



## IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

18 July 2019

### Imagion Biosystems receives FDA Breakthrough Device Designation

MELBOURNE — Imagion Biosystems Limited (ASX: IBX) (the **Company**), a company dedicated to improving healthcare through the earlier detection of cancer, today announced that it has received notification from the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) that the MagSense System and Test for staging HER2 breast cancer has qualified for and been granted designation as a Breakthrough Device.

“The FDA’s designation of our MagSense technology and HER2 test as a Breakthrough Device is a significant step in our clinical development program” said Bob Proulx, Executive Chairman. “Qualifying as a Breakthrough Device will allow us to expedite our dialog with the agency and validates that our MagSense technology is not just another medical device but, indeed, represents a transformative opportunity for healthcare and could improve the standard of care for staging HER2 breast cancer.”

The purpose of the Breakthrough Device Program is to expedite and improve communications between a device manufacturer and the agency during device development and throughout the review process and provides priority review. 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” and meet one of the following criteria:

- (a) represent breakthrough technologies;
- (b) address an application for which no approved or cleared alternatives exist;
- (c) offer significant advantages over existing approved or cleared alternatives; or
- (d) be considered that the availability of the device is in the best interest of patients.

The Company’s MagSense test for the staging of HER2 breast cancer aims to eliminate the unnecessary surgeries and concomitant morbidity resulting from the current standard of care biopsy procedure. The Company is currently discussing with the FDA and clinical study sites its plans to undertake a first-in-human study of the MagSense HER2 Test.

**-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](http://www.imagionbiosystems.com)

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