

## ASX ANNOUNCEMENT MARKET RELEASE

19 April 2023

### Quarterly Activity Report and Appendix 4C for Q3 FY23

#### Highlights:

- FDA progress
- Board and management changes
- Board strengthened with new Director
- Market entry and regulatory approval status
- Cash preservation initiatives ongoing
- Cash position \$22.9m as at 31 March 2023

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 March 2023.

#### FDA progress

The key focus of the Company this quarter was the continued work on the US Food & Drug Administration approval process. This work has progressed well since our last update and is following the revised approach outlined in our first quarter update.

There is a clear timeline in place, with Artrya now close to lodging a Q-sub submission in preparation for a Q-sub meeting with the FDA expected in mid-2023. The Q-sub meeting is an important part of the FDA process at which Artrya will present its approach to software development and clinical reader study design to get FDA agreement on how the product is being developed. Typically, the FDA will answer questions that will help smooth the development and testing process.

It is expected that the final 510k application will be submitted to the FDA by the end of October 2023.

Gaining FDA approval to allow Artrya to move into the large and lucrative US market remains the Company's highest priority. In the US, Coronary Computed Tomography Angiography (CCTA) is the fastest growing test for coronary artery disease with nuclear medicine stress tests significantly decreasing.

AI driven software that aids in analysis of CCTA scans (as provided by Artrya's Salix Coronary Anatomy (SCA) product) showing the risk of heart attack is now reimbursed at \$US800 or more through a patient's health insurance in the US.

#### Board and management changes

This quarter saw an important moment in the evolution of the Company with the appointment of Mr Mathew Regan as Chief Executive Officer after the resignation of Managing Director and co-founder Mr John Barrington AM.

Mr Barrington, and the Artrya Board agreed that the Company would benefit from a fresh leadership approach to ensure Artrya's ongoing success as it pursues regulatory approvals in the United States, and business opportunities in the jurisdictions in which it has approval.

Mr Regan is an experienced executive who has worked for ASX listed companies, including Imdex and Quintis Sandalwood.

He has worked in multi-disciplinary environments, from supply chain and logistics to finance and trading, and is skilled in business strategy, culture and human resources, information technology, cyber security, innovation, digital and artificial intelligence.

He has a background of leading large information technology teams and delivering transformative change in large corporate environments.

Chairman Mr Bernie Ridgeway said that he and the Board were confident Mr Regan had the skills necessary to lead the Company in the next phase of its evolution and growth.

“Mathew is a talented executive who understands how to lead transformation and growth in businesses. He has an impressive track record of delivering outstanding results,” he said.

Mr Ridgeway paid tribute to Mr Barrington for his vision and resilience in founding Artrya and successfully listing it on the Australian Securities Exchange.

### **Board strengthened with new director**

The Artrya Board was strengthened in February with the appointment of Ms Kate Hill as an independent non-executive director.

Ms Hill is an experienced non-executive director of ASX listed companies and has expertise at board level in both technology companies and also the biotech and medical devices sectors.

In addition, she has experience of other listing exchanges including Nasdaq (US) and AIM (UK).

Ms Hill previously spent over 20 years as an audit partner at Deloitte, serving both ASX listed and privately owned clients.

She has worked extensively in regulated environments including assisting with Initial Public Offerings, capital raising and general compliance, as well as operating in an audit environment.

Ms Hill is a member of the Institute of Chartered Accountants in Australia and New Zealand, and a graduate of the Australian Institute of Company Directors. She holds a BSc (Hons) in Mathematics and Statistics from the University of Bristol, UK.

Co-founder and Executive Director John Konstantopoulos resigned from the Artrya Board and remains with the Company.

### **Market entry and regulatory approval status**

#### **United States**

As explained above.

#### **Australia and New Zealand**

Artrya Salix is already listed on the Australian Register of Therapeutic Goods (ID 347719). Commercial release of Salix Coronary Anatomy (SCA) product in Australia is planned for mid-CY23.

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.

#### **United Kingdom and Europe**

Artrya Salix has regulatory approval in both the United Kingdom and Europe. The UK provides Artrya's biggest market opportunity to date, while Europe is a substantial future market opportunity.

Artrya has a four-year contract to supply the National Health Service Trust Hospitals in the UK with the SCA product. The company continues to work with the NHS to gain access to the Trust Hospitals.

## Healthcare Forum presentation

In February, Artrya presented at the Euroz Hartleys Healthcare Forum highlighting the progression of the company and future plans.

The presentation was an opportunity to note 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:

- 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

## Financials

Cash at call as of 31 March 2023 is \$22.9 million with an average net monthly cash burn for the quarter of \$1.3 million.

Net operating cash outflow for the quarter was \$3.9 million, up from \$3.6 million in Q2 FY23. Operating costs related to continued R&D and software development of Artrya Salix, regulatory activities, clinical support, commercialisation development, and administration.

Payments to related parties consist of Directors' fees and salaries of \$286,054 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 (\$'000)	Actual for the quarter ended 31 March 2023 (\$'000)	Actual to 31 March 2023 (\$'000)
Clinical, R&D & Regulatory	13,300	760	5,205
Product Development	9,500	1,979	8,594
Sales & Marketing	6,100	281	3,060
Corporate & Administrative	8,300	916	7,679
Costs of Offer	2,800	-	2,839
<b>TOTAL</b>	<b>40,000</b>	<b>3,936</b>	<b>27,377</b>

a. 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 Q3 FY23 results and provide an update at 1pm AEDT (11am AWST) tomorrow Thursday, 20 April 2023.

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

*This announcement was approved by the CEO.*

**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](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 March 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(335)	(1,652)
(b) product manufacturing and operating costs	(1,121)	(1,913)
(c) advertising and marketing	(183)	(649)
(d) leased assets	(75)	(214)
(e) staff costs	(1,821)	(5,944)
(f) administration and corporate costs	(724)	(2,416)
1.3 Dividends received (see note 3)		-
1.4 Interest received	143	314
1.5 Interest and other costs of finance paid	(12)	(36)
1.6 Income taxes paid		-
1.7 Government grants and tax incentives	228	487
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,900)</b>	<b>(12,023)</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	(17)	(252)
(d) investments (term deposit maturity)	-	19,726
(e) intellectual property	(19)	(108)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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>(36)</b>	<b>19,366</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	26,851	15,558
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,900)	(12,023)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(36)	19,366

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 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	2	6
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>22,917</b>	<b>22,917</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	22,917	26,851
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>22,917</b>	<b>26,851</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	286
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: **19 April 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.