

## ASX ANNOUNCEMENT MARKET RELEASE

26 July 2022

### Quarterly Activity Report and Appendix 4C for Q4 FY22

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#### Highlights:

- First US clinical partnership commenced with Huntsville Heart Center
  - Dr Jacob Agris M.D. PhD appointed as new Chief Medical Officer
  - Initial FDA application not approved, however opportunity to re-apply
  - NZ Medsafe regulatory registration received for Salix Coronary Anatomy
  - Continued testing with Australian pilots
  - Scientific award at global SCCT conference
  - Strong cash position with \$35.6 million held as of 30 June 2022
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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 June 2022.

#### Market Entry & Development

##### United States

###### *Clinical Partnership*

In May 2022, the Company announced its first U.S. clinical partnership with Alabama-based Huntsville Heart Center Inc, a national leader in coronary computed tomography angiography (CCTA) that treats more than 80,000 cardiac patients per year.

Heart Center Research, LLC, a division of Huntsville Heart Center, is conducting the study to determine the efficacy of Artrya's technology. This multi-scanner retrospective study compares the performance of Artrya Salix Coronary Anatomy (SCA) against the interpretation of multiple expert readers. Study results are expected during Q2FY23 and will inform further product development, regulatory applications and scientific publications.

###### *FDA Application*

The US Food and Drug Administration advised in June 2022 that the Company's 510(k) application was not approved as the SCA product was determined to be not substantially equivalent to the selected predicate device. In providing feedback, the FDA invited resubmission of a further 510(k) application.

Based on the feedback provided, the Company is confident in addressing the issues raised in future submissions.

An international regulatory advisory firm was commissioned to undertake an external review of the Company's regulatory processes. The firm has relevant FDA experience in medical device applications and in working with Artrya. This review has now been completed and the recommendations arising are being

implemented. In particular, internal regulatory capabilities are being enhanced with the appointment of senior personnel in the United States.

An internal review is also being completed in Q1FY23 to determine specific pathways for future applications. Based on this review, management will make a decision regarding whether to pursue a 510(k) or De Novo FDA application.

In the interim, market development activities will continue in the US to ensure Artrya's technology is in the hands of users and potential customers prior to an FDA approval.

**Australia**

Testing of the Salix Coronary Anatomy product continued at the three existing pilot sites during the quarter, informing ongoing software development. A further pilot site commenced during the quarter and additional sites will be brought on during Q2FY23. The Company is planning for commercial release of the product in FY23.

Current SCA performance in reporting calcium score, stenosis and vulnerable plaque biomarker low attenuation plaque volume is as follows:

- Calcium 96%
- Stenosis >50% 93%
- LAP volume 79%

Salix Coronary Flow (SCF) research with a pilot site has been agreed and is subject to final ethical approval. The research is expected to commence during the first half of FY23.

**New Zealand**

On the basis of the Australian regulatory approval (ARTG 347719), the Salix Coronary Anatomy product received NZ Medsafe registration in July 2022. This will allow the company to commercialise the product in the New Zealand market.

**United Kingdom**

An experienced marketing executive was appointed during the quarter to manage the UK National Health Service 2+2-year Framework Agreement that introduces Artrya to 1,250 Trust Hospitals in the United Kingdom.

A research protocol has been developed with a National Health Service Trust Hospital to undertake a study assessing the efficacy of the Salix Coronary Anatomy product in the NHS environment. It is expected the study will commence in the first half of FY23. This study is independent of regulatory approval processes.

The results of this study, along with the economic model already developed, will support UK sales and marketing activities.

Artrya passed CE Mark/UKCA regulatory audits in March and June 2022 and in June also passed the Technical File Review. The Company is progressing with the UKCA regulatory applications.

## **Clinical Research & Publication**

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

Three studies were submitted for publication and conferences during the quarter.

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, USA this month. The research paper, titled 'Comprehensive assessment of coronary artery disease on CCTA using deep learning methods' won Best Abstract Award, attracting considerable 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.

The high accuracy results achieved by Artrya SCA algorithms highlight the opportunity of artificial intelligence to improve the diagnosis of coronary artery disease.

Artrya and Envision Medical Imaging delivered a joint presentation to the Association for Medical Imaging Management conference, also held in the US in July 2022.

## **Senior Appointments**

Dr Jacob Agris M.D. PhD was appointed during the quarter as the Company's new Chief Medical Officer.

Dr Agris will oversee the Company's medical activity, clinical development, research studies and global regulatory strategy.

His knowledge as a practising physician, along with his experience leading AI development in health care and navigating regulatory approvals, brings significant credentials to the Artrya leadership team.

As research is key to driving Artrya's innovation, former CMO Professor Girish Dwivedi was appointed Chief Scientific Officer, leveraging his world-renowned research expertise in coronary plaque.

During the quarter, Dr John (Jack) Lewin, former CEO of the American College of Cardiology representing over 40,000 cardiologists across the United States, was appointed to the Artrya Clinical Advisory Board.

The Company intends to appoint a further Director to the Australian Board this quarter to add clinical knowledge, US market understanding and regulatory experience to the current skill set.

## **COVID-19**

The Company is managing the impact of a resurgence in COVID and it is noted the latest omicron subvariant may limit access to Australian medical centres in some jurisdictions. Staff absences due to illness and working from home have had a minor impact on research and development activities and it is noted that marketing may be curtailed if restrictions are strongly supported or mandated by state governments.

## Financials

The Company's total cash at call and on deposit was \$35.6 million as of 30 June 2022. Net operating cash outflow for the quarter was \$4.2 million, relating to continued Salix product development, clinical and regulatory expenses, commercialisation, and administration expenses. Of these, \$1.2 million related to activities in the US. During the quarter Artrya received cash of \$15,000 from the Federal Government's EMDG program and a lessor incentive of \$898,000.

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

	Prospectus dated 15 Oct 2021 (\$'000)	%	Quarter ended 30 Jun 2022 (\$'000)	% of total
Clinical, R&D & Regulatory	\$13,300	33%	\$1,218	9.2%
Product Development	\$9,500	24%	\$1,348	14.2%
Sales & Marketing	\$6,100	15%	\$448	7.4%
Corporate & Administrative	\$8,300	21%	\$1,719	20.7%
Costs of Offer	\$2,800	7%	\$0	0.0%
<b>TOTAL</b>	<b>\$40,000</b>	<b>100%</b>	<b>\$4,733</b>	<b>11.8%</b>

The expenditure for the quarter ended 30 June 2022 set out in the table above is in accordance with the Use of Funds outlined in the Company's prospectus dated 15 October 2021. There are no material variances against the estimated Use of Funds.

### Related Party Transactions (Listing Rule 4.7C.3)

Payments to related parties included in Item 6 of the attached Appendix 4C Cash Flow Report for the quarter comprised \$278,625 in salaries and superannuation guarantee payments for executive and non-executive directors.

*This announcement was approved by the Artrya Board.*

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### 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")**

30 June 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 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	(1,110)	(2,589)
(b) product manufacturing and operating costs	(562)	(2,746)
(c) advertising and marketing	(397)	(2,099)
(d) leased assets	(78)	(78)
(e) staff costs	(1,696)	(1,703)
(f) administration and corporate costs	(371)	(3,698)
1.3 Dividends received (see note 3)		-
1.4 Interest received	20	(1,116)
1.5 Interest and other costs of finance paid	(13)	(3)
1.6 Income taxes paid		-
1.7 Government grants and tax incentives	15	992
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(4,192)</b>	<b>(13,040)</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	(1,007)	(1,906)
(d) investments **	9,000	(20,000)
(e) intellectual property	(75)	(243)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	4	4
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>7,922</b>	<b>(22,145)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	40,000
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	-	(3,023)
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)	898	898
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>898</b>	<b>37,885</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	10,925	12,853
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,192)	(13,106)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	7,922	(22,145)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	898	37,885
4.5	Effect of movement in exchange rates on cash held	5	5
<b>4.6</b>	<b>Cash and cash equivalents at end of period **</b>	<b>15,558</b>	<b>15,558</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 **	15,558	10,925
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>15,558</b>	<b>10,925</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	279
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:

*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 \$20m, which have been excluded from cash and cash equivalents in accordance with para. 7 of AASB 107 Statement of Cash Flows. If these term deposits were so included, item 8.4 total available funding would be \$35.6m and item 8.5 estimated quarters of funding available would equal to 8.53 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: **26 July 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.