ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE

24 July 2023

Quarterly Activity Report and Appendix 4C for Q4 FY23

Highlights:

- FDA regulatory focus - Important progress
- Market entry and regulatory approval status
- Cost management and personnel refocus
- Point-of-care advantage
- Cash position $20.1m as at 30 June 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 30 June 2023.

FDA regulatory focus - Important progress

The Company's major focus during the quarter was on progress with it's pursuit of US Food and Drug Administration (FDA) regulatory clearance for the Salix Software System product.

The innovative technology aids radiologists and cardiologists in the analysis of 2D/3D coronary images acquired from Coronary Computed Tomography Angiographic (CCTA) scans. A favourable reimbursement regime in the US, together with the US healthcare system putting significant value on AI tools for clinical decision support, provide a fertile opportunity for the Salix Software System in the US.

The Company made significant and meaningful progress during the quarter in the pursuit of FDA regulatory clearance. In May, the Company lodged a Q-Submission (Q-Sub) with the FDA, a key enabling step in the US regulatory process. This was followed in early June by a successful Q-Sub meeting with the FDA in the USA as announced on the 8th of June 2023. This was a key step in increasing our success in the US regulatory process.

During the Q-Sub meeting, Artrya and the FDA agreed on a pathway to 510(k) regulatory clearance for the Salix product.

Artrya discussed our multi-reader, multi-site study with the FDA and received feedback on the study design in preparation for the 510(k) submission.

The Artrya 510(k) application is now being updated to include feedback and guidance from the FDA. This is a critical step for a successful 510(k) submission.

The Q-sub meeting enabled Artrya to obtain invaluable feedback on our regulatory strategy, product definition, intended use, product performance and testing, and clinical validation requirements. It was a significant moment for the Company.

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Artrya is now embarking on a clinical validation study with expert clinicians from several key institutes and hospital groups within the US. This study will validate that our software is safe and effective and also put the software in the hands of clinicians in the US for testing, prior to our formal FDA submission.

The final 510(k) pre-market application is intended to be submitted by the 31st of October 2023 and 510(k) clearance is subject to FDA final review and approval. This remains in line with previous advice to the market.

Point-of-care advantage highlighted at Digital Health Forum presentation

In June, Artrya presented to the MST Financial Digital Health Forum highlighting the progression of the Company and future plans. (Refer ASX announcement dated 13 June 2023).

The presentation explained the importance of addressing the growing global problem of coronary artery disease and the significant market opportunity for Artrya particularly in our targeted markets of the US, UK and Australia.

The power of Artrya's SCA software was featured in the presentation with particular focus on the point-of-care advantages the product can bring to the clinical environment.

Salix significantly cuts the overall scan-to-report time at the point-of-care, a clear advantage particularly in an acute environment when patients present with chest pain.

The referring clinician will have the SCA report within 15 minutes of the scan, while most current competing workflows require offsite human Intervention thus lengthening the process where as SCA allows for a point-of-care intervention on site.

The presentation also noted that in the US a CPT reimbursement code has been designated for AI-driven software that aids in the interpretation of Coronary Computed Tomography Angiography (CCTA). This would enable Artrya to receive immediate reimbursement for our software when commercially launched in the United States. US healthcare is putting significant value on AI tools for clinical decision support and is driving adoption by allocating a high reimbursement of US$800-$1,000 per CCTA scan for use of the software. This will accelerate entry into the US market and will drive adoption since the facility and practice will share in the reimbursement for Artrya Salix-aided interpretation of CCTAs.

The presentation also noted that in the US over the next two decades the number of Americans with cardiovascular disease will rise to 131.2 million with an expected cost of US$1.1 trillion.

Market entry and regulatory approval status

United States

The main focus for the quarter, as explained above, was progressing the pathway to regulatory approval.

Australia and New Zealand

Artrya Salix is already listed on the Australian Register of Therapeutic Goods (ID 347719). Commercial pilot release of the Salix Coronary Anatomy (SCA) product is planned for October 2023.

Focus in this quarter has been on improving the product interface and optimising the software ready for commercial release.

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 European Union

Artrya Salix has regulatory approval in both the United Kingdom and the European Union. 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.

More focus will come onto the UK and European Union when the 510(k) FDA process is completed.

Cost management and personnel focus

Fiscally responsible personnel changes were implemented across the quarter as the Company continues to focus on cost management.

The refocussed employee mix was embarked upon to better deliver core function for the business in the vital areas of clinical operations, data science, regulatory and quality control.

This places Artrya in a strong position as the Company works through the US FDA process, which is the overwhelming focus and key goal in coming months.

Financials

Cash at call as of 30 June 2023 is $20.1 million and net operating cash outflow for the quarter was $2.7 million, after a tax refund of $1.9m received during the quarter. Average monthly gross cash burn was $1.53m including one-off costs for staff terminations. Operating costs are related to continued R&D and software development of Artrya Salix, regulatory activities, clinical support, commercialisation development, corporate costs, and general administration.

Payments to related parties consist of Directors' fees and salaries of $712,295 paid to Directors and their related entities. This includes termination payments of $621,269 to the former Managing Director.

Use of Funds (Listing Rule 4.7C.2)

Use of Funds [a]	Use of Funds Statement ($'000)	Actual for the quarter ended 30 June 2023 ($'000)	Actual to 30 June 2023 ($'000)
Clinical, R&D & Regulatory	13,300	663	5,868
Product Development	9,500	2,361	10,955
Sales & Marketing	6,100	157	3,217
Corporate & Administrative	8,300	(378)	7,300
Costs of Offer	2,800	-	2,839
TOTAL	**40,000**	**2,803**	**30,179**

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 Quarterly Q4 FY23 results and provide an update at 2pm AEDT (12pm AWST) tomorrow Tuesday, 25 July 2023.

Join the conference call on Zoom by clicking here.

This announcement was approved by the CEO.

For further information please contact:

Investor Enquiries:

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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

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 2023

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	(242)	(1,894)
	(b) product manufacturing and operating costs	(1,457)	(3,370)
	(c) advertising and marketing	(45)	(694)
	(d) leased assets	(72)	(286)
	(e) staff costs	(2,656)	(8,600)
	(f) administration and corporate costs	(226)	(2,642)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	133	447
1.5	Interest and other costs of finance paid	(19)	(55)
1.6	Income taxes paid	(19)	(19)
1.7	Government grants and tax incentives	1,872	2,359
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,731)**	**(14,754)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(55)	(307)
	(d) investments (term deposit maturity)	-	19,726
	(e) intellectual property	(11)	(119)
	(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:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	3	3
	(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**	**(63)**	**19,303**

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	10	20
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)	-	-
3.10	**Net cash from / (used in) financing activities**	**10**	**20**

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	22,917	15,558
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,731)	(14,754)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(63)	19,303

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)	10	20
4.5	Effect of movement in exchange rates on cash held	(1)	5
4.6	**Cash and cash equivalents at end of period**	**20,132**	**20,132**

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	20,132	22,917
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)**	**20,132**	**22,917**

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	712
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.

There were no financing facilities in place at the end of June 2023.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,731)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,132
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,132
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.37

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: N/A

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: N/A

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: **24 July 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.