



IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

23 August 2019

Imagion Biosystem's August Newsletter

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

The newsletter details recent key company developments and upcoming moves including:

- FDA Breakthrough Device Designation
- Completion of the toxicology study
- Dr Marie Zhang presenting at the World Molecular Imaging Congress in September in Canada
- CEO Bob Proulx speaks with Scott Power from the Morgans Podcast

The Investor newsletter can be viewed below. Imagion Biosystems normally distributes this update as an e-newsletter. To receive these updates in future please register via email to imaginationbiosystems@we-buchan.com.

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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.imaginationbiosystems.com

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Imagion Biosystems Receives FDA "Breakthrough Device" Designation

Imagion Biosystems has 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 purpose of the Breakthrough Device Program is to expedite and improve communications between a device manufacturer and the agency during device development. Bob Proulx, Executive Chairman, said, "Qualifying as a Breakthrough Device validates our MagSense technology as a transformative opportunity for healthcare, and could improve the standard of care for staging HER breast cancer."

Read about it [here](#).

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[Bob Proulx on Recent Stock Price Move](#)



[Listen](#)

CEO Bob Proulx recently caught up with Scott Power from the Morgans Podcast to talk about Imagion and the Company's next steps. Bob

Toxicology Study Completed



On 23 May, 2019, Imagination Biosystems announced the successful completion of a toxicology safety study of lead MagSense™ nanoparticle formulation for the detection of HER2 metastatic breast cancer. The study was completed on time and no adverse effects were reported.

"It is good to have this hard evidence in hand," said Bob Proulx, Executive Chairman. "We will be breaking new ground in medical imaging bringing a targeted bio-safe nanoparticle to first-in-human studies."

Read the announcement [here](#).

Imagion Biosystems at WMIC 2019

Marie Zhang, PhD, Vice President of Research and Pre-Clinical Development at Imagination Biosystems, will present the poster "Targeted Magnetic Nanoparticles Detectable by both SPMR and MRI" at the 2019 World Molecular Imaging Congress, to be held 4-7 September in Montréal Québec.



Session Title: Poster Session 4: Oncology

Poster Title: Targeted Magnetic Nanoparticles Detectable by both SPMR and MRI

Session Date/Time: Saturday, 10:30AM - 11:30AM

Location: Exhibit Hall 517

Poster Number: P348

discussed how the MagSense technology could dramatically change healthcare, as over the past 50 years there has only been five ways to image the body, and MagSense could be the new imaging technology that fills the functional imaging gap to accurately detect cancer.

[Read](#)

Imagination Biosystems was recently featured in Next Biotech. This article gives a comprehensive overview of the technology and investment thesis.

[Imagion Gets A\\$2 Million in R&D Tax Incentives](#)

Q&A with Bob Proulx



Bob Proulx joined Imagination Biosystems as CEO in February 2015. He has extensive experience across the medical diagnostic, computer and life sciences industries. In this article, we ask Bob a few questions about his career and experience in bringing products to market.

1. Tell us about your career before joining IBX?

After leaving my graduate studies in human evolutionary biology, I began working in the computer industry just at the time that the personal computer was being introduced. That led to an opportunity to work with a biotech company developing an instrument for measuring biological samples. This role made me realize that I enjoyed combining my knowledge in biology with designing and developing scientific products. Now, I have spent last 30 years in various leadership roles developing and commercializing all kinds of interesting scientific instrumentation used in biological research and medical diagnostics. Some of these instruments include semiconductor chip technologies for DNA diagnostic testing and imaging tumor cells for cancer, along with robotic liquid handling technology that was used for high throughput drug discovery and in clinical laboratory automation.



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2. What do you think are the critical success factors to successfully commercializing a med-tech product?

Firstly, you have to know that there is a market for the technology. All too often new technology is created because it is scientifically or technically interesting, but there is no clear commercial opportunity. I've seen lots of cool technology die because the company fails to have a clear path to commercial utility. Secondly, you need a clear understanding of who the target customer (buyer) is and how it will be paid for. Sales or distribution channels can be complex and expensive but partnering cedes responsibility and control to someone else. There is a big difference between commercializing a new device or technology that is an incremental improvement over existing technology versus introducing a new category of product or technology and changing the paradigm.

3. What have you done to test the commercial appeal of IBX's technology?

One of the first things I did when I joined Imagination was investigate and characterize the product's potential for success. We focused on two main areas of market validation. First, we found that if we could achieve the utility we were aiming for with the technology, there would be large opportunities across multiple types of cancer for diagnosis and patient treatment. Secondly, we confirmed with a cohort of medical oncologists and primary care physicians that if the utility were achieved, they would use the technology. I think the recent notice we received from the U.S. Food and Drug Administration designating our MagSense System as a Breakthrough Device is a good indication that we are addressing an unmet need.

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4. Where do you see the future of cancer detection and treatment going?

The medical community is soundly behind the idea that earlier detection of cancer would improve patient outcomes. I believe the so-called liquid biopsy or blood-based testing for tumor cells is going to improve our ability to screen for early warning signs of cancer. If we can combine better screening with improvements in medical imaging, which is the goal at Imagion, I think we have a good chance of detecting cancer earlier, and with that, improving the effectiveness of treatments.

To hear more about Bob's background and his views on the opportunity for Imagion listen to this recent interview with Morgans analyst Scott Power