ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE

30 July 2024

Artrya enters into final phase of US FDA application process

Quarterly Activity Report and Appendix 4C for Q4 FY24

Q4 FY24 Highlights

- **Lodges Q-Submission (Q-Sub) with the US FDA as a key step to finalise 510(k) application process**
- **Enters into a Strategic Partnership Agreement with US hospital group Cone Health to secure integration of Artrya's Salix® Coronary Anatomy software into key healthcare systems pre-FDA market clearance and rollout of Salix into five hospitals and multiple clinics post-FDA approval**
- **Salix AI to access world's largest database of CCTA images being developed with a $3.3 million federal grant awarded under the Medical Research Future Fund and managed by Head of Harry Perkins Cardiovascular and Diabetes Program**
- **Cash on hand at 30 June is $7.13m with operational cash burn of $3.93m (net cash burn $3.98m) for the quarter.**

Artrya Limited (ASX: AYA) ("Artrya" or the "Company"), a medical technology company focused on commercialising its patented artificial intelligence platform that detects, diagnoses, and helps address coronary artery disease, provides an update on its activities for the quarter ended 30 June 2024, alongside the Company's Appendix 4C.

Commenting on the Company's progress over Q4 FY2024, Artrya CEO Mathew Regan said: *"This quarter we have gained significant momentum with our life-saving AI-driven Salix Coronary Anatomy platform in both Australia and the United States.*

"We have moved into the final phase of our application process for US FDA approval. During the quarter we requested a second Q-sub meeting with the FDA to validate and confirm the activity of recent months. This process gives us a high level of confidence our application is on track for a successful submission.

"In parallel to the FDA application process, we signed a strategic agreement with US hospital group Cone Health. This is the third strategic agreement we've made with three major hospital groups on the US east coast specifically chosen for their expertise and market share in cardiovascular care. Over the past two quarters, Salix has been validated and integrated with our strategic partners in a non-clinical setting to prove our approach, meaning we can immediately move to sales with FDA approval.

"Our first commercial agreement in Australia with Cardiac Centre NSW is now in full swing with first revenues to Artrya due 1Q FY25. We are also receiving good feedback on ease of use from cardiologists and support staff.

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"Our collaboration with Harry Perkins and the University of Western Australia will significantly advance the world's understanding of cardiovascular disease by showing how AI can improve diagnosis. Led by Dr Girish Dwivedi, the team will liaise with clinics across the country to build a comprehensive national repository of CCTA images. Health data across Australia is quite segregated. With this library, we have at our disposal the biggest collection of CCTA images ever compiled for analysis. Salix AI will analyse this data to identify critical markers of heart disease not routinely picked up by current diagnostic methods.

"The prudent cost management we've shown over the past few quarters continues and we are well placed to continue towards commercialisation and first revenues this year. The Board and I are continuing to evaluate both dilutive and non-dilutive options in relation to our short- and medium-term funding requirements. In addition, we are continuously looking at pathways to increase and maximise shareholder value."

US FDA approval process

During the quarter, Artrya lodged a request for a second Q-Sub as a key step in the process to finalise its US Food and Drugs Administration (FDA) application. This is a formal written request seeking feedback from the FDA to help guide product development and/or application preparation. The second Q-Sub has been set for 19 August this year and expectations are high for a positive outcome which would clear the path for our 510(k) application shortly after that.

Artrya successfully conducted the first Q-Sub meeting with the FDA in June 2023, during which a pathway to 510(k) regulatory clearance for the Salix Coronary Anatomy product was determined. A 510(k) is a premarket submission made to the FDA to demonstrate the device to be marketed is as safe and effective, that is, substantially equivalent to an existing FDA approved software as a medical device. Artrya has requested this second meeting to validate and confirm the approach taken since the first Q-Sub meeting as a key final step in completing the FDA application process.

Strategic partnership agreements in the United States

Artrya entered into a third contract in the United States with a strategic agreement with Cone Health, an integrated network providing healthcare to communities in North Carolina, United States. Cone Health will work with Artrya in a strategic agreement to non-clinically validate and integrate Salix® Coronary Anatomy into Cone Health's workflow while the product continues the FDA 510(k) clearance process. Cone Health will also work closely with Artrya to develop and expand the specific use cases for Artrya's software products across five hospitals, six ambulatory care centres, three outpatient surgery centres, eight urgent care centres, two retirement communities, and more than 120 physician practices across North Carolina that form Cone Health.

Post-FDA 510(k) clearance, Cone Health will work with Artrya to rollout and expand its point-of-care Salix Coronary Anatomy solution to clinicians and patients across their health network in North Carolina.

CCTA database

Artrya is set to access the world's largest repository of Coronary Computed Tomography Angiography (CCTA) images under a national database to advance research into heart disease. Artrya's AI-driven Salix software will analyse the CCTA images to identify critical markers of heart disease not routinely picked up by current diagnostic methods.

The national database will be created after a joint proposal, 'National Australian Cardiac CT Platform for Automated Cardiac Reporting,' was successfully submitted to the Australian Government's National Critical Research Infrastructure Initiative by Harry Perkins Institute of Medical Research, and the University of Western Australia, and Artrya. The project is one of 10 grants awarded from the Medical Research Future Fund to

harness the power of AI in the healthcare system. The $3.3 million grant will be managed by Head of Harry Perkins Cardiovascular and Diabetes Program, Professor Girish Dwivedi, who will coordinate with leading Australian cardiac CT institutions to compile the images into a central repository.

Pilot programs in key overseas jurisdictions

Pilot evaluation programs are still progressing in the UK with a key cardiology centre evaluating the accuracy and reporting efficiency of Salix.

Life sciences research and patents

Artrya research was accepted into the prestigious SCCT global conference in Washington, displayed in July. This research continues to build Artrya's credibility within the clinical community.

Cost efficiencies

Prudent cost management remains a key pillar of the Company's strategy. The average monthly cash burn of approximately $1.3 is under continuous review with a focus on prudence and a reduced cost burden that clears the path to commercialisation and first sales during FY2025.

Financials

Cash as of 30 June 2024 is $7.13 million with a net cash burn for the quarter of $3.98 million. Operating cash outflow for the quarter was $3.93 million. Operating costs reflect ongoing activity in clinical performance analysis in the US, along with software platform and implementation development supporting the recent commercial release of Salix® in Australia.

Payments to related parties of $92,253 were made during the quarter, consisting of fees and salaries paid to Directors and their related entities.

Outlook

Artrya CEO Mathew Regan said: *"We have an exciting few months ahead as we start to move into FDA application submission phase and expand into commercial agreements. On the commercialisation front, we are in deep discussions with more imaging providers in Australia for the use of Salix, including a top five radiology group in Australia. Our first revenues from our recent 12-month agreement with Cardiac Centre NSW, which is using the Salix® Coronary Anatomy software for the diagnosis of cardiovascular disease, are also expected in 1QFY25.*

"On the research front, our CCTA program will give us access to the largest bank of CCTA images in the world, helping to train and refine our AI-system even more. We are also examining additional grant opportunities made possible by our industry-leading technology. And of course, we will continue to focus efforts on the final stages of our FDA application."

Investor briefing details

CEO Mathew Regan will participate in an investor webinar covering the Company's quarterly update at **12:00pm AEST** on Thursday, **8 August** 2024. Participants will have an opportunity to ask questions at the end of the webinar.

To attend, please pre-register at:

https://us02web.zoom.us/webinar/register/WN_IGm2mAj8To-JrBE7pW3wTw

This announcement was approved by the Board.

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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 at-risk patients. The company has developed deep learning AI algorithms that predict and prevent 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 June 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(745)	(3,219)
	(b) product manufacturing and operating costs	(1,164)	(3,695)
	(c) advertising and marketing	(38)	(402)
	(d) leased assets	(78)	(282)
	(e) staff costs	(1,737)	(7,104)
	(f) administration and corporate costs	(233)	(1,479)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	73	457
1.5	Interest and other costs of finance paid	(9)	(58)
1.6	Income taxes paid	-	(60)
1.7	Government grants and tax incentives	-	2,923
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,931)**	**(12,919)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(21)	(48)
	(d) investments	-	-
	(e) intellectual property	(27)	(169)
	(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	-	-
	(d) investments	-	125
	(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**	**(48)**	**(92)**

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	-	12
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 (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**12**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	11,118	20,132
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,931)	(12,919)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(48)	(92)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	12
4.5	Effect of movement in exchange rates on cash held	(5)	1
4.6	**Cash and cash equivalents at end of period**	**7,134**	**7,134**

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	7,134	11,118
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)**	**7,134**	**11,118**

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	92
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** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *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 (please specify)	-	-
7.4	**Total financing facilities**	-	-

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

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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,931)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,134
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,134
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.81

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: Yes, noting that net operating cash flows will fluctuate depending on the timing of future sales revenue, R&D tax credit refunds and potential grant funding receipts. The Company is focused on growing revenue through commercialising the Salix product and securing grant funding to support the Company's growth initiatives.

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: The Company is actively considering its funding strategies, including R&D tax credit financing, grant applications, and equity raising. The Company continues to monitor its cashflow on an ongoing basis and will be able to curtail discretionary expenditure should this need be required. The Directors are confident that the Company will be able to secure sufficient additional funding as required.

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: Yes. Based on the responses above the Company believes it will be able to continue its operations and meet its business objectives.	
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: **30 July 2024**

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.