ARTRYA™

Coronary Artery Disease. We see you.

ASX ANNOUNCEMENT
MARKET RELEASE
30 November 2023

2023 CHAIRMAN AND CEO ANNUAL GENERAL MEETING ADDRESSES

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 and CEO's address 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

Good morning shareholders,

On behalf of the Board of Directors, I welcome you to the 2023 AGM for Artrya. My name is Bernie Ridgeway, and I am the Chair. I am delighted to be here today to update you all on the significant progress we've made since my address to you at our inaugural meeting last year.

While FY23 provided some challenges for Artrya, we have worked hard throughout the year to improve the technical performance of our Salix Coronary Anatomy (SCA) product. This improved performance provides a good platform for gaining paying customers in Australia and markets where we have approval and entry into the US market, pending FDA approval.

We have signed an agreement with Northeast Georgia Health Ventures (NGHV) in the US, which allows us to test integration of our Salix Coronary Anatomy solution into a significant healthcare system during the FDA pre-approval phase. Post-FDA approval, we will launch and rollout our product into their five hospitals and multiple outpatient settings which provides heart disease diagnosis to over 100,000 patients each year[1].

Further afield, we are collaborating with NGHV on the development of a novel point of care, non-invasive blood flow assessment solution – fractional flow reserve or CT-FFR. I'm proud our clinical advisor and sponsor within the NGHV is internationally recognised interventional cardiologist Dr Habib Samady.

The company has also recently commenced an SCA pilot program in Australia and we expect more of these arrangements over the short term. Our customers for these pilot programs have been specifically chosen from a strategic viewpoint as we want to maximise our learning and gain traction across a wide section of potential customers through these pilot testing programs.

We held a positive meeting with the FDA in June and are continuing with the clinical trials to validate the SCA software to satisfy FDA requirements. Assuming these trials are positive, we estimate FDA approval in mid calendar 2024.

In preparation for this key milestone, we will approach other healthcare organisations in the US, so we are well positioned to generate revenue as early as possible once FDA approval is obtained.

This year we welcomed seasoned executive Mathew Regan as chief executive officer, replacing co-founder John Barrington. Mathew has focused on our pathway to commercialisation, including helping resolve product issues to allow us to advance through the FDA regulatory process. We also welcomed Ms Kate Hill as an independent non-executive director. Kate is a genuine asset to the Board and we will continue to strengthen the Board going forward.

Finally, I'd like to thank you, our shareholders, for your continued support and confidence in the company. While the capital markets environment has remained difficult for pre-revenue companies like Artrya, the Board remains confident about our medium to long term success.

I'll now hand over to Mathew to brief you on the key developments during the period and to outline our strategic objectives moving forward.

Bernie Ridgeway
Chairman
30 November 2023

1. https://www.nghs.com/wp-content/uploads/2023/06/NGHS_2023_Fact_Sheet_FY2022-1.pdf

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CEO's Address to the Annual General Meeting of Shareholders

Good morning and thank you for joining us for our second Annual General Meeting since listing on the ASX.

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, diagnosis and care of coronary artery disease.

Since my arrival, I have focussed on three key areas. The first is progressing Salix through the FDA process to allow us to commercially launch into the US, a market where US$320 billion[2] is spent each year on heart disease. The second is to commercialise Salix within Australia and the Research Use Only markets, and finally to streamline our business operations ensuring we have the right mix of capability, costs and capacity.

USA market

As Bernie mentioned, our meeting with the FDA in June gave us a clear and detailed roadmap for regulatory approval. This FDA feedback and guidance has been critical to how we develop Salix for our 510(k) product. We are diligently working through this roadmap, and I am confident we will be cleared for approval in the US by the end of FY24.

One of my key goals is that Artrya becomes the 'ideal' FDA applicant as our product roadmap involves interacting with the FDA for several more applications over the next few years. As all our products share a common code base, advancements with Salix will flow through to other products we develop. With this knowledge, we are confidently engaging with strategic clients in Australia and around the world.

To reiterate the importance of the strategic agreement we recently signed with Northeast Georgia Hospital Ventures (NGHV) that Bernie mentioned, our agreement with NGHV is pivotal as it allows us to conserve cash and expedite the development-to-commercialization trajectory into the US market with a major player. And of course, this collaboration opens the door for potential future investments in North America.

The immense market opportunity in the US for our product is driven by the scale of heart disease, which kills one person every 34 seconds[3], and enhanced by new a Medicare CPT reimbursement code released for plaque assessment that helps clinicians interpret Coronary Computed Tomography Angiography (CCTA) scans. Clinicians who use our Salix solution will have access to reimbursement of US$900-1,000[4] leveraging our novel plaque assessment post FDA approval.

Australia and the Research Use Only market

Australia benefits greatly from having a home-grown product as it means the technology becomes available here first. Typically, software products developed overseas take many years to reach our shores, so it's a great source of pride that Australians will benefit from our products.

One critical step in getting our product to market, is real world clinical testing,. This is the rationale behind our push to pilot Salix with a top-five diagnostic group in Australia. Pilots allow for clinicians to test the speed, accuracy, and usability of our Salix Coronary Anatomy solution against standard methods. Pilots are important for product validation as well as to get real world feedback from clinicians.

2. https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.120.053216
3. https://hms.harvard.edu/news/heart-disease-risk-factors-rise-young-adults
4. https://www.rsna.org/news/2022/october/cms-code-supports-qiba-goals

Pilots also help us to understand how Salix integrate into client's systems and workflow. We will be strategic with who we engage with during our early commercialization as we conduct further pilots and introduce our first clients during FY24.

As well as expanding our homegrown market, we have focused on promoting Salix into the global Research Use Only market as this enhances clinical credibility of our unique product by placing it into the hands of clinicians that form our growing network of key thought and opinion leaders globally.

Operations

A significant part of my role has been to streamline costs while increasing our internal team capability, including bringing in additional skills in software and AI development along with experienced global regulatory affairs and clinical operations specialists from Verily, an Alphabet Inc Life Sciences organisation (Google). I am confident we now have the right mix of people and capabilities to move Artrya forward.
FY2023 saw an average monthly net cash burn of $1.26 million and a closing cash position at 30 June of $20.1 million. We are confident we will see our first revenue in FY2024.

Our focus over the next twelve months will be to increase our commercial partnerships in Australia and in the US once we obtain FDA approval. In addition, we will concentrate on bringing our second major product, CT Fractional Flow Reserve (FFR) to market. Everything we've learned from the FDA approval process for Salix means we can more efficiently move through the approvals process FFR, which is set to be the world's first point-of-care, non-invasive blood flow assessment. The opportunity here is strong as another CPT code has been designated for reimbursement to analyse FFR from CCTA scans.

There is still much to do. However, our momentum is increasing through this parallel approach to commercialisation.

Artrya's AI-driven Salix Coronary Anatomy software provides the first new approach to coronary heart diagnosis and care in 50 years. We are therefore well placed to take advantage of the growing need for a holistic point-of-care and non-invasive coronary heart disease solution that allows for patients to be accurately diagnosed within minutes.

Thank you for your ongoing support and we look forward to continuing our journey together.

Mathew Regan
Chief Executive Officer
30 November 2023