IMAGION BIOSYSTEMS LIMITED

(ASX**: IBX**)

29 March 2021

Imagion Biosystems March 2021 Investor Newsletter

MELBOURNE — Imagion Biosystems Limited (ASX: IBX), a company dedicated to improving healthcare through the earlier detection of cancer, is pleased to provide its investors with its March 2021 Investor Newsletter.

The newsletter details recent new company developments and activities, including:

- Message from the CEO, Mr Robert Proulx
- Study design at a glance - MagSense™ HER2 breast cancer Phase 1 study
- CSIRO funding received to jump start prostate cancer project
- Prostate Cancer Q&A with Professor Lisa Horvarth, IBX Scientific Advisory Board and Professor Roger Daly, Monash University
- Imagion Biosystems 2020 Annual Report
- How to exercise your options

The investor newsletter can be viewed below. Imagion Biosystems normally distributes this update as an e-newsletter. Investors can sign up to receive email updates at this link: http://ems.gs/3FuT0frcGxD

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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

Authorisation & Additional information
This announcement was authorised by the Disclosure Committee of Imagion Biosystems Limited

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INVESTOR NEWSLETTER
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Message from the CEO

Dear Shareholders,

It is with pleasure that I present our latest investor newsletter and an update on our recent activities.

With the Phase 1 study for our MagSense™ HER2 breast cancer imaging agent underway, the task of recruiting patients is now largely in the hands of our clinical sites. Monash Health, our first site is actively screening for eligible patients, and our second site has now completed site initiation and training and will soon be able to commence the process of recruiting patients as well.

One of the impacts of COVID-19 reported in Australia has been a decline in the number of patients undertaking initial screening (e.g. routine mammogram), with the Cancer Council Victoria reporting a 30% drop in diagnostic procedures in the first six months of the pandemic. Our sites have confirmed that the trend of fewer patients coming in for assessment has since remained below normal levels. We are expanding our efforts to bring on additional sites and are productively working with our sites and clinicians to help educate and reach eligible patients to mitigate risks to enrolment.

We have always expected that it would take about nine months to conduct the study given the relatively small population in Australia and the requirement of only enroling newly diagnosed HER2 breast cancer subjects that have not yet undergone any treatment. We remain committed to completing the study in a timely manner and, as noted above, are working with our advisors and investigators to ensure the study is a success. A summary of the study can be found below and details of the study design can be found on the Australia New Zealand Clinical Trial Registry.

With the study underway, we have turned our R&D efforts towards planning for the next phase of development to support a larger pivotal trial, and to expanding the MagSense™ product pipeline. For example, the recently announced CSIRO grant will provide funds in support of a prostate cancer project. More details on this collaboration are in this newsletter.

I look forward to keeping our investors informed as we progress this year. We will provide updates to the ASX when there are material updates in respect to the study and other activity. And we invite you to follow our social channels – and read our newsletters – for information that will help provide further education and insight into our technology and operational progress.

With best regards,

Robert Proulx,
President & CEO

Study Design at a Glance - MagSense™ HER2 Breast Cancer Phase 1 study

Full details of the clinical trial protocol have now been published on the Australia New Zealand Clinical Trial Registry. The objective of the study is, primarily, to assess whether our MagSense™ nanoparticles are safe for use in humans, but it will also provide valuable insights into imaging efficacy. These learnings will be important in informing the next steps of the development program for MagSense™ and as we pursue our goal of commercialisation.

The technology:

- A new way to detect and localise cancer without radiation – a significant breakthrough in medical imaging.
- Bio-safe MagSense™ nanoparticles carrying a HER2 targeting molecule are injected into the body and are able to bind to HER2 positive cancer cells if present. Once bound, they produce a magnetic signature which is detectable by our proprietary magnetic relaxometry sensor. If no cancer is present, the nanoparticles do not produce a magnetic signature and are harmlessly metabolised.
- We are also investigating if the MagSense™ nanoparticles can be used as an alternative to general purpose MRI contrast agents, providing a more sensitive and specific image.

Patient eligibility:

The study is recruiting patients who have characteristics that include:

- Must be female aged 18 or older;
- Have histologically confirmed HER2-positive primary breast cancer which has not seen any prior treatment (including surgery, radiotherapy, or systemic treatment); and
- Have clinical indication of lymph nodal involvement and scheduled for biopsy.

Study process:

1. Before undergoing treatment, patients would have a background MRI followed by injection of the MagSense™ HER2 nanoparticle test reagent.
2. Patients will return for post-injection MRI scans to assess for image contrast.
3. Following the last MRI, a biopsy will be taken for assessment by magnetic relaxometery.
4. Patient safety and tolerability to the injection will be made throughout the study period.

Outcomes:

- The primary endpoint of the study is to determine if the single dose of MagSense™ HER2 Test Reagent is safe and well tolerated for use in human subjects. The study also aims to demonstrate if MagSense™ HER2 nanoparticles detect breast cancer that has spread to lymph nodes using Imagion's proprietary magnetic relaxometry method and/or MRI.

Further information on study process, patient enrolment and outcomes can be found on the ANZCTR website here.

How to exercise your options

Imagion frequently receives enquiries from option holders on how to exercise IBXO, IBXOA and other options. If you are an option holder and you wish to exercise your options and convert them into IBX shares, please contact our CFO and Company Secretary, Geoff Hollis, who will manage requests.

Please send your request via email to corpsecretary@imagionbio.com.

CSIRO funding received to jump start prostate cancer project

Imagion has received an Innovations Connections Federal Government grant, administered by CSIRO, and plans to use the funds to help jump start its prostate cancer project.

The $50,000 grant will be used to support a preclinical research project between Imagion and researchers at Monash University where they have developed extensive expertise in prostate cancer research. The research project aims to achieve an early proof of concept validation of a MagSense™ prostate cancer imaging agent.

Exploring new indications plays directly into our strategy to build the pipeline of MagSense™ products and this funding provides an opportunity to leverage federal funds to advance the MagSense™ technology for another important diagnostic use.

You can read the announcement **here**.

Prostate cancer imaging Q&A with Professor Lisa Horvarth, IBX Scientific Advisory Board and Professor Roger Daly, Monash University





Imagion is pleased to collaborate with researchers at Monash University on a preclinical research project that will jump start our prostate cancer project and advance our MagSense™ technology for a new cancer indication, supported by CSIRO funding.

We recently spoke about prostate cancer imaging and the importance of this collaboration with Scientific Advisory Board member Professor Lisa Horvarth from the Chris O'Brien Lifehouse, and Roger Daly of the Biomedicine Discovery Institute, Monash University. You can read the Q&A below.

Hi Lisa, what is the current standard of care for prostate cancer imaging?
Lisa: Prostate cancer imaging is an evolving field. Localised prostate cancer is staged using multiparametric MRI for detailed anatomical detail and radiological assessment of cancer grade. PSMA-PET scan is being increasingly used to assess the involvement of pelvic lymph nodes, and the presence or absence of metastases. This imaging is essential for guiding clinical management.

How would a new imaging technique improve outcomes for patients potentially?
Lisa: Both these modalities (MRI and PSMA-PET) have limits of detection, so small cancer foci in lymph nodes may not be detected. Imagion's new imaging technology would allow precision mapping of the lymph nodes, identifying smaller foci of cancer that current imaging modalities are unable to identify. This would guide the treatment of the lymph nodes either by surgery or radiotherapy

Roger, why is the team at Monash excited to collaborate with Imagion?
Roger: We are very excited by the new imaging technologies being developed by Imagion that could allow early detection of cancer development and its spread, and the role we can play in assisting Imagion in the rapid translation of these strategies into the clinic. Improvements in detection are urgently needed for effective management of specific cancers, such as prostate cancer and specific breast cancer subtypes. In the longer term, we also believe that there is great potential for linking Imagion's technologies to our development pipeline for novel cancer diagnostic and prognostic biomarkers.

What expertise or insight will Monash bring to the partnership?
Roger: Monash BDI will provide expertise in preclinical xenograft models of particular cancers and their expression profile of specific molecular targets, so that these models can be used for testing of Imagion's imaging approaches.



Discover more about our breakthrough MagSense™ technology in our 2020 Annual Report

2020 was a significant year of progress for Imagion that saw the Company advance development of MagSense™ to initiate our first in-human study for HER2 metastatic breast cancer.

Imagion released its 2020 Annual Report to Shareholders in February 2020. In the report, you can read highlights of our progress and learn what makes our MagSense™ technology a breakthrough in early cancer detection.

You can read the Annual Report by clicking the image above or here.

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