ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE

31 January 2024

Artrya prepares for commercial launch in US and Australia

Quarterly Activity Report and Appendix 4C for Q2 FY24

Q2 FY24 Key Points:

- **Strategic Partnership Agreement between Artrya and Northeast Georgia Health Ventures to secure integration of Artrya's Salix Coronary Anatomy software into key healthcare systems pre-FDA market clearance and rollout of Salix into the hospital system post-FDA approval**
    - **Includes collaboration to develop novel point-of-care, non-invasive blood flow assessment solution, Fractional Flow Reserve**
- **US FDA clearance for Artrya's Medical Device Data System, Salix Ingest, a key component in our FDA approval process for Salix Coronary Anatomy platform (Salix)**
- **Two pilot programs in Australia with tier one and tier two imaging centres**
- **Cash on hand at 31 December is $15.2m with operational cash burn of $3.95m (net cash burn $1.2m) 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 31 December 2023, alongside the Company's Appendix 4C.

Commenting on the Company's progress over Q2 FY2024, Artrya CEO Mathew Regan said:

"We continued to make progress during the quarter in preparation for commercial launch in the US and Australia in 2024, including advancing with US FDA regulatory approval, and entering strategic partnerships and pilots which gets our product into the hands of clinicians for validation and test integration into key health systems.

"Our approach to building credibility with the US FDA is to have key operational components of our technology platform approved or cleared during the process. Our medical device data and security system Salix Ingest is an important part of this process and I'm pleased to report the FDA has now accepted our US registration and listing of Salix Ingest.

"Salix Ingest will streamline how data moves between Salix and our users' clinical systems, ensuring all data remains secure and private while being protected from cyber threats that target critical health infrastructure. This product is an important step in receiving FDA regulatory 510(k) clearance for Salix, which pending unforeseen delays, remains on track.

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“Our first commercial contract in the United States, a five-year strategic partnership with Northeast Georgia Health Ventures and Northeast Georgia Health System, means we hit the ground running as soon as our product is approved in the US, getting our lifesaving technology immediately into five hospitals that comprise the Northeast Georgia Health System. This will be a significant entry into our main target market, the US, where US$320 billion is spent each year on heart disease.

“During the quarter we progressed with commercialisation plans for Australia with two pilot agreements with tier one and tier two imaging centres to test the speed and accuracy of Salix Coronary Anatomy against standard methods. Pilots are important for product validation as well as to get our technology in the hands of clinicians for testing integration into their systems, and we will continue to roll out further pilots as we commercialise in Australia. Artrya benefits from valuable feedback and the potential to launch our product into the diagnostic imaging sector in Australia.

"I'm also pleased to report our first international patent application was granted in the UK, further validating our technology, and we have published three critical studies on plaque and heart assessment leveraging AI, building our credibility within the global clinical community.

"We continue to carefully manage costs as the strategic changes we implemented last year extend our runway as we move towards commercialisation this year."

Strategic partnership agreement with Northeast Georgia Health Ventures

Artrya entered its first commercial contract in the United States with a strategic partnership agreement with Northeast Georgia Health Ventures (NGHV), a part of Northeast Georgia Health System (NGHS), an integrated network providing healthcare and other services to the community.

Under the Agreement, NGHV will work with Artrya in an Innovation Participation Agreement to validate Salix Ingest and Salix Coronary Anatomy (SCA) into the NGHS workflow and network while SCA progresses through the FDA 510(k) clearance process. Post-FDA clearance, NGHV will work with Artrya to rollout and expand its point-of-care SCA solution to clinicians and patients across NGHS, which provides prevention and care for over 100,000 heart disease patients each year in the US state of Georgia, as well as the system’s wider network of relationships. NGHV will also advise Artrya on future product development improvements and roadmap priorities and provide technical guidance from their cardiology subject matter experts during the development of a novel point-of-care, non-invasive blood flow assessment solution module, Fractional Flow Reserve.

US FDA approval process

In December, Artrya received FDA Salix 510(k) registration and listing of its Medical Device Data System (MDDS), Salix Ingest, that will be used in Artrya’s Salix Coronary Anatomy platform and compatible image analysis clinical platforms. Salix Ingest manages the secure exchange of private data between clinical systems and Salix. The data exchange system clearance is a key step in the process for receiving FDA 510(k) clearance for Artrya’s Salix Coronary Anatomy technology platform.

Pilot programs in Australia

Artrya commenced two pilot programs with significant hospitals and imaging centres across Australia. These pilots involve in depth testing of Artrya’s Salix Coronary Anatomy algorithms to detect the presence and absence of calcified, non-calcified, and high-risk plaque (low-attenuation plaque), together with calcium score and stenosis measurements. Further pilots will be launched in upcoming months as we commercialise Salix in Australia.

Life sciences research and patents

During the quarter Artrya successfully published two key studies and a third accepted for publication, in peer-reviewed journals, further confirming the accuracy and market opportunity of plaque detection in the field of coronary heart disease.

- Coronary artery stenosis and high-risk plaque assessed with an unsupervised fully automated deep learning technique
- Deep learning-based computed tomography quantification of left ventricular mass
- Evaluation for artificial intelligence–based coronary artery calcification scoring model efficiency and accuracy.

Artrya was granted its first patent in the United Kingdom published in the Patents Journal of UKIPO.

Cost efficiencies

Prudent cost management remains a key pillar of the Company strategy. The monthly cash burn is under continuous review resulting in a reduced cost burden and clears the path to commercialisation in 2024.

Investor briefing details

CEO Mathew Regan will participate in a "Meet the CEO" interview covering the Company's quarterly update at **11am AEDT** on Wednesday, **7 February** 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_X-wYBKz5Rj-Upnb2rT70vw

Financials

Cash as of 31 December 2023 is $15.2 million with a net cash burn for the quarter of $1.2 million after government grants and tax incentives of $2.8m. Operating cash outflow for the quarter was $3.95 million, comparable to $3.8 million in Q1 FY24. Operating costs are related to the investment in 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 $94,658 paid to Directors and their related entities.

Use of Funds (Listing Rule 4.7C.2)

Use of Funds[1]	Use of Funds Statement ($'000)	Actual for the quarter ended 31 December 2023 ($'000)	Actual to 31 December 2023 ($'000)
Clinical, R&D & Regulatory[2]	13,300	701	7,599
Product Development[3]	9,500	1,768	14,675
Sales & Marketing[4]	6,100	267	3,586
Corporate & Administrative[5]	8,300	(1,537)	6,454
Costs of Offer	2,800	-	2,839
TOTAL	40,000	1,199	35,153

[1]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.

[2] The Clinical, R&D and Regulatory costs shown in the Uses of Funds Statement above was based on the expectation that the Company's 510(k) application with the FDA for Salix Coronary Anatomy (SCA) would be granted in early 2022. The focus of the forecast costs was on preparation for market entry, with an escalation in R&D and clinical activity around further regulatory approvals for additional products. In June 2022 the Company announced that based on its initial 510(k) application, the Salix Coronary Anatomy did not receive clearance for commercial use from the FDA. As a result, activities have been focussed on evaluating the feedback from the FDA and product development required to achieve US regulatory approval. Whilst clinical studies, regulatory applications, and other related activities remain in progress, a significant amount of the spend will be reflected in future periods.

[3]Product development costs have risen due to the accelerated activity required to implement product feedback received from the FDA and shorten the timeline to resubmission of the 510(k) application. The acceleration of work streams has included the use of external contractors to supplement the in-house team.

[4]As the Company has not yet received FDA regulatory approval for commercial use of the Salix product in the USA, sales and marketing activity, and associated costs of commercialisation, are below the forecast amount in the Use of Funds Statement at this time. These costs will be incurred in future periods.

[5]Corporate & Administrative actuals for the quarter include a Research and Development Tax Incentive refund of $2.79m and Export Market Development Grant of $15k.

Outlook

Artrya CEO Mathew Regan said: *"This year will be very exciting for Artrya as we enter production at both a commercial and Research Use Only level in the United States and Australia, and we anticipate first revenue later this financial year. We will carefully manage cashflow to gain momentum as we get close to FDA approval. We will continue to build further partnerships with hospital systems in the US similar to NGHS, so we can scale revenue quickly in that market once we achieve FDA approval. Likewise, our pilots underway in Australia are proceeding well, with the view to turning them in commercial agreements and use by universities for research in the near future, and we will continue to launch more pilots in coming months."*

This announcement was approved by the Board.

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 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	31 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(185)	(663)
	(b) product manufacturing and operating costs	(1,097)	(2,318)
	(c) advertising and marketing	(267)	(303)
	(d) leased assets	(67)	(133)
	(e) staff costs	(1,719)	(3,681)
	(f) administration and corporate costs	(725)	(944)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	141	266
1.5	Interest and other costs of finance paid	(17)	(35)
1.6	Income taxes paid	(17)	(23)
1.7	Government grants and tax incentives	2,803	2,923
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,150)**	**(4,911)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(13)
	(d) investments (term deposit maturity)	-	-
	(e) intellectual property	(49)	(58)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**(49)**	**(71)**

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	-	8
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**	**-**	**8**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	16,364	20,132
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,150)	(4,911)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(49)	(71)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	8
4.5	Effect of movement in exchange rates on cash held	(12)	(5)
4.6	**Cash and cash equivalents at end of period**	**15,153**	**15,153**

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	15,153	16,364
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)**	**15,153**	**16,364**

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 (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)	(1,150)
8.2	Cash and cash equivalents at quarter end (item 4.6)	15,153
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	15,153
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	13.18

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: **31 January 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.