ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE

29 February 2024

Artrya progresses FDA application ahead of US commercial launch

Appendix 4D and Half-Year Financial Report

1H FY24 Highlights

- **Strategic Partnership Agreement between Artrya and Northeast Georgia Health Ventures to secure integration of Salix Coronary Anatomy into the Northeast Georgia Health System pre-FDA market clearance and rollout of Salix Coronary Anatomy into the hospital system post-FDA approval**
    - **Includes collaboration to develop novel point-of-care, non-invasive blood flow assessment solution, Salix Coronary Flow**
- **Progress towards US FDA clearance for the Salix Coronary Anatomy solution with FDA approval for Medical Device Data System, Salix Ingest, a key component of Salix Coronary Anatomy**
- **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 $7.27m (net cash burn $4.98m) for the half-year.**

Artrya Limited (ASX: AYA), ("Artrya" or the "Company"), a medical technology company focused on commercialising its patented AI platform that detects, assesses, and helps address coronary artery disease, provides an update on its activities for the first half ended 31 December 2023, alongside the Company's Appendix 4D.

Commenting on the Company's progress over 1H FY2024, Artrya CEO Mathew Regan said:

"While FY23 provided some challenges for Artrya, we have worked hard to streamline our business operations ensuring we have the right mix of capability, costs and capacity, and I'm pleased to report we have made substantial progress over the first half of FY24 putting us on track to launch our products in the US and Australia over coming months.

"We have diligently worked through an extensive program of work with the US regulatory authorities to ensure we fulfil all requirements and can deliver a quality application leading to FDA approval of our Salix Coronary Anatomy solution. We have seen early success with our efforts with the FDA approving Salix Ingest, the medical device and data security system underpinning our entire tech platform.

"FDA approval will allow us to move rapidly into the expanding US market, where a favourable medical insurance regime allows clinicians to access US$800-$1000 in reimbursement for coronary plaque assessment from a CCTA (Coronary Computed Tomography Angiography) scan. Clinicians will also be reimbursed US$800-$1000 for non-invasive blood flow or Fractional Flow Reserve from a CCTA scan, presenting a significant opportunity for Artrya as we move to commercialise our non-invasive blood flow solution, Salix Coronary Flow.

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“In anticipation of FDA clearance, we have laid the groundwork for launch in the US with a strategic partnership with Northeast Georgia Health Ventures and Northeast Georgia Health System that sees our product tested and integrated into five major hospitals. Importantly, this collaboration will see our Salix Coronary Flow solution further developed.

“In parallel, we are running pilots in Australia as the precursor to first sales, and continuing to build our credibility within the global clinical community by publishing critical studies on how AI can be leveraged for accurate plaque and heart assessment.

"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 into the NGHS workflow and network while Salix Coronary Anatomy progresses through the FDA 510(k) clearance process. Post-FDA clearance, NGHV will work with Artrya to rollout and expand its point-of-care Salix Coronary Anatomy 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, Salix Coronary Flow.

US FDA approval process

Artrya made important progress to advance the 510(k) application for the Company’s Salix Coronary Anatomy solution with the US Food and Drug Administration (FDA) following the roadmap established with the FDA during a Q-Submission meeting in June 2023. During the half-year, Artrya addressed FDA feedback on the regulatory strategy, product definition, intended use, product performance testing, and clinical validation requirements.

In December 2023, Artrya received FDA 510(k) registration and listing of its Medical Device Data System (MDDS), Salix Ingest, that will be used in the Salix Coronary Anatomy solution and compatible clinical image analysis 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 Salix Coronary Anatomy.

Pilot programs in Australia

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

Clinical research and patents

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

Focus of studies:

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

Artrya was granted its first patent in the United Kingdom and published in the Patents Journal of the UK Intellectual Property Office (UKIPO).

Cost efficiencies

Prudent cost management remains a key pillar of the Company strategy. The average monthly operational cash burn of $1.2 million is under continuous review resulting in a reduced cost burden and clears the path to commercialisation in 2024.

Financials

Cash as of 31 December 2023 is $15.2 million with a net cash burn for the half-year of $4.98 million after government grants and tax incentives of $2.8m. Operating cash outflow for the period was $7.27 million, comparable to $6.31 million in 1H FY23. Operating costs are related to the investment in R&D and software development of the Salix system, regulatory activities, clinical support, commercialisation development, corporate costs, and general administration.

Outlook

Artrya CEO Mathew Regan said: *"Given that heart disease is the number one cause of death in the world, the need for our technology is clear. Artrya delivers the most advanced and seamless technology platform on the market for the detection, assessment, and care of coronary artery disease.*

"The progress we've made provides a strong platform for gaining paying customers in Australia and markets where we already have approval, and entry into the US market, pending successful FDA approval.

"In preparation for a US launch, we will continue to approach other healthcare systems in the US, so we are well positioned to generate revenue as early as possible once FDA approval is obtained."

"Our focus over coming months will be to continue to prudently manage cashflow as we move closer to FDA submission, and to convert our strategic agreements and pilots into first sales."

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 detect and assess acute coronary events.

For more information, see www.artrya.com