



Quarterly Activity Report

Quarter ended 31 March 2023

IMAGION BIOSYSTEMS LIMITED

(ASX: IBX)

28 April 2023

Highlights:



Reported positive results of independent review of utility for MagSense® HER2 breast cancer detection



Announced plan to advance MagSense® HER2 program to multi-site US study



Received 2nd CSIRO Federal Government grant for prostate cancer project



Opened a non-renounceable entitlement offer to raise up to \$2.4 million



Secured a \$15 million funding facility with Mercer Street Global Opportunity Fund, LLC



MELBOURNE – Imagination Biosystems (**ASX:IBX**), a company dedicated to improving healthcare through the early detection of cancer, today released its Appendix 4C Quarterly Cashflow report and update on company activities for the quarter ended 31 March 2023 (Q1 FY2023).





“The momentum from 2022, where we were able to report positive in-human data from the MagSense® HER2 Phase 1 study, has continued into 2023 with further advancements in relation to the HER2 program as well as reporting positive pre-clinical data for our Ovarian Cancer program,” commented CEO Bob Proulx.

“The positive independent review of our Phase 1 data by an independent panel of radiologists has given us the confidence to move forward with planning for a multi-site study in the US for the MagSense® HER2 imaging agent. We have had good dialogue with the FDA and feel confident moving forward to an Investigational New Drug (IND) filing which we feel it is achievable in late 2023 or early 2024.”

Summary of Activities

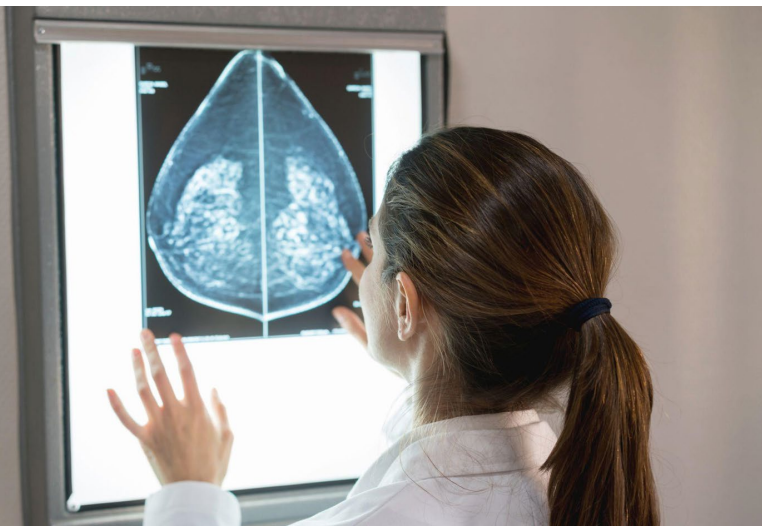
MagSense® HER2 breast cancer program

During the quarter the Company announced that an independent blinded review by a panel of expert breast cancer radiologists corroborated the Company's previously reported positive findings from its MagSense® HER2 breast cancer phase 1 study.

The radiologists ascertained that the MagSense® HER2 imaging agent produces a change in Magnetic Resonance Image (MRI) contrast and that the contrast in nodes highly suspicious for tumour is distinctly different from the MRI contrast seen in non-involved nodes. The independent reviews are consistent with the Company's previous assertion that the MagSense® imaging agent provides new information for the radiologist not available through conventional methods, like ultrasound, and has the potential to aid in the clinical assessment of nodal metastasis in HER2 positive breast cancer. The Company now plans to prioritise the development of its pipeline of tumour targeting MagSense® imaging agents for use with widely available commercial MRI systems.

This approach is expected to provide a faster path to patients and commercialization and eliminates near-term expense and risks associated with developing and introducing the Company's proprietary detection technology (Magnetic Relaxometry). The Company plans to collaborate with academic and industry partners on a new generation of small magnetic sensors that could enable the use of magnetic relaxometry in a doctor's office.

Please refer to the Company's announcement on 5 Feb 2023 for further information:
<https://imaginationbiosystems.com/news/priority-path-to-market-for-magsense-technology/>



During the quarter, Imagion also announced it has been in communication with the U.S. Food and Drug Administration (FDA) related to its interest in advancing the MagSense® HER2 breast cancer clinical investigations to include sites in U.S. The Company noted that the guidance and recommendations received from the FDA are consistent with regulatory oversight for products entering Phase 2. The Company now plans to proceed with an IND filing in the US for the MagSense® HER2 imaging agent.

The Company noted that activities in the coming quarters would include: collecting additional non-clinical and clinical data (pharmacokinetics) in support of commencing a US Phase 2 study; manufacturing additional MagSense® HER2 imaging agent material to support the US Phase 2 study; and establishing the initial clinical investigators and sites to support the study. Imagion expects to be able to file the IND submission in Q4 of 2023 or Q1 of 2024.

Please refer to the Company's announcement on 27 March 2023 for further information:

<https://imagionbiosystems.com/news/imagion-to-proceed-to-file-an-ind-for-the-magsense-her2-imaging-agent/>



MagSense® prostate cancer program

During the quarter the Company qualified for a second grant of \$50,000 under the Entrepreneurs' Programme of the Australian Government Department of Industry, Science, Energy and Resources. Imagion used the first grant in 2021 to support its early preclinical research efforts for prostate cancer detection in collaboration with researchers at Monash University. The second grant will be used to continue that program, building on the preclinical results that were reported at the World Molecular Imaging Conference in September 2022. These funds will help to further advance the MagSense® prostate cancer imaging agent for use with Magnetic Resonance Imaging (MRI) for clinical detection of the Company's MagSense® molecular imaging technology.

MagSense® ovarian cancer program

Subsequent to quarter end Imagion's VP of R&D, Dr. Marie Zhang, presented two scientific posters related to the Company's ovarian cancer detection program at the Annual Association of Cancer Research in Florida.

Poster 1: *Targeted Detection of Ovarian Cancer Using Functionalized Iron Oxide Nanoparticles*

Poster 2: *In Vivo Targeted Detection and Imaging of Ovarian Cancer by SPMR and MRI Using Anti-Folate Receptor Functionalized Iron Oxide Nanoparticles*

Please visit the link to obtain copies of the posters: <https://info.imagionbio.com/aacr-2023-poster-request>

Intellectual Property

Subsequent to quarter end the Company announced that it had filed a provisional patent application related to the image patterns(s) associated with the presence of the MagSense® targeted imaging agent. The new IP would extend Imagion's proprietary position for our magnetic nanoparticles across Magnetic Relaxometry (MRX) and Magnetic Resonance Imaging (MRI), providing broader protection against other imaging agents that might try to replicate targeted detection by MRI. Whilst there is no guarantee that the patent will issue, the new IP will provide significant value to Imagion and its commercial partners.

Since all MagSense® targeted imaging agents use the same underlying nanoparticle technology, the Company would look to apply the intellectual property position broadly across the portfolio of MagSense® nanoparticle imaging agents.

Strategic partnering

Now that the Company's MagSense® imaging agent for HER2 breast cancer is progressing towards Phase 2 and our technology is showing positive preclinical results in other areas of high unmet need, including prostate cancer and ovarian cancer, we have a potentially substantial value proposition for the medical imaging sector and are now well-placed to initiate discussions around strategic options with potential commercial partners.

To facilitate this process, we have established a secure data room where we can share confidential information related to the MagSense® HER2 program as well as our growing pipeline of imaging agents and will begin outreach programs to potential partners in an effort to gauge market interest in our technology.

Funding initiatives

During the quarter the Company announced an entitlement offer seeking to raise up to \$2.4 million as well as a funding facility of up to \$15 million with Mercer Street Global Opportunity Fund, LLC (Mercer).

The entitlement offer, which closed on 14 April 2023, provided funds of \$413k (before costs) from existing shareholders. There is a shortfall of up to \$1.97 million available for the Company to place to new or existing shareholders prior to 14 July 2023. The ability for the Company to place this shortfall will be dependent on market conditions and Imagion's share price trading on or above the entitlement offer price (being \$0.017 or 1.7cents per share).

The funding facility with Mercer initially provided an investment of \$1.5 million in convertible securities, which was received during the quarter. A further investment of \$1.0 million in convertible securities has been committed by Mercer and is subject to shareholder approval at the Company's upcoming AGM to be held on 25 May 2023. The facility provides for up to a further \$12.5 million in convertible securities subject to mutual agreement between the Company and Mercer as well as either receiving shareholder approval at the upcoming AGM or having available placement capacity in accordance with the ASX Listing Rules.

Please refer to the Company's announcement on 7 March 2023 for further information:

<https://imagionbiosystems.com/news/imagion-funding-update/>

The decision to enter into the funding agreement was taken to assist in providing liquidity for the Company as it advances its clinical development towards an IND filing and commencement of a multi-site Phase 2 study in the US. The advancement of any medical technology company towards Phase 2 studies and beyond requires significant investment and the Company is utilising its positive relationship with Mercer to provide another avenue of liquidity. This liquidity is in addition to the capital markets and prior to the ability to find any strategic commercial partners (refer above for initiatives in this area). In making this decision the Company is cognisant of the depressed capital markets, particularly in relation to microcap and pre-revenue companies, in Australia and to a lesser extent the US.

At this stage the Company has no intention to fully utilise the Mercer facility but is pleased to have this facility as part of its overall capital requirements.



Summary of cash flows

Imagion's cash balance at 31 March 2023 was \$2.6 million, a decrease of \$1.8 million from the prior quarter. The Company reported an operating cash outflow of \$2.9 million in the quarter, similar to the prior quarter's operating cash outflow (when adjusting for the receipt of the \$2.5 million research and development tax incentive received in Q4 2022). This was in line with the Company's expectations.

Administration and corporate costs, and staff costs increased slightly on the prior quarter while research and development costs reduced slightly. Repayment of borrowings and interest costs reduced slightly during the quarter. These relate to the allocation of rent for our San Diego facility, in line with the lease accounting provisions of the accounting standards.

We anticipate administration and corporate costs to remain relatively consistent through the remainder of 2023. Research and development costs are expected to increase during the remainder of 2023 as the MagSense® HER2 Breast Cancer program progresses towards an IND filing and undertakes activities outlined above. In addition, the Company will also be planning to advance its development pipeline, and therefore this may add to research and development expenditures.

In relation to liquidity the Company anticipates receiving up to \$4.9 million from the following financing proceeds in Q2 2023: receipt of \$1.0 million (pre-costs) for the second tranche of convertible securities from Mercer (subject to shareholder approval at the Company's upcoming AGM); receipt of its research and development tax incentive in respect of the 2022 year which is anticipated to be \$3.5 million (this has been lodged with the Australian Taxation Office); and receipt of \$413k (pre-costs from the Company's recent Entitlement Offer). In addition to this the Company has the ability to raise a further \$1.97 million under the shortfall associated with the entitlement offer should favorable market conditions prevail.

The Company also paid \$151k to related parties and their associates. These payments are related to director fees and executive director salaries.

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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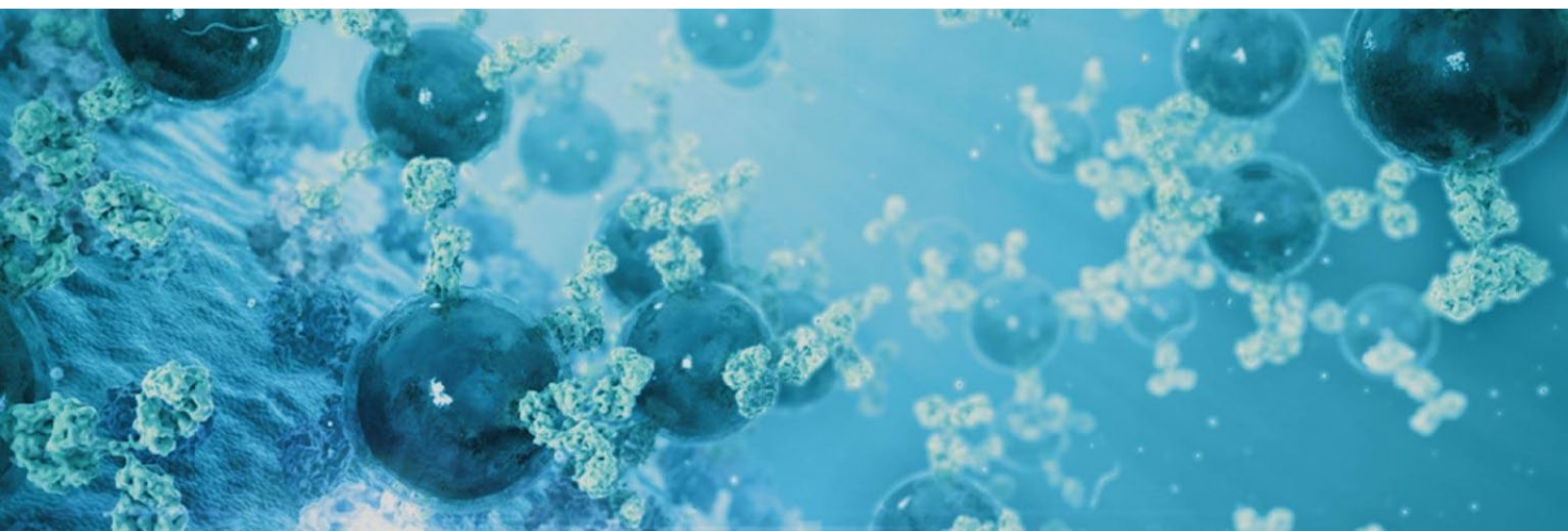
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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Imagion Biosystems Limited

ABN

42 616 305 027

Quarter ended ("current quarter")

31 March 2023

| Consolidated statement of cash flows | Current quarter \$A'000 | Year to date (3 months) \$A'000 |
|---|------------------------------------|--|
| 1. Cash flows from operating activities | | |
| 1.1 Receipts from customers | 85 | 85 |
| 1.2 Payments for | | |
| (a) research and development | (839) | (839) |
| (b) product manufacturing and operating costs | - | - |
| (c) advertising and marketing | (92) | (92) |
| (d) leased assets | - | - |
| (e) staff costs | (1,492) | (1,492) |
| (f) administration and corporate costs | (587) | (587) |
| 1.3 Dividends received (see note 3) | - | - |
| 1.4 Interest received | 8 | 8 |
| 1.5 Interest and other costs of finance paid | (41) | (41) |
| 1.6 Income taxes paid | - | - |
| 1.7 Government grants and tax incentives | - | - |
| 1.8 Other (provide details if material) | 41 | 41 |
| 1.9 Net cash from / (used in) operating activities | (2,917) | (2,917) |
| 2. Cash flows from investing activities | | |
| 2.1 Payments to acquire or for: | | |
| (a) entities | - | - |
| (b) businesses | - | - |
| (c) property, plant and equipment | (7) | (7) |
| (d) investments | - | - |
| (e) intellectual property | - | - |
| (f) other non-current assets | - | - |

| Consolidated statement of cash flows | | Current quarter \$A'000 | Year to date (3 months) \$A'000 |
|--------------------------------------|---|----------------------------|---------------------------------------|
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | - |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |
| 2.3 | Cash flows from loans to other entities | - | - |
| 2.4 | Dividends received (see note 3) | - | - |
| 2.5 | Other (provide details if material) | - | - |
| 2.6 | Net cash from / (used in) investing activities | (7) | (7) |

| | | | |
|-------------|---|--------------|--------------|
| 3. | Cash flows from financing activities | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | - |
| 3.2 | Proceeds from issue of convertible debt securities | 1,500 | 1,500 |
| 3.3 | Proceeds from exercise of options | - | - |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (176) | (176) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | (306) | (306) |
| 3.7 | Transaction costs related to loans and borrowings | - | - |
| 3.8 | Dividends paid | - | - |
| 3.9 | Other (provide details if material) | - | - |
| 3.10 | Net cash from / (used in) financing activities | 1,018 | 1,018 |

| | | | |
|-----------|--|---------|---------|
| 4. | Net increase / (decrease) in cash and cash equivalents for the period | | |
| 4.1 | Cash and cash equivalents at beginning of period | 4,446 | 4,446 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (2,917) | (2,917) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (7) | (7) |

| Consolidated statement of cash flows | | Current quarter \$A'000 | Year to date (3 months) \$A'000 |
|--------------------------------------|---|----------------------------|---------------------------------------|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 1,018 | 1,018 |
| 4.5 | Effect of movement in exchange rates on cash held | 23 | 23 |
| 4.6 | Cash and cash equivalents at end of period | 2,563 | 2,563 |

| 5. | Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | Current quarter \$A'000 | Previous quarter \$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances | 2,563 | 4,446 |
| 5.2 | Call deposits | - | - |
| 5.3 | Bank overdrafts | - | - |
| 5.4 | Other (provide details) | - | - |
| 5.5 | Cash and cash equivalents at end of quarter (should equal item 4.6 above) | 2,563 | 4,446 |

| 6. | Payments to related parties of the entity and their associates | Current quarter \$A'000 |
|-----|--|----------------------------|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 151 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

| | | | |
|-----------|--|---|--|
| 7. | Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i> | Total facility amount at quarter end \$A'000 | Amount drawn at quarter end \$A'000 |
| 7.1 | Loan facilities | - | - |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | 15,000 | 1,500 |
| 7.4 | Total financing facilities | 15,000 | 1,500 |
| 7.5 | Unused financing facilities available at quarter end | | 13,500 |
| 7.6 | <p>Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.</p> <p>The Company has a \$15 million convertible note facility with \$13.5 million undrawn at quarter end. \$1.5 million was drawn during the quarter. \$1.0 million of the remaining capacity is subject to shareholder approval at the Company's next AGM (to be held on 25 May 2023) and will be drawn if approved. The remaining \$12.5 million is also subject to shareholder approval and/or use of the Company's 15% placement capacity as well as mutual consent with the lender and the Company prior to drawdown. The facility is secured over the Company's assets and has no coupon payable.</p> | | |

| | | |
|-----------|--|----------------|
| 8. | Estimated cash available for future operating activities | \$A'000 |
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (2,917) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 2,563 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | 13,500 |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 16,063 |
| 8.5 | Estimated quarters of funding available (item 8.4 divided by item 8.1) | 5.5 |
| | <i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i> | |
| 8.6 | If item 8.5 is less than 2 quarters, please provide answers to the following questions: | |
| 8.6.1 | Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not? | |
| | Answer: N/A | |
| 8.6.2 | Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful? | |
| | Answer: N/A | |

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

28 April 2023

Date:

By the Board of Imagion Biosystems Limited

Authorised by:
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.