IMAGION BIOSYSTEMS LIMITED

(ASX**: IBX**)

25 May 2023

AGM – Transcript of Chairman's Address

Dear Shareholders,

As we noted in our Annual Report, 2022 was a momentous year. We showed that our imaging agent technology was safe and well tolerated, not just in healthy volunteers like most Phase 1 studies, but in actual breast cancer patients. Additionally, we ended the year being the first company ever to conduct a clinical study and present clinical data for the targeted imaging of cancer using magnetic nanoparticles. We have shown that our nanoparticle imaging technology could be used to non-invasively detect cancer, not just in laboratory animals but actual human patients. From both a scientific perspective and a business perspective, this is a major success.

Yes, recruitment has been challenging, but WE DID IT. We have positive data from patients with metastatic breast cancer. If you compare our achievement to the number of drugs or devices that fail in early-stage clinical studies, we've delivered a significant milestone.

And now we have carried the momentum from 2022 into 2023. In early February we reported that a review of our Phase 1 data by an independent group of radiologists corroborated two key findings:

1. that our MagSense imaging agent was detectable in the patient's lymph nodes; and
2. that using Magnetic Resonance Imaging, the radiologist observed a differentiated image between normal lymph nodes and nodes that could contain cancer cells.

This independent corroboration of the study imaging results has enabled us to shift the strategy for our nanoparticle pipeline towards using MRI for the molecular imaging of cancer. The MRI approach opens the door to a faster and more economical path to commercialisation than developing and introducing a new type of detection technology. We anticipate that by leveraging existing MRI we can develop a more proximate revenue pathway for our imaging agents, initially targeting HER2 breast cancer, and in the future other cancers such as ovarian and prostate cancer. This year we will continue to advance our pipeline for molecular MRI as we believe this strategy to be more attractive for strategic partners and more likely to achieve commercial success sooner for us.

By prioritizing molecular MRI for our nanoparticle technology, our development path has become clearer and less complicated. And as a result, we were able to initiate communication with the U.S. FDA to expand our MagSense® HER2 development for breast cancer detection to a Phase 2 study. Over the next several months we will be completing additional work and preparing for our submission of an Investigational New Drug (IND) application to the FDA. Receiving clearance of an IND is a major technical and regulatory milestone in-and-of itself. Most biotech and pharma companies see the IND as a significant milestone and value inflection point because of the rigor and supporting evidence needed to gain FDA's IND clearance.

Since the beginning of this year, we have continued to enrol into the Phase 1 study and are expecting soon to complete the second cohort of patients. Given the satisfactory evidence supporting our primary and secondary endpoints and the recent guidance we have received from the FDA regarding our plans for the Phase 2 study, we believe we can now begin winding down the Phase 1 study. I acknowledge that it has taken longer to complete than we thought when we initiated the study, but the positive outcome of this study marks an important accomplishment for the company.

In summary, in the last two years we have taken our lead product for breast cancer from benchtop to a positive outcome in a Phase 1 study. Additionally, we have demonstrated that our nanoparticle technology is, indeed, a platform for targeted molecular imaging having reported preclinical results for both prostate cancer and ovarian cancer. Pursuing use of our nanoparticle technology with conventional MRI will reduce the risk, time and cost of our development path. Additionally, it is more likely to be an attractive commercial prospect for partners, while still preserving the opportunity for our proprietary magnetic relaxometry technology to play a role in the future.

With the success we are claiming from our Phase 1 study you may be asking why we need to do a Phase 2 study or what we expect to gain from it. Firstly, I'd like to remind everyone that the Phase 1 study was always intended as a proof-of-principle for our nanoparticle technology. Since our nanoparticles had never been tested in human subject before, it was important that we start with a limited study before committing to larger numbers of patients. And because no one had ever tested a targeted imaging agent before, and because we weren't only testing for safety in healthy volunteers, in our Phase 1 study we had to take our best guess as to what dose to give patients and at what time point or points we should be imaging. But by including this as part of the Phase 1, we now have data to inform the next study. As challenging as it has been these first patients have been instrumental in establishing the baseline for our future work.

In the Phase 2 study we will start with dose ranging, that is, reducing the dose to see how low we can go while still achieving detectability. Think of this for a moment. This is good all around. Patient safety is likely to be better with smaller doses and our gross margins can be higher if we use a smaller amount of imaging agent to achieve the same diagnostic outcome and price. Additionally, in the first patients of the Phase 2 study we will be looking to optimize the timing of when the MRI is taken. Once we have established a more optimal dose and timing, we will expand the study to a larger group of patients.

Given the slow recruitment into the Phase 1 Study here in Australia, what does that mean for recruiting a larger number of patients for Phase 2? There are three things working in our favour. Firstly, in many other countries, including the US, population size means there are just a lot more patients. Secondly, we can have many more sites recruiting in parallel. And thirdly, since we were only going to test a limited number in the Phase 1 study, we had to focus on patients suspected of nodal disease. This has meant that more than half of the HER2 breast cancer patients have not been eligible. In the Phase 2 study we will recruit from all HER2 positive patients.

In 2022 we made real progress in our mission to improve cancer detection and have charted a clear path with and updated strategy that will move us towards our goal of commercializing our nanoparticle platform. I understand that for our shareholders it can be hard to be enthusiastic about these “wins” or accomplishments and the prospects for the future when the share price is suffering; and the fact that over the last year approximately 80% of the ASX bio-techs have been trading down is no real consolation.

Recently, I heard of an analyst who has been watching IBX. He told a colleague that he liked the IBX story but that we still had some wood to chop. I liked this analogy because it implies if we do the work, we have the makings of a roaring fire. In my opinion, and that of our Board, the IBX share price does not reflect the value we have created and are creating.

Over this past year we have seen a number of the large pharma companies including Novartis, Merck, and Bayer being interested in the diagnostic imaging space and licensing and partnering with companies developing targeted radiotracers and radiopharmaceuticals. We believe this bodes well for our strategic plan of partnering, and towards that end we recently opened a secure data room where we can share confidential information with prospective strategic partners. With our MagSense® imaging agent for breast cancer now laying the groundwork for our technology to be first in class for molecular imaging by MRI, we believe we can help to change the way we see cancer.

To realize this potential, we have to continue to push forward. Every additional step through the clinical and regulatory process adds value and takes risks off the table; but it also requires having access to working capital. We know that markets and economic conditions in Australia, and indeed globally, have been difficult and may continue to be so. So I’d particularly like to thank the shareholders that participated in the recent entitlement offer. Your support for the company is greatly appreciated. But it is exactly those market conditions that also highlight why having a financing instrument like we have put in place with Mercer Street Capital is so important for a company like Imagion. We don't intend to solely rely on this instrument to fund the company, but having it means we have access to working capital without having to worry about timing of market conditions. With $3.5M of funds expected to come in this quarter from our ATO tax credit, we aim to use the Mercer funding judiciously to keep our drive towards the IND on track.

Now before closing my remarks and moving on to the formal meeting, I'd like to speak briefly to the recent announcement of my plans to retire from the role of CEO. While I am not the founder of the company, I have fully vested myself in the vision and mission of Imagion and believe strongly in what we are trying to accomplish and the value it will create. So I can assure our shareholders that my plans to retire from the role of CEO does not mean I will be riding off into the sunset. The Board and I are fully committed to the principles of good governance and plan for me to remain as Chairman of the Board to keep the momentum going and ensure we preserve the knowledge and history gained over the years of my leadership so that we are successful in the next phase of our journey.

In closing, I'd like to thank all the Imagion stakeholders for their support – shareholders, customers, collaborators, advisors, employees, Directors, and particularly those breast cancer patients that have, despite their medical diagnosis, participated in our study and the physicians and study teams who executed on the protocol. We are looking forward to our future and to achieving our goal of changing the way we see cancer to positively impact patient outcomes.

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About Imagion Biosystems
Imagion Biosystems is developing a new non-radioactive and precision diagnostic molecular imaging technology. Combining biotechnology and nanotechnology, the Company aims to detect cancer and other diseases earlier and with higher specificity than is currently possible.

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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