ARTRYA™

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ASX ANNOUNCEMENT
MARKET RELEASE

19 October 2023

Artrya makes important progress towards US regulatory approval for Salix solution

Quarterly Activity Report and Appendix 4C for Q1 FY24

Q1 FY24 Highlights:

- Important progress towards US regulatory approval for Salix solution
- Vastly improved speed, useability, and functionality of the Salix platform and expediting product entry into Australian markets and global Research Use Only markets
- Cash position of $16.4M at the end of 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 September 2023, alongside the Company's Appendix 4C.

Commenting on the Company's progress over Q1 FY2024, Artrya CEO Mathew Regan said:

"During the quarter we focused on three core areas advancing our path to commercialisation. "The first is our FDA 510(K) submission where we have made important progress on the roadmap set out during our successful Q-Sub meeting with the FDA in June, which gave us detailed feedback and clarity on how to reduce the time between lodging the submission and obtaining approval.

"We have methodically worked through the priority checklist set out in the roadmap and are on track to deliver a quality application in coming months. The additional time taken in this phase means our submission will not be made at the end of October, as previously estimated. The deferral of the submission ensures it will be of the highest standard and compliant with all FDA requirements, important to support a timely approval process, which we anticipate to be late June 2024.

"Part of the work we are conducting for the application requires us to optimise our Salix platform for speed, functionality and usability. This not only strengthens our submission, but benefits our whole offering, namely the Australian and Research Use Only product, which has been our second focus this quarter.

"Allowing our Salix product to be used in research not only builds the credibility of our unique technology but promotes its use among leading global clinicians. We also benefit from access to increased data that further strengthens our AI algorithms.

"To this end, we have engaged with clients in both the Australian and global Research Use Only markets, and anticipate positive announcements in the coming months. We are deliberately being very selective with our first few clients to ensure both parties get maximum benefit as we move into a commercial environment for the first time.

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"And finally, we continue to focus on our financial position to ensure we have the long-term capacity to achieve our goals. We are starting to see the results of cost efficiencies that have seen a significant drop in our monthly cash burn rate compared to the same period last year, extending our runway as we move towards commercialisation."

Comprehensive FDA focus

Artrya has made important progress to advance the 510K application for the Company's Salix Software System Solution with the US Food and Drug Administration (FDA) following the roadmap established with the FDA during a Q-Submission meeting in June.

During the quarter, Artrya has thoroughly addressed FDA feedback on the regulatory strategy, product definition, intended use, product performance testing, and clinical validation requirements. The Company continues to undertake the body of work to ensure the highest quality of the submission thereby improving the chance of success with the FDA. The Company is now on track to deliver a quality submission that meets stringent FDA requirements. We continue to anticipate a late June 2024 approval date.

Final FDA approval will allow the Company to move rapidly into the expanding US market. A favourable reimbursement regime has been established in the US, with current procedural terminology (CPT) codes allowing US$800-$1000 to be reimbursed for use of AI in assessing CCTA scans. An additional CPT code allowing reimbursement of US$800-$1000 for non-invasive blood flow products presents a significant future opportunity for Artrya.

Product improvement and market entry

During the quarter Artrya has vastly improved the speed, useability, and functionality of the Salix platform as part of the requirements for US regulatory approval. These performance improvements also benefit the Australian and Research Use Only products allowing the Company to selectively engage with key future commercial clients.

Allowing the Salix Coronary Anatomy product to be used in research builds the credibility of the product and promotes its use among leading global clinicians.

Cost efficiencies

Fiscally responsible cost management remains a key pillar of the Company strategy. The monthly cash burn rate has reduced 27% compared to the same quarter last year ($3.8M in Q1 FY24, $5.2M in Q1 FY23) and extends the runway as we move towards commercialisation.

It is important to note that during our clinical validation study our cash burn will be elevated above our business as usual cash burn owing to the investment required in the FDA team and validation studies.

Financials

Cash at call as of 30 September 2023 is $16.4 million with an average net monthly cash burn for the quarter of $1.3 million.

Net operating cash outflow for the quarter was $3.8 million, up from $2.7 million in Q4 FY23. 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 $87,564 paid to Directors and their related entities.

Use of Funds (Listing Rule 4.7C.2)

Use of Funds[1]	Use of Funds Statement ($'000)	Actual for the quarter ended 30 September 2023 ($'000)	Actual to 30 September 2023 ($'000)
Clinical, R&D & Regulatory[2]	13,300	1,031	6,898
Product Development[3]	9,500	1,952	12,907
Sales & Marketing[4]	6,100	103	3,319
Corporate & Administrative	8,300	689	7,990
Costs of Offer	2,800	-	2,839
TOTAL	40,000	3,775	33,953

[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.

Outlook

Artrya CEO Mathew Regan said: *"We have started the financial year with key foundational work in both our technical development and clinical studies and expect to move towards commercialisation in Australia and Research Use Only markets and maintain our velocity with regard to our FDA approval process. I expect us to have our first key clients by the end of the calendar year and am hopeful of a successful FDA outcome in late June 2024."*

Investor call

The Company advises it will be holding an investor call to discuss the Quarterly Q1 FY24 results and provide an update at 2pm AEDT (11am AWST) Tuesday 24 October 2023. Join the conference call on Zoom by clicking here.

This announcement was approved by the CEO.

For further information please contact:

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About Artrya

Based in Perth, Australia, Artrya was founded in 2018 with operations starting in early 2019. The Company was listed on the Australian Securities Exchange (ASX: AYA) in 2021.

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 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 2023

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	(478)	(478)
	(b) product manufacturing and operating costs	(1,221)	(1,221)
	(c) advertising and marketing	(36)	(36)
	(d) leased assets	(66)	(66)
	(e) staff costs	(1,962)	(1,962)
	(f) administration and corporate costs	(219)	(219)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	125	125
1.5	Interest and other costs of finance paid	(18)	(18)
1.6	Income taxes paid	(6)	(6)
1.7	Government grants and tax incentives	120	120
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,761)**	**(3,761)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(13)	(13)
	(d) investments (term deposit maturity)	-	-
	(e) intellectual property	(9)	(9)
	(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**	**(22)**	**(22)**

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	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**	**8**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	20,132	20,132
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,761)	(3,761)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(22)	(22)

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)	8	8
4.5	Effect of movement in exchange rates on cash held	7	7
4.6	**Cash and cash equivalents at end of period**	**16,364**	**16,364**

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	16,364	20,132
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)**	**16,364**	**20,132**

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	88
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)	(3,761)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,364
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	16,364
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	4.35

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: **19 October 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.