ARTRYA™

Coronary Artery Disease. We see you.

# ASX ANNOUNCEMENT
# MARKET RELEASE
18 October 2022

## Quarterly Activity Report and Appendix 4C for Q1 FY23

### Highlights:

- FDA strategy defined & resourced
- Product refinements continuing from pilot sites processing 400 scans per month
- UK commercial radiology practice contracted for non-regulated use of Salix (Q2 FY23)
- UK NHS hospital research contract progressing
- Major award received from prestigious Society of Cardiovascular Computed Tomography conference
- Cash preservation initiatives implemented
- Cash position $30.5m as at 30 September 2022

Artrya Limited (ASX: AYA), ("Artrya" or the "Company"), a medical technology company focused on commercialising its patented artificial intelligence platform, is pleased to release its Quarterly Activity Report and Appendix 4C Cash Flow Report for the quarter ended 30 September 2022.

### Overview

This quarter was defined by a series of important strategic decisions driven by pilot site learnings and Food & Drug Administration feedback received in the United States last quarter.

Those decisions have provided focus on the foundational areas of product development, regulatory approval and revenue generation.

Important refinements have been made to the Salix Coronary Anatomy (SCA) product to incorporate field experience, setting us up for a revised approach to the US FDA approval process.

Following the advice last quarter that, based on the initial 510(K) application, clearance for commercial use of SCA was not received from the FDA, management made the commercial decision to cut costs from the business to focus on the areas of greatest immediate return and preserve capital. The earlier cost base, primarily in marketing and operational areas, had been established so the business could move swiftly to market had the FDA application been successful. The work accomplished and relationships developed by these areas stands Artrya in a strong position for the future. Those functions can be reactivated quickly when required. Previous spend in those areas has been reallocated into the 3 strategic areas of product refinement, regulatory preparation and revenue generation. Business development activities continued in Australia and the United Kingdom building on domestic regulatory approval (TGA) already gained and opportunities in the UK.

Scientific activity supporting product refinement, regulatory applications and revenue generation through credible research output also continued during the quarter with a major award being received at the prestigious Society of Cardiovascular Computed Tomography conference in July 2022.

The strategic decisions taken this quarter also came on the back of the broader correction in the capital markets and the re-pricing of pre-revenue companies like Artrya, which combined with the FDA decision meant

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Artrya's share price suffered. We are confident of addressing that valuation gap and in the medium- to long-term success of the Company.

The business case for the use of Salix has not changed:

1. The market for the Salix solution continues to grow, particularly in the US, due to:
    a. Ageing population
    b. COVID-driven global health issues
    c. Community focus on health and wellness
    d. Increasing awareness of and interest in screening for heart health
2. All people to whom we have demonstrated Salix provide positive feedback
3. The clinical and efficiency benefits delivered by Salix

It is expected that on FDA approval, Artrya will receive a significant re-rating as the fundamental need and original business case for the use of Salix has not receded but has grown.

## Market entry and regulatory approval status

**United States**

The Food & Drug Administration regulatory approval strategy has been redefined based on feedback received from the initial submission.

The Salix product comprises components of software that function in ways substantially similar to approved products and also AI driven functions that are novel.

The complexity of SCA will be reduced by segmenting it into modules to separate the novel medical image analysis components that are likely de novo, as there is no predicate.

Segmenting SCA into the component parts of substantially equivalent and novel equates to FDA 510(k) and de novo applications.

Artrya will pursue both pathways commencing early calendar 2023, allowing for earlier 510(k) approval while the longer-term de novo application will run in parallel.

This regulatory strategy allows for ongoing submissions to be made as the Salix suite of software functionality evolves.

The product refinement discussed above incorporates appropriate software segmentation to enable the revised FDA strategy as described.

While working towards a new FDA application the Company has reduced costs in US operations to enable appropriate investment in the key area of regulatory approval. Recruitment of FDA-experienced personnel to lead the Company's regulatory strategy is now well advanced.

**Australia and New Zealand**

The focus this quarter was on refinement of the SCA product following learnings and feedback from our pilot site testing programme.

Over 400 scans per month are being processed through the SCA product allowing for continued refinement and calibration.

Feedback and review of the trials to date have been focused on three key areas of development:

- Data ingestion
- Accuracy improvement
- Performance enhancement

The Company has worked closely with clinicians to make important refinements to incorporate field experience, setting up a revised approach to the US FDA approval process.

The refinement of the product has now placed us in a strong position in Australia and New Zealand where we have full regulatory approval for SCA.

There are approximately 30 prospective sites where discussions have commenced as we move towards the commercial release of the product this financial year.

**United Kingdom**

Business development activities in the UK have yielded prospective uses of SCA for quality assurance purposes to aid in ongoing performance evaluation within a radiology practice, which can be enacted ahead of regulatory approval. A contract with a commercial imaging practice was signed in October 2022.

A research contract with a National Health Service Trust Hospital to study the efficacy of the Salix Coronary Anatomy product in the NHS environment has progressed. This study is independent of regulatory approval processes. The results of this study will support UK sales and marketing activities.

Continued progress is being achieved with the UK regulator. This quarter the UKCA regulatory process continued with Artrya passing two further assessment stages.

## Scientific Milestones

Research and publication of product performance results provides evidence of the clinical accuracy with which SCA detects and reports coronary artery disease biomarkers.

In July 2022 Artrya's paper titled '*Development and Evaluation of an Artificial Intelligence Coronary Artery Calcium Scoring Model from Cardiac Computed Tomography'* was accepted by the European Radiology Journal, becoming our first published paper, in collaboration with the Harry Perkins Institute of Medical Research.

Artrya research was recognised at the world's leading scientific conference for cardiac CT, being the Society of Cardiovascular Computed Tomography held in Las Vegas, in July 2022. The research paper, titled '*Comprehensive assessment of coronary artery disease on CCTA using deep learning methods*' won Best Abstract Award, attracting strong interest. The research evaluated the feasibility and accuracy of a novel artificial intelligence algorithm developed by Artrya for rapidly identifying coronary artery blockages and coronary plaque that increase the risk of heart attack.

## Appointments

In August, Dr Jacque Sokolov was appointed as a non-executive director to the Artrya Ltd Board. Dr Sokolov is a recognised leader in the US healthcare sector and provides expertise across US regulatory clearance and market entry strategies. Dr Sokolov is Chairman and President of Artrya USA Inc and chairs Artrya's Clinical Advisory Board.

This quarter, the Company announced the appointment of Kevin Hart as Company Secretary, replacing Nathan Bartrop. Both Mr Hart and Mr Bartrop are from Endeavour Corporate.

Artrya continues to work with a Sydney-based search firm to identify a suitable ASX-experienced non-executive director to join the Artrya Board in 2023.

## Financials

Artrya remains in a strong position financially with $30.5 million of cash at call and on deposit as of 30 September 2022 and a net monthly cash burn of $1.7 million, providing an extended runway as we move towards commercialisation.

Fiscally responsible changes have been made across global operations to ensure investments can be made in the key areas of product development, regulatory approval and revenue generation.

As a result of these cost cutting measures implemented across the business, it is anticipated that the cash burn will reduce in the short- to medium-term.

Net operating cash outflow for the quarter was $5.1 million, relating to continued Salix product development, clinical trial and regulatory expenses, commercialisation costs, and administration.

Payments to related parties consist of Directors' fees and salaries of $332,529 paid to Directors and their related entities.

During the quarter Artrya received cash of $259,262 from the Federal Government's BMTH grant programme.

**Use of Funds (Listing Rule 4.7C.2)**

| | Prospectus dated 15 Oct 2021 ($'000) | % | Quarter ended 30 Sept 2022 ($'000) | % of total |
|---|---|---|---|---|
| Clinical, R&D & Regulatory | $13,300 | 33% | $1,102 | 8.3% |
| Product Development | $9,500 | 24% | $1,378 | 14.5% |
| Sales & Marketing | $6,100 | 15% | $539 | 8.8% |
| Corporate & Administrative | $8,300 | 21% | $2,129 | 25.7% |
| Costs of Offer | $2,800 | 7% | $0 | 0.0% |
| TOTAL | $40,000 | 100% | $5,148 | 12.9% |

## Investor Call

The Company advises it will be holding an investor call to discuss the Quarterly Q1 FY23 results and provide an update at 2pm AEDT (11am AWST) today.

Join the conference call on Zoom by clicking here.

*This announcement was approved by the Board of Artrya Limited.*

**For further information please contact:**


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**About Artrya**

Based in Perth, Australia, Artrya was founded in 2018 and commenced operations in early 2019. Artrya Ltd is listed on the Australian Securities Exchange (ASX: AYA).

Artrya is an applied artificial intelligence healthcare company that works alongside clinicians to improve the diagnosis of coronary heart disease and develop a holistic overview of a patient at risk. The company has developed deep learning algorithms that will allow for the prediction and prevention of acute coronary events.

For more information, see www.artrya.com

# Appendix 4C

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

| **Name of entity** | |
|---|---|
| Artrya Limited | |
| **ABN** | **Quarter ended ("current quarter")** |
| 53 624 005 741 | 30 September 2022 |

| **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 | - | - |
| 1.2 | Payments for | | |
| | (a) research and development | (996) | (996) |
| | (b) product manufacturing and operating costs | (129) | (129) |
| | (c) advertising and marketing | (155) | (155) |
| | (d) leased assets | (73) | (73) |
| | (e) staff costs | (2,350) | (2,350) |
| | (f) administration and corporate costs | (1,274) | (1,274) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 33 | 33 |
| 1.5 | Interest and other costs of finance paid | (12) | (12) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 259 | 259 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(4,697)** | **(4,697)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | (159) | (159) |
| | (d) investments ** | (274) | (274) |
| | (e) intellectual property | (28) | (28) |
| | (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: | | |
| | (g) entities | - | - |
| | (h) businesses | - | - |
| | (i) property, plant and equipment | - | - |
| | (j) investments | - | - |
| | (k) intellectual property | - | - |
| | (l) 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** | **(461)** | **(461)** |

| **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 | - | - |
| 3.3 | Proceeds from exercise of options | 10 | 10 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | - | - |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | - | - |
| 3.7 | Transaction costs related to loans and borrowings | - | - |
| 3.8 | Dividends paid | - | - |
| 3.9 | Other (rental incentives) | - | - |
| **3.10** | **Net cash from / (used in) financing activities** | **10** | **10** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 15,558 | 15,558 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (4,697) | (4,697) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (461) | (461) |

| 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) | 10 | 10 |
| 4.5 | Effect of movement in exchange rates on cash held | 14 | 14 |
| **4.6** | **Cash and cash equivalents at end of period **** | **10,424** | **10,424** |

| 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 ** | 10,424 | 15,558 |
| 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)** | **10,424** | **15,558** |

| 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 | 333 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **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 (see table 7.6 below) | 285 | 2 |
| 7.4 | **Total financing facilities** | 285 | 2 |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | 283 |

7.6 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.

Other financing facilities – corporate credit cards

| Facility | Facility limit $A'000 | Amount drawn $A'000 | Interest rate | Secured |
|---|---|---|---|---|
| American Express – credit cards | 160 | 1 | 6.99% p.a. | No |
| Bankwest – credit cards | 125 | 1 | 17.99% p.a. | Guarantee deposit |
| | **285** | **2** | | |

| **8.** | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (4,697) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 10,424 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | 283 |
| 8.4 | Total available funding (item 8.2 + item 8.3) ** | 10,707 |

| | | |
|---|---|---|
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1) ** ** | 2.28 |

*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.*

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.*

**** Note: Cash and cash equivalents**

Estimated cash available for future operating activities does not include term deposit funds of $20.3m, of which $274k relates to restricted cash. The amount has been excluded from cash and cash equivalents in accordance with para. 7 of AASB 107 Statement of Cash Flows. If $20m of these term deposits were so included, item 8.4 total available funding would be $30.7m and item 8.5 Estimated quarters of funding available would equal to 6.54 quarters.

## 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.

Date: **18 October 2022**

Authorised by: **Board of Directors, Artrya Limited**

(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.