ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE

31 October 2024

Artrya submits US FDA application

Quarterly Activity Report and Appendix 4C for Q1 FY25

Q1 FY25 Highlights

- **Submitted 510(k) application to the US Food and Drug Administration (FDA) for regulatory clearance of Salix® Coronary Anatomy**
- **Received first revenues and processed 546 CCTA scans from The Cardiac Centre NSW**
- **Successfully integrated Salix into Tanner Health System as part of Artrya's pre-FDA process**
- **Validated and improved product roadmap with Northeast Georgia and Tanner Health Systems in the United States**
- **Cash on hand at 30 September is $6.5m with operational cash burn of $4.33m (net cash inflow $0.64m) 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, assesses, and helps address coronary artery disease, provides an update on its activities for the quarter ended 30 September 2024, alongside the Company's Appendix 4C.

Commenting on the Company's progress over Q1 FY25, Artrya CEO Mathew Regan said:

"The major accomplishment of the quarter was finalising and submitting our application for regulatory clearance by the US FDA. This followed a rigorous 12-month-process where we carefully and diligently met the requirements for submission.

"This is the first 510(k) application in our product roadmap, allowing us to access the US market post clearance and provide the foundation for further applications such as more detailed plaque quantification and Fractional Flow Reserve (FFRCT), among others.

"As we await the response from the FDA, we are preparing for new FDA applications as well as progressing the integration of Salix® Coronary Anatomy software with the three hospital groups we are working with during this pre-FDA clearance phase.

"We have successfully integrated Salix into Tanner Health System and are at the final stages of validating our product roadmap with Northeast Georgia Health System and Tanner Health. Collectively, these agreements mean Salix will be integrated into 15 hospitals and multiple cardiovascular and outpatient clinics across two states following an FDA clearance.

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"In Australia, we will seek to upgrade Salix to a Class II TGA approved product. Given the excellent feedback we have received so far from clinicians using Salix in Australia, we are eager to get the updated product in clinics across the country.

"I'm also pleased to report we have received first revenues from The Cardiac Centre NSW where we've successfully processed over 500 CCTA scans.

"We are maintaining prudent cost management, exploring funding options and actively seeking ways to enhance shareholder value as we move toward full commercialisation in 2025."

US FDA clearance process

During the quarter Artrya submitted its application for regulatory clearance for the Salix® Coronary Anatomy product with the US FDA. This followed feedback from the FDA in two Q-Submission (Q-sub) meetings in June 2023 and August 2024. Q-sub meetings are a key part of the application process which consists of formal written requests from a company and resulting meetings for feedback from the FDA to help guide the preparation of applications. These meetings validated and confirmed the approach that Artrya has taken to ensure it meets requirements for a compliant 510(k) application.

The Cardiac Centre NSW

Artrya received first invoices and revenues during the quarter, successfully processing 546 CCTA scans.

Update on Tanner Health System, Northeast Georgia Health System and Cone Health

Artrya has finalised integration of Salix into Tanner Health hospital systems and is at final stages with Northeast Georgia Health System. These integrations are key in testing and validating image and CCTA report data flow to and from Salix to these systems, so that normal workflow within a health system is not changed.

Major publications

Two research abstracts were presented at Society of Cardiovascular Computed Tomography (SCCT24) and Cardiovascular Society of Australia and New Zealand (CSANZ24) conferences, both focused on improving cardiovascular risk prediction. The first study explored enhancing MACE (major adverse cardiovascular event) prediction by combining patient demographics with detailed anatomical data from CT coronary angiography. The second study proposed a new composite measure, the CAC-DAD score, incorporating calcium dispersion and density to better predict myocardial infarction and cardiovascular death compared to current methods.

Cost efficiencies

Effective cost management continues to be a fundamental part of the of the Company's strategic approach. The average monthly cash outflow of approximately $1.4m is closely monitored to ensure efficiency. With revenue generation already underway, we continue to streamline costs to support ongoing commercialisation efforts and scale-up throughout FY2025.

Financials

Cash as of 30 September 2024 is $6.5 million with a net cash inflow for the quarter of $0.64 including an R&D tax credit refund of $3.65m. Operating cash outflow for the quarter was $4.33 million. Operating costs reflect continuing activity clinical validation work in the US to support the FDA application, together with

software platform, implementation, and support development following the commercial release of Salix® in Australia.

Related party payments of $91,600 were made during the September quarter, consisting of fees and salaries paid to Directors and their related entities.

Outlook

Artrya CEO Mathew Regan said: *"Our focus over the next few months is to prepare for subsequent FDA applications in the new calendar year and continue to expand on our current Australian product offering while pursuing additional grant opportunities."*

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 September 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(443)	(443)
	(b) product manufacturing and operating costs	(1,426)	(1,426)
	(c) advertising and marketing	(40)	(40)
	(d) leased assets	(79)	(79)
	(e) staff costs	(1,810)	(1,810)
	(f) administration and corporate costs	(525)	(525)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	52	52
1.5	Interest and other costs of finance paid	(8)	(8)
1.6	Income taxes paid	(2)	(2)
1.7	Government grants and tax incentives	3,674	3,674
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(607)**	**(607)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(10)	(10)
	(d) investments (term deposit maturity)	-	-
	(e) intellectual property	(24)	(24)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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)	-	-
2.6	**Net cash from / (used in) investing activities**	**(34)**	**(34)**

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	-	-
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	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,134	7,134
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(607)	(607)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	(34)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(17)	(17)
4.6	**Cash and cash equivalents at end of period**	**6,476**	**6,476**

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	6,476	7,134
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)**	**6,476**	**7,134**

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 (see table 7.6 below)	-	-
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) after add back of Government grants and tax incentives - $3,674	(4,281)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,476
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,476
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.5

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, recognising that net operating cash flows will vary depending on the timing of sales revenue, R&D tax credit refunds, and potential grant funding receipts. The Company remains focused on driving revenue growth in Australia while pursuing regulatory approvals in the US to enable the commercialisation of the Salix product suite.

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 continues to monitor its cashflow on an ongoing basis and the Board is confident that the Company will have access to the required funding to take advantage of the opportunities for its market leading software products. The Company continues to actively assess appropriate capital raising strategies with its advisors and the Directors remain confident that the Company will secure sufficient additional funding as required. The Company retains the flexibility to curtail discretionary expenditure should this be necessary.

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: **31 October 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.