

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

22 July 2020

AGM – TRANSCRIPT OF CHAIRMAN’S ADDRESS

Dear Shareholders,

It is with great pleasure that I address you at our Annual General Meeting for the financial year ending 31 December 2019.

As much as I would love to be in Melbourne and be able to give this address personally, we appreciate the ASX temporary rules change that allows us to hold a virtual meeting, and which provides an opportunity for shareholders based in other parts of Australia and the US to join our AGM. Thanks to all for your attendance and support of the company.

Before we get into the formal business of the meeting, I wanted to spend a few minutes reflecting on the past year and sharing our vision for the future of the company.

In many ways, 2019 – and indeed the first six months of 2020 – has been a breakthrough period for Imagion Biosystems with important advancements both in the science and technology and in our business operations.

At the time of last year’s AGM we had completed the toxicology study – a major milestone for any biotech company, and, over the course of this past year, we have delivered on a number of key milestones that have paved the way for commencement of our first in human study. In doing so, we have made every effort to move ahead as fast as possible – often with limited resources – while trying to ensure we that we don’t just achieve a milestone but that we are actually setting ourselves up for future success. I’d like to provide three examples from this past year.

- Once we knew that our toxicology data supported our expected safety profile, we began working with our contract manufacturers on the plan to make the material under the manufacturing guidelines necessary for use in human studies. But because we are bringing a novel technology into the clinic for the first time, we took extra care to ensure that the material to be produced would meet the requirements for human research. As a result, we were able to commence manufacturing earlier this year and now remain on track to have the MagSense nanoparticle material available in Q4;
- Similarly, after our initial communications with the FDA, we were able to successfully apply for and obtain the FDA Breakthrough Device designation. This designation is only assigned to technologies that are considered to be potentially transformative in terms of patient care or outcomes. Our work with the FDA now provides support and justification for our Australian study and will expedite our communications with the agency when we move forward with seeking regulatory and marketing clearance for our technology in the US;

- And finally, after having identified that our MagSense nanoparticles could have commercial potential with existing MRI systems, we followed that with a collaboration agreement with Siemens Australia to further investigate this potential and we are now planning to incorporate MRI as one of two imaging modes in our upcoming study.

I believe each of these examples and the list of key achievements illustrate that we understand our business and operate in a diligent and prudent manner to achieve meaningful outcomes and value for the company.

As our recent announcement indicated, we are now making ready to undertake our early feasibility (or Phase 1) study in Australia. Like all Phase 1 studies, a primary goal of this study is to determine whether our MagSense™ nanoparticles are safe for use in humans.

Based on the toxicology study we completed last year and the known history of use of iron-oxide nanoparticles, we expect to meet this primary endpoint for safety. But the study should also provide initial insights regarding the effectiveness our HER2 targeting nanoparticles for determining the presence and spread of HER2 breast cancer in the lymph nodes. Being able to non-invasively identify which patients have metastatic disease will significantly improve care since as many as 50-70% of patients are negative but are still required to have surgical or biopsy procedures to find that out.

This initial study is small, with an aim of testing our tumor targeting nanoparticles in approximately 15-20 patients – which is enough to assess safety and get an initial view of their bio-functionality for detecting metastatic disease. Based on the outcome of this initial study we can then have a better idea of how quickly we can or should proceed with larger studies for regulatory clearance.

Thankfully, to-date our business operations have not been significantly impaired by the coronavirus pandemic. Many of the tasks that remain ahead of us are clerical in nature, such as getting contracts in place and submitting the study for Ethics review and approval. These, we believe, can continue through our collective new normal of remote working conditions. However, we remain mindful that extensive restrictions imposed to curb the spread of the pandemic could impact our clinical sites and their ability to start the study as we currently plan. We will keep investors apprised as we make progress and learn more.

Showing that our novel MagSense™ technology can improve the detection of HER2 breast cancer should provide important shareholder value creation, but our vision has always been more expansive because our nanoparticle technology has significant potential in the diagnosis and treatment of many diseases. Many investors might recognize this slide since it has been a part of our investor presentation material since early on. I think it is important for our shareholders to see that the content of this slide is not pie in the sky or just wishful thinking.

This year, in addition to the progress we have made on our first product for breast cancer, we've made some important announcements that give insight into that vision and our progress. For example, as I mentioned earlier, in September we announced scientific evidence that our nanoparticles could be used as an effective MR contrast agent. Those results were instrumental in being able to attract a collaboration with Siemens, one of the world's leading medical imaging companies. That collaboration has accelerated our ability to include MRI scans in our clinical study and will move us one step closer to understanding the commercial opportunity for our technology there.

The recent announcement of our collaboration with Boston University, similarly, moves us one step closer to seeing how our technology could be employed in the doctor's office. The work this centre is doing is incredibly innovative – if we can reduce the size and cost of our technology – we can greatly improve accessibility and enhance the commercial appeal and accessible market. It's our vision that our MagSense instrument could someday be a small hand-held device, used ubiquitously in doctor's surgeries.

From a corporate perspective, we have raised a total of \$6.1 million over the past year, in two transactions, with our Board and Management participating in those raises. Additionally, we successfully achieved an Overseas Finding for our R&D Tax credit which added a further \$4.2 million of non-dilutive capital, and we continue to book revenue from the sale of our nanoparticles.

Our progress over the past 12 months has resulted in heightened interest and liquidity in IBX with a number of new shareholders coming onto the register. We very much appreciate the support, and especially want to acknowledge our longer-term holders.

We have taken steps at every opportunity to reduce operational costs in order to conserve cash. We expect conducting our trial in Australia will also deliver cost benefits – although that has not been the primary driver for that decision.

Finally, I'd like to acknowledge the Executive Team, Board and Advisors at Imagion Biosystems. For a small company, that is still in development, we have gathered an exceptional team of leaders and advisors – and I think this is a strong testament to the transformational nature and potential of our technology.

Our Board consists of industry professionals, like Mike Harsh the former CTO and VP of Medical Imaging at GE, who continue to serve because of their belief in and commitment to the company, despite being compensated at below industry levels.

I would like to formally welcome Di Angus to her first AGM. Di has been a fantastic addition to the Board. Her experience and counsel have already proven to be invaluable in her short time with us.

This year we also appointed an impressive group of researchers and clinicians to our Scientific Advisory Board. This group will be instrumental in guiding us as we progress through clinical research and look to develop the commercial pathways. I'd like to thank Dr John Hazle, Chair of the Department of Imaging Physics at MD Anderson, one of the world's leading cancer treatment and research centres, for taking on the role as Chair of the Advisory board and to all the Advisors for giving us their time and expertise.

Finally, I would like to say thank you to Brian Conn – our outgoing CFO who has played an instrumental role in the company for the past three years. Brian is leaving to take on a full-time role with another of his clients. Although I am sad to see Brian go, this creates an opportunity for us to realign management. It is our intention to bring someone on to the team that is based in Australia – closer to our investors and experienced with ASX listing requirements and the Australian capital markets.

We will continue to build out a team of highly skilled, highly regarded leaders with the expertise



and knowledge to guide us through our next phase as a company. I am very proud of what we have achieved – particularly in this past year – and I'm very excited about what lays ahead.

We still lose too many lives to cancer, and so at Imagion we have a clear purpose - to provide a better, safer way to detect and ultimately treat cancer. Every step closer we come to achieving that goal, is an opportunity to create value for shareholders. We thank you for your support, and we look forward to sharing this next stage of our journey with you.

-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 Board of Directors of Imagion Biosystems Limited

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IMAGION
BIOSYSTEMS

Imagion Biosystems Limited (ASX:IBX)

AGM PRESENTATION

22nd July 2020

www.imagionbiosystems.com

2019 – 2020 Key Achievements



- ✓ March 2019 – Patent claims in US extended to include treatment.
- ✓ May 2019 - Successful completion of key toxicology safety study for the MagSense™ HER2 nanoparticle formulation.

- ✓ July 2019 Receives designation from the FDA that the MagSense™ System for HER2 metastatic breast cancer is a *Breakthrough Device*.
- ✓ October 2019 – Establishes Scientific Advisory Board with prominent US and Australian clinical advisors.
- ✓ November 2019 – Global patent protection on the core magnetic relaxometry method extended to include large India market.

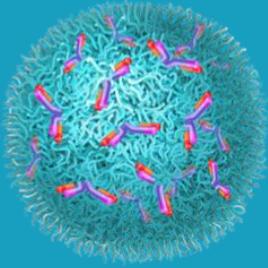
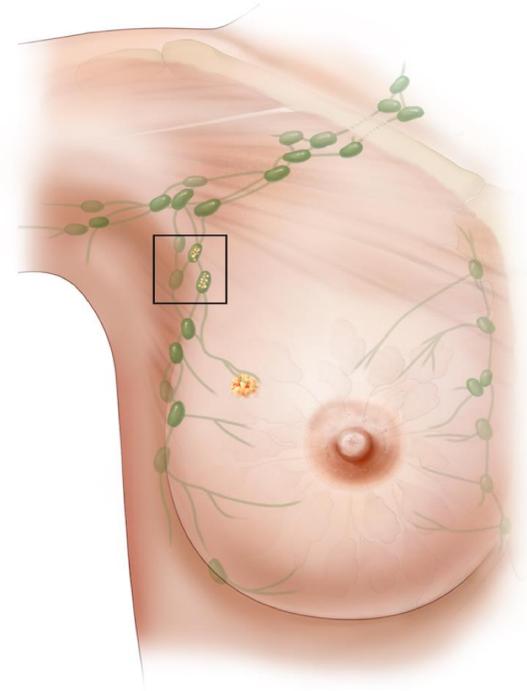
- ✓ February 2020 - GMP manufacturing commenced
- ✓ May 2020 – Collaboration agreement with Siemens Healthineers established to investigate clinical use of MRI with MagSense™ nanoparticles.
- ✓ June 2020 - Confirmation of plans to conduct trial in Australia in two imaging modes
- ✓ Total \$6.1M capital raised and \$4.2M received in R&D tax refunds

MagSense™ Technology



Study Overview

Staging of HER2 metastatic breast cancer by the detection of tumor cells in lymph nodes



Phase I Study

- Primary endpoint is testing for patient safety
- 2nd endpoint is an initial assessment of effectiveness



Multi-Site in AUS

- 3-5 clinical sites in Australia (VIC and NSW)
- Goal of testing 15-20 subjects up to a maximum 40



Timing

- Enrolment expected to commence in Q4
- Study duration of 6-9 months depending on subject availability and number of sites

Pathway to Study Initiation



✓ CRO Appointed

Human Research Ethics Committee (HREC) Submission and Approval

Completion of Manufacturing of the MagSense™ nanoparticles

Clinical sites and Principal Investigators contracted

Targeting Subject Enrolment Q4 2020

Platform for growth

Strategic plan provides path to future products and shareholder value



STAGING BREAST CANCER

Reduce unnecessary surgery

\$700M
>\$140B

TUMOR DETECTION

Breast, prostate, lung & ovarian

\$7B

MRI CONTRAST

Safer alternative to current product, Gadolinium

>\$3B

TREATMENT MONITORING

Monitor tumor size and adjust treatment accordingly

>\$2B

DOCTORS OFFICE

Hand-held MagSense instrument

>\$14B

DETECTION & THERAPY

Provide both detection & delivery of therapy

Addressable Markets