### **ARTRYA**

Coronary Artery Disease. We see you.

# ASX ANNOUNCEMENT MARKET RELEASE

28 November 2024

## 2024 CHAIRMAN AND CEO ANNUAL GENERAL MEETING ADDRESSES AND PRESENTATION

Artrya Limited (ASX:AYA), ('Artrya' or the 'Company'), a medical technology company focused on commercialising its patented artificial intelligence platform that detects key coronary artery disease imaging markers, advises the Chairman, CEO's address and Presentation to the Annual General Meeting of Shareholders to be held at 10:00 am AWST today are attached to this announcement.

This announcement was approved by the Board.

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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

### Chairman's Address to the Annual General Meeting of Shareholders

Welcome to everyone attending our 2024 Annual General Meeting whether that be in person or virtually. It has been another tough year for Artrya but I can say with confidence that we have laid solid foundations for the growth ahead. Mat Regan, as the Company's CEO, had much work to do when he joined in April last year. His main priorities were:

- to get things back on track with the FDA including employing US based competent and experienced experts with a proven track record in dealing with the FDA; and
- increase the capability of the product development team and commercialise the software.

In relation to the first priority, a Q-Sub meeting was held with the FDA in June 2023 where the roadmap of work to be undertaken by Artrya was agreed. The right people to undertake this work were employed and changes were made at senior levels within the Company as well as with the product development team.

At last year's Annual General Meeting, Dr Girish Dwivedi and Abdul Ihdayhid demonstrated the software which was close to having a product for commercial use. I am pleased to say that with further development, we have a commercial product that clinicians can use, subject to having the necessary regulatory approvals.

We intend to do a presentation shortly of the current version of the software as a clinician would use it. In parallel with the further development of the product to FDA application status, Artrya has also concluded pre-FDA agreements with Northeast Georgia Health System, Tanner Health and Cone Health in the US. The purpose behind these agreements is to generate income from these health systems as soon as possible post FDA clearance. In total, these health systems conduct approximately 15,000-20,000 Coronary Computed Tomography Angiography (CCTA) scans per year.

We are in advanced discussions with much larger US health systems and we will continue to work with them to execute contracts during CY25.

One of the key benefits of the Artrya software is the real time, point of care approach. Clinicians can treat the patient shortly after the CCTA scan is taken, retaining control over the reporting and their patient. This is becoming important as US hospital systems increasingly adopt a value-based care approach to patient care. Our competitors do not offer a cloud-based point of care solution, which is a key differentiator for Artrya and a clear market advantage. John and Mat will cover this in more detail in their presentation and product demonstration shortly.

Closer to home, we are generating small revenue from our first commercial client in Australia, The Cardiac Centre of NSW based in Wollongong.

We are dealing with much larger Australia wide radiology groups and are confident of entering into commercial arrangements with them in the coming months.

Having said that, I want to be clear that our primary focus is very much on the US market where substantial reimbursement codes already exist for the use of Al-assisted CCTA scan interpretation for coronary artery disease detection.

The US is a large market where approximately 4.4 million<sup>1</sup> CCTA scans are conducted every year and growing at over 6% per annum. This growth will be further fuelled by a recent decision by the Centers for Medicare and Medicaid Services (CMS) to more than double the Medicare reimbursement rates for CCTA scans, raising

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 $<sup>^{</sup>m 1}$  Frost & Sullivan Analysis – Artrya Prospectus - refer ASX release24 November 2021

payments from US\$175 to US\$357<sup>2</sup>. Upon FDA clearance of our current 510(k) application, Artrya will be well positioned to access this reimbursement.

The payment rate for Automated Plaque Analysis remains at US\$950² per scan, while Fractional Flow Reserve reimbursement has increased from US\$997 to US\$1,017². Artrya is targeting FDA approvals for Salix Coronary Plaque (SCP) and Salix Coronary Flow (SCF) by the end of CY25 giving us access to a combined reimbursement of approximately US\$2,000 for both procedures.

The American College of Cardiology (ACC) and the Society of Cardiovascular Computed Tomography (SCCT) are recommending CCTA as the first line test for patients with chest pain, rather than other traditional modalities.

The tailwinds for Artrya are clear and favourable.

The staff are all aligned and incentivised around achieving FDA approval for the SCA, SCP and SCF products during CY25.

It goes without saying that a growth company such as Artrya cannot deliver on the opportunities available if the Company isn't well funded. To that end, we completed a successful \$5m raising earlier this month. The Board decided that we needed to extend the runway before running cash too low and reduce the risks associated with the state of capital markets. Dilution was minimised and we brought on a number of new institutional shareholders, as well as Healthliant Ventures, the venture arm of US hospital system Tanner Health, enhancing and widening our investor support base.

In closing, I would like to thank our long-standing shareholders for your patience and offer a big welcome to our new shareholders who have joined us for what we consider to be an exciting journey ahead. I would also like to pay a big thank you to my fellow Board members in Kate and Jacque, to Mat and JK and the whole Artrya team who have worked tirelessly over the last 12 months to get us to this point and provide a great springboard for the year ahead.

Thank you

Bernie Ridgeway Chairman 28 November 2024

### CEO's Address to the Annual General Meeting of Shareholders

Good morning, and thank you, Bernie, and thank you all for joining us for our Annual General Meeting. My name is Mat Regan, and I am the CEO of Artrya.

As Bernie mentioned, my primary focus over the past year has been to refine our Salix product to meet the high-performance standards expected of a commercial solution.

On Slide 3, I have listed the key achievements in the last 12 months.

A key priority has been re-engaging with the FDA to prepare for entry into the U.S. market, all while carefully managing our financial runway. Our goal is to secure FDA clearance for Salix Coronary Anatomy, which we anticipate in the first quarter of CY25.

We took a cautious yet strategic approach by scheduling a second Q-Sub meeting with the FDA in August this year to ensure we were on track. We submitted our 510(k) application at the end of September this year with a high level of confidence.

On the commercial front, we secured strategic partnerships with three U.S. hospital groups. These partnerships serve three critical purposes:

- 1. Testing our software into hospital imaging workflow systems,
- 2. Further validating our software by clinicians, and
- 3. Streamlining the sales cycle to generate revenue as soon as possible after SCA achieves FDA clearance.

Closer to home, we successfully launched Salix in Australia and have begun generating revenue. The feedback from clinicians has been positive, particularly regarding the benefits of our plaque assessment and unique point-of-care approach. Our collaboration with The Cardiac Center NSW has increased awareness and interest, and we are in active discussions with top-tier imaging groups across Australia.

The rigorous process of preparing our 510(k) submission has also strengthened our ability to navigate future applications with greater assurance.

Looking at our Product Roadmap on Slide 4, across the bottom of the slide is Salix Coronary Anatomy which is the subject of our current FDA application. Our intention is to file the 510(k) application for Salix Coronary Plaque (SCP) (left hand side of the slide) in the first half of CY25 followed by Salix Coronary Flow (SCF) mid next year. The goal is to have both SCP and SCF approved by the end of CY25.

Slide 5 sets out the current CCTA reporting state and the approach that our main US competitors take. The current system, which is the top line, is very manual, time consuming and generally does not report the high-risk plaque because it is very time consuming and difficult to see with the human eye.

The middle line depicts our main competitors being HeartFlow, Cleerly and Elucid. The CCTA scans get sent off-site to their premises where there is manual work up of the images, a fixed report is generated and sent back to the clinician. This process is time consuming, expensive, and the clinician cannot amend the report if he disagrees with the findings and has to request an additional report at extra cost.

The bottom line shows the Salix process which is fully cloud based with no human in the loop. It is the only Point of Care approach which takes approximately 10 minutes to generate the report for the clinician. The clinician can review, amend where necessary and approve the report and provide a treatment regime for the patient in the same visit.

Slide 6 sets out why we are focused on the US market.

There are 4.4 million scans per annum and growing at a rate of better than 6% year on year. The Centres of Medicare and Medicaid (CMS) has recently increased the re-imbursements for CCTA to encourage clinicians to use this pathway and we expect further CCTA growth because of this.

Slide 7 drills down to show how Artrya fits into the re-imbursement regime.

Post FDA clearance, Artrya will charge a monthly subscription for the use of SCA. When SCP is approved, we can charge a fee per scan where the re-imbursement is established at US\$950 per scan. Approximately 70% of patients who have a scan will require a plaque analysis. About 50% of those patients who have a plaque assessment will have a potentially obstructive lesion and will be sent for a non-invasive blood flow assessment. Once SCF is cleared by the FDA, Artrya can access the re-imbursement of US\$1,017 per scan.

On Slide 8, there are significant tailwinds and drivers of growth in the US market. The American College of Cardiology and the American Heart Association are recommending CCTA as the first line evaluation for patients with chest pain.

As mentioned earlier, attractive re-imbursement exists for AI enabled CCTA. This is a tremendous advantage as many healthcare businesses trying to penetrate the US market spend years getting access to re-imbursement codes. Additionally, there are now newly published studies and pathways for the treatment of patients that have non-calcified and high-risk plaque.

I would now like to invite John to conduct a demonstration of the software.

On slide 10, our priorities for CY25 are clear:

- 1. We are focused on the US market given the attractive reimbursement landscape.
- 2. To access that market, we will continue to engage with the FDA to approve SCA, SCP and SCF
- 3. Secure U.S. revenue as soon as the respective approvals are granted, and
- 4. Expand our client base in Australia to further validate Salix and grow our US pipeline with strategic hospital groups to drive growth.

In closing, I want to extend my heartfelt thanks to our team for their dedication and hard work, to our partners for their invaluable support, and to you, our shareholders, for your continued trust.

As we look to the future, we are more energized than ever to drive progress and deliver on our mission. Thank you for your support, and I look forward to the journey ahead.

Mathew Regan Chief Executive Officer 28 November 2024

## ARTRYA

Coronary Heart Disease
We See You

2024 AGM ARTRYA Presentation



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## **FY24 Achievements**

Considerable momentum towards commercialising Salix, primarily in Australia and the US



Completed second Q-Sub with the FDA (Aug 24) for Salix Coronary Anatomy



510(k) FDA application submitted (Sept 24) for Salix Coronary Anatomy



Received FDA registration for medical device data system, Salix Ingest, a key component of Salix Coronary Anatomy



Commercial launch in Australia with The Cardiac Centre NSW



Strategic Partnerships with three hospital groups in the US, providing access to 15 hospitals and hundreds of specialist clinics along the US East Coast



Granted first patent in the UK



Secured agreement for Salix AI to analyse world's largest database of CCTA images, funded by \$3.3 million under the Medical Research Future Fund

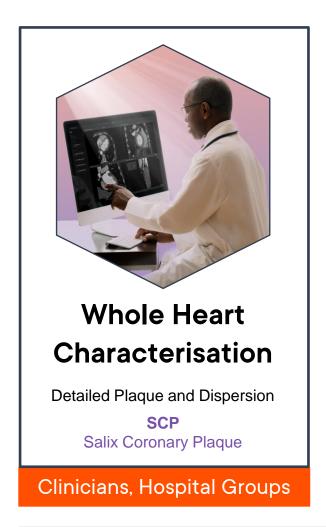


Contributed three articles to peer-reviewed journals building Artrya's credibility in the global clinical community

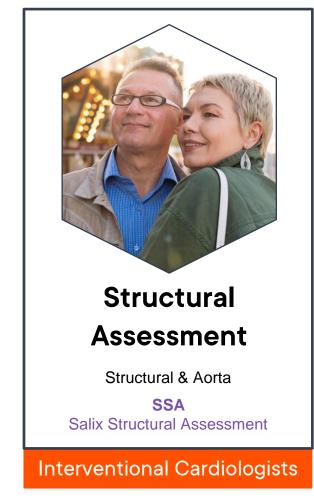


## Salix® Product Roadmap

Artrya's product pipeline goes further & moves us towards predicting the patient at risk.









## **Salix Coronary Anatomy**

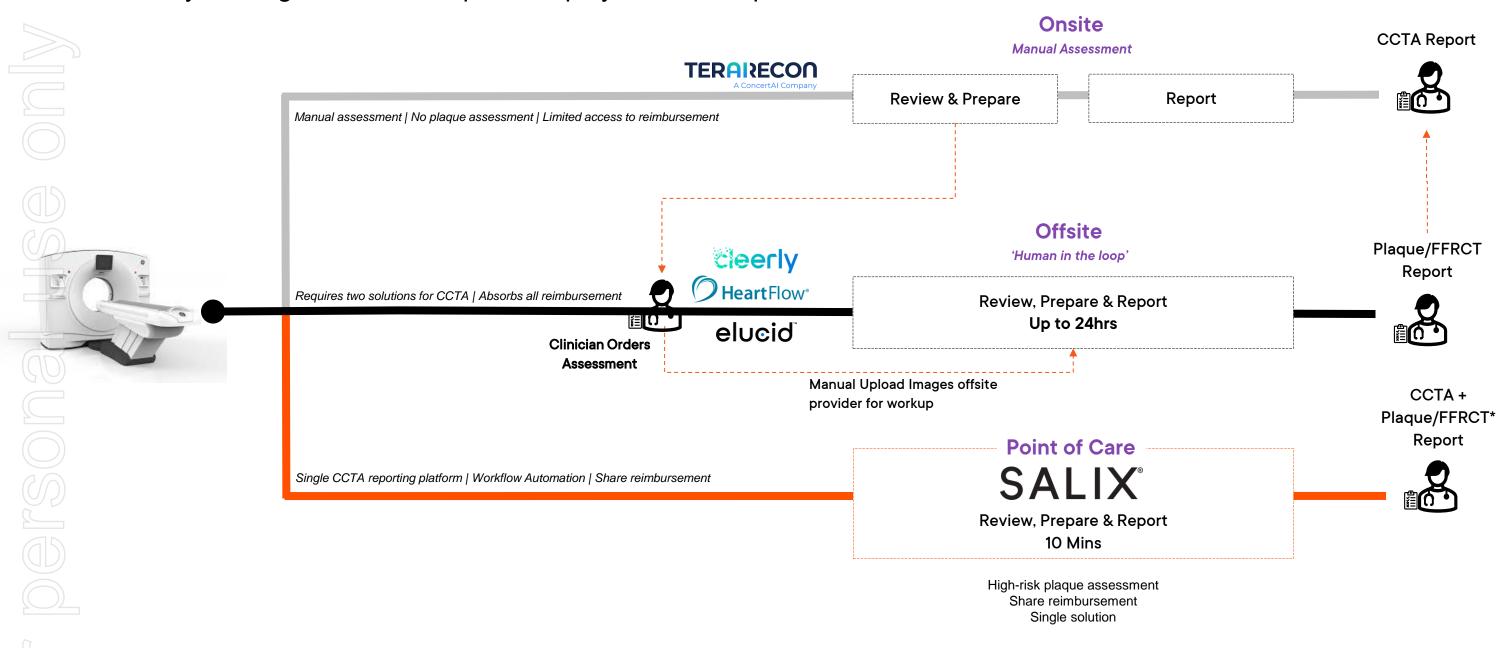
Plaque Visualisation, Workflow Optimisation, Physician Productivity, CCTA reporting SCA

Clinicians, Hospital Groups, Interventional Cardiologists



## **Current State/Competition**

Salix® is system agnostic and simple to deploy, use, and update



<sup>\*</sup> Future product - in Development

Heart disease is a large and growing health challenge, particularly in the US

US\$4.18 billion\*

**Total Addressable Market (US)** 

U.S. patients undergoing CCTA + Plaque Assessment

12.6 million CCTA scans (RoW)<sup>2</sup>

4.4
million CCTA
scans<sup>2</sup>

6.2% YOY

Projected growth in Cardiac CCTA scans to 2028<sup>1</sup>

## **Targeted Approach in US**

### Greenfield

- Focus on large/medium regions and multi-facility health systems.
- Groups with simple pre-authorization and value-based care focus.

### **Replace Existing Market Share**

 Target dissatisfied customers looking for point-of-care, cost-effective CCTA solutions.

### **Limited Focus**

Small, regional markets and physician practices.

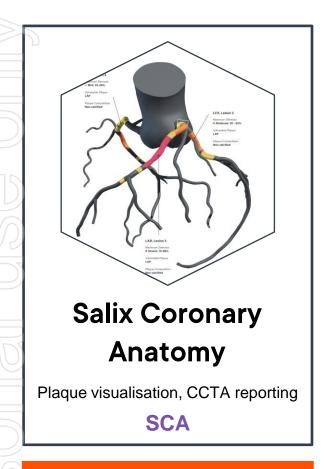
### \* Assumptions

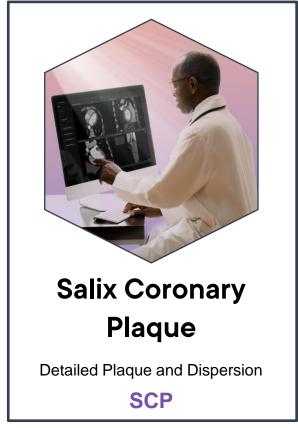
- National Average Medicare Rate
  - Reimbursement for Automated Plague US\$950 (CPT 0625T3)
  - o Reimbursement for FFRCT US\$1,017 (CPT 755803)
- TAM estimated as total of all scans receiving Plaque reimbursement only
- FFRCT procedures have not been included in TAM

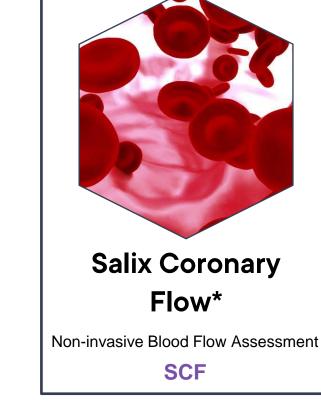


## Salix® SaaS Pricing Model – US example

Hybrid monthly subscription and fee-per-analysis pricing model







### **Benefits:**

- Provides a single CCTA reporting platform, saving costs
- Flexibility on which patients should receive plaque or FFR assessment
- Enhances clinician efficiency and productivity

## **Monthly Subscription**

All CCTA scans attract this monthly fee

## Fee-per-Analysis

70%<sup>2</sup> of scans attract this fee US\$950<sup>1</sup> (CPT 0625T)

### Fee-per-Analysis

50% of SCP attract this fee US\$1,017<sup>1</sup> (CPT 75580)

- 1 https://cardiovascularbusiness.com/topics/cardiac-imaging/cms-increases-medicare-payments-cardiac-ct-ccta
- 2 https://pubmed.ncbi.nlm.nih.gov/34127407/



## **Drivers of Growth in US Market**

Industry tailwinds fuel the high growth outlook, rapidly accelerating growth of CCTA and plaque assessment

### Associations and Reimbursement

- ACC and AHA recommend CCTA as a first-line evaluation for patients with chest pain, in their guidelines<sup>1</sup>
- CCTA reimbursement has doubled to US\$357 per scan<sup>2</sup>
- FFR-CT reimbursement increased to US\$1,017<sup>2</sup>
- Al Plaque analysis now classified as a category 1 code under CMS with reimbursement of \$950<sup>2</sup>







## Plaque Assessment and Treatment

- **SCOT-HEART trial** Further results show CCTA management led to a lasting 10-year reduction in deaths and heart attacks.<sup>3</sup>
- **Plaque Staging** A new plaque-burden staging system helps clinicians tailor treatments based on plaque volume.<sup>4</sup>
- **CONFIRM2 Study** Best predictors of major heart risks are non-calcified plaque volume and % diameter stenosis only.<sup>5</sup>
- PREVENT Study Preventive coronary intervention lowered major heart risks in patients with high-risk plaques better than medical therapy alone.<sup>6</sup>

1 https://doi.org/10.1161/CIR.0000000000001029

2 https://cardiovascularbusiness.com/topics/cardiac-imaging/cms-increases-medicare-payments-cardiac-ct-ccta

3 https://www.auntminnieeurope.com/clinical-news/ct/article/15682946/researchers-unveil-10year-results-of-scottish-ct-trial#:~:text=After%2010%20years%20of%20follow,%3D%2090%2C%204.3%25%20vs.

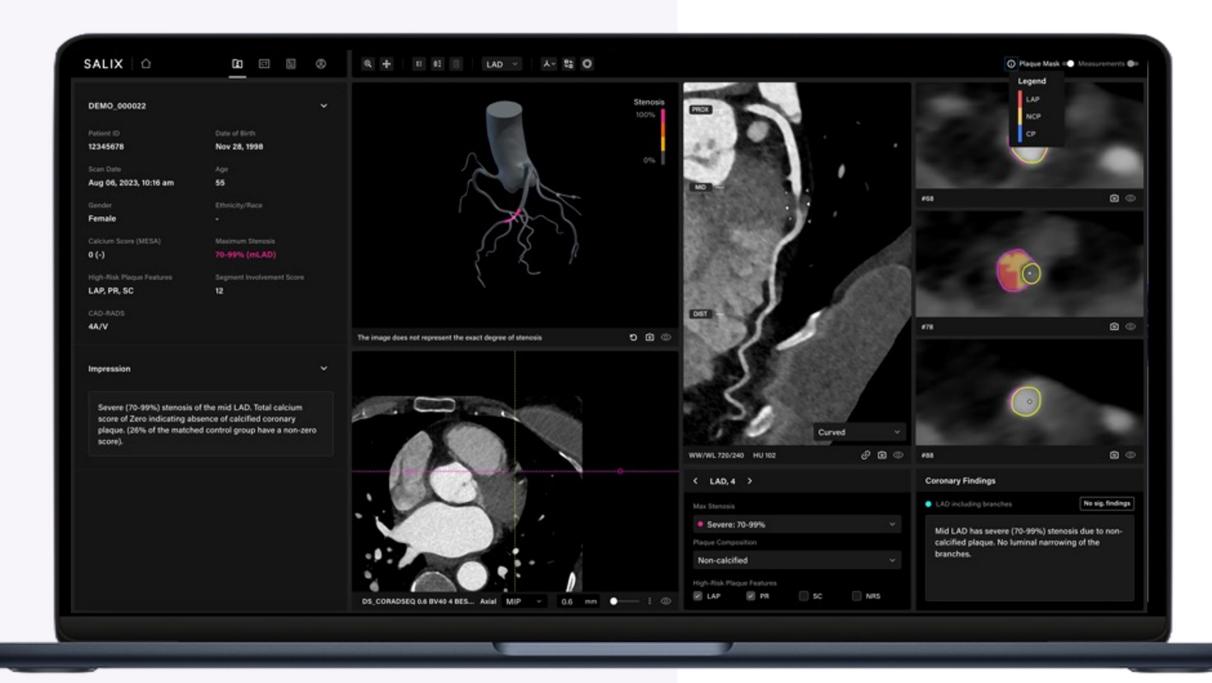
4 Coronary CTA plaque volume severity stages according to invasive coronary angiography and FFR - Journal of Cardiovascular Computed Tomography

5 https://www.tctmd.com/news/confirm2-shows-power-ai-qct-use-plaque-features-predict-cad-events

6 https://www.acc.org/Latest-in-Cardiology/Articles/2024/04/02/17/02/mon-11am-preventive-pci-acc-2024#:~:text=PCI%20performed%20preventively%20in%20patients,Late%2DBreaking%20Clinical%20Trial%20session



## Salix® Demonstration



## Outlook - six key priorities for CY25

Complete regulatory approvals and enter US market

- 1 2 3 4 Salix Coronary Anatomy: clearance expected first half of CY25
  - Salix Coronary Plaque: clearance targeted for end of mid 2025
  - Salix Coronary Flow: clearance targeted for end of CY25
  - First USA Revenues: second half of CY25
- **US market:** continue to expand client base and conclude agreements with large health systems
  - Australian Clients: continue to validate and commercialise our product with new Australian clients

# Thank You

