ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE
14 November 2022

CHAIRMAN'S AND MANAGING DIRCTOR'S ADDRESSES TO THE ANNUAL GENERAL MEETING

Perth, Western Australia - Australian medical technology company, Artrya Limited (ASX: AYA, **Artrya or the Company**) creator of the AI-based solution, Artrya Salix, that supports physicians in the diagnosis of coronary artery disease, today advises that, the Chairman's address and Managing Director's address to the Annual General Meeting of Shareholders to be held at 11:00am (AWST) today are attached to this announcement .

This announcement was authorised for release by the Board.

For further information please contact:

Investor Enquiries:
John Barrington
Artrya Limited
+61 419 850 502
investors@artrya.com

Media Enquiries:
Brett McCarthy
Artrya Limited
+61 401 704 451
brett.mccarthy@artrya.com

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 a patient at risk. The company has developed deep learning algorithms that will allow for the prediction and prevention of acute coronary events.

For more information, see www.artrya.com

Chairman's Address to the Annual General Meeting of Shareholders
Monday 14 November 2022

On behalf of the Board I am pleased to address you at what is our first Annual General Meeting since Artrya's successful listing on the Australian Securities Exchange on November 26 last year.

That initial public offering was over-subscribed, raising $40 million and giving Artrya a $105.6 million implied market capitalisation.

Since then, there has been a broader correction on the capital markets and a re-pricing of pre-revenue companies such as Artrya.

Those factors, combined with an initial US Food and Drug Administration decision not to clear our Salix Coronary Anatomy product for commercial use have meant that Artrya's share price has suffered.

However recent regulatory approvals in the UK and Europe, which John will talk more about soon, is very positive news. The team has worked hard to get these approvals in place.

The UK market is an important one for us and we are well placed to move into that market.

In the US we have strengthened our leadership and brought on further regulatory expertise as we continue to seek FDA regulatory approval.

Artrya now has regulatory approvals in Australia, New Zealand, the UK and 28 countries in Europe courtesy of recently obtaining CE Mark approval.

Overall Artrya has continued to focus on the fundamentals and the Board is confident of addressing the valuation gap and of the medium to long-term success of the Company.

Capital raised during the initial public offering is financing the expansion of our research, product and market development and regulatory activities.

We have more than doubled our scientific and engineering headcount, enabling the fastest path to revenue.

Cost control is a continual focus of the management team and monitored closely by the Board.

In August, we strengthened our leadership and governance by welcoming US based Dr Jacque Sokolov to the Artrya Board, as Non-Executive Director.

Dr Sokolov's wealth of knowledge in US healthcare will be critical when we ultimately receive FDA approval.

We will continue to seek further board members who will strengthen the breadth and depth of our experience and capability.

I want to pay tribute to our dedicated team led by John Barrington. They have remained focused on their goals. There are always challenges in business and particularly in start-up businesses, but the team face those challenges with resilience, enterprise and passion.

I would like to thank my fellow Board members, particularly Jacque Sokolov who is based in the US and continues to make himself available out of normal working hours.

I thank all shareholders for your ongoing support. Some of you have been with Artrya since the beginning and others are more recent. I hope we will continue this journey together as we fight against the world's biggest killer.

I would now like to welcome John to begin his address.

Bernie Ridgeway
Chairman
14 November 2022

Managing Director's Address to the Annual General Meeting of Shareholders Monday 14 November 2022

Good morning and thank you for joining us for our first Annual General Meeting as an ASX listed company.

I want to start with some news that we announced just a week ago and put it into some context.

It was a landmark day for Artrya when we received regulatory approval for our Salix Coronary Anatomy product in the United Kingdom.

It provided further validation of that product and was the culmination of 12 months of sustained effort.

The regulatory scope includes UKCA certification in accordance with the UK Medical Devices Regulations 2002 and Artrya's Salix AI Coronary Software met or exceeded all regulatory requirements.

Importantly once the UKCA certificate has been issued, Artrya is able to market the Salix software in the UK.

Our business activities in the UK are advanced and we are well positioned to take advantage of the regulatory approval in this significant market.

Artrya already has a four-year contract in place to supply 1,250 National Health Service Trust Hospitals throughout the UK with the SCA product. This contract was the product of a global tender process in which we were the successful bidder.

The company is now able to approach these hospitals to finalise arrangements for the product roll out.

This is Artrya's biggest market opportunity to date and we aim to take full advantage of it.

In the UK someone is admitted to hospital every five minutes due to a heart attack and 180 people die each day[1] [2].

Waiting times for assessment and treatment of cardiovascular diseases have escalated since the start of the COVID-19 pandemic. The number of patients in England being forced to wait for more than the supposed maximum 18 weeks for cardiac assessment and treatment has trebled[3].

More than 30,000 patients in England have needlessly died of heart attacks since the start of the pandemic, amid continuing delays to care and soaring waiting lists[4].

[1] https://www.bhf.org.uk/what-we-do/news-from-the-bhf/contact-the-press-office/facts-and-figures
[2] https://www.bhf.org.uk/-/media/files/research/heart-statistics/bhf-cvd-statistics---uk-factsheet.pdf
[3] https://www.theguardian.com/society/2022/jun/16/record-6-5-million-people-waiting-for-nhs-hospital-treatment-in-england
[4] https://www.bhf.org.uk/tipping-point

It is estimated that 350,000 CCTAs are required to be performed per annum in the UK to adequately deliver on cardiac diagnostic pathways[5]. Prior to the pandemic, less than 100,000 CCTAs were performed in the UK per annum[6].

The UK regulatory approval came less than two weeks after we received European regulatory approval, with notification we were successful in our assessment for European CE Marking.

This will allow Artrya to market the Salix software in 28 European Economic Area member countries. It is a substantial future market opportunity.

So we now have regulatory approval in Australia, New Zealand, the United Kingdom and Europe.

We will initially focus on the Australian, NZ and UK markets.

In the US our strategy has been refined following the advice in June this year that, based on the initial 510(K) application, clearance for commercial use of SCA was not received from the Food and Drug Administration.

The Salix product comprises components of software that function in ways substantially similar to approved products and also AI driven functions that are novel.

The complexity of SCA will be reduced by segmenting it into modules to separate the novel medical image analysis components that are likely de novo, as there is no predicate.

Segmenting SCA into the component parts of substantially equivalent and novel equates to FDA 510(k) and de novo applications.

Artrya will pursue both pathways commencing early calendar 2023, allowing for earlier 510(k) approval while the longer-term de novo application will run in parallel. This regulatory strategy allows for ongoing submissions to be made as the Salix suite of software functionality evolves.

We've appointed an experienced regulatory affairs professional in the US to guide Artrya through the FDA process.

James W. Monroe has become North America Head of Regulatory and he brings extensive experience in medical device regulatory affairs to Artrya.

James has successfully gained more than 30 FDA 510(k) clearances in the US, and approvals in the EU, Canada, South Korea, and Japan.

He will be pivotal to our regulatory success in the US.

We expect that on FDA approval, Artrya will receive a significant re-rating as the fundamental need and original business case for the use of Salix has not receded but has grown.

The business case was based on the fact:

1. The market for the Salix solution continues to grow, particularly in the US, due to:
    a. Ageing population
    b. COVID-driven global health issues

[5] https://bsci.org.uk/standards-and-guidelines/nice-cg95-update-2016/
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6927513/

    c. Community focus on health and wellness
    d. Increasing awareness of and interest in screening for heart health
2. All people to whom we have demonstrated Salix provide positive feedback
3. The clinical and efficiency benefits delivered by Salix

Just two weeks ago it was reported that the COVID-19 pandemic led to a significant rise in heart disease-related deaths in the United States, according to a new analysis funded by the Centres for Disease Control and Prevention. Prior to the pandemic, the country had made considerable progress getting that number to go down.

The study's authors found that the U.S. heart disease death rate had dropped 9.8% from 2010 to 2019. In 2020 alone, however, that rate climbed back up 4.1%. For some patient populations, including younger adults and non-Hispanic Black adults, the increases were especially troubling[7].

The authors said while they expected to see an increase in heart disease death rates among adults, the magnitude of the increase was striking.

In Australia trials of our product have proceeded for a longer period than we originally anticipated. However, we have continued to take feedback from those trials, which are seeing some 400 scans being processed through Salix per month. That feedback is vital for ongoing product refinement.

We have over 30 prospective users of the system in Australia and New Zealand and are proceeding with business development in these markets.

Following the FDA decision earlier this year we moved quickly to redefine our strategy.

We took the decision to focus on the foundational areas of product development, regulatory approval and revenue generation.

Our commercial decision was to cut costs from the business to focus on those areas of greatest immediate return and to preserve capital.

As a business we are very focused on our costs and remain willing and able to make the hard calls with the goal of creating shareholder value. This focus will be ongoing.

Artrya remains in a strong position financially with $30.5 million of cash at call and on deposit as of 30 September 2022 and a net monthly cash burn of $1.7 million, providing an extended runway as we move towards commercialisation.

Fiscally responsible changes have been made across global operations to ensure investments can be made in the key areas of product development, regulatory approval and revenue generation.

Net operating cash outflow for the first quarter was $5.1 million, relating to continued Salix product development, clinical trial and regulatory expenses, commercialisation costs, and administration. This net cash outflow is lower than the prospectus budget for that period of $5.3 million.

As I outlined earlier our FDA strategy is now defined & well resourced.

[7] https://cardiovascularbusiness.com/topics/clinical/acute-coronary-syndromes/heart-disease-related-deaths-increased-due-covid-19?utm_source=newsletter&utm_medium=cvb_care

Product refinements are continuing from pilot sites processing 400 scans per month, we have over 30 prospective users of Salix Coronary Anatomy in Australia, the first commercial contract has been signed in the UK and Artrya now has regulatory approvals in four jurisdictions – Australia, NZ, Europe and the UK, where we have contracted access to 1,250 National Health Service Hospitals.

Artrya is well placed to commercialise the product in the key market focus areas of Australia, New Zealand and the UK.

The business case for our product remains strong and Artrya is a good position to continue executing our strategy.

I thank you for your support.

John Barrington AM
Managing Director and CEO
14 November 2022