

# ARTRYA™

UPDATE DECEMBER 2021

Coronary Artery Disease. We see you.

Dear Shareholders,

It is with pleasure that we provide this brief update, our first as an ASX listed company. Following quotation on the Australian Securities Exchange on 26 November 2021, management has remained focused on the execution of product and market development plans.

All activities are proceeding to schedule and this letter provides an update on progress since the Prospectus was lodged with the ASX on 15 October 2021.

### **Product Development & Regulatory Approval**

The Salix Coronary Anatomy (SCA) product, currently in pilot sites in Perth and Sydney, continues to be developed with further improvement in performance and the incorporation of additional features. The next version is on track to meet the scheduled release of mid-January 2022.

Regulatory applications for SCA have been submitted in the US (Food & Drug Administration), Canada (Health Canada), Europe (CE Mark) and the United Kingdom (UKCA). Internal and external audits have been successfully concluded as part of the CE Mark and UKCA approval processes.

The Salix Coronary Flow (SCF) beta product is on track for completion by the scheduled date of 31 December 2021. Calibration, testing and validation against gold-standard data, including that from Monash Health, will commence in the new year and the product will be submitted for regulatory approval in mid-2022.

### **Market Entry & Development**

Active planning for further pilot site establishment is proceeding with more than twenty radiology chains and practices across Australia. Discussions have also commenced with the Australian hospital sector.

Commercial release of SCA in Australia is targeted for Q2 calendar 2022.

Management is continuing to work closely with our US team to refine the US market entry strategy well ahead of FDA approval, which is anticipated to be received around the middle of 2022. The entry strategy has been refined with the conclusion of market research of the provider, payer and patient sectors. Work has also commenced on preparing for research studies with major institutions and the identification of prospective locations for research and development facilities. All market planning and implementation initiatives continue to run to schedule.

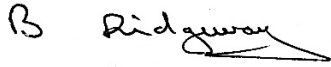
In the UK, Artrya has partnered with global life sciences firm Eversana to activate the National Health Service (NHS) 2+2-year Framework Agreement, which introduces Artrya Salix to 1,250 Trust Hospitals throughout the United Kingdom. Appointment to the Framework Agreement against global competition is testament to the capability of Salix Coronary Anatomy and SCA is the only such product on the panel agreement. Artrya contracted with Eversana earlier in 2021 to provide integrated commercial services and the UK contract builds on the market research that Eversana has completed across the Australian, US, Canadian and UK markets.

As with the US plan, research studies will be conducted in the United Kingdom to extend product credence and build awareness within the UK market. Discussions have commenced with a major UK research institute and further details will be announced when the research agreement is finalised.

Calendar 2022 should be an exciting year as we are well funded and confident on delivering key regulatory approvals, market entry - primarily in international markets, product development (particularly SCF) and market acceptance in Australia leading to first revenues in 2HFY22.

In summary, Artrya continues to progress to schedule against both market and product development milestones.

As always, we remain appreciative of your continuing support and take this opportunity to wish you all the very best for the festive season and a prosperous 2022.



**BERNIE RIDGEWAY**  
**CHAIR**



**JOHN BARRINGTON AM**  
**MANAGING DIRECTOR**

*This announcement was approved by the Company's Managing Director, John Barrington, on behalf of the Artrya Board.*