IMAGION BIOSYSTEMS LIMITED

(ASX**: IBX**)

02 October 2019

Imagion Biosystems Investor Update

Highlights

- **Company takes steps to reduce operating expenses and restructure workforce**
- **Progress report on first-in-human study plan**

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 capital management and progress towards its first-in-human study.

In September the Company has undertaken prudent measures to preserve its working capital by reducing staff by one-third, as well as initiating other expense reduction measures. For the past two years Imagion's small team has been predominantly focused on preclinical research activities. This restructuring will allow the Company to better align resources with expenditures as the Company advances into the clinic working with outside collaborators and partners.

The Company's cash balance as of June 30, 2019 was $1.1 million, with a $2 million Australian R&D tax rebate received subsequent to the quarter end. Although the recent headcount and expense reduction measures will reduce the rate of cash burn, the Company is a development stage company and is not expecting to generate significant operating revenues in the next few years. Therefore, our ability to continue operations is dependent on equity and non-dilutive funding sources. As such, the Company anticipates raising capital in the current quarter.

Imagion Biosystems' Executive Chairman, Bob Proulx said: "We have taken steps to proactively reduce expenditures and have a capital management strategy in place which we expect will secure the funding to see us through to completion of the first-in-human study. We are encouraged by the reception received at our recent meetings with existing investors, new brokers and institutional investors, who have responded positively to the recently announced FDA Breakthrough status and understand the significance of achieving our next key milestone as a value inflection point for the Company."

First-in-human study progress update

As we have previously indicated, with sufficient funding and the appropriate regulatory and clinical approvals, we would expect to commence a First-in-Human study for our HER2 metastatic breast cancer test in the first half of 2020.

To achieve this, the focus of our attention is on three main areas:

- **Obtaining the Regulatory approval needed to commence the study**. Since filing our 2018 pre-submission, the Company has maintained a working dialogue with the FDA. With the designation of our MagSense technology as a Breakthrough Device we have been able to accelerate our communication with the agency, and we are confident that our team, along with our consultants, can navigate this process. We will advise investors when the approval is received.

- **Finalizing the clinical study plan and site selection.** We are working towards establishing contracts to undertake the study and receiving institutional approval from our selected study sites, which will be required to commence the study. To that effect, we are currently in discussions with the MD Anderson Cancer Center, where the Company has had a long-standing research collaboration. Although the study will be small (likely less than 20 patients) it is essential that we have access to sufficient qualified subjects to meet the study objectives. Therefore, the Company is also working with additional sites to ensure the study will have the necessary subject enrolment and to reduce the overall time of the study. We do not anticipate using multiple sites to significantly change the cost of the study since the total number of patients to be tested will be the same even if alternate sites are used.
- **Manufacturing of the injectable nanoparticle formulation for use in the study.** Having successfully worked with our contract manufacturer to produce material for the toxicology study earlier this year, the Company now must make the product under Good Manufacturing Process (GMP) conditions, in order for this formulation to be administered to human subjects. Manufacturing under GMP is a more lengthy and expensive process than that which was previously used to produce research grade material. Because it requires significant in-process validation and a larger batch of material than we have previously made, the Company has been working closely with our vendors to prepare for the issues of scale up and process validation in anticipation of initiating production. We expect GMP production to cost approximately $1.2m and take 7-8 months if the transition to GMP goes smoothly. Since the cost and time to produce the material exceeds our current cash runway, the Company will be judicious in controlling expenditures related to production to be commensurate with our available resources.

"We anticipate there will be a high level of interest in this study both from the medical imaging industry as well as our investors. Based on the strong body of data that we have, we have a high degree of confidence that we will achieve positive outcome for our study and that it provides us with our fastest path to regulatory clearance and commercialization," concluded Bob Proulx.

- ENDS

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

U.S. Media Contact:
Matthew Wygant
matthew@biotechwriting.com
+1-408-905-7630

Australian Media & Investor Relations:
Kyahn Williamson, WE Buchan
ImagionBiosystems@we-buchan.com
+61-3-9866-4722