

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

16 September 2021

Imagion Biosystems September 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 September 2021 Investor Newsletter.

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

- Message from the CEO, Mr Robert Proulx;
- Q&A with Jane Fox, Director of Breast Services at Monash Health, and Principal Investigator of the MagSense® HER2 breast cancer clinical study;
- Expanding the MagSense® pipeline to brain cancer;
- IBX SAB member Dr Andrew Scott Appointed to VCCC Alliance;
- Imagion Biosystems 1H2021 Half-Year Report;
- Employment of Chief Development Officer; and
- Update on Nanoparticle Sales.

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>

-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

Authorisation & Additional information

This announcement was authorised by the Disclosure Committee of Imagion Biosystems Limited

U.S. Media Contact:

Matthew Wygant
matthew@biotechwriting.com
+1 408-905-7630

Australian Media & Investor Relations:

Evonne Grosso, WE Communications
egrosso@we-worldwide.com
+61 450 603 182

Imagion Biosystems Limited

ACN 616 305 027

Level 25, 525 Collins Street, Melbourne VIC 3000
www.imagionbiosystems.com



Message from the CEO

Dear Shareholders,

I'm happy to share with you our latest Investor Newsletter with updates on Imagination's recent activities.

Since our last Investor Newsletter in March, the most important accomplishment for our company has been our progression to "clinical stage" with the start of our MagSense® HER2 breast cancer Phase I study. Getting into the clinic is a significant achievement for any biotech company, and our efforts now are focused on working diligently with our investigators and advisors to ensure the priority of recruitment and study endpoints are met.

In March we had noted that Cancer Council Victoria had been reporting a noticeable drop in cancer screening and we were saddened to see the August 9th article in the [Sydney Morning Herald](#) indicating breast cancer screening clinics were being shut down and that more than 2500 cancer diagnoses were likely missed due to the pandemic.

We've seen the pandemic effect the progress of clinical studies globally, including the ability for hospitals and staff to initiate studies and access patients. And while we are tackling these factors for our own first-ever human trial, our broader concern is for the health and welfare of Australians and cancer patients globally. Delays in routine screening will ultimately result in a surge

in detected cases once screening resumes, only the cancer will, in some cases, be more advanced. We applaud the Victorian Government's "[dontwaitmate](#)" campaign to encourage maintaining best healthcare practices and are looking forward to the return of routine cancer screening for all.

The constantly changing picture of regional lockdowns has made it difficult to predict the impact on timing and duration of our study so we have focused on trying to increase the number of sites and build awareness of the study in the catchment areas. Our third site (located in Brisbane) is actively screening patients and we look forward to their contribution to our study. The NSW site we mentioned in our half-yearly results engages with a substantive patient population and is in the final steps of meeting their local contractual and governance requirements which will allow us to proceed with site training and initiation of patient screening.

Our work to expand the MagSense® product pipeline has also made progress in the last few months. In addition to the CSIRO funded collaboration with Monash University researchers in prostate cancer (covered in the last Newsletter), we have since added a collaboration with Patrys Limited (ASX:PAB), in which we are exploring the use of a Patrys' deoxymab with our nanoparticles for brain tumour imaging and diagnosis.

Lastly, I think the [recent announcement](#) of our Joint Development Agreement with Global Cancer Technology is worth mentioning. GCT's nanoscintillator technology has the potential to improve the utility of low dose radiation for the treatment of solid tumours through x-ray induced phototherapy. We're excited to be part of this project and look forward to lending our expertise to the development of a new way of treating breast cancers.

As we continue to push further forward with recruitment for our clinical study and the expansion of our product pipeline, I wish to thank shareholders for their continued support of the Company. Despite the short-

term challenges, we remain confident in our path forward and look forward to continued success together.

With best regards,

Robert Proulx,
President & CEO

In this issue:

Message from the CEO

-

Q&A with Jane Fox, Director of Breast Services at Monash Health, and Principal Investigator of the MagSense's HER2 Breast Cancer clinical study

-

Expanding the MagSense® pipeline to brain cancer

-

IBX SAB member Dr Andrew Scott Appointed to VCCC Alliance

-

Half Year Report

-

Chief Development Officer

-

Nanoparticle Sales

Q&A with Jane Fox, Director of Breast Services at Monash Health, and Principal Investigator of the MagSense's HER2 Breast Cancer clinical study

With the Phase I study for the MagSense® HER2 imaging agent underway, we thought it would be interesting to hear from the study's Principle Investigator, Jane Fox.

Why did you decide to get involved in the MagSense® study?

There is a focus in several areas of cancer research in determining who will, and who won't benefit from particular treatments, with a desire to avoid both undertreatment and overtreatment. My interest was piqued by the MagSense® study because of the opportunity to personalise patient management with a focus on refining the information available to medical, surgical and radiation oncologists. For example, when there is uncertainty about whether there is a disease in the lymph nodes or not, it can make planning neoadjuvant systemic therapy, or surgery or radiotherapy, more difficult. It would be good to have more certainty about the nodal disease without the patient needing an operation to obtain it.

What are some of the challenges you are seeing in recruiting patients for the study?

Remembering that HER2 positive cancers are about 15% of all the breast cancer diagnosed, we are starting with a relatively small target population. While the full impact of COVID remains to be seen, I think there is some reluctance to attend hospitals for more than necessary care but we are continuing to screen all our eligible patients through our multidisciplinary meetings and offering the study to all potential participants and are looking forward to the new sites contributing to the study.

Chief Development Officer



We're very pleased to welcome Dr Yalia Jayalakshmi as Chief Development Officer responsible for leading our global clinical development strategy and execution.

Dr Jayalakshmi's comes to Imagion with deep background, knowledge and leadership in cancer imaging and nanotechnology at a depth that is not regularly seen in the industry. Her experience spans drug, device, nanoparticle delivery and diagnostic imaging products in oncology, ophthalmology and other therapeutic areas for companies such as Onyx Pharma, Genetech, and Cygnus. Her most recent role was Vice President

Clinical Development at OncoNano Medicine.

We look forward to her providing leadership for our current MagSense® HER2 breast cancer Phase I study, and all our future clinical programs.



IBX SAB member Dr Andrew Scott appointed to VCCC Alliance

The Board, Executive and clinical research teams at Imagion Biosystems would like to congratulate our Scientific Advisory Board member, Dr Andrew Scott for his appointment as Research Translation and Commercialisation Lead for VCCC Alliance.

As a member of the Company's Scientific Advisory Board, Imagion has benefitted from of Dr Scott's experience in bridging technology and innovation with healthcare and clinical practice.

We wish Dr Scott all the best in his new appointment and look forward to continuing to work together.

Half Year Report

Imagion released its Appendix 4D Half Year Financial Report to Shareholders in August 2021.

Detailing the Company's milestones in the H1 period, the release provides a further update on the company's financial reporting, our MagSense® HER2 Breast Cancer Clinical Trial and other initiatives.

You can read the Half Year Report [here](#).

Expanding the MagSense® pipeline to brain cancer

In May, we extended our collaborative research program with Patrys Limited, in which Imagion is investigating the use of Patrys' novel deoxymabs in combination with the imaging capabilities of the MagSense® technology.

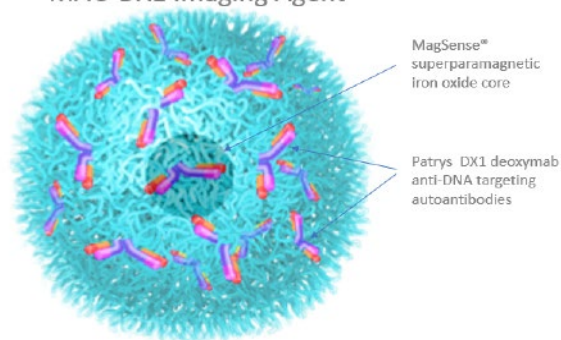
Our preliminary research has demonstrated that the Patrys PAT-DX1 molecule can be attached to the MagSense nanoparticles and provide bio-functionality for targeting certain cancer cell lines.

[A recently published article](#) by Patrys and researchers from Yale University School of Medicine indicated that PAT-DX1 is effective in targeting brain tumors in animal studies. If we achieve positive research results using DX1 to have targeted delivery of an imaging agent, Imagion has an exclusive option to license the Patrys molecule for use in magnetic imaging.

Conventional MRI has been the standard modality to identify and localize brain tumors for many years as MRI provides improved sensitivity compared to CT. Gadolinium-based contrast agents are often used for brain imaging, but recent concerns of both nephrotoxicity and neurotoxicity stemming from use of gadolinium have been raised. Positron Emission Tomography (PET) is also used for brain imaging due to its sensitivity and ability to co-register images with other imaging modalities, but PET has low spatial resolution, radiation exposure, and relatively high cost. A bio-safe contrast agent, such as MAG-DX1, could provide high sensitivity and specificity for detecting and monitoring brain tumors.

You can read the announcement [here](#).

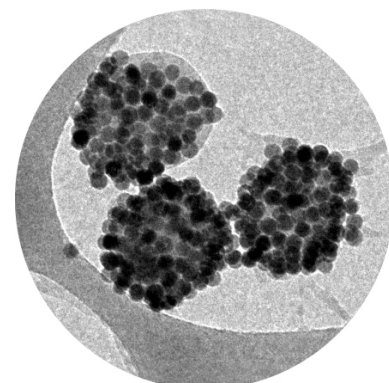
MAG-DX1 Imaging Agent



Nanoparticle Sales

In 2019 we first reported that New Phase, an Israeli company developing a hyperthermia treatment for cancer, had placed a standing order for our super-paramagnetic iron oxide nanoparticles, which they incorporate into their Sarah Nanoparticle (SaNP). We've continued to supply our nanoparticles to New Phase throughout 2020 and 2021, working closely with them as they progress their pre-clinical research of the SaNP product.

We are pleased to report that we have recently received an updated purchase order for additional supply of our nanoparticles for the remainder of 2021. We look forward to continuing to work closely with them in anticipation of transitioning their SaNP hyperthermia treatment into clinical development.



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

Australian Media & Investor Relations

Evonne Grosso, WE Communications
we-auimagionbiosystems@we-worldwide.com
+61-450-603-182

U.S. Media Contact:

Matthew Wygant
matthew@biotechwriting.com
+1-408-905-7630