 its progress and plans for manufacturing of its proprietary nanoparticle formulation in advance of the first in human study currently planned for mid-2020.

The Company has previously reported that since the nanoparticle formulation is an injectable component intended to be used in human clinical research, it must be made following Good Manufacturing Processes (GMP) and that manufacturing under GMP adds significant time and cost to production due to stringent requirements of materials used and the need for process controls and traceability.

The Company has worked throughout 2019 with multiple GMP qualified Contract Manufacturing Organizations (CMO), and with consultants familiar with FDA guidance on injectable devices, to de-risk the manufacturing process and is now prepared to commence the GMP manufacturing process.

Due to the unique nature of this first-in-class imaging technology, the transition to GMP manufacturing has been both time consuming and technically challenging. Over the past 12 months the Company has invested significant effort and resources to develop the manufacturing processes for its novel product, and to solve certain technical problems associated with the transfer of the manufacturing process from small scale batches to GMP production at scale. Such challenges have included:

- Securing independent verification that the materials and equipment to be used in the production process can be qualified for use in a GMP environment;
- Resolving production scale-up issues with respect to the integrity and stability of the intermediate steps involved in producing the precise bio-functional nanoparticles needed for targeted magnetic detection of breast cancer cells;
- Developing in-process analytical tests to ensure product integrity is maintained throughout the production process; and,
- Implementing quality control measures required to ensure the resultant product will meet product purity requirements acceptable for safe use in human subjects.

Based on the Company's experience to-date, we aim to increase our planned expenditure for GMP production to A$1.6M to ensure we have budgeted sufficiently for this critical activity. Since both the cost and the expected timeline of 7-8 months, as previously reported, exceeds our current cash runway, the Company will continue to defer initiation of GMP production until additional capital is available to fully fund the production of the GMP material and the undertaking of the first-in-human study.

"We are well-placed to move into GMP manufacturing, pending availability of funds," said Bob Proulx, Imagion Biosystems' Executive Chairman. "The FDA has recognized that our technology will be a breakthrough for breast cancer patients. This recognition makes me very proud of our work, as our small team has overcome the many unforeseen and technically challenging obstacles

encountered, while paving the way for the Company to advance to the clinical stage of development."

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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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