

## ASX ANNOUNCEMENT MARKET RELEASE

16 January 2023

### Quarterly Activity Report and Appendix 4C for Q2 FY23

#### Highlights:

- United Kingdom regulatory approval
- European regulatory approval
- Revised FDA strategy progressing well
- Successful product refinements implemented following pilot site feedback
- Cash preservation initiatives ongoing
- Cash position \$26.8m as at 31 December 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 31 December 2022.

#### Market entry and regulatory approval status

##### United Kingdom and Europe

The regulatory approval of Artrya's Salix Coronary Anatomy product (SCA) in both the United Kingdom and Europe were major milestones for the Company this quarter.

The separate approval notifications were delivered within a two-week period in late October and early November, providing significant endorsements of the SCA product's efficacy.

The United Kingdom provides Artrya's biggest market opportunity to date and the Company is well positioned to take advantage of the regulatory approval.

The assessment scope of Artrya's European Notified Body (BSI) includes UKCA certification in accordance with the UK Medical Devices Regulations 2002. Artrya's Salix Artificial Intelligence coronary software met or exceeded all regulatory requirements.

Artrya has a four-year contract in place to supply National Health Service Trust Hospitals throughout the UK with the SCA product. The Company is now working through the next steps with the NHS for access to the Trust Hospitals.

The European regulatory approval provides a substantial future market opportunity for Artrya. When the CE Mark certification is issued Artrya is able to market the Salix software in 28 European Economic Area countries.

The Conformité Européenne (CE) Mark certifies that a product has met EU health, safety and environmental requirements which ensure consumer safety.

##### United States

The revised approach to the US Food & Drug Administration approval process, as outlined in our Q1 FY23 update, is moving rapidly with further updates expected in the first half of 2023.

News from the US this quarter is that a CPT reimbursement code has been designated for AI-driven software that aids in the interpretation of Coronary Computed Tomography Angiography (CCTA), enabling Artrya to receive immediate reimbursement for their software when commercially launched in the United States.

US healthcare is putting significant value on AI tools for clinical decision support and is driving adoption by allocating a high reimbursement of US\$800-\$1,000 per CCTA scan for use of the software.

This will accelerate entry into the US market and will drive adoption since the facility and practice will share in the reimbursement for Artrya Salix-aided interpretation of CCTAs. Our strong pipeline will result in potentially more than double this reimbursement once Artrya releases software for Fractional Flow Reserve (FFR) because another CPT code has been designated for reimbursement to analyse FFR from CCTA scans.

### **Australia and New Zealand**

Artrya Salix is already listed on the Australian Register of Therapeutic Goods (ID 347719). Commercial release of SCA in Australia is planned during FY23.

On the basis of the Australian regulatory approval (ARTG 347719), the SCA product received NZ Medsafe registration in Q1 FY23. This will allow the Company to commercialise the product in the New Zealand market.

### **Product development**

Successful refinement of the SCA product, based on feedback from our pilot site testing programme, was achieved this quarter by the development team in Australia.

Refinement was focused on improving the performance, accuracy and scalability of the SCA product. The development team reported significant advances in each of those areas.

Performance, accuracy and scalability will remain the central focus of the development team as they continue to refine and enhance the SCA product.

### **Annual General Meeting**

This quarter Artrya held its first Annual General Meeting as an ASX listed company. Chairman Bernie Ridgeway and Managing Director and CEO John Barrington AM outlined the Company's achievements and the strategies for future success.

The three resolutions put to the meeting were overwhelmingly endorsed by Shareholders. The resolutions were: to adopt the remuneration report; elect Jacque Sokolov M.D. as a Director and grant performance rights to Managing Director and CEO John Barrington.

### **Strength of business case**

In November, Managing Director and CEO John Barrington AM and Executive Director John Konstantopoulos delivered a presentation to the Bell Potter Health Care conference outlining the progression of Artrya and future plans.

The presentation noted the growing global need to address coronary artery disease, a major cause of death worldwide. The business case for the use of Salix and the market for the Salix solution continues to grow, particularly in the US due to:

- American College of Cardiology (ACC) and American Heart Association (AHA) define CCTA as the Class 1 standard for patients with stable and acute chest pain
- AI software reimbursement code of US\$800 - \$1,000 now available
- Ageing population
- Covid-driven global health issues
- Community focus on health and wellness
- Increasing awareness of and interest in screening for heart health
- All people to whom we demonstrated Salix provide positive feedback
- The clinical and efficiency benefits delivered by Salix

While current medical practices reporting coronary artery disease focus on calcification and narrowing of coronary arteries, Salix's breakthrough technology maps vulnerable plaque and other coronary biomarkers.

Vulnerable plaque is the silent killer, the reason so many people suffer heart attacks with no warning signs.

The SCA product improves the detection of coronary artery disease, which affects 126 million people worldwide, causing nine million deaths annually.

## Financials

Cash at call as of 30 December 2022 is \$26.8 million with an average net monthly cash burn of \$1.2 million.

The net operating cash outflow for the quarter was \$3.6 million, down from \$5.1 million in Q1 FY23. The Q2 FY23 spend related to continued Salix product R&D, software development, clinical and regulatory expenses, commercialisation costs and administration.

Payments to related parties consist of Directors' fees and salaries of \$321,838 paid to Directors and their related entities.

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

Use of Funds <sup>(a)</sup>	Use of Funds Statement	Actual for the quarter ended 31 December 2022	Actual to 31 December 2022
	(\$'000)	(\$'000)	(\$'000)
Clinical, R&D & Regulatory	13,300	667	4,445
Product Development	9,500	1,492	6,615
Sales & Marketing	6,100	421	2,780
Corporate & Administrative	8,300	983	6,763
Costs of Offer	2,800	-	2,839
<b>TOTAL</b>	<b>40,000</b>	<b>3,563</b>	<b>23,441</b>

<sup>(a)</sup> The use of funds table is a statement of current intentions at the date of the Prospectus. As with any budget, intervening events and new circumstances have the potential to affect the manner in which the funds are ultimately applied. The Board reserves the right to alter the way funds are applied on this basis.

## Investor Call

The Company advises it will be holding an investor call to discuss the Quarterly Q2 FY23 results and provide an update at 2pm AEDT (11am AWST) tomorrow Tuesday, 17 January 2023.

Join the conference call on Zoom by [clicking here](#).

*This announcement was approved by the Artrya Board.*

---

### For further information please contact:

#### Investor Enquiries:

John Barrington  
Artrya Limited  
+61 419 850 502  
investors@artrya.com

## **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](http://www.artrya.com)

## Appendix 4C

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

**Name of entity**

Artrya Limited

**ABN**

53 624 005 741

**Quarter ended ("current quarter")**

31 December 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(321)	(1,317)
(b) product manufacturing and operating costs	(663)	(792)
(c) advertising and marketing	(311)	(466)
(d) leased assets	(66)	(139)
(e) staff costs	(1,773)	(4,123)
(f) administration and corporate costs	(418)	(1,692)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	138	171
1.5 Interest and other costs of finance paid	(12)	(24)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	259
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,426)</b>	<b>(8,123)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(76)	(235)
(d) investments (term deposit closure)	20,000	19,726
(e) intellectual property	(61)	(89)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>19,863</b>	<b>19,402</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>10</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	10,424	15,558
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,426)	(8,123)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	19,863	19,402

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	10
4.5	Effect of movement in exchange rates on cash held	(10)	4
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>26,851</b>	<b>26,851</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	26,851	10,424
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>26,851</b>	<b>10,424</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	322
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		



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.

Date: **16 January 2023**

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.