ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE

28th April 2025

QUARTERLY ACTIVITIES REPORT

Q3 FY25 UPDATE – January - March 2025

Key highlights

- **Receives milestone Food and Drug Administration (FDA) 510(k) clearance for Salix® Coronary Anatomy for commercial sale in the US. Salix® Coronary Anatomy to be formally launched across hospital systems in the US**
- **Secures three-year commercial contracts with Sonic Healthcare Australia – Radiology and Lumus Imaging, two of Australia's largest and leading diagnostic imaging providers, for the use of Salix® Coronary Anatomy platform**
- **Good progress made on clinical validation of Salix® Coronary Plaque (SCP) in preparation for FDA 510(k) submission. Ongoing development and calibration of Salix® Coronary Flow (SCF) product in preparation for FDA clinical study.**
- **Development of flagship study, SAPPHIRE which seeks to assess Artrya's novel Plaque Dispersion Score and accelerate commercialisation in US**
- **Capital raise of $15m was successfully completed, with Tranche 1 proceeds of $4.65m (net of costs) received during the quarter and Tranche 2 proceeds of $9.38m (net) received subsequently.**
- **Cash on hand at 31 March is $7.63m (totalling ~$17m including Tranche 2 funds received post Q3 FY25) with operational cash burn of $4.60m for the quarter.**

Artrya Limited (ASX: AYA) ("Artrya" or the "Company"), a medical technology company focused on commercialising its patented AI platform that detects, diagnoses, and helps address coronary artery disease, releases its activities report for the quarter ended 31 March 2025, alongside the Company's Appendix 4C. All amounts disclosed herein are unaudited and are denoted in AUD unless otherwise stated.

Commenting on the Company's progress over Q3 FY25, Artrya CEO Mathew Regan said: *"We've delivered a tremendous quarter, achieving key milestones that position Artrya for commercial rollout of our flagship platform, Salix® Coronary Anatomy, across the US – our largest target market.*

"Securing FDA clearance validates our technology for clinical use in the US, and we are now able to commence commercial sales starting with our established US hospital partnerships of Tanner Health, Northeast Georgia Health System, and Cone Health. The groundwork we achieved over the past year by pre-testing integration into these hospital systems means we can now accelerate our entry into the US market.

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"We are also building strong commercial traction in Australia, with three-year contracts signed with Sonic Healthcare Australia – Radiology and Lumus Imaging – two of the nation's largest diagnostic providers – validating Salix® Coronary Anatomy's clinical value and opportunity."

US FDA 510(k) clearance of Salix® Coronary Anatomy platform

Artrya has secured US FDA 510(k) clearance for the Salix® Coronary Anatomy (SCA) platform enabling commercialisation in the US, a substantial market for Artrya that currently performs 4.4m CCTA scans per year[1].

This clearance represents a large opportunity for market growth by becoming the primary CCTA reporting solution for hospital systems and providing clinicians with accurate, real-time information on the presence and extent of plaque, and reducing the time and costs to analyse CCTA scans.

In FY24, Artrya formed strategic agreements with three US hospital groups – Northeast Georgia Health System, Tanner Health, and Cone Health – to non-clinically validate and integrate Salix® Coronary Anatomy into their workflows while awaiting FDA approval. With clearance now granted, Artrya will move to commercial deployment across 15 hospitals, outpatient centres, and heart and vascular facilities in the US Southeast.

Commercial contracts in Australia

During the quarter Artrya signed two commercial contracts with leading Australian providers for the use of Salix® Coronary Anatomy.

Artrya signed a three-year contract with Sonic Healthcare Australia – Radiology. As the second-largest radiology diagnostic imaging group in Australia, Sonic manages over 125 radiology centres with a network of 1,800 radiologists and pathologists, supported by more than 17,000 medical scientists, radiographers, sonographers, technicians, and nurses. Under the agreement, Salix® Coronary Anatomy will be integrated into all Sonic Healthcare Radiology centres that perform Coronary Computed Tomography Angiography (CCTA) scans for coronary heart disease detection.

Artrya also signed a three-year contract with Lumus Imaging, one of Australia's largest diagnostic imaging providers. Under the agreement, Salix® Coronary Anatomy will first be deployed at Lumus' St George Private Hospital centre in Sydney before being rolled out to Lumus centres across Australia. Lumus will leverage Salix® Coronary Anatomy to accurately and efficiently detect heart disease from CTCA scans generated by a Photon Counting CT scanner. Lumus Imaging is one of only two centres in the southern hemisphere equipped with this cutting-edge scanner, regarded as the most advanced CT technology globally.

Salix® Coronary Plaque (SCP) FDA submission preparation

Significant progress was made during the quarter on the clinical validation study of Salix® Coronary Plaque (SCP). The study aims to establish a ground truth by leveraging assessments from expert US-based clinicians, alongside a separate group of non-expert clinicians using Salix® Coronary Plaque supported by AI. The objective is to demonstrate that Salix® Coronary Plaque achieves accuracy comparable to the expert-defined ground truth.

"In line with the approach taken for Salix® Coronary Anatomy, and in light of the current regulatory environment at the FDA, we are taking deliberate steps to prepare a submission for Salix® Coronary Plaque that provides the FDA with a clear, streamlined pathway to review and approve the application efficiently.

[1] Frost & Sullivan Analysis – Artrya Prospectus – https://wcsecure.weblink.com.au/pdf/AYA/02456983.pdf

Once cleared, Salix® Coronary Plaque will be eligible for the newly established Category 1 reimbursement code for automated plaque assessment, valued at US$950[2]."

Salix® Coronary Flow (SCF) development and calibration

Development of Artrya's point-of-care, real-time blood flow assessment solution progressed well during the quarter. Ongoing calibration efforts have focused on achieving clinically relevant accuracy targets and ensuring that blood flow simulations are within the same 10-minute timeframe as Salix® Coronary Plaque (SCP) which continues to support our point of care and real-time approach across all our products.

Artrya expects to lodge a 510(k) submission on Salix Coronary Flow in Q3 CY2025 with FDA clearance by end CY2025.

Once cleared, Salix® Coronary Flow will be eligible for a Category 1 reimbursement code for non-invasive blood flow assessment, valued at US$1,017.

SAPPHIRE Study to test novel Plaque Dispersion Score and accelerate US commercialisation

Appropriate diagnosis and therapy of patients at risk of cardiovascular events is important for improving outcomes. Traditionally, patient risk is assessed using clinical risk models however many of these risk models work well when applied to large populations, but they lack personalisation and may not be accurate at a patient level.

Artrya is reshaping this approach with a novel solution called the Plaque Dispersion Score. This new approach integrates plaque dispersion patterns with both traditional and advanced imaging features to more accurately identify "true" high-risk patients.

To further accelerate this new risk assessment, Artrya developed the SAPPHIRE study. The study will seek to show that the novel Plaque Dispersion Score (PDS) can predict patient risk better than current risk methods and demonstrate that the PDS can be used to appropriately tailor therapy to individuals at highest risk.

Several high volume CCTA centres and credible hospital systems across the US have been identified as study collaborators. We have engaged in varying stages of discussions with these collaborators during the quarter.

The SAPPHIRE Study will also support our US commercialisation plans with the goal of converting the participating hospital systems into commercial agreements during the study. It will enable us to achieve market penetration in the US without the need for a large direct sales force.

Cost management

Average monthly cash outflow has increased from $1.2m to $1.5m during the quarter, predominantly due to accelerating clinical performance testing in the US ahead of FDA applications for SCP and SCF. This brought-forward expenditure is expected to continue into the next quarter to support the 510(k) submission for Salix® Coronary Plaque. The Company continues to manage its cash prudently, prioritising essential spending on achieving US regulatory clearances, supporting current Australian customers, and preparing for US market entry.

[2] https://cardiovascularbusiness.com/topics/cardiac-imaging/cms-increases-medicare-payments-cardiac-ct-ccta

Financials

Cash as of 31 March 2025 is $7.63m with operating cash outflows for the quarter of $4.60m (net cash inflows 0.012m). This includes net funds of $4.65m from Tranche 1 of the company's February 2025 capital raising of $15m (before costs). Further cash from Tranche 2 of $9.38m (net) was received in early April, increasing cash to approximately $17m. Operating expenditure has been focussed on the ongoing activities in the US in support of FDA submissions, alongside enhancements to the software platform, customer onboarding, IT systems and security measures, ongoing AI research and development, and supporting corporate and administrative costs.

Related party payments of $94,696 were made during the March quarter, consisting of fees and salaries paid to Directors and their related entities.

Outlook

Artrya CEO Mathew Regan said: *"Our focus over coming months is to accelerate the commercial rollout of Salix® Coronary Anatomy (SCA) in both the US and Australia, deepen clinical adoption, and expand through strategic partnerships that support scalable, sustainable growth.*

"With strong momentum domestically and FDA clearance for SCA platform now secured, we anticipate first revenues from Sonic and Lumus in the coming months.

"In parallel, we are advancing our broader product pipeline Salix® Coronary Plaque (SCP) and Salix® Coronary Flow (SCF). We are taking deliberate steps to ensure a high quality 510(k) submission for SCP which we are on track to file in the current quarter. Our current guidance remains for clearance in Q3 CY2025.

"We are now ramping up our US commercialisation efforts and launching our flagship plaque study, SAPPHIRE, which is attracting strong interest and engagement from large, credible hospital systems with high CCTA volumes in the US."

Investor Webinar

CEO Mathew Regan and Co-Founder & Executive (Commercial and Strategy) John Konstantopoulos will provide an update on the Company's highlights during the third quarter of FY25 (Q3 FY25).

Shareholders will have an opportunity to participate in a Q&A session at the end of the briefing.

Date: 1 May 2025

Time: 10:00am AWST / 12:00pm AEST

To pre-register for this conference, please use the following link below:

Artrya Q3 FY25 Investor Webinar Registration

This announcement was approved by the Board of Artrya Limited.

ENDS

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About Artrya

Artrya Limited (ASX: AYA) is an Australian medical technology company developing AI-powered solutions to improve the detection and management of coronary artery disease. Its proprietary software analyses coronary CT scans to identify key biomarkers of heart disease, supporting clinicians in diagnosing patients more accurately and efficiently. Artrya's mission is to advance cardiac care through innovative technology, with regulatory and commercial activities underway across key international markets.

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	31 March 2025

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	6	21
1.2	Payments for		
	(a) research and development	(798)	(1,526)
	(b) product manufacturing and operating costs	(1,151)	(3,679)
	(c) advertising and marketing	(44)	(130)
	(d) leased assets	(90)	(249)
	(e) staff costs	(2,040)	(5,731)
	(f) administration and corporate costs	(537)	(1,295)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	63	153
1.5	Interest and other costs of finance paid	(7)	(23)
1.6	Income taxes paid	-	(5)
1.7	Government grants and tax incentives	-	3,674
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(4,598)**	**(8,790)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(33)	(79)
	(d) investments	-	-
	(e) intellectual property	-	(24)
	(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:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(33)**	**(103)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	4,963	9,981
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	45
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(316)	(677)
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**	**4,647**	**9,349**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,615	7,134
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,598)	(8,790)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(33)	(103)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,647	9,349
4.5	Effect of movement in exchange rates on cash held	(4)	37
4.6	**Cash and cash equivalents at end of period**	**7,627**	**7,627**

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	7,627	7,615
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)**	**7,627**	**7,615**

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	95
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)	(4,598)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,627
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,627
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.66

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 timing of future sales revenue and R&D tax credit refunds.

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: Yes. On 14 Feb 2025, the company announced it had received binding commitments for $15 million (before costs) under a two-tranche placement. Tranche 1, totalling ~$5.0 million, was settled in February 2025. Tranche 2 was subject to shareholder approval, which was received on 2 April 2025. Settlement of the remaining ~$10.0 million occurred on 8 April 2025.

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. The net proceeds from settlement will increase the 31 March 2025 cash position to ~$17.0 million. The Company continues to monitor its cashflow on an ongoing basis. The directors are confident that the Company will be able to secure additional funding as required.

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: **28 April 2025**

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.