Filed pursuant to Rule 424(b)(4)
Registration No. 333-283414

PROSPECTUS

14,800,000 SHARES

Anteris Technologies Global Corp.

Common Stock

This is an initial public offering of shares of common stock, par value $0.0001 per share ("Common Stock"), of Anteris Technologies Global Corp. ("Anteris" or the "Company"). We are offering 14,800,000 shares of our Common Stock to be sold in this offering at an initial public offering price of $6.00 per share. Prior to this offering, there has been no public market for our Common Stock.

Our operations are currently conducted by Anteris Technologies Ltd ("ATL"), an Australian public company originally registered in Western Australia, Australia and listed on the Australian Securities Exchange ("ASX"). Prior to completion of this offering, we will receive all of the issued and outstanding shares of ATL pursuant to a scheme of arrangement under Australian law between ATL and its shareholders (the "Scheme") under Part 5.1 of the Australian *Corporations Act 2001* (Cth) (the "Corporations Act"). Contemporaneously with implementation of the Scheme, ATL will also cancel all existing options it has on issue in exchange for the Company issuing replacement options to acquire Common Stock pursuant to a scheme of arrangement between ATL and its optionholders (the "Option Scheme") under Part 5.1 of the Corporations Act. Pursuant to the Scheme, we will issue to the shareholders of ATL either one share of Common Stock for every ordinary share of ATL or one CHESS Depositary Interest over the Common Stock (a "CDI") for every one ordinary share of ATL, in each case, as held on the Scheme record date. Additionally, pursuant to the Option Scheme, each outstanding option to acquire ordinary shares of ATL will be cancelled, and the Company will issue replacement options representing the right to acquire shares of Common Stock on the basis of one replacement option for every one existing ATL option held. All conditions to the Scheme and the Option Scheme, other than those related to the closing of this offering, have been satisfied prior to the date of this prospectus.

The ordinary shares of ATL were listed on the ASX until December 5, 2024 (AEDT), when they were suspended from quotation in order to facilitate the Scheme and the Option Scheme. On December 5, 2024, the last reported sale price of ATL's ordinary shares on the ASX was A$10.54 per ordinary share, equivalent to a price of approximately $6.78 per share, assuming an exchange rate of A$1.00 to $0.6430, the conversion rate for Australian dollars on December 4, 2024 as published by Bloomberg.

Our Common Stock has been approved for listing on The Nasdaq Global Market ("NASDAQ") under the symbol "AVR." We expect that our CDIs will commence trading on the ASX on an ordinary settlement basis one trading day following the closing of this offering under the symbol "AVR." Concurrent with the closing of this offering, ATL will de-list its securities from the ASX. All dollar amounts in this prospectus are in U.S. dollars, unless otherwise indicated.

We are an "emerging growth company" and a "smaller reporting company" as defined under the U.S. federal securities laws and, as such, have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future reports after the closing of this offering. See "*Prospectus Summary — Implications of Being an Emerging Growth Company and a Smaller Reporting Company.*"

Investing in our Common Stock involves risks. See the section titled "*Risk Factors*" beginning on page 12 of this prospectus to read about factors you should consider before buying shares of our Common Stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$6.00	$88,800,000
Underwriting discounts and commissions[(1)]	$0.42	$ 6,216,000
Proceeds to us, before expenses	$5.58	$82,584,000

(1) See the section titled "*Underwriting*" for additional information regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to an additional 2,220,000 shares of Common Stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $7.1 million and the total proceeds to us, before expenses, will be $95.0 million.

Delivery of the shares of Common Stock is expected to be made on or about December 16, 2024.

Joint Book-Running Managers

TD Cowen **Barclays** **Cantor**

Lead Manager

Lake Street

Prospectus dated December 12, 2024.

TABLE OF CONTENTS

We have not, and the underwriters have not, authorized anyone to provide you any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor the underwriters take responsibility for, or provide any assurance as to the reliability of, any other information others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the shares of our Common Stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For Investors Outside the United States (the "U.S."): We have not, and the underwriters have not, done anything that would permit this offering or the possession or distribution of this prospectus or any free writing prospectus in connection with this offering in any jurisdiction where action for that purpose is required, other than in the U.S. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of Common Stock and the distribution of this prospectus and any such free writing prospectus outside the United States. See the section titled "*Underwriting*."

BACKGROUND

Anteris Technologies Global Corp. (the "Company" or "Anteris") is issuing its common stock, par value $0.0001 per share ("Common Stock") in this offering. The Company was incorporated in the State of Delaware on January 29, 2024 for the purpose of reorganizing the operations of Anteris Technologies Ltd ("ATL"), an Australian public company originally registered in Western Australia, Australia and listed on the Australian Securities Exchange ("ASX"), into a structure whereby the ultimate parent company will be a Delaware corporation. See the section entitled "*Business — Corporate History*."

Prior to completion of this offering, the Company will receive all of the issued and outstanding shares of ATL pursuant to a scheme of arrangement under Australian law between ATL and its shareholders (the "Scheme") under Part 5.1 of the Australian *Corporations Act 2001* (Cth) (the "Corporations Act"). Contemporaneously with implementation of the Scheme, ATL will also cancel all existing options it has on issue in exchange for the Company issuing replacement options to acquire Common Stock pursuant to a scheme of arrangement between ATL and its optionholders (the "Option Scheme") under Part 5.1 of the Corporations Act.

The Scheme was approved by ATL's shareholders at a general meeting of shareholders, which was held on December 3, 2024. The Option Scheme was approved by ATL's optionholders at a general meeting of optionholders held on the same day. ATL obtained approval of the Scheme and the Option Scheme by the Supreme Court of Queensland on December 4, 2024. All conditions to the Scheme and Option Scheme, other than the closing of this offering, have been satisfied.

Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." The Company expects that the CDIs (as defined below) will commence trading on an ordinary settlement basis on the ASX one trading day following the closing of this offering under the symbol "AVR." Concurrent with the closing of this offering, ATL will de-list its securities from the ASX.

Throughout this prospectus, these transactions are referred to as the "Reorganization." Pursuant to the Reorganization, the Company will issue to the shareholders of ATL either one share of Common Stock for every ordinary share of ATL or one CHESS Depositary Interest over the Common Stock (a "CDI") for every one ordinary share of ATL, in each case, as held on the Scheme record date. Eligible shareholders of ATL (being those whose residence at the Scheme record date is in Australia, New Zealand, Hong Kong, Singapore, Israel, Belgium, Canada, Denmark, Germany, Ireland, the Netherlands, Sweden, Switzerland or the United States) will receive CDIs by default. In order to receive Common Stock, eligible shareholders were required to complete and submit an election form to ATL's registry no later than 5:00 pm (AEDT) on December 5, 2024. Ineligible shareholders will not receive CDIs or shares of Common Stock but will instead receive the proceeds from the sale of the CDIs to which they would otherwise be entitled by a broker appointed by ATL. ATL shareholders holding 35 or less ordinary shares of ATL as at the Scheme record date ("Small Shareholders") will have the CDIs to which they would otherwise be entitled under the Scheme instead issued to, and sold by, a broker appointed by ATL, with the net proceeds from the sale remitted to the relevant ATL shareholder, unless the Small Shareholder notified ATL's registry that they wished to receive CDIs or Common Stock by no later than 5:00 pm (AEDT) on December 5, 2024. The appointed broker will sell the CDIs in accordance with the terms of a sale facility agreement and will remit the proceeds to ineligible shareholders and Small Shareholders (other than those Small Shareholders who opt out). Additionally, pursuant to the Option Scheme, each outstanding option to acquire ordinary shares of ATL will be cancelled, and the Company will issue replacement options representing the right to acquire shares of Common Stock on the basis of one replacement option for every one existing ATL option held.

Following completion of the Reorganization, ATL's ordinary shares will be de-listed from the ASX and ATL will become a wholly-owned subsidiary of the Company.

Upon completion of the Reorganization, excluding the shares of Common Stock to be issued in this offering, we will have 21,139,816 shares of our Common Stock outstanding held by 3,662 record holders. Based on elections made by holders of ATL ordinary shares in connection with the Reorganization, 20,360,496 of the Company's outstanding shares of Common Stock as of the completion of the Reorganization will be represented by CDIs.

The Common Stock issued to ATL shareholders pursuant to the Reorganization will be exempt from registration under Section 3(a)(10) of the Securities Act of 1933 (the "Securities Act").

Prior to completion of the Reorganization, the Company will have had no business or operations and following completion of the Reorganization, the business and operations of the Company will consist solely of the business and operations of ATL and its subsidiaries. As a result of the Reorganization, the Company will become the parent company of ATL, and for financial reporting purposes the historical financial statements of ATL will become the historical financial statements of the Company as a continuation of the predecessor.

Except as otherwise indicated or unless the context otherwise requires, the information in this prospectus assumes and gives effect to the completion of the Reorganization.

Upon the effectiveness of the registration statement of which this prospectus forms a part, the Company became subject to the requirements of Regulation 13A under the Securities Exchange Act of 1934 (the "Exchange Act") and will be required to file annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and will be required to comply with all other obligations of the Exchange Act applicable to issuers filing registration statements pursuant to Section 12(b) of the Exchange Act. Upon the closing of this offering, the Company's executive officers, directors and stockholders beneficially owning more than 10% of its Common Stock will become subject to Section 16 of the Exchange Act and will be required to file Forms 3, 4 and 5 with the U.S. Securities and Exchange Commission (the "SEC"). Stockholders beneficially owning more than 5% of the Company's Common Stock will be required to file Schedules 13D/G with the SEC pursuant to Sections 13(d) or (g) of the Exchange Act.

CAUTIONARY NOTE REGARDING INDUSTRY AND MARKET DATA

This prospectus includes information concerning the Company's industry and the markets in which it will operate that is based on information from various sources including public filings, internal company sources, various third-party sources and management estimates. In addition, this prospectus contains information from a report prepared by Future Market Insights, Inc. ("FMI"), a market research firm that we commissioned to provide information on the global transcatheter heart valve replacement market. Management estimates regarding the Company's position, share and industry size are derived from publicly available information and its internal research and are based on a number of key assumptions made upon reviewing such data and the Company's knowledge of such industry and markets, which it believes to be reasonable. In some cases, we do not expressly refer to the sources from which this information is derived. While the Company believes the industry, market and competitive position data included in this prospectus is reliable and is based on reasonable assumptions, such data is necessarily subject to a high degree of uncertainty and risk and is subject to change due to a variety of factors, including those described in "*Cautionary Note Regarding Forward-Looking Statements*," "*Risk Factors*" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates included in this prospectus. The Company has not independently verified any data obtained from third-party sources and cannot assure you of the accuracy or completeness of such data.

CONVENTIONS WHICH APPLY IN THIS PROSPECTUS

Unless the context requires otherwise all references in this prospectus to the "Company," "we," "us" and "our" refer to Anteris Technologies Ltd prior to the Reorganization and Anteris Technologies Global Corp. (the issuer of Common Stock in this offering) after the Reorganization, and for purposes of this prospectus only:

- "Acellularized" refers to when all cellular antigens (such as cells and cell remnants) known to initiate inflammation and interrelated calcification mechanisms have been removed.
- "ADAPT® anti-calcification tissue" refers to the tissue produced by the ADAPT® tissue engineering process, which transforms xenograft tissue (bovine heart tissue) into a durable bioscaffold which Anteris uses in its DurAVR® THV to mimic human tissue in aortic valve replacement.
- "Aldehydes" refers to organic compounds.

- "Aortic stenosis" refers to the narrowing of the aortic valve restricting the flow of blood from the left ventricle (lower chamber of the heart) to the aorta (main artery).
- "Bioscaffold" refers to a durable structure engineered from biological material.
- "Biostability" refers to the ability of a material to maintain its physical and chemical integrity after implantation into a living tissue and organs.
- "Coaptation" refers to the portion of the leaflets that touch when the aortic valve is in the closed position.
- "ComASUR® delivery system" refers to the balloon expandable system which provides controlled deployment and accurate placement of the DurAVR® THV, designed to achieve precise alignment with the heart's native commissures to achieve ideal valve positioning.
- "Commissure alignment" refers to the position of the transcatheter aortic valve replacement valve leaflets in line with the anatomical orientation of the recipient's native valve leaflets.
- "Commissures" refers to where the valve leaflets are attached to the aortic wall inside the aortic sinus of Valsalva.
- "Cytotoxicitiy" refers to toxicity to cells.
- "Doppler velocity index" and "DVI" refer to the index that expresses the EOA as a proportion of valve area, with DVI representing the physical ratio of a patient's aortic valve area to the left ventricular outflow tract area. A higher DVI indicates improved blood flow through the aortic valve. DVI is independent of the flow state (like gradient) and diameter (like EOA).
- "DurAVR® THV" refers to a transcatheter heart valve ("THV") developed by Anteris. It is a novel biomimetic (meaning human-like) valve made from a single piece of native-shaped ADAPT® tissue and is used for the treatment of aortic stenosis. The DurAVR® THV (new aortic valve) is placed within the diseased aortic valve via a minimally invasive procedure.
- "Effective orifice area" and "EOA" refer to the smallest cross-sectional area of the aortic valve opening that is available for blood flow. A larger EOA reduces the work the left ventricle (heart chamber) must do to pump blood through the valve. Patients with severe aortic stenosis typically have an EOA of $\leq 1cm^2$.
- "Exercise capacity" refers to a measure of a patient's exercise ability, measured in clinical trials by a six minute walk test ("6MWT"), which scores a person on the distance they can cover in six minutes of walking.
- "Flow displacement" and "FD" refer to a marker of flow eccentricity in the ascending aortic root. Flow in the ascending aortic root is mainly laminar with a flow displacement ranging from 6 – 15% only. A higher degree of FD reflects abnormal turbulent flow.
- "Flow reversal ratio" or "FRR" is calculated at peak systole in the ascending aorta. At this point there should be almost no backward flow, and any backward flow is considered abnormal. FRR represents the ratio of backward and forward flow at peak systole.
- "Hemodynamics" refers to how blood flows through the blood vessels.
- "Laminar flow" refers to a smooth, streamlined flow of blood. In a healthy heart, aortic flow is predominantly laminar during systole (when the left ventricle contracts and pumps blood into the aorta). Abnormal aortic flow is associated with turbulence, which can increase the risk of morbidity and increase the stress on the valve leaflets leading to increased wear and tear and subsequent structural valve deterioration.
- "Mean pressure gradient" and "MPG" refer to the average pressure across the aortic valve between the left ventricle and aorta. Patients with severe aortic stenosis have MPG $\geq$ 40 mmHg. Post-TAVR MPG is expected to decrease, which indicates that the left ventricle is not working as hard to pump blood through the aortic valve.
- "Transcatheter aortic valve replacement" or "TAVR" refers to a minimally invasive procedure for the treatment of aortic stenosis. A new aortic valve is placed inside the diseased valve, meaning the old, damaged valve is not removed.

- "Xenograft" refers to a tissue that is derived from a species that is different from the recipient of the specimen, meaning tissue from animal species.

This prospectus contains translations of certain foreign currency amounts into U.S. dollars for the convenience of the reader. Unless otherwise stated, all translations of Australian dollars (A$) into U.S. dollars ($) in this prospectus were made at the rate of A$1 to $0.6828, the noon buying rate on December 29, 2023, as set forth in the H.10 statistical release of the U.S. Federal Reserve Board, with the exception of the amounts set out in this prospectus that were derived from our Consolidated Financial Statements, which have been translated in accordance with the accounting policies set forth therein. We make no representation that the Australian dollar or U.S. dollar amounts referred to in this prospectus could have been or could be converted into U.S. dollars or Australian dollars, as the case may be, at any particular rate or at all. On December 6, 2024, the noon buying rate for Australian dollars was A$1.00 to $0.6382.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that you should consider before deciding to invest in our Common Stock. You should read this entire prospectus carefully, including the sections titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," and our financial statements and related notes included elsewhere in this prospectus before making an investment decision.

Business Overview

We are a structural heart company committed to discovering, developing and commercializing innovative medical devices designed to improve the quality of life for patients with aortic stenosis. Our lead product, the DurAVR® transcatheter heart valve ("THV") system, represents a unique product opportunity in a new THV class of single-piece heart valves, for the treatment of aortic stenosis. Our DurAVR® THV system consists of a single-piece, biomimetic valve made with our proprietary ADAPT® tissue-enhancing technology and deployed with our ComASUR® balloon-expandable delivery system. ADAPT® is our proprietary anti-calcification tissue shaping technology that is designed to reengineer xenograft tissue into a pure, single-piece collagen bioscaffold. Our proprietary ADAPT® tissue has been clinically demonstrated to be calcium free for up to 10 years post-procedure, according to *Performance of the ADAPT-Treated CardioCel® Scaffold in Pediatric Patients With Congenital Cardiac Anomalies: Medium to Long-Term Outcomes*, published by William Neethling et. al., and has been distributed for use in over 55,000 patients globally in other indications. Our ComASUR® balloon-expandable delivery system, which was developed in consultation with physicians, is designed to provide precise alignment with the heart's native commissures to achieve accurate placement of the DurAVR® THV system.

We clinically developed our DurAVR® THV system over several years with significant physician input with the goal of addressing hemodynamic limitations of the current standard-of-care products. To date, a total of 73 patients have been treated with the DurAVR® THV system across the United States, Canada and Europe. In November 2021, we commenced our first-in-human ("FIH") study at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia.

Aortic valve stenosis is one of the most common and serious valvular heart diseases. It is fatal in approximately 50% of patients if left untreated after two years, and no pharmacotherapy is available to treat this disease. Aortic stenosis causes a narrowing of the heart's aortic valve, which reduces or blocks the amount of blood flowing from the heart to the body's largest artery, the aorta, and from there to the rest of the body. Minimally-invasive transcatheter aortic valve replacement ("TAVR"), which the U.S. Food and Drug Administration (the "FDA") initially approved in 2011 for high surgical risk patients, has emerged as an alternative to open-heart surgery. In 2019, the FDA also approved TAVR for use in low-risk surgical patients. These low-risk surgical patients are often younger persons within the geriatric population that require heart valves with longer durability and pre-disease hemodynamics for an improved quality of life. More generally, patients with aortic valve stenosis are now being diagnosed at a younger age.

While previous generations of TAVRs were designed for older, high risk, less-active patients, our DurAVR® THV system is designed to be a solution for all patients, including both older, less-active patients and younger patients. DurAVR® THV is a single-piece valve with a novel biomimetic design that aims to replicate the normal blood flow of a healthy human aortic valve as compared to traditional three-piece aortic valves. In our FIH study, we have observed promising results in relation to hemodynamics, laminar flow and exercise capacity. In addition, our DurAVR® THV system has been developed with the aim to increase durability and last longer than traditional three-piece designs through the use of our ADAPT® anti-calcification tissue including a molded single piece of tissue designed to mimic the performance of a pre-disease human aortic valve, which we believe can result in improved hemodynamics as compared to traditional three-piece designs. These designs and features cumulatively aim to provide a better quality of life as compared to the current standard of care associated with traditional three-piece designs. We intend to test these features in the randomized global pivotal study (the "Pivotal Trial") against commercially approved TAVR devices.

The design and scope of the Pivotal Trial will be finalized following completion of our submission to the FDA and receipt of feedback from the FDA. The purpose of the Pivotal Trial will be to demonstrate non-inferiority of the DurAVR® THV system compared with commercially available TAVR systems for treatment of subjects with severe calcific aortic stenosis. We anticipate that the design of the Pivotal Trial will be a prospective, randomized, controlled multicenter, international study wherein subjects will be randomized to receive either TAVR using the DurAVR® THV system or TAVR using any commercially available and approved THV from competitors. We anticipate that the subjects will include a broad array of risk profiles. We anticipate that subjects with a failed surgical bioprosthesis in need of a valve-in-valve ("ViV") TAVR will be enrolled in a separate parallel registry.

In November 2022, we received approval from the FDA to commence an early feasibility study ("EFS") to treat 15 patients with severe aortic stenosis using the DurAVR® THV system in up to seven heart valve centers across the United States building on data obtained in the FIH study. The EFS has now completed enrollment of 15 patients. In addition, the FDA determined on March 24, 2023 that approval of an investigational device exemption ("IDE") supplement is not required to manufacture the DurAVR® valve for investigational use in clinical trials at our facility in a suburb of Minneapolis, Minnesota. We are currently planning to submit an IDE for the DurAVR® THV system Pivotal Trial to the FDA by Q1 of 2025. If we obtain approval from the FDA, we intend to perform site activation and seek Institutional Review Board ("IRB") approval for commencement of the study at each site. Subject to the foregoing, we anticipate enrollment to begin in the third quarter of 2025. Such a trial would be designed to provide the primary clinical evidence on which the FDA could base a decision for Pre-Market Approval that is required for commercialization of the DurAVR® THV system in the United States.

We are a development stage company and have incurred net losses in each year since inception; however, we believe that we have significant growth potential in a large, underpenetrated and growing market. Since the inception of the TAVR procedure, the annual volume of TAVR procedures in the United States has increased significantly year-over-year, with an estimated 73,000 patients having undergone a TAVR procedure in the United States in 2019 according to the STS/ACC TVT Registry (the "TVT Registry"). According to FMI, the total global market opportunity for TAVR in relation to severe aortic stenosis and in relation to ViV procedures is expected to reach $9.9 billion and $2.5 billion, respectively, in 2028. The key specific markets that our Company is initially targeting are North America and Europe due to these markets accounting for the majority of the above global opportunity. FMI indicated that the North American and European markets averaged 53% and 38% of the global market share, respectively, during the period 2016 to 2023. FMI forecasts that the market opportunity in relation to severe aortic stenosis for North America and Europe will reach $5.5 billion and $3.7 billion, respectively, in 2028; and the market opportunity in relation to ViV procedures is forecast to reach $1.5 billion and $0.8 billion, respectively, in 2028. To calculate these future market values, FMI has relied on actual data from 2023 collated from a variety of published sources and key medical experts and applied a projected Compound Annual Growth Rate ("CAGR") of 14.9% for the global market, 16.2% for the North American market, and 14.0% for the European market. A non-exhaustive list of factors that may impact these forecast calculations include key players' historic growth; companies and manufacturers working together to develop new, affordable and timesaving technologies; new product launches and approvals; rising demand for THV replacement; availability and cost of products; growing investment in healthcare expenditure; and increased regulatory focus on patient safety and reimbursement policies. In addition, we expect the TAVR market to benefit from general trends, including an aging population, earlier diagnosis of aortic stenosis, increased incidence of obesity and diabetes (which contribute to heart disease), as well as the broader patient populations' desire to pursue a more active lifestyle.

Our innovation-focused R&D practice is driven by rapid technological advancement and significant input from leading interventional cardiologists and cardiac surgeons. As a company that is primarily in the development phase, we currently generate small amounts of revenue and income which are insufficient to cover our investment in research, development and operational activities resulting in recurring net operating losses, incurred since inception. We, like other development stage medical device companies, experience challenges in implementing our business strategy due to limited resources and a smaller capital base as we prioritize product development, minimize the period to the commencement of commercial sales, ensure our focus on quality as well as scale our operations. The development and commercialization of new medical devices is highly competitive. Those competitors may have substantial market share, substantially greater

capital resources and established relationships with the structural heart community potentially creating barriers to adoption of our technology. Our success will partly be based on our ability to educate the market about the benefits of our disruptive technology including current unmet clinical needs compared to commercially available devices as well as how we plan to capture market share post commercialization.

We are dedicated to developing technological enhancements and new indications for existing products, and less invasive and novel technologies to address unmet patient needs. That dedication leads to our initiation and participation in clinical trials that seek to prove our pipeline is safe and effective as the demand for clinical and economic evidence remains high.

From time to time, we enter into strategic agreements aimed at enhancing our business operations and profitability. For example, in April 2023, we invested in, and entered a development agreement with, v2vmedtech, inc. ("v2vmedtech"), which develops an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation.

Overview of U.S. FDA Regulation of Medical Devices

Our products are regulated as medical devices in the United States. Accordingly, our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as well as under other federal, state and local regulatory authorities in the United States, and under foreign regulatory authorities for medical devices. For devices intended for commercial distribution in the United States, the FDA regulates product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance to assure their safety and effectiveness for their intended uses.

The FDA classifies medical devices into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

CardioCel™, VascuCel™ and ADAPT® are pericardial tissue products regulated by the FDA as Class II medical devices. Replacement heart valves, including the DurAVR® THV, are classified as Class III medical devices. Additionally, because the ComASUR® delivery system is required for use of the DurAVR® THV, the ComASUR® delivery system will be regulated as a component of the DurAVR® THV Class III device. Accordingly, the ComASUR® delivery system will be reviewed under any PMA submitted for the DurAVR® THV.

Summary Risk Factors

Our business and any investment in our securities involves risks. You should carefully consider the risks described under the section entitled "*Risk Factors*" immediately following this prospectus summary before making a decision to invest in our Common Stock. If any of these risks actually occur, our business, financial condition and results of operations would likely be materially adversely affected. In such case, the trading price of our securities would likely decline, and you may lose all or part of your investment. Set forth below is a summary of some, but not all, of the principal risks we face:

- We have a history of operating losses and may not achieve or maintain profitability in the future.
- There is substantial doubt about our ability to continue as a going concern.
- Even if this offering is successful, we will require substantial additional future financing and may be unable to raise sufficient capital, which could have a material impact on our research and development programs or commercialization of our products.
- Unsuccessful clinical trials or procedures relating to our products could have a material adverse effect on our prospects.
- If we are unable to successfully identify, develop, obtain and maintain regulatory clearance or approval and ultimately commercialize any of our current or future products, or experience significant delays in doing so, our business may be harmed.

- Even if a product receives regulatory clearance or approval, it may still face development and regulatory difficulties that could delay or impair future sales of products.
- Some of our products are in development and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition, and results of operations.
- We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in clinical trials, which could delay or prevent clinical trials and make those trials more expensive to undertake.
- We operate in a highly competitive and rapidly changing industry, and if we do not compete effectively, our business will be harmed.
- The success of many of our products may depend upon certain key physicians and heart valve centers.
- We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory clearance and approval for or commercialize our products may be delayed.
- We are subject to various risks relating to international activities that could affect our profitability, including risks associated with currency fluctuations and changes in foreign currency exchange rates.
- Any failure to protect our information technology infrastructure and our products against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and harm our business.
- Increased emphasis on environmental, social, and governance matters may have an adverse effect on our business, financial condition, results of operations and reputation.
- We could become exposed to product liability claims that could harm our business, and we may be unable to obtain insurance coverage at acceptable costs and adequate levels.
- Use of our products in unapproved circumstances could expose us to liabilities.
- Our products and operations are subject to extensive government regulation, including environmental, health and safety regulations, which could result in substantial costs. Furthermore, any failure to comply with applicable requirements could harm our business.
- Healthcare policy changes may have a material adverse effect on us.
- Even with regulatory clearance or approval to bring a product to market, our profitability may be impacted by ongoing coverage and reimbursement determinations by government health care programs and other third-party payors for our products, or procedures and services that rely on our products.
- We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims.
- Tax laws, regulations, and enforcement practices are evolving and may have a material adverse effect on our results of operations, cash flows and financial position.
- Our success depends on our ability to protect our intellectual property and our proprietary technology.
- Intellectual property rights of third parties could adversely affect our ability to commercialize our products.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Any difficulty with protecting our intellectual property could diminish the value of our intellectual property rights in the relevant jurisdiction.

- We may be unable to achieve some or all of the benefits that we expect to achieve from the Reorganization, which could materially adversely affect our business, financial condition and results of operations.
- We have incurred significant costs associated with the Reorganization and will incur significant ongoing costs as a company whose Common Stock is publicly traded in the United States, and our management is required to devote substantial time to compliance initiatives and corporate governance practices, which could divert their attention from the operation of our business.
- The market price and trading volume of our Common Stock may be volatile and may be affected by economic conditions beyond our control.
- An active trading market for our Common Stock may not develop and you may not be able to resell your shares of Common Stock at or above the public offering price, if at all.
- We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Common Stock.
- Our Second Amended and Restated Certificate of Incorporation (our "Second Amended and Restated Certificate of Incorporation") and Amended and Restated Bylaws will contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Corporate History

ATL is an Australian public company originally registered in Western Australia, Australia that was incorporated in 1999. ATL's ordinary shares were admitted for official quotation on the ASX on March 24, 2004.

The Company was incorporated in the State of Delaware on January 29, 2024, for the purposes of effecting the Reorganization. The Company is a global company with its principal executive offices located at Toowong Tower, Level 3, Suite 302, 9 Sherwood Road, Toowong, QLD 4066, Australia, and other key locations located at 860 Blue Gentian Road, Suite 340, Eagan, Minnesota 55121 as well as two other sites in Minnesota and sites in Western Australia, Australia and Geneva, Switzerland. The Company's telephone number is +61 7 3152 3200. Additional information can be found on our website address: *www.anteristech.com*. Information contained on, or that is accessible through, the website does not constitute part of this prospectus and we do not incorporate any such information into this prospectus. The Company has included its website address in this prospectus solely as an inactive textual reference.

Prior to closing of this offering, the Company will receive all of the issued and outstanding shares of ATL pursuant to the Scheme. Contemporaneously with implementation of the Scheme, ATL will also cancel all existing options it has on issue in exchange for the Company issuing replacement options to acquire Common Stock pursuant to the Option Scheme. The Scheme was approved by ATL's shareholders at a general meeting of shareholders, which was held on December 3, 2024. The Option Scheme was approved by ATL's optionholders at a general meeting of optionholders held on the same day. ATL obtained approval of the Scheme and the Option Scheme by the Supreme Court of Queensland on December 4, 2024. All conditions to the Scheme and Option Scheme, other than the closing of this offering, have been satisfied.

Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." We expect that the CDIs will commence trading on an ordinary settlement basis on the ASX one trading day following the closing of this offering under the symbol "AVR." Concurrent with the closing of this offering, ATL will de-list its securities from the ASX.

Pursuant to the Reorganization, the Company will issue to the shareholders of ATL either one share Common Stock for every ordinary share of ATL or one CDI for every one ordinary share of ATL, in each case, as held on the Scheme record date. Eligible shareholders of ATL (being those whose residence at the record date of the Scheme is in Australia, New Zealand, Hong Kong, Singapore, Israel, Belgium, Canada,

Denmark, Germany, Ireland, the Netherlands, Sweden, Switzerland or the United States) will receive CDIs by default. In order to receive Common Stock, eligible shareholders were required to complete and submit an election form to ATL's registry no later than 5:00 pm (AEDT) on December 5, 2024. Ineligible shareholders will not receive CDIs or shares of Common Stock but will instead receive the proceeds from the sale of the CDIs to which they would otherwise be entitled by a broker appointed by ATL. Small Shareholders will have the CDIs to which they would otherwise be entitled under the Scheme instead issued to, and sold by, a broker appointed by ATL, with the net proceeds from the sale remitted to the relevant ATL shareholder, unless the Small Shareholder notified ATL's registry that they wished to receive CDIs or Common Stock by no later than 5:00 pm (AEDT) on December 5, 2024. The appointed broker will sell the CDIs in accordance with the terms of a sale facility agreement and will remit the proceeds to ineligible shareholders and Small Shareholders (other than those Small Shareholders who opt out). Additionally, pursuant to the Option Scheme, each outstanding option to acquire ordinary shares of ATL will be cancelled, and the Company will issue replacement options representing the right to acquire shares of Common Stock on the basis of one replacement option for every one existing ATL option held.

Following completion of the Reorganization, ATL's ordinary shares will be de-listed from the ASX and ATL will become a wholly-owned subsidiary of the Company.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock (including Common Stock represented by CDIs) held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we will present in this prospectus only two years of audited annual financial statements, plus any required unaudited interim condensed financial statements, and related management's discussion and analysis of financial condition and results of operations;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our independent registered public accounting firm on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require non-binding, advisory stockholder votes on executive compensation or golden parachute arrangements.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period for any new or revised accounting standards during the period in which we remain an emerging growth company.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies. However, we may adopt certain new or revised accounting standards early.

We are also a "smaller reporting company," as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our Common Stock (including

Common Stock represented by CDIs) held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our Common Stock (including Common Stock represented by CDIs) held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

THE OFFERING

Common Stock Offered by Us	14,800,000 shares.
Option to Purchase Additional Shares	We have granted the underwriters an option to purchase up to 2,220,000 additional shares of Common Stock from us at any time within 30 days from the date of this prospectus.
Common Stock to be Outstanding Immediately After this Offering	35,939,816 shares (or 38,159,816 shares if the underwriters exercise their option to purchase additional shares in full), including 20,360,496 shares represented by CDIs.
Use of Proceeds	We estimate that the net proceeds to us from this offering will be $80.0 million (or $92.3 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $6.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, primarily for the ongoing development of DurAVR® THV and the preparation and enrollment of the Pivotal Trial of DurAVR® THV for treating severe aortic stenosis, with the remaining for working capital and other general corporate purposes determined from time to time, including the repayment of amounts owed under the Convertible Note Facility (as defined below). See the section titled "*Use of Proceeds*."
Risk Factors	See the section titled "*Risk Factors*" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to invest in our Common Stock.
Reorganization	Prior to the completion of this offering, the Company will receive all of the issued and outstanding shares of ATL pursuant to the Scheme and will issue to the shareholders of ATL either one share Common Stock for every ordinary share of ATL or one CDI for every ordinary share of ATL, in each case, as held on the Scheme record date. Contemporaneously with implementation of the Scheme, ATL will also cancel all existing options it has on issue in exchange for the Company issuing replacement options to acquire Common Stock pursuant to the Option Scheme.
Listing	Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." We expect that our CDIs will commence trading on the ASX on the trading day following the closing of this offering under the symbol "AVR."

Unless otherwise indicated, the number of shares of our Common Stock to be outstanding after this offering is based on 21,139,816 shares of Common Stock outstanding as of September 30, 2024 (after giving effect to the completion of the Reorganization and the distribution of shares of our Common Stock in connection therewith), and excludes:

- shares issuable upon exercise of 6,118,807 options to purchase ATL ordinary shares and 49,388 warrants for the purchase of ATL ordinary shares during the period from September 30, 2024 to 12:00 pm (AEDT) on the business day prior to the record date for the Scheme, as such exercise would increase the number of shares of our Common Stock distributed in the Reorganization; and

- 5,163,023 shares of our Common Stock that will be available for future equity awards under the Equity Plan (as defined below) (which includes an annual evergreen increase) and became effective upon the execution of the underwriting agreement for this offering.

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- an initial public offering price of $6.00 per share;
- completion of the Reorganization and the distribution of 21,139,816 shares of our Common Stock in connection therewith;
- the filing of our Second Amended and Restated Certificate of Incorporation and the adoption of our Amended and Restated Bylaws immediately prior to the completion of the Reorganization and the closing of this offering;
- no conversion of the Convertible Notes;
- no exercise of the outstanding options of ATL following September 30, 2024; and
- no exercise by the underwriters of their option to purchase additional shares of our Common Stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our historical financial data for the periods and as of the dates indicated. We have derived the summary statements of operations and comprehensive loss data for the years ended December 31, 2023 and 2022 from our audited consolidated financial statements and related notes included elsewhere in this prospectus. We have derived the summary statements of operations and comprehensive loss data for the nine months ended September 30, 2024 and 2023, except for pro forma amounts, and the summary balance sheet data as of September 30, 2024, except for pro forma and pro forma as adjusted amounts, from our unaudited interim condensed financial statements and related notes as of and for the nine months ended September 30, 2024 and 2023, as applicable, included elsewhere in this prospectus. Our historical results are not necessarily indicative of results that may be expected in the future. You should read the following summary financial data together with our audited financial statements and related notes included elsewhere in this prospectus and the information in the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*."

Statement of Operations Data:

	Nine Months Ended September 30,		Year Ended December 31,	
	2024	2023	2023	2022
	(in U.S. dollars)			
Net Sales	2,166,888	$ 2,190,665	$ 2,734,821	$ 3,200,711
Costs and expenses:				
Cost of product sold	(1,229,242)	(1,500,686)	(1,858,021)	(2,902,328)
Research and development expense	(38,135,103)	(21,254,062)	(30,889,993)	(17,590,090)
Selling, general and administrative expense	(19,655,764)	(12,262,458)	(17,360,629)	(15,439,777)
Acquired in-process research and development	—	(131,617)	(131,617)	—
Net foreign exchange (losses)/gains	(456,541)	701,571	(634,549)	1,617,209
Operating loss	**(57,309,762)**	**(32,256,587)**	**(48,139,988)**	**31,114,275**
Other non-operating income, net	637,352	935,808	1,935,415	1,456,276
Interest and amortization of debt discount and expense	(39,154)	(52,434)	(67,089)	(648,709)
Fair value movement of derivatives and other variable liabilities	(54,486)	39,128	9,512	(257,092)
Loss on asset acquisition of a variable interest entity	—	(501,247)	(501,247)	—
Loss before income taxes from continuing operations	**(56,766,050)**	**(31,835,332)**	**(46,763,397)**	**(30,563,800)**
Income tax (expense)/benefit	—	—	—	—
Loss after income tax	**(56,766,050)**	**(31,835,332)**	**(46,763,397)**	**(30,563,800)**
Net income/(loss) attributable to non-controlling interests and redeemable non-controlling interests	149,768	—	(741,556)	—
Loss Attributable to ATL	**(56,915,818)**	**(31,835,332)**	**(46,021,841)**	**(30,563,800)**
Basic and diluted loss per share	$ 2.97	$ 2.09	$ 2.95	$ 2.29
Basic and diluted weighted average shares outstanding	19,144,910	15,221,827	15,605,878	13,362,583

Balance Sheet Data:

	As of September 30, 2024		
	Actual	Pro Forma[1][2]	Pro Forma As Adjusted[2][3]
		(in U.S. dollars)	
Cash and cash equivalents	$ 10,617,616	$ 10,617,617	$ 91,317,617
Working capital[4]	669,060	669,060	80,669,060
Current assets	15,170,399	15,170,399	95,170,399
Total assets	21,102,239	21,102,239	101,102,239
Current liabilities	16,282,538	16,282,538	16,282,538
Total liabilities	18,205,764	18,205,764	18,205,764
Common Stock	252,491,184	2,114	3,594
Additional paid in capital	16,624,207	269,113,277	349,111,797
Accumulated other comprehensive loss	(8,953,218)	(8,953,218)	(8,953,218)
Accumulated deficit	(257,012,631)	(257,012,631)	(257,012,631)
Total stockholders' equity	$ 3,149,542	$ 3,149,542	$ 83,149,542
Noncontrolling interest	(253,067)	(253,067)	(253,067)
Total equity	$ 2,896,475	$ 2,896,475	$ 82,896,475

(1) The pro forma column in the balance sheet data gives effect to the Reorganization, as if the Reorganization had occurred on September 30, 2024. The Reorganization incorporates the Company's assets ($1 cash and cash equivalents), the elimination of any intercompany balances ($10 between Anteris Technologies Corporation and the Company) and an adjustment to Common Stock to reflect the 21,139,816 shares outstanding at a par value of $0.0001 per share, with the excess over par value recognized as additional paid in capital.

(2) The pro forma column in the balance sheet data does not give effect to the issuance of the Convertible Notes (as defined below).

(3) The pro forma as adjusted column in the balance sheet data above gives effect to (i) the adjustments described in footnote (1) above, (ii) the sale and issuance of 14,800,000 shares of Common Stock by us in this offering at the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (iii) the filing of our Second Amended and Restated Certificate of Incorporation and the adoption of our Amended and Restated Bylaws, which will occur immediately prior to completion of the Reorganization and the closing of this offering. The pro forma as adjusted balance sheet includes estimated transaction costs directly attributable to the offering, including underwriting discounts and commissions, legal and accounting fees, and other related costs. These costs totaling $8.8 million are reflected as: (i) a reduction in cash and cash equivalents ($8.1 million); and (ii) deferred offering costs ($0.7 million) which had been included in other current assets prior to the completion of the offering. The total transaction costs are reflected as a reduction in additional paid in capital after the offering. The actual transaction costs incurred may differ from these estimates and will be adjusted accordingly in the final financial statements of the period in which this offering is completed. Transaction costs included in the pro forma as adjusted column are limited to those incurred subsequent to the determination that this offering was probable.

(4) Working capital is defined as current assets less current liabilities (excluding the warrant and operating lease liabilities).

RISK FACTORS

Investing in shares of our Common Stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this prospectus, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and related notes included elsewhere in this prospectus, before making an investment decision. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe not to be material, could materially and adversely affect our business, financial condition, reputation or results of operations. In such case, the trading price of shares of our Common Stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

Risks Related to Our Operating History and Financial Position

We have a history of operating losses and may not achieve or maintain profitability in the future.

We have experienced significant recurring operating losses and negative cash flows from operating activities since inception. For the nine months ended September 30, 2024 and 2023, we had total comprehensive losses of $56.2 million and $33.4 million, respectively, and negative cash flows from operating activities of $43.0 million and $26.7 million, respectively. For the years ended December 31, 2023 and 2022, we had total comprehensive losses of $46.4 million and $32.7 million, respectively, and negative cash flows from operating activities of $34.6 million and $29.4 million, respectively. As of September 30, 2024 and December 31, 2023, we had an accumulated deficit of $257.0 million and $200.1 million, respectively. We expect to continue to incur additional losses for the foreseeable future. The losses and negative cash flows have primarily been due to the substantial investments we have made to develop our products, costs related to our sales and marketing efforts, costs related to clinical and regulatory initiatives to obtain marketing approval, and infrastructure improvements.

We are a clinical-stage medical device company focused on the development and commercialization of innovative minimally invasive devices to treat heart valve diseases. The success of any product development is uncertain. We expect our operating expenses to increase in the future as we grow our business, including the continuing development and potential future commercialization of DurAVR® THV, as well as continuing to invest in research and development. Moreover, there is a substantial risk that we may not be able to complete the development of DurAVR® THV or develop other products. It is possible that none of our products will be successfully commercialized and, if that were to be the case, this would prevent us from ever achieving profitability.

We may also encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage medical technology companies in rapidly evolving fields. In addition, as a public company, we will incur significant legal, accounting and other expenses. Accordingly, we expect to continue to incur significant operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our capital requirements needed to operate our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and could cause the market price of our Common Stock to decline.

To become and remain profitable, we must succeed in identifying, developing, conducting successful clinical trials for, obtaining regulatory clearance and approval for, and eventually commercializing, manufacturing and supplying products, including DurAVR® THV, that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our products, continuing to discover and develop additional products, obtaining regulatory clearance and approval for any products that successfully complete clinical trials, developing manufacturing processes and methods, devising and implementing processes for transferring technology and manufacturing processes to a network of third-party manufacturing sites, establishing necessary quality control, establishing marketing capabilities, and commercializing and ultimately selling any approved products. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue

that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the price of our Common Stock could be materially adversely affected.

Because of the numerous risks and uncertainties associated with the development of medical device products, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or comparable foreign regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any of our products, our expenses could increase and commercial revenue could be further delayed and become more uncertain, which will have a material adverse impact on our business.

There is substantial doubt about our ability to continue as a going concern.

As a result of our net loss and net cash outflows from operating activities, our independent external auditor included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2023 that indicated our results raise substantial doubt on our ability to continue as a going concern. The conditions giving rise to this uncertainty and our plan with respect to this uncertainty are disclosed in Note 3 to our consolidated financial statements. Our future viability as an ongoing business is dependent on our ability to attract additional capital and ultimately, upon our ability to develop future profitable operations. There is no assurance that we will be successful in obtaining sufficient funding to fund continuing operations on terms acceptable to us, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence from investors and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

Even if this offering is successful, we will require substantial additional future financing and may be unable to raise sufficient capital, which could have a material impact on our research and development programs or commercialization of our products.

Developing medical device products, including conducting clinical trials and preclinical studies, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and our expenses will continue to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials of, and seek regulatory clearance and approval for, our current products, including DurAVR® THV, and future products we may develop or otherwise acquire. Even if one or more of our products is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product, including manufacturing and supply costs, as well as costs associated with establishing a sales and end-to-end supply chain management infrastructure.

We have historically devoted most of our financial resources to research and development. To date, we have financed a significant amount of our operations through equity financings, and to a lesser extent, through the divestment of business segments and incurrence of indebtedness. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings or strategic collaborations. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future products;
- the number and size of clinical trials required for regulatory clearance and approval of our current or future products;
- the costs, timing and outcome of regulatory review of any of our current or future products;

- the costs associated with acquiring or licensing additional products, technologies or assets;
- the cost of manufacturing clinical and commercial supplies of our current or future products;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending against any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and end-to-end supply chain management, for any of our products for which we receive regulatory clearance and approval;
- the revenue, if any, received from commercial sales of our products for which we receive regulatory clearance and approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a dual-listed public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in additional businesses, products and technologies.

The amount of such future net losses, as well as the possibility of future profitability, will also depend on our success in developing and commercializing products that generate significant revenue. Until our products become commercially available, we will need to obtain additional funding in connection with the further development of our products. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. As such, additional financing may not be available to us when needed, on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or obtain funds by entering agreements on unattractive terms.

Furthermore, any additional equity and equity-linked fundraising in the capital markets may be dilutive for stockholders and any debt-based funding may bind us to restrictive covenants and curb our operating activities and ability to pay potential future dividends even when profitable. In addition, the issuance of additional equity and equity-linked securities by us, or the possibility of such issuance, may cause the market price of our Common Stock to decline. We cannot guarantee that future financing will be available in sufficient amounts or on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we will be prevented from pursuing research and development efforts. This could harm our business, operating results and financial condition and cause the price of our Common Stock to fall.

We may encounter difficulties in managing our growth, which could negatively impact our operations.

We have experienced rapid growth and expect to continue to grow in the future. As we advance our clinical development programs for our products, seek regulatory clearance and approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product development, scientific and administrative headcount. Due to the complexity in managing a company that has scaled very quickly and anticipates continued growth, we may not be able to scale our headcount and operations effectively to manage the expansion of our product pipeline or recruit and train the necessary additional personnel. As our operations expand, we also expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. We will also need to establish commercial capabilities in order to commercialize any products that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources.

Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues.

In addition, in order to continue to meet our obligations as a publicly listed company in both Australia and the United States and to support our anticipated long-term growth, we will need to increase our general and administrative capabilities. Our management, personnel and systems may not be adequate to support this future growth.

If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be harmed.

Unstable market and economic conditions, including as a result of geopolitical events, such as the war in Ukraine, may have serious adverse consequences on our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. Following the COVID-19 pandemic and in connection with geopolitical conflicts, global economic and business activities continue to face widespread uncertainties. There can be no assurance that future deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our products, delayed ability to obtain patents and other intellectual property protection, weakened demand for our products, if approved, or our ability to raise additional capital when needed on acceptable terms. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers, suppliers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Additionally, in February 2022, Russia commenced a military invasion of Ukraine. The ongoing conflict and political and physical conditions in Ukraine and Russia, as well as in neighboring countries, may disrupt our FIH study in Tbilisi, Georgia, including the ability of third parties on which we rely to perform in accordance with our expectations. Moreover, our ability to conduct 12-month follow-ups with our study participants may be adversely affected as a result of the ongoing conflict, which could significantly delay our clinical development plans and potential clearance or approval of products or cause us to increase our research and development expenses to conduct one or more additional studies, any of which could increase our costs and jeopardize our ability to successfully commercialize our products, if approved.

Risks Related to Our Industry

Unsuccessful clinical trials or procedures relating to products could have a material adverse effect on our prospects.

The regulatory clearance and approval process for new products and new intended uses for existing products can require extensive clinical trials and feasibility studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary clearances and approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be enrolled or completed in a timely or cost-effective manner or result in positive clinical data or a commercially viable product. Clinical trials or procedures may experience significant setbacks even if earlier trials have shown promising results. Furthermore, preliminary results from clinical trials or procedures may be contradicted by subsequent analyses. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks or any other reasons, and any such delay, suspension, or termination could have a material adverse effect on our prospects or the market's view of our future prospects.

In particular, our lead product, DurAVR® THV, is undertaking clinical trials designed to provide the primary clinical evidence on which the FDA could base a decision for Pre-Market Approval (as defined under "*Business — Government Regulation — U.S. FDA Regulation of Medical Devices*") required for commercialization of the DurAVR® THV system in the United States. There can be no assurance that we will successfully complete the clinical trials and obtain Pre-Market Approval for the DurAVR® THV system.

If we are unable to successfully identify, develop, obtain and maintain regulatory clearance or approval for and ultimately commercialize any of our current or future products, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

The clinical development, manufacturing, sales and marketing of our products are subject to extensive regulation as medical devices by regulatory authorities in the United States, the United Kingdom, the European Union, Australia and elsewhere. Our ability to generate revenue from sales of any of our products depends heavily on the successful identification, development, regulatory clearance or approval for and eventual commercialization of any products. All of our products, including DurAVR® THV, will require significant preclinical and clinical development, regulatory clearance or approval, establishment of sufficient manufacturing supply, including commercial manufacturing supply, and may require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our products before we receive regulatory clearance or approval from the FDA or comparable foreign regulatory authorities. Obtaining regulatory clearances and approvals for new products and manufacturing processes can take a number of years and involve expenditure of substantial resources, and, despite the substantial time and expense invested, we may never receive such regulatory clearance or approval for DurAVR® THV or other products. The development and commercialization of our products is subject to many risks, including:

- additional clinical trials may be required beyond what we currently expect;
- the risk that our financial and other resources are not sufficient to complete the necessary clinical trials;
- regulatory authorities may disagree with our interpretation of data from our clinical trials or may require that we conduct additional trials;
- we may be unable to obtain and maintain regulatory clearance or approval of our products in any jurisdiction;
- regulatory authorities may identify deficiencies in manufacturing processes;

- regulatory authorities may change their clearance or approval policies or adopt new regulations;
- we, or our third-party manufacturers, may not be able to source or produce current Good Manufacturing Practice ("cGMP") materials for the production of our products or product candidates;
- our products, if approved, may not be able to be manufactured at a cost or in quantities necessary to make commercially successful products;
- we may experience delays in the commencement of, enrollment of patients in and timing of our clinical trials;
- we may not be able to achieve and maintain compliance with all regulatory requirements applicable to our products or operations;
- we may not be able to maintain a continued acceptable safety profile of our products following clearance or approval;
- the market may not accept our products, if approved;
- we may be unable to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations, and the effectiveness of our own or any future strategic collaborators' marketing, sales and distribution strategy and operations will affect our profitability;
- we may experience competition from existing products or new products that may emerge;
- we may be unable to successfully obtain, maintain, defend and enforce intellectual property rights important to protect our products; and
- we may not be able to obtain and maintain coverage and adequate reimbursement from third-party payors.

If any of these risks materialize, we could experience significant delays or an inability to successfully develop and commercialize our products, which would have a material adverse effect on our business, financial condition and results of operations.

The successful development of our pipeline of products is highly uncertain and requires significant expenditures and time. In addition, obtaining necessary government clearances and approvals is time-consuming and not assured. If we do not obtain the necessary regulatory clearances or approvals, then we would be unable to commercialize our products.

We currently have a number of products, including DurAVR® THV, in development. We conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our products in order to obtain regulatory clearance or approval for the sale of our products. Preclinical studies and clinical trials are expensive, complex, can take many years and have uncertain outcomes. None of, or only a small number of, our research and development programs may actually result in the commercialization of a product. We will not be able to commercialize our products if preclinical studies do not produce successful results or if clinical trials do not demonstrate safety and efficacy in humans.

Success in preclinical studies or early-stage clinical trials does not ensure that later stage clinical trials will be successful nor does it ensure that regulatory clearance or approval for the product will be obtained. In addition, the process for the completion of preclinical and clinical trials is lengthy and may be subject to a number of delays for various reasons, which would delay the commercialization of any successful product. If our development projects are not successful or are significantly delayed, we may not recover our substantial investments in the product and our failure to bring these products to market on a timely basis, or at all, could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock to decline.

Obtaining regulatory clearances and approvals for new products and manufacturing processes can take a number of years and involve the expenditure of substantial resources. Despite the substantial time and expense invested, regulatory clearance or approval is never guaranteed. The number, size and design of clinical

trials that will be required will vary depending on the product or condition for which the product is intended to be used and the regulations and guidance documents applicable to any particular product. Additionally, during the review process and prior to approval, the FDA or other regulatory bodies could require additional data, which could delay approval. The FDA or other regulators can delay, limit or deny clearance or approval of a product for many reasons or adopt new policies or regulations requiring new or different evidence of safety and efficacy for the intended use of a product. In addition, even if such clearance or approval is secured, the approved labeling may have significant labeling limitations, including limitations on the indications for which we can market a product, or require onerous risk management programs. Furthermore, from time to time, changes to the applicable legislation, regulations or policies may be introduced that change these review and approval processes for our products, which may make it more difficult and costly to obtain or maintain regulatory clearances and approvals.

Successful results in clinical trials and in the subsequent application for marketing approval are not guaranteed. If we are unable to obtain regulatory clearances and approvals, we will not be able to commercialize and generate revenue from our products. Even if we receive regulatory clearance or approval for any of our products, our profitability will depend on our ability to commercialize and generate revenues from their sale or the licensing of our technology. The failure to commercialize our products could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock to decline.

Even if a product receives regulatory clearance or approval, it may still face development and regulatory difficulties that could delay or impair future sales of products.

Following initial regulatory clearance or approval of any products, we will be subject to continuing regulatory review by various government authorities in those countries where our products are marketed or intended to be marketed, including the review of potential malfunctions and adverse events that are reported after products become commercially available. In addition, we will be subject to ongoing audits and inspections of our facilities and products by the FDA, as well as other regulatory agencies in and outside the United States. Previously unknown problems with the product could result in restrictions on the marketing of the product, including withdrawal of the product from the market.

In addition, if we were to receive regulatory clearance or approval to sell DurAVR® THV or another product, the relevant regulatory authorities could, nevertheless, impose significant restrictions on the indicated uses, manufacturing, labelling, packaging, adverse event reporting, storage, advertising, promotion and record keeping or impose ongoing requirements for post-approval studies.

If we fail to comply with the regulatory requirements in those countries where our products are sold, we could lose our marketing clearances or approvals or be subject to fines or other sanctions. Also, as a condition to granting marketing clearance or approval of a product, the applicable regulatory agencies may require a company to conduct additional clinical trials or remediate cGMP issues, the results of which could result in the subsequent loss of marketing approval, changes in product labeling or new or increased concerns about side effects or efficacy of a product.

In addition, incidents of medical device related adverse events or unintended side effects or misuse relating to our products could result in additional regulatory controls or restrictions, or lead to a recall or withdrawal of the product from the market. A recall or market withdrawal, whether voluntary or required by a regulatory authority, may involve significant costs to us, potential disruptions in the supply of our products to our customers and reputational harm to our products and business, all of which could harm our ability to market our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our Common Stock to decline.

Even with regulatory clearance or approval to bring a product to market, our profitability may be impacted by ongoing coverage and reimbursement determinations by government health care programs and other third-party payors for our products, or procedures and services that rely on our products.

Our products and technologies may be paid for by the Centers for Medicare & Medicaid Services (“CMS”) and other government or third-party payors or will be used by hospitals and health care providers who are reimbursed for procedures and services involving our products. Such payment determinations are

subject to pre-approval qualifications and satisfaction of appropriate criteria. CMS, or other third-party payors, may seek to lower costs or limit use of our products as a means to achieve lower health care costs. The sale and demand for our products may be adversely impacted by such coverage and reimbursement determinations.

Participation in government health care programs and contracts with third-party payors will require ongoing compliance with federal and state health care laws and agreement terms.

We will be subject to ongoing monitoring for compliance with federal and state laws, as well as contractual terms, if we receive third-party payor reimbursement for our products, or are engaged with entities that receive reimbursement for procedures and services involving our products. Violation of such laws or contractual terms may result in significant fines and fees, withholding of payment, or removal from the third-party payor programs, which would impact our profitability.

Our products that are in development may not achieve market acceptance, if approved, which could limit our growth and adversely affect our business, financial condition and results of operations.

Even if the FDA or any comparable foreign regulatory authority clears or approves the marketing of any product that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. DurAVR® THV and other products are still in the development stage, and are based on our proprietary technologies. We do not have proven marketing or sales strategies for such new products, nor do we know if customers will accept our products, if approved, and therefore we do not know how the introduction of any approved products will affect our business. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. Our product portfolio continues to expand, and we are investing significant resources to enter into, and in some cases create new markets for, our products. We are continuing to invest resources to achieve clearance and approval and market acceptance of our products but are unable to guarantee that we will succeed.

The degree of market acceptance of our products, if approved, will depend on a number of factors, including:

- the timing of market introduction of our products, as well as competitive products;
- the clinical indications for which a product is approved;
- perceived benefits from our products;
- perceived cost effectiveness of our products;
- perceived safety and effectiveness of our products;
- the effectiveness of sales and marketing efforts;
- the terms of any clearances or approvals and the countries in which clearances and approvals are obtained;
- our ability to provide acceptable evidence of safety and efficacy;
- marketing, manufacturing and supply support;
- potential product liability claims;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;
- in certain instances, reimbursement available through government and private healthcare programs for using our products; and
- introduction and acceptance of competing products or technologies.

If our products do not gain market acceptance or if our customers prefer our competitors' products, our potential revenue growth would be limited, which would adversely affect our business, financial condition and results of operations. Even if some of our products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

Failure to successfully innovate and develop new and differentiated products in a timely manner and effectively market these products could have a material effect on our prospects.

Our continued growth and success depend on our ability to innovate and develop new and differentiated products in a timely manner and effectively market these products. Without the timely innovation and development of products, our products could be rendered obsolete or less competitive because of the introduction of a competitor's newer technologies. Innovating products requires the devotion of significant financial and other resources to research and development activities; however, there is no certainty that the products we are currently developing will complete the development process, or that we will obtain the regulatory or other clearances or approvals required to market such products in a timely manner or at all. Even if we timely innovate and develop products, our ability to successfully market them could be constrained by a number of different factors, including competitive products and pricing, barriers in patients' treatment pathway, the need for regulatory clearance or approval, restrictions imposed on cleared or approved indications, and uncertainty over third-party reimbursement. Failure in any of these areas could have a material effect on our prospects.

We may find it difficult to enroll patients in our clinical trials, and patients could discontinue their participation in clinical trials, which could delay or prevent clinical trials and make those trials more expensive to undertake.

Identifying and qualifying patients to participate in current and future clinical trials of our products is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our products. Patients could be unavailable for various reasons, including competitive clinical trials for similar patient populations, eligibility criteria for the clinical trial, and the proximity of patients to clinical sites. In addition, the process of identifying, confirming eligibility and enrollment of patients may prove costly, and there is a risk that patients enrolled in clinical trials will drop out of the trials before the administration of our products or trial completion. As such, the timeline for recruiting patients, conducting trials and obtaining regulatory clearance or approval of products may be delayed. If we have difficulty enrolling a sufficient number of patients to conduct any clinical trials as planned or maintaining such enrollment, we may need to delay, limit or discontinue those clinical trials. Clinical trial delays could result in increased costs, slower product development, setbacks in testing the safety and effectiveness of our technology or discontinuation of the clinical trials altogether. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the delay or denial of regulatory clearance or approval of our products.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular

product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically a significant volume of data and other information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain clearance or approval for, and commercialize, our products may be harmed, which could harm our business, operating results, prospects or financial condition.

We operate in a highly competitive and rapidly changing industry, and if we do not compete effectively, our business will be harmed.

The medical technology industry is highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain regulatory clearance or approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large healthcare companies, academic institutions, government agencies and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our products. Mergers and acquisitions in the medical technology industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

We expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any products that we successfully develop and commercialize will compete with existing products and new products that may become available in the future. The highly competitive nature of and rapid technological changes in the medical technology industry could render our products or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, development, technical and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, easier to implement or have fewer or less severe side effects;
- obtain quicker regulatory clearance or approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected. Competing products could present superior alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive product approaches may make any products we develop obsolete or non-competitive before we recover the expense of developing and commercializing our products.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The success of many of our products may depend upon certain key physicians and heart valve centers.

We work with leading global physicians who form our Global Medical Advisory Board, which provides guidance to us on building clinical validation of DurAVR® THV. These physicians provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, product

trainers and consultants and as public speakers. If new laws or other developments limit our ability to appropriately engage these professionals or with the heart valve centers of which they are a part or to continue to receive their advice and input or we are otherwise unsuccessful in maintaining strong working relationships with these physicians or their heart valve centers, then the development, marketing and use of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Operations

Our operating results could be adversely affected if we are unable to accurately forecast demand for any of our products that receive marketing clearance or approval and if we are unable to adequately manage our inventory.

If one or more of our products receives marketing clearance or approval, and we commercialize the product, to ensure adequate inventory supply, we will be required to forecast inventory needs and expenses and place orders sufficiently in advance with our suppliers and contract manufacturers, based on our estimates of future demand for our products. Failure to accurately forecast our needs could result in manufacturing delays or increased costs. Due to the lead times necessary to obtain and install new equipment and ramp up production of product lines, if we fail to adequately forecast the need for additional manufacturing capacity, we may be unable to scale production in a timely manner to meet demand for our products. In addition, the technically complex manufacturing processes required to manufacture our products increase the risk of production failures and can increase the cost of producing our products. As a result, because the production process for our products is complex and sensitive, the cost of production and the chance of production failures and lengthy supply interruptions is increased, which can have a substantial impact on our inventory levels.

Our ability to accurately forecast demand could be affected by many factors, including changes in demand for our products, changes in demand for the products of our competitors and the weakening of economic conditions or confidence in future economic conditions. This risk could be exacerbated by the fact that we may not carry a significant amount of inventory and may not be able to satisfy short-term demand increases, or at times will have an excess in inventory that we are unable to effectively utilize. If we fail to accurately forecast demand, we could experience excess inventory levels or a shortage of products available for sale and any such shortage could have a material impact on our business operations.

The expansion of our manufacturing capabilities may be unsuccessful.

We have been manufacturing the ADAPT® tissue for many years. However, to continue the development of our current and future products, we will need to expand our manufacturing capabilities, including potentially outsourcing specific manufacturing processes. Problems with expansion of our manufacturing capabilities, including issues with third-party manufacturers, could delay clinical trials and the commercialization of our products, if approved.

We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our products may be delayed.

We are dependent on third parties to conduct our clinical trials and preclinical studies for our DurAVR® THV system. Specifically, we rely on, and will continue to rely on, medical institutions, clinical investigators, lab service providers, and consultants to conduct clinical trials and preclinical studies, in each case in accordance with trial protocols and regulatory requirements. These third parties play a significant role in the conduct, monitoring, project and site management, data management, safety and lab services of our trials studies, including subsequent analysis of data. Though we expect to carefully manage our relationships with such third parties, there can be no assurance that we will not encounter challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Furthermore, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol

and legal, regulatory and scientific standards and requirements, and our reliance on third parties does not relieve us of our regulatory responsibilities.

While the third parties upon which we rely change from time to time and for each study, historically these partners include:

- IQVIA Inc ("IQVIA"), which is a clinical research organization that provides us with clinical data monitoring, project and site management, data management, and safety reporting services for the EFS;
- Cardiovascular Research Foundation ("CRF"), which provides us with core lab services for the EFS and an independent clinical events committee; and
- QMED Consulting A/S ("QMED"), which provides clinical trial support for the EU, including the provision of life science services in the areas of regulatory affairs, training, quality assurance and control, clinical trial consultancy and submission support to the EU authorities.

In addition, we and the third parties we work with are required to comply with Good Laboratory Practice ("GLP") and Good Clinical Practice ("GCP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of the third parties we work with or our trial sites fail to comply with applicable GLP, GCP or other requirements, the data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional studies or trials before approving our marketing applications, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and our goal of receiving Pre-Market Approval for a product.

There is no guarantee that any of the third parties with whom we work will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other activities that could harm our competitive position.

In addition, the third parties with whom we work have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding additional third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new third-party service provider commences work. As a result, delays can occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with the third parties with whom we work, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties for the supply of materials and for the design and manufacture of our products. Any failure by or loss of a vendor could result in delays and increased costs, which may adversely affect our business.

We currently rely on a limited number of suppliers, including several single-source suppliers, to supply raw materials and other components and on contract manufacturers to design and manufacture certain products. The facilities used by our contract manufacturers must be approved for the manufacture of our products by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that may be conducted by or for regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, contract manufacturers for compliance with cGMP requirements for manufacture of those products. If these contract manufacturers cannot successfully manufacture such products in a manner that

conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities.

We also purchase certain supplies and services from single sources for reasons of quality assurance, cost-effectiveness, availability, constraints resulting from regulatory requirements and other reasons. We experience from time to time, and may continue to experience, supply interruptions due to a variety of factors, including:

- general economic conditions that could adversely affect the financial viability of our vendors;
- vendors' election to no longer service or supply medical technology companies, including due to the burdens of applicable quality requirements and regulations or for no reason at all;
- the limitation or ban of certain chemicals or other materials used in the manufacture of our products; and
- delays or shortages due to trade or regulatory embargoes.

Additionally, any significant increases in the cost of raw materials, whether due to inflationary pressure, supply constraints or regulatory changes could adversely impact our operating results. A change or addition to our vendors could require significant effort due to the rigorous regulations and requirements of the FDA and other regulatory authorities. It could be difficult to establish additional or replacement sources on a timely basis or at all, which could have a material adverse effect on our business. See the section entitled "*Business — Suppliers*" for a description of the agreements we are party to with our single-source suppliers.

We have limited control over our suppliers, contract manufacturers, and logistic partners, and such limited control could subject us to significant risks, including the potential inability to produce or obtain quality products and services on a timely basis or in sufficient quantity.

We currently rely on a limited number of suppliers to supply raw materials and other components for certain of our products, contract manufacturers to manufacture certain of our products, and logistics partners to transport certain of our products. We have limited control over our suppliers, contract manufacturers and logistics partners. Such limited control could subject us to the following risks:

- inability to satisfy demand for our current and future products and services;
- reduced control over delivery timing and related customer experience and product reliability;
- reduced ability to monitor the manufacturing process and components used in our products;
- limited ability to develop comprehensive manufacturing specifications that take into account any materials shortages or substitutions;
- variance in the manufacturing capability of our third-party manufacturers;
- price increases;
- failure of a significant supplier or manufacturer partner to perform its obligations to us for technical, market or other reasons;
- variance in the quality of services provided by our third-party partners;
- inability of suppliers to comply with applicable provisions of the FDA's Quality System Regulation or other applicable laws enforced by the FDA, state regulatory authorities or non-U.S. regulatory authorities;
- inability to ensure the quality of products and components manufactured by third parties;
- production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- difficulties in establishing additional supplier or manufacturer partner relationships if we experience difficulties with our existing suppliers, manufacturers or logistics partners;

- shortages of materials or components;
- production shortages resulting from any events affecting raw material supply;
- misappropriation of our intellectual property;
- exposure to natural catastrophes, epidemics such as a pandemic, political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products or the components are sourced;
- changes in local economic conditions in the jurisdictions where our suppliers, manufacturers, and logistics partners are located;
- the imposition of new laws, including those relating to labor conditions, quality and safety standards, imports, duties, tariffs, taxes and trade restrictions; and
- insufficient warranties and indemnities on components supplied to our manufacturers or performance by our partners.

If our suppliers became unable to provide components in the volumes needed or at an acceptable price, we would have to identify and qualify acceptable replacements from alternative sources of supply. The process of qualifying suppliers is lengthy. Delays or interruptions in the supply of our requirements could limit or stop our ability to provide sufficient quantities of devices on a timely basis or meet demand for our devices, which could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, our failure or the failure of our manufacturing partners and suppliers to maintain compliance with the applicable regulatory requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our manufacturing partners or suppliers fails to maintain compliance with our or governmental quality requirements, we may have to qualify a new manufacturing partner or supplier, and we could experience manufacturing delays as a result.

The occurrence of any of these risks could cause us to experience a significant disruption in our ability to produce and deliver our products to our customers and could harm our brand and reputation.

Health and safety hazards may adversely affect our business operations.

We have been engaged in manufacturing and research and development activities for a number of years. Our manufacturing and research and development activities are conducted within our premises in Australia and the United States. In light of our business, there are health and safety risks that our employees and contractors could be exposed to. Such health and safety risks include all hazards and risks related to work activities, including both physical and mental health risks. There is a heightened level of risk in a manufacturing environment but health and safety risks also arise in research and development facilities as well as office environments. They may arise due to insufficiently trained or qualified personnel, equipment failure, staff fatigue, unsafe work environments and/or deficient health and safety management systems.

Health and safety incidents in the workplace could directly impact staff, including injury or fatality, mental health and operational performance. It could also result in an increase in litigation and insurance claims, reputational impacts and regulatory intervention. Thus, any health and safety incident occurring to our employees and contractors could materially affect our business operations.

Our research and development efforts will be jeopardized if we are unable to retain key personnel and cultivate key academic and scientific collaborations.

Changes in our senior management can be disruptive to our business and may adversely affect our operations. For example, when we have changes in senior management positions, we may elect to adopt different business strategies or plans. Any new strategies or plans, if adopted, may not be successful and if any new strategies or plans do not produce the desired results, our business may suffer.

Moreover, competition for qualified employees is intense and as such we may not be able to attract and retain personnel critical to our success. Our success depends on our continued ability to attract, retain and

motivate highly qualified management, clinical and scientific personnel, manufacturing personnel, sales and marketing personnel and on our ability to develop and maintain important relationships with clinicians, scientists and leading academic and health institutions. Given the specialized nature of our products, there is an inherent scarcity of experienced personnel in these fields. As we continue developing products in our pipeline, we will require personnel with medical, scientific or technical qualifications specific to each program. The loss of key personnel, in particular our senior leadership team, could delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the medical technology industry is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our product development and commercialization activities.

We may in the future seek to identify and acquire certain assets, products and businesses, and there can be no guarantee that we will be able to successfully consummate such transactions.

We may in the future seek to identify and acquire complementary businesses, products, technologies or other assets to augment our pipeline. Such transactions may be complex, time consuming and expensive. There can be no guarantee that we will be able to successfully consummate acquisitions or other arrangements, which could result in significant diversion of management and other employee time, as well as substantial out-of-pocket costs. If such transactions are not completed for any reason, we may incur significant costs and the market price of our Common Stock may decline.

In addition, even if an acquisition is consummated, the integration of the acquired business, product or other assets into our company may be complex and time-consuming, and we may not achieve the anticipated benefits, cost-savings or growth opportunities we expect. Potential difficulties that may be encountered in the integration process include the following: integrating personnel, operations and systems, while maintaining focus on selling and promoting existing and newly-acquired products; coordinating geographically dispersed organizations; preventing the distraction of management and employees from operations; retaining existing customers and attracting new customers; maintaining the business relationships the acquired company has established, including with health care providers; and managing inefficiencies associated with integrating the operations of our company and the acquired business, product or other assets.

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

The rapid pace of technological development in the medical technology industry and the specialized expertise required in different areas of medicine make it difficult for one company alone to develop a broad portfolio of technological solutions. In addition to internally generated growth through our research and development efforts. We expect to make future investments where we believe that we can stimulate the development or acquisition of new technologies and products to further our strategic objectives and strengthen our existing businesses. Collaborative arrangements and strategic alliances in and with medical technology companies are inherently risky, and we cannot guarantee that any of our previous or future investments or investment collaborations will be successful or will not materially adversely affect our business, results of operations, financial condition and cash flows.

Any collaboration arrangement or alliance we have or may have in the future could be terminated for reasons beyond our control or we may not be able to negotiate future alliances on acceptable terms, if at all. These arrangements and alliances could result in us receiving less revenue than if we sold our products directly, place the development, sales and marketing of our products outside of our control, require us to relinquish important rights or otherwise be on unfavorable terms.

Collaborative arrangements or strategic alliances will also subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our strategic partners/collaborators may devote to the products;
- strategic partners/collaborators may experience financial difficulties;

- the failure to successfully collaborate with third parties may delay, prevent or otherwise impair the development or commercialization of our products or revenue expectations;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete their obligations under any arrangement;
- a collaborator could independently move forward with a competing product developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development of, and may increase the cost of developing, products.

We are subject to various risks relating to international activities that could affect our overall profitability.

Our international operations subject us to a number of risks, which may vary significantly from the risks we face in our U.S. operations, including:

- fluctuations in currency exchange rates;
- domestic and global economic conditions such as inflation or recession;
- healthcare legislation and other regulations;
- differing standards and privacy requirements for the conduct of clinical trials;
- differing procedures and standards for regulatory approval and commercialization;
- tariffs and other trade barriers;
- compliance with foreign medical device manufacturing regulations;
- challenges with obtaining required supplies of components for our devices;
- difficulty in enforcing agreements and collecting receivables through foreign legal systems;
- reduction in third-party payor reimbursement for our products;
- inability to obtain import licenses;
- the impact from health epidemics/pandemics on the global economy;
- the impact of geopolitical tensions and/or conflicts, including the war in Ukraine;
- changes in trade policies and in U.S. and foreign tax policies;
- possible changes in export or import restrictions;
- differing labor regulations and difficulty in staffing and managing foreign operations;
- the modification or introduction of other governmental policies with potentially adverse effects; and
- limitations on our ability under local laws to protect our intellectual property.

We are subject to risks associated with currency fluctuations and changes in foreign currency exchange rates could impact our results of operations.

If the Australian dollar weakens against the U.S. dollar, then, if we decide to convert our Australian dollars into U.S. dollars for any business purpose, appreciation of the U.S. dollar against the Australian dollar would have a negative effect on the U.S. dollar amount available to us. To the extent that we need to convert U.S. dollars we receive into Australian dollars for our operations, appreciation of the Australian dollar against the U.S. dollar would have a negative effect on the Australian dollar amount we would receive from the conversion. Consequently, appreciation or depreciation in the value of the Australian dollar relative to the U.S. dollar would affect our financial results. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

Any failure to protect our information technology infrastructure and our products against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business and operating results.

The operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial

functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches and data corruption.

In addition, our information technology infrastructure and products are vulnerable to cyber-based attacks. Cyber-based attacks can include computer viruses, denial-of-service attacks, phishing attacks, ransomware attacks and other introduction of malware to computers and networks; unauthorized access through the use of compromised credentials; exploitation of design flaws, bugs or security vulnerabilities; intentional or unintentional acts by employees or other insiders with access privileges; and intentional acts of vandalism by third parties and sabotage. In addition, laws of applicable jurisdictions can expose us to investigations and enforcement actions by regulatory authorities and claims from individuals potentially resulting in penalties and significant legal liability if our information technology security efforts are inadequate.

Significant disruption in either our or our service providers' or suppliers' information technology could impede our operations or result in decreased sales, result in liability claims or regulatory penalties, or lead to increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

Our business, data, services and products are or may become subject to U.S. federal and state and international data privacy laws and regulations and any failure to comply with these laws and regulations could harm our reputation, expose us to damages and otherwise adversely affect our business.

As a global company, we are or may become subject to laws and regulations in the United States and other countries concerning the handling of personal data, including but not limited to those related to the collection, storage, handling, use, disclosure, transfer, and security of personal data. These laws and regulations include, for example, the European Union's General Data Protection Regulation and the California Consumer Privacy Act, and other similar U.S. state privacy laws. These laws and regulations are continuously evolving and developing, creating significant uncertainty as privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements. Our compliance with privacy and data protection laws may result in significant costs and challenges that are likely to increase over time. Any failure, or perceived failure, by us or third-party service providers to comply with our privacy or security policies or privacy-related legal obligations may result in governmental enforcement actions, litigation, or negative publicity, and could have an adverse effect on our operating results and financial condition.

Increased emphasis on environmental, social, and governance ("ESG") matters may have an adverse effect on our business, financial condition, results of operations and reputation.

Investors, regulators, legislators, customers, consumers, employees, and other key stakeholders are increasingly focusing on areas of corporate responsibility, and particularly matters related to ESG factors. Such matters could include, among other things, environmental stewardship, diversity, equity, and inclusion initiatives, supply chain practices, good corporate governance, workplace conduct, and support for local communities. Institutional investors have expressed expectations with respect to ESG matters that they use to guide their investment strategies and may, in some cases, choose not to invest in us if they believe our ESG policies are lagging or inadequate. Other stakeholders also have expectations regarding ESG factors, such as employees or potential employees who desire to work for a company that reflects their personal values. These areas of focus are continuing to evolve, as are the criteria on which investors assess companies' performance in these areas. Investors are increasingly looking to companies that demonstrate strong ESG and sustainability practices as an indicator of long-term resilience, especially in light of events such as the COVID-19 pandemic. Keeping up with and meeting these expectations may disrupt our business and divert the attention of our management, and we may be unable to make the investments in ESG programs that our competitors with greater financial resources are able to make. Failure to meet the expectations of investors and other stakeholders in these areas may damage our reputation, impact employee retention, impact the willingness of our customers to do business with us, or otherwise impact our financial results and stock price.

Risks Related to Legal and Regulatory Matters

We could become exposed to product liability claims that could harm our business.

The clinical trials and sales of medical products entails an inherent risk of product liability. We rely on a number of third-party researchers and contractors to produce, collect, and analyze data regarding the safety and efficacy of our products. We also have quality control and quality assurance in place to mitigate these risks and have historically obtained professional liability and clinical trial insurance on our clinical trials to cover financial damages in the event that human testing is done incorrectly or the data is analyzed incorrectly.

Notwithstanding our control procedures, we could face product liability exposure related to the testing of our products in clinical trials. If any of our products are approved for sale, we could face exposure to claims by an even greater number of persons than were involved in the clinical trials once marketing, distribution and sales of our products begin.

Regardless of merit or eventual outcome, liability claims could result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenues; and
- the inability to commercialize products.

If a claim is made against us in conjunction with these research testing activities, the market price of our Common Stock could be negatively affected.

Use of our products in unapproved circumstances could expose us to liabilities.

The marketing approvals, if any, from the FDA and other regulators of certain of our products are expected to be limited to specific indications. Such approvals would prohibit us from marketing or promoting any unapproved use of our products. Physicians, however, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although we intend that the product training we will provide to physicians and other healthcare professionals will be conducted in compliance with applicable laws, and therefore, will be mainly limited to approved uses or for clinical trials, no assurance can be given that claims might not be asserted against us if our products are used in ways or for procedures that are not approved.

Disputes could substantially disrupt our business operations.

Even if resolved in our favor, litigation or other legal proceedings commenced against us by stockholders, regulatory authorities, employees, competitors or other third parties could cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to develop our products, continue our internal research programs or enter into strategic collaborations that could help us bring our products to market. As a result, uncertainties resulting from the initiation and continuation of litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Our products and operations are subject to extensive government regulation and any failure to comply with applicable requirements could harm our business.

Our medical devices are subject to rigorous regulation and scrutiny by the FDA and other governmental authorities. Government regulation applies to nearly all aspects of our products' lifecycles, including testing, clinical study, manufacturing, transporting, sourcing, safety, labeling, storing, packaging, recordkeeping, reporting, advertising, promoting, distributing, marketing, and importing or exporting of medical devices and products. In general, unless an exemption applies, a medical device or product must receive regulatory clearance or approval or clearance before it can be marketed or sold. Modifications to existing products or the marketing of new uses for existing products also may require regulatory clearance or approvals, or supplemental approvals. If we are unable to obtain these required marketing authorizations, our ability to commercialize new products will be delayed or adversely impacted.

Regulatory agencies may refuse to grant approval or clearance or disagree with our interpretation of the data, or disagree with our interpretation of the regulatory requirements, such as products that are subject to enforcement discretion or consumer products that do not meet the definition of an FDA-regulated medical device. Furthermore, the FDA and other regulatory agencies could change their policies, adopt additional regulations, or revise existing regulations, each of which could impact how our products are regulated, prevent or delay approval or clearance of devices, or could impact our ability to market a previously cleared, approved, or unregulated device. Our failure to comply with regulatory requirements of the FDA or other applicable regulatory requirements in the United States or elsewhere could subject us to administratively or judicially imposed sanctions. These sanctions could include warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and/or promotion. Any of the foregoing actions could have a material adverse effect on our financial condition and results of operations. In addition to any such sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection or investigation could divert substantial management attention from the operation of our business and, as a result, have an adverse effect on our business.

Our operations are subject to environmental, health, and safety regulations that could result in substantial costs.

Our operations are subject to environmental, health, and safety laws, and regulations concerning, among other things, the generation, handling, transportation, and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We may incur in the future expenditures in connection with environmental, health and safety laws, and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or could become the basis for new or increased liabilities that could be material.

We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims.

The design, manufacture and marketing of medical device products involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products could lead to negative publicity, government investigation, litigation or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA, or similar governmental authorities in other countries) and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. In some circumstances, such adverse events could also cause delays in new product clearance and commercialization plans.

The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Product liability insurance is expensive and, if available, may not be available on acceptable terms at all periods of time. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of our products, cause a significant financial burden on us, or both, which in either case could have a material adverse effect on our business and financial condition.

Healthcare policy changes may have a material adverse effect on us.

There have been and continue to be actions and proposals by several governments, regulators and third-party payers globally, including the U.S. federal and state governments, to control healthcare costs and, more generally, to reform healthcare systems. Certain of these actions and proposals, among other things, limit the prices we are able to charge for our products or the amounts of reimbursement available for our products, increase the importance of our ability to compete on cost, and could limit the acceptance and availability of our products. These actions and proposals could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We are subject to various U.S. and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, any breach of which could cause a material, adverse effect on our business, financial condition, and profitability.

Our relationships with physicians, hospitals, and other healthcare providers are subject to scrutiny under various U.S. and international bribery, anti-kickback, false claims, privacy, transparency, and similar laws, often referred to collectively as "healthcare compliance laws." Healthcare compliance laws are broad, sometimes ambiguous, complex, and subject to change and changing interpretations. Possible sanctions for violation of these healthcare compliance laws include fines, civil and criminal penalties, exclusion from government healthcare programs, and despite our compliance efforts, we face the risk of an enforcement activity or a finding of a violation of these laws. While our relationships with healthcare professionals and organizations are structured to comply with such laws and we conduct training sessions on these laws and codes, it is possible that enforcement authorities may view our relationships as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties or debarment. In any event, any enforcement review of or action against us as a result of such review, regardless of outcome, could be costly and time consuming. Additionally, we cannot predict the impact of any changes in or interpretations of these laws, whether these changes will be retroactive or will have effect on a going-forward basis only.

Tax laws, regulations, and enforcement practices are evolving and may have a material adverse effect on our results of operations, cash flows and financial position.

Tax laws, regulations, and administrative practices in various jurisdictions are evolving and may be subject to significant changes due to economic, political, and other conditions. There are many transactions that occur during the ordinary course of business for which the ultimate tax determination is uncertain, and significant judgment is required in evaluating and estimating our provision and accruals for taxes. Additionally, the Australian Taxation Office's interpretation of specific expenditures' eligibility may vary, potentially leading to variances to our estimations. Governments are increasingly focused on ways to increase tax revenues, particularly from multinational corporations, which may lead to an increase in audit activity and aggressive positions taken by tax authorities.

Developments in relevant tax laws, regulations, administrative practices and enforcement practices could have a material adverse effect on our operating results, financial position and cash flows, including the need to obtain additional financing.

We are subject to tax audits by various tax authorities in many jurisdictions.

Our income tax returns are based on calculations and assumptions that require significant judgment and are subject to audit by various tax authorities. In addition, the calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws. We regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technology.

Our success is to a certain degree also dependent on our ability to obtain and maintain patent protection. We could be materially adversely affected by any failure or inability to protect our intellectual property rights.

Similarly, any know-how that is proprietary or particular to our technologies could be subject to risk of disclosure by employees or consultants despite having confidentiality agreements in place.

Any future success will depend in part on whether we can obtain and maintain patents to protect our own products and technologies; obtain licenses to the patented technologies of third parties; and operate without infringing on the proprietary rights of third parties. Patent matters can involve complex legal and scientific questions and it is impossible to predict the outcome of patent claims. There is a risk that future patent applications that we make may not be approved, or we may not develop additional products or processes that are patentable. Some countries in which we may sell our products or license our intellectual property may fail to protect our intellectual property rights to the same extent as the protection that may be afforded in the United States or Australia.

In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws could diminish the value of our intellectual property or narrow the scope of our patent protection. Even if we are able to obtain patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

Moreover, any of our pending applications may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), the European Patent Office, the Intellectual Property Office in the United Kingdom, and the Australian Patent and Trademark Office. In addition, any patents issued could become involved in opposition, derivation, reexamination, post-grant review, interference proceedings or other patent office proceedings or litigation challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to exploit our intellectual property or develop or commercialize current or future products.

The issuance of a patent is not conclusive as to the inventorship, scope, validity or enforceability and our patents could be challenged in the courts or patent offices. Such challenges could result in loss of ownership or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the duration of the patent protection of our technology and products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation and thus require us to allocate significant resources to preventing such circumvention. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in certain jurisdictions. Such developments could also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize our products.

Our commercial success may depend upon our future ability and the ability of our potential collaborators to develop, manufacture, market and sell our products without infringing valid intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the medical technology industry, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post-grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Furthermore, patent reform and changes to patent laws in the United States and in foreign jurisdictions add uncertainty to the possibility of challenge to our patents in the future, and could diminish the value of patents in general, thereby impairing our ability to protect our products. We cannot assure you that our

products and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities.

If a third-party intellectual property right exists it could require the pursuit of litigation or administrative proceedings to nullify or invalidate the third-party intellectual property right concerned, or entry into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all. Third-party intellectual property right holders, including our competitors, may bring infringement claims against us. If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- litigation, which may be expensive and time-consuming and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our products, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our products. We cannot provide any assurances that valid third-party patents do not exist which might be enforced against our current or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. As the medical technology industry expands and more patents are issued, the risk increases that our products may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or other intellectual property, or that we are otherwise employing their proprietary technology without authorization and may sue us. We believe that we have reasonable defenses against possible allegations of infringement, such as noninfringement or invalidity defenses; however, there can be no assurance that these defenses will succeed. It is also possible that patents owned by third parties of which we are aware or might become aware, but which we believe are not valid, or do not believe are relevant to our products and other proprietary technologies we may develop, could be found to be infringed by our products. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products may infringe. In addition, our competitors or other third parties, many of which have substantially greater resources than we do and have made substantial investments in patent portfolios and competing technologies, may obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our products, and may claim that use of our technologies or the manufacture, use or sale of our products infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or products, or if we are found to otherwise infringe a third party's intellectual property rights, the holders of any such patents may be able to block, including by court order, our ability to develop, manufacture or commercialize the applicable product unless we obtain a license under the applicable patents or other intellectual property, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our products may be impaired or delayed, which could in turn significantly harm our business.

The medical technology industry has produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our products, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we collaborate with various organizations and academic institutions on the advancement of our technology and products, we may, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets will become known by potential competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, discovery by a third party of our trade secrets or other unauthorized use or disclosure would impair our intellectual property rights and protections in our products.

In addition, these agreements typically restrict the ability of our collaborators, advisors, employees and consultants to publish data potentially relating to our trade secrets. Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In some cases, publication rights are controlled exclusively by us. In other cases, we may share these rights with other parties. Despite our efforts to protect our trade secrets, our competitors could discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and other governmental patent agencies outside of

the United States in several stages over the lifetime of the patents and applications. The USPTO and various corresponding governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Confidentiality and invention assignment agreements with our employees, advisors and consultants may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, advisors and consultants to enter into confidentiality and invention assignment agreements with us. However, current or former employees, advisors and consultants could unintentionally or willfully disclose our confidential information to competitors, and confidentiality and invention assignment agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality and invention assignment agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

Intellectual property rights do not address all potential threats to our business prospects.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to ours but that are not covered by our intellectual property rights.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights.
- We or any of our collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license.
- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license.
- It is possible that any pending patent applications that we have filed, or will file, will not lead to issued patents.
- Issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- Ownership of our patents or patent applications may be challenged by third parties.

- Our patents may only be valid for a limited period of time.
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Any difficulty with protecting our intellectual property could diminish the value of our intellectual property rights in the relevant jurisdiction.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, the United Kingdom, the European Union and Australia. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in other jurisdictions, then the value of these rights could be diminished and we could face additional competition from others in such other jurisdictions.

Some countries in Europe and China have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are, or any of our licensors is, forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position or commercial advantage may be impaired and our business and results of operations may be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products and any future products.

The U.S. Supreme Court in recent years has issued rulings either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in non-U.S. jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Risks Relating to the Reorganization

We may be unable to achieve some or all of the benefits that we expect to achieve from the Reorganization, which could materially adversely affect our business, financial condition and results of operations.

The full strategic and financial benefits we expect to result from the proposed Reorganization may not be achieved, or such benefits may be delayed. ATL's board of directors (the "ATL Board of Directors") believes that the Reorganization is in the best interests of ATL's shareholders and optionholders because, as a Delaware corporation whose Common Stock has been approved for listing on NASDAQ, it has the potential to improve the attractiveness of our company as a potential target for a change of control transaction such as a sale of substantially all of the assets of our company, a takeover of our company or a merger of our company with another company, may increase our company's access to lower-cost debt or equity capital when compared to remaining an Australian company solely listed on the ASX, has the potential to create additional opportunities with potential licensing, distribution or joint venture partners due to increased exposure as a Delaware corporation listed on the NASDAQ, has the potential to provide access to a broader range of investors in a market which is familiar with and has a stronger interest in early to mid-stage medical technology companies, and may lead to a stronger valuation of our company and improved liquidity in trading of our securities.

Furthermore, after carefully considering the relative merits of the Reorganization, the ATL Board of Directors is of the view that the potential advantages outweigh the potential disadvantages. In particular, the ATL Board of Directors believes that the Reorganization could provide the following potential benefits:

- ATL is planning to complete the Pivotal Trial for its DurAVR® THV for treating severe aortic stenosis, which is estimated to include approximately 1,000 to 1,200 patients, including a 12-month

patient follow-up as well as preparations to commercialize the DurAVR® THV. The Pivotal Trial will require significant additional funding over this period, and the ATL Board of Directors believes that the Reorganization has the potential to provide ATL with access to a broader range of U.S. investors in a market which is familiar with and generally has a stronger interest in early to mid-stage medical technology and biotechnology companies. This in turn may lead to improved access to lower-cost debt and equity capital in the U.S. market, which is significantly larger and more diverse than the Australian capital market, which could enable future financing to be obtained at lower costs;

- exposure to the U.S. market may also lead to increased visibility and global profile, including through potential greater exposure to research analyst coverage;
- as a U.S. corporation whose Common Stock is approved for listing on NASDAQ, the Reorganization has the potential to improve our attractiveness as a potential target for change of control transactions (such as a sale of substantially all of the assets of our company, a takeover of our company or a merger of our company with another company);
- it may create additional opportunities with potential licensing, distribution or joint venture partners due to increased exposure as U.S. listed corporation; and
- it will align our corporate and operations structure, as a significant portion of our current business and employees are already located in the United States.

We may not achieve these or other anticipated benefits for a variety of reasons, including, among others, because the Reorganization will require significant amounts of management's time and effort, which may divert management's attention from operations. In addition, we may experience unanticipated competitive developments, including changes in the conditions of our industry and the markets in which we operate, that could negate some or all of the potential benefits from the Reorganization.

If we do not realize some or all of the benefits we expect to result from the Reorganization, or if such benefits are delayed, our business, expected future financial and operating results and our prospects could be adversely affected.

Certain of our directors reside outside of the United States and it may be difficult to bring or enforce judgments against them in the United States.

Certain of our directors and executive officers are residents of countries other than the United States, including directors Mr. Denaro and Dr. Gu, and Chief Financial Officer Mr. McDonnell, who reside in Australia. Furthermore, a portion of our and their assets are located outside the United States. As a result, it may not be possible for you to effect service of legal process, within the United States or elsewhere, upon certain of our directors, including matters arising under U.S. federal securities laws. This may make it difficult or impossible to bring an action against these individuals in the United States in the event that a person believes that their rights have been violated under applicable law or otherwise. Even if an action of this type is successfully brought, the laws of the United States and of Australia may render a judgment unenforceable.

We have incurred significant costs associated with the Reorganization and will incur significant ongoing costs as a company whose Common Stock is publicly traded in the United States, and our management is required to devote substantial time to compliance initiatives.

We have incurred significant costs associated with planning for and completing the necessary legal, accounting, regulatory and other associated steps to complete the Reorganization. On completion of the listing of our Common Stock on NASDAQ, as a company whose Common Stock is publicly traded in the United States, we will incur significant legal, accounting, insurance and other expenses. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure controls and internal control over financial reporting. The listing of our CDIs on ASX, and registration as a foreign company in Australia under the Corporations Act, will also result in the imposition of various requirements on the Company, including the requirements of the ASX Listing Rules and limited obligations under the Corporations Act. Our management and other

personnel need to devote a substantial amount of time to these compliance initiatives, and we may need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as our senior management. Furthermore, if we are unable to satisfy our obligations as a public company in the United States, we could be subject to delisting of our Common Stock, fines, sanctions and other regulatory action and potentially civil litigation. The Company may be subject to similar sanctions in the event it fails to comply with its compliance obligations under Australian law.

Risks Relating to Our Common Stock

The market price and trading volume of our Common Stock may be volatile and may be affected by economic conditions beyond our control.

The market price of our Common Stock may be highly volatile and subject to wide fluctuations. In addition, the trading volume of our Common Stock may fluctuate and cause significant price variations to occur. If the market price of our Common Stock declines significantly, you may be unable to resell your Common Stock at a competitive price. We cannot assure you that the market price of our Common Stock will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of our Common Stock or result in fluctuations in their price and trading volume include:

- actual or expected fluctuations in our prospects or operating results;
- announcements relating to our products, including the results of clinical trials by us or our collaborators;
- changes in the demand for our products;
- additions or departures of our key personnel;
- changes or proposed changes in laws, regulations or tax policy;
- sales or perceived potential sales of our Common Stock by us or our executive officers, directors or stockholders in the future;
- announcements or expectations concerning additional financing efforts; and
- conditions in the United States, Australian and global financial markets, or in our industry in particular, or changes in general economic or political conditions.

In recent years, the stock market in general, and the market for medical technology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our Common Stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering.

When the market price of a stock has been volatile, as our Common Stock price may be, holders of that stock have occasionally brought securities class action litigation claims against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit were without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Our Common Stock will be listed to trade on NASDAQ in U.S. dollars and our CDIs will be listed to trade on the ASX in Australian dollars, and this may result in price variations.

Shares of our Common Stock have been approved for listing on NASDAQ in U.S. dollars and our CDIs will be listed to trade on the ASX in Australian dollars. Dual-listing may result in price variations between the exchanges due to a number of factors. Our Common Stock will trade in U.S. dollars on

NASDAQ and our CDIs will trade in Australian dollars on the ASX. In addition, the exchanges are open for trade at different times of the day and the two exchanges also have differing vacation schedules. Differences in the trading schedules, as well as volatility in the exchange rate of the two currencies, among other factors, may result different trading prices for our Common Stock and CDIs on the two exchanges. Other external influences may have different effects on the trading price of our Common Stock and CDIs on the two exchanges.

An active trading market for our Common Stock may not develop and you may not be able to resell your shares of Common Stock at or above the public offering price, if at all.

Prior to this offering, while the ordinary shares of ATL have been traded on the ASX since March 2004, there has been no public market on a U.S. national securities exchange for ATL's ordinary shares in the United States, and there has been no public market for our Common Stock. Our Common Stock has been approved for listing on NASDAQ and, accordingly, shares of our Common Stock will be able to be traded by the public on NASDAQ. However, an active or liquid public market for our Common Stock may not develop or be sustained, which means you may experience a decrease in the value of the shares of our Common Stock, regardless of our operating performance. Moreover, the initial public offering price for our Common Stock was determined through negotiations with the underwriters, and may vary from the market price of our Common Stock following this offering. As a result of these and other factors, you may be unable to resell your shares of our Common Stock at or above the initial public offering price, at the time you wish to sell them, or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Common Stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of Common Stock as consideration.

We do not anticipate paying dividends in the foreseeable future.

ATL (which will become a subsidiary of the Company following completion of the Reorganization) did not declare any dividends during fiscal years 2020, 2021, 2022 or 2023 and we do not anticipate that we will do so in the foreseeable future. We currently intend to retain future earnings, if any, to finance the development of our business. Dividends, if any, on our outstanding Common Stock will be declared by and subject to the discretion of our Board of Directors on the basis of our earnings, financial requirements and other relevant factors, and subject to Delaware and federal law. We cannot assure you that our Common Stock will appreciate in value. You may not realize a return on your investment in our Common Stock and you may even lose your entire investment in our Common Stock.

If U.S. securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price and trading volume of our Common Stock could decline.

The trading market for our Common Stock will be influenced by the research and reports that U.S. securities or industry analysts publish about us or our business. Securities and industry analysts may discontinue research on us, to the extent such coverage currently exists, or in other cases, may never publish research on us. If no or too few U.S. securities or industry analysts commence coverage of our company, the trading price for our Common Stock would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our Common Stock or publish inaccurate or unfavorable research about our business, the market price of our Common Stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Common Stock could decrease, which might cause our price and trading volume to decline. In addition, research and reports that Australian securities or industry analysts may, initiate or may continue to, publish about us, our business or our Common Stock may impact the market price of our Common Stock.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our Common Stock less attractive to investors and, as a result, adversely affect the price of our Common Stock and result in a less active trading market for our Common Stock.

We are an "emerging growth company" as defined in the JOBS Act and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that

are not emerging growth companies. For example, we have elected to rely on an exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act relating to internal control over financial reporting, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements.

We may avail ourselves of these disclosure exemptions until we are no longer an "emerging growth company." We cannot predict whether investors will find our Common Stock less attractive because of our reliance on some or all of these exemptions. If investors find our Common Stock less attractive, it may adversely affect the price of our Common Stock and there may be a less active trading market for our Common Stock.

We will cease to be an "emerging growth company" upon the earliest of:

- the last day of the fiscal year during which we have total annual gross revenues of $1,235,000,000 (as such amount is indexed for inflation every five years by the SEC) or more;
- the last day of our fiscal year following the fifth anniversary of the closing of this offering;
- the date on which we have, during the previous three-year period, issued more than $1,000,000,000 in non-convertible debt; or
- the date on which we are deemed to be a "large accelerated filer," as defined in Rule 12b-2 of the Exchange Act.

Furthermore, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard, until such time we are no longer considered to be an emerging growth company. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies for so long as we are a smaller reporting company.

We will incur increased costs as a result of operating as a U.S. listed public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices, which could divert their attention from the operation of our business.

As a U.S. listed public company, and particularly after we are no longer an "emerging growth company," we will incur significant additional legal, accounting, and other expenses. The Dodd-Frank Wall Street Reform and Consumer Protection Act, the Sarbanes-Oxley Act, the listing requirements of NASDAQ, and other applicable securities rules and regulations impose various requirements on public companies, including the filing of reports with respect to our business and operating results, establishment and maintenance of effective disclosure controls and procedures, maintenance and reporting of our system of internal control over financial reporting, and other corporate governance practices. We expect that we will need to hire additional accounting, finance, legal, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a U.S. public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these

requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. In addition, we expect that the rules and regulations applicable to us as a U.S. public company may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our Board of Directors or executive officers.

We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our Common Stock.

In connection with the preparation of our financial statements for the years ended December 31, 2023 and 2022, our management and our independent auditors identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified by our management and our independent auditors relate to (i) a lack of appropriately designed, implemented and documented procedures and controls, and (ii) deficiencies in the segregation of duties.

To remediate these material weaknesses, we are in the process of implementing measures designed to improve our internal control over financial reporting, including supplementing automated controls with additional manual controls and documentation thereof. We have an active project to complete documentation of our entity-level and key financial reporting processes and controls. This includes the preparation and review of account reconciliations, journal entries and information technology systems. In addition, we are undertaking a review of segregation of duties across financial reporting streams.

The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. These remediation measures will be time consuming and require financial and operational resources. If one or both of these material weaknesses are not remediated, they could result in a material misstatement of our annual or interim financial statements that might not be prevented or detected.

As a public company, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2025. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting and will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may discover additional weaknesses in our system of internal control over financial reporting that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Additionally, when we cease to be an "emerging growth company" under the federal securities laws, our independent registered public accounting firm may be required to express an opinion on the effectiveness of our internal control over financial reporting. If we are unable to confirm that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an unqualified opinion on the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could cause the

price of our Common Stock to decline. We could also become subject to investigations by NASDAQ, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

Our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws will contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, which will be effective immediately prior to the completion of the Reorganization and the closing of this offering, contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by the current members of our Board of Directors or take other corporate actions, including effecting changes in our management. These provisions include:

- the ability of our Board of Directors to issue shares of Preferred Stock (defined in the section entitled "*Description of Capital Stock*") and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- a staggered Board of Directors divided into three classes serving staggered three-year terms, such that not all members of our Board of Directors will be elected at one time;
- allowing only our Board of Directors to fill director vacancies, which prevents stockholders from being able to fill vacancies on our Board of Directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- a requirement for the affirmative vote of holders of at least 75% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend certain provisions of our Second Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our Board of Directors to amend our Amended and Restated Bylaws, which may allow our Board of Directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the Amended and Restated Bylaws to facilitate an unsolicited takeover attempt;
- advance notice procedures with which stockholders must comply to nominate candidates to our Board of Directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- a prohibition of cumulative voting in the election of our Board of Directors, which would otherwise allow less than a majority of stockholders to elect director candidates.

Future equity financings and sales by existing holders could adversely affect the voting power or value of our Common Stock.

We may from time to time raise funds through the issuance of Common Stock or the issuance of debt instruments or other securities convertible into Common Stock. We cannot predict the size or price of future issuances of Common Stock or the size or terms of future issuances of debt instruments or other securities convertible into Common Stock, or the effect, if any, that future issuances and sales of our securities will have on the market price of the Common Stock. Sales or issuances of substantial numbers of shares of Common Stock, or the perception that such sales or issuances could occur, may adversely affect prevailing market prices of the Common Stock. With any additional sale or issuance of Common Stock, or securities convertible into Common Stock, investors will suffer dilution to their voting power and we may experience dilution in our earnings per share.

Our Second Amended and Restated Certificate of Incorporation, which will be effective immediately prior to the completion of the Reorganization and the closing of this offering, will authorize us to issue, without the approval of our stockholders, one or more classes or series of Preferred Stock having such designations, preferences, limitations and relative rights, including preferences over our Common Stock respecting dividends and distributions, as our Board of Directors may determine. The terms of one or more classes or series of Preferred Stock could adversely impact the voting power or value of our Common Stock. For example, we might grant holders of Preferred Stock the right to elect some number of our directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we might grant to holders of Preferred Stock could affect the residual value of our Common Stock.

Our failure to meet NASDAQ's continued listing requirements could result in a delisting of our Common Stock.

If, following completion of this offering, we fail to satisfy the continued listing requirements of NASDAQ, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to delist our Common Stock. Such a delisting would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with the listing requirements of NASDAQ.

If NASDAQ delists our Common Stock from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our Common Stock;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules, which could result in a reduced level of trading activity in the secondary trading market for our Common Stock;
- more limited news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Post-Reorganization, we will be a holding company and, as such, we will depend on our subsidiaries to support our operations.

Post-Reorganization, we, as the ultimate parent entity, will be a holding company and essentially all of our assets will be the capital stock of our subsidiaries. As a result, investors in our company are subject to the risks attributable to our subsidiaries. As a holding company, we conduct all of our business through our subsidiaries. Therefore, our ability to fund and conduct our business, service our debt and pay dividends, if any, in the future will principally depend on the ability of our subsidiaries to continue their research and development activities and, post-commercialization, generate sufficient cash flow to make upstream cash distributions to us. Our subsidiaries are separate legal entities, and although they are wholly-owned and controlled by us, they have no obligation to make any funds available to us, whether in the form of loans, dividends or otherwise. The ability of these entities to pay dividends and other distributions will depend on their operating results and will be subject to applicable laws and regulations which require that solvency and capital standards be maintained by such companies and contractual restrictions contained in the instruments governing any debt obligations. In the event of a bankruptcy, liquidation or reorganization of any of our material subsidiaries, holders of indebtedness and trade creditors may be entitled to payment of their claims from the assets of those subsidiaries before our company.

Our Amended and Restated Bylaws will designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our Amended and Restated Bylaws, which will be effective immediately prior to the completion of the Reorganization and the closing of this offering, will provide that, unless we consent in writing to the selection

of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Second Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine, in each such case subject to such Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein. Our Amended and Restated Bylaws will further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will, to the fullest extent permitted by law, be the sole and exclusive forum for the resolutions of any complaint asserting a cause of action arising under the Securities Act. We note that there is uncertainty as to whether a court would enforce the choice of forum provision with respect to claims under the Securities Act, and that investors cannot waive compliance with the Securities Act and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our Amended and Restated Bylaws described in the preceding sentence. This forum selection provision is not intended to apply to any actions brought under the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

These choice-of-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons. These choice-of-forum provisions may also impose additional litigation costs on stockholders in pursuing any such claims against us and/or our directors, officers, employees, or agents, to the extent the provisions require the stockholders to litigate in a particular or different forum. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our choice-of-forum provisions. Our choice-of-forum provisions may impose additional litigation costs on stockholders who assert that the provisions are not enforceable or invalid.

Alternatively, if a court were to find these provisions of our Amended and Restated Bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or operating results.

Our ability to use our U.S. net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2023, per Anteris Technologies Ltd's Audited Consolidated Financial Statements, we had U.S. federal net operating loss ("NOL") carryforwards of $64.4 million, which may be available to offset federal income tax liabilities in the future. In addition, we may generate additional NOLs in future years. In general, a corporation's ability to utilize its NOLs may be limited if it experiences an "ownership change" as defined in Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). An ownership change generally occurs if certain direct or indirect "5-percent shareholders," as defined in Section 382 of the Code, increase their aggregate percentage ownership of a corporation's stock by more than 50 percentage points over their lowest percentage ownership at any time during the testing period, which is generally the three-year period preceding any potential ownership change. If a corporation experiences an ownership change, the corporation will be subject to an annual limitation that applies to the amount of pre-ownership change NOLs that may be used to offset post-ownership change taxable income. This limitation is generally determined by multiplying the value of the corporation's stock immediately before the ownership change by the applicable long-term tax-exempt rate. Any unused annual limitation may, subject to certain limits, be carried over to later years, and the limitation may under certain circumstances be increased by built-in gains in the assets held by such corporation at the time of the ownership change. Similar rules and limitations may apply for state income tax purposes.

Previous issuances and sales of ATL's ordinary shares, completion of the Reorganization, this offering of our Common Stock, and future issuances and sales of our Common Stock (including certain transactions involving our Common Stock that are outside of our control) could have caused or could cause an "ownership change." If an "ownership change" either had occurred or were to occur, Section 382 of the Code would impose an annual limit on the amount of pre-ownership change NOL carryforwards and other tax attributes we could use to reduce our taxable income, potentially increasing and accelerating our liability for income taxes, and also potentially causing certain tax attributes to expire unused. It is possible that such an ownership change could materially reduce our ability to use our U.S. NOL carryforwards or other tax attributes to offset taxable income, which could adversely affect our profitability.

Our ability to use our Australian net operating and capital loss carryforwards to offset future taxable income are subject to the satisfaction of loss tests.

As of December 31, 2023, per Anteris Technologies Ltd's Audited Consolidated Financial Statements, we had Australian net operating and capital loss ("NOCL") carryforwards of $53.6 million, which may be available to offset Australian income tax liabilities in the future. In addition, we may generate additional NOCLs in future years.

In general, a corporation's ability to utilize its NOCLs is impacted if it does not satisfy one of two loss tests — the continuity of ownership test (where there is a change in majority ownership and control) or failing that, the business continuity test. These tests are set forth in Divisions 165 and 166 of the Income Tax Assessment Act ITAA1997. The loss tests are applied to each parcel of NOCLs that arise in a particular income year.

The continuity of ownership test is failed where a majority interest in shareholders' rights to dividends, rights to capital distributions and voting rights are not maintained (i.e., there is a change in majority ownership and control). A concession applies whereby all shareholders with less than 10% of these rights are deemed to be held by a single notional shareholder. If the total of the single notional shareholder interests falls below 50%, the continuity of ownership test may be failed and the NOCLs (either all or particular parcels) may only be utilized if the business continuity test is satisfied.

The business continuity test considers whether ATL has maintained a similar or same business at the relevant testing times.

Previous issuances and sales of ATL's ordinary shares, completion of the Reorganization, this offering of our Common Stock, and future issuances and sales of our Common Stock (including certain transactions involving our Common Stock that are outside of our control) could have caused or could cause a failure of the continuity of ownership test. If this either has occurred or were to occur, and the business continuity test could not be satisfied, the NOCLs may not be utilized to reduce taxable income. This could potentially increase and accelerate our liability for income taxes.

Risks Related to this Offering

Future sales of our Common Stock in the public market could cause the price of our Common Stock to fall. This risk is heightened by the fact that, in addition to the shares sold in this offering, shares of our Common Stock distributed in the Reorganization and CDIs representing those shares will be freely tradable in the public markets immediately upon completion of this offering, and a substantial majority of the shares of our Common Stock distributed in the Reorganization and the CDIs representing those shares will not be subject to lock-up agreements.

The market price of shares of our Common Stock could decline as a result of sales of our Common Stock or CDIs representing those shares following this offering, particularly sales by legacy ATL shareholders that receive CDIs or shares of our Common Stock in the Reorganization, or the perception that these sales could occur. Immediately after this offering, we will have 35,939,816 outstanding shares of our Common Stock, calculated as of the date, in the manner and subject to the assumptions set forth under "*Prospectus Summary — The Offering*." All of the shares of our Common Stock outstanding immediately after this offering (which will consist of the shares sold in this offering and the shares distributed in the Reorganization), as well as CDIs representing shares distributed in the Reorganization, will be freely tradable in the public markets except for shares and CDIs that are held by our "affiliates" (as defined for purposes of the Securities Act), but, as of the date of this prospectus, only 44,414 shares, or 0.1% of the number of shares of our Common Stock that will be outstanding immediately after this offering and the Reorganization, will be

subject to lock-up agreements described under the section entitled "*Underwriting*." This means that the 35,895,402 remaining shares, or 99.9% of the number of shares of Common Stock to be outstanding immediately after this offering (and, in the case of shares distributed in the Reorganization, CDIs representing those shares), may be sold in the public markets immediately after this offering. Because of the substantial number of shares of Common Stock and CDIs representing those shares that will be freely tradable in the public markets but will not be subject to lock-up agreements, there is a substantial risk that sales of these shares or CDIs may cause the market price of our Common Stock to decline, perhaps significantly, and that these declines may occur immediately after our Common Stock and the CDIs begin to trade on NASDAQ and the ASX, respectively, or at any time thereafter. For more information, please see the section entitled "*Shares Eligible for Future Sale*."

Certain ATL shareholders reside or are located in jurisdictions where, as a result of local securities laws, they will not be permitted to receive CDIs or shares of our Common Stock distributed in the Reorganization (we sometimes refer to these shareholders as ineligible foreign shareholders). Accordingly, CDIs that would otherwise be distributed in the Reorganization to these ineligible foreign shareholders will instead be delivered to a sales facility agent, who will then sell those CDIs on the ASX following the closing of this offering at such prices as the sales facility agent determines, and remit the proceeds to the ineligible foreign shareholders. These sales may result in a decline, which could be substantial, in the market price of our Common Stock.

Our Equity Plan (as defined herein) is expected to provide for the issuance of shares of our Common Stock, which may include annual increases beginning with our fiscal year commencing January 1, 2025, in the number of shares that will be available for issuance under such plan, as described under "*Executive Compensation — Anteris Technologies Global Corp. Equity Incentive Plan (New)*." We also intend to file a registration statement on Form S-8 to register shares of our Common Stock that may be issued upon exercise of these options or that we may otherwise issue under our Equity Plan. Once we register these shares, they will be freely tradable in the public market upon issuance. Significant sales of our Common Stock pursuant to options and equity incentive plans could also harm the prevailing market price for our Common Stock.

In addition, in the future, we may issue additional shares of Common Stock, or other equity or convertible debt securities convertible into Common Stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Common Stock to decline.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

Our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline. For additional details see the section titled "*Use of Proceeds*."

If you purchase shares of our Common Stock in our initial public offering, you will experience substantial and immediate dilution.

If you purchase shares of Common Stock in this offering, you will experience substantial and immediate dilution of $3.63 per share, giving effect to the Reorganization and assuming the conversion of all of our outstanding Convertible Notes (defined below) at a conversion price of $6.00 per share, which is equal to the initial public offering price per share in this offering (the "Convertible Note Conversion"), as of September 30, 2024. That is because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the Common Stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the assumed initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options exercise their right to purchase Common Stock under our equity incentive plans or when we otherwise issue additional shares of Common Stock. For additional details see the section titled "*Dilution*."

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, particularly in the sections titled "*Prospectus Summary*," "*Risk Factors*," "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and "*Business*." All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product development, and plans and objectives of management for future operations, are forward-looking statements. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "budget," "target," "aim," "strategy," "plan," "guidance," "outlook," "intend," "may," "should," "could," "will," "would," "will be," "will continue," "will likely result" and similar expressions, although not all forward-looking statements contain these identifying words. Forward-looking statements, which are subject to risks, include, but are not limited to, statements about:

- our current and future research and development activities, including clinical testing and manufacturing and related costs and timing;
- sufficiency of our capital resources;
- our product development and business strategy, including the potential size of the markets for our products and future development and/or expansion of our products in our markets;
- our ability to commercialize products and generate product revenues;
- our ability to raise additional funding when needed;
- any statements concerning anticipated regulatory activities, including our ability to obtain regulatory clearances;
- our research and development expenses; and
- risks facing our operations and intellectual property.

We have based the forward-looking statements contained in this prospectus largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled "*Risk Factors*" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

This prospectus contains certain data and information that we obtained from various publications, including industry data and information from FMI. Statistical data in these publications also include projections based on a number of assumptions. The global, North American and European TAVR markets may not grow at the rate projected by market data or at all. Failure of the global, North American and European TAVR markets to grow at the projected rate may have a material and adverse effect on our business and the market price of our Common Stock and CDIs. In addition, the nature of the medical technology

industry results in significant uncertainties for any projections or estimates relating to the growth prospects or future condition of our industry. Furthermore, if any one or more of the assumptions underlying the market data are later found to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be $80.0 million (or $92.3 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering as follows:

- approximately $74.4 million for the ongoing development of DurAVR® THV and the preparation and enrollment of the Pivotal Trial of DurAVR® THV for treating severe aortic stenosis; and
- the remaining for working capital and other general corporate purposes determined from time to time, including the repayment of amounts owed under the Convertible Note Facility, as described under "*Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Convertible Note Facility*".

The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to fund the development of DurAVR® THV through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize that product. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. The amounts and timing of any expenditures will vary depending on numerous factors, including the progress of our ongoing and planned clinical studies, the amount of cash used by our operations, competitive, scientific and data science developments, the rate of growth, if any, of our business, and other factors described in the section titled "*Risk Factors*." Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of these net proceeds. Due to the many inherent uncertainties in the development of our products and the regulatory approval process, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, our ability to obtain additional financing, the cost and results of our clinical activities, the timing of clinical studies we may commence in the future, the timing of regulatory submissions, any collaborations that we may enter into with third parties for our products or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending the uses described above, we intend to invest the net proceeds from this offering in interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and we do not anticipate paying any cash dividends in the foreseeable future. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business. Any future determination as to the declaration or payment of dividends on our Common Stock will be made at the discretion of our Board of Directors and will depend upon, among other factors, our financial condition, results from operations, current and anticipated cash needs, plans for expansion and other factors that our Board of Directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2024:

- on an actual basis;
- on a pro forma basis to reflect, immediately prior to the closing of this offering, the Reorganization, as if the Reorganization had occurred on September 30, 2024; and
- on a pro forma as adjusted basis to reflect: (i) the adjustments set forth above, (ii) the sale and issuance of 14,800,000 shares of Common Stock by us in this offering at the initial public offering price of $6.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and (iii) the filing of our Second Amended and Restated Certificate of Incorporation and the adoption of our Amended and Restated Bylaws, which will occur immediately prior to completion of the Reorganization and the closing of this offering.

The pro forma and pro forma as adjusted information discussed below do not give effect to the issuance of the Convertible Notes. The pro forma as adjusted information discussed below is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. This table should be read in conjunction with the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our audited consolidated financial statements and related notes included elsewhere in this prospectus.

	As of September 30, 2024		
	Actual[1]	Pro Forma[2]	Pro Forma As Adjusted
	(in U.S. dollars)		
Cash and cash equivalents	**$ 10,617,616**	**$ 10,617,617**	**$ 91,317,617**
Debt obligations:	1,092,451	1,092,451	1,092,451
Stockholders' equity:			
Common Stock: 21,139,816 ordinary shares issued and outstanding, actual; 400,000,000 shares of Common Stock, par value $0.0001 per share authorized, 21,139,816 shares of Common Stock, par value $0.0001 per share, issued and outstanding, pro forma; 400,000,000 shares of Common Stock, par value $0.0001 per share, authorized, 35,939,816 shares of Common Stock, par value $0.0001 per share, issued and outstanding, pro forma as adjusted	252,491,184	2,114	3,594
Additional paid in capital	16,624,207	269,113,277	349,111,797
Accumulated other comprehensive loss	(8,953,218)	(8,953,218)	(8,953,218)
Accumulated deficit	(257,012,631)	(257,012,631)	(257,012,631)
Total stockholders' equity	**3,149,542**	**3,149,542**	**83,149,542**
Total capitalization	**$ 4,241,993**	**$ 4,241,993**	**$ 84,241,993**

(1) Reflects historical consolidated financial information of ATL.

(2) Cash and cash equivalents includes the Company's cash of $1. Common Stock has been adjusted to reflect the 21,139,816 shares outstanding at a par value of $0.0001 per share, with the excess over par value recognized as additional paid in capital.

The number of shares of our Common Stock to be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 21,139,816 of ATL's ordinary shares outstanding as of September 30, 2024, and:

- excludes shares issuable upon exercise of 6,118,807 options to purchase ATL ordinary shares and 49,388 warrants for the purchase of ATL ordinary shares during the period from September 30, 2024 to 12:00 pm (AEDT) on the business day prior to the record date for the Scheme, as such exercise would increase the number of shares of our Common Stock distributed in the Reorganization;
- excludes 5,163,023 shares of our Common Stock that will be available for future equity awards under the Equity Plan (which includes an annual evergreen increase) and became effective upon the execution of the underwriting agreement for this offering.
- gives effect to the initial public offering price of $6.00 per share;
- gives effect to the completion of the Reorganization and the distribution of 21,139,816 shares of our Common Stock in connection therewith;
- gives effect to the filing of our Second Amended and Restated Certificate of Incorporation and the adoption of our Amended and Restated Bylaws immediately prior to the completion of the Reorganization and the closing of this offering;
- assumes no conversion of the Convertible Notes;
- assumes no exercise of the outstanding options of ATL following September 30, 2024; and
- assumes no exercise by the underwriters of their option to purchase additional shares of our Common Stock.

DILUTION

If you purchase shares of our Common Stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our Common Stock in this offering and the pro forma as adjusted net tangible book value per share of our Common Stock immediately after this offering.

Dilution results from the fact that the per share offering price of our Common Stock is substantially in excess of the book value per share attributable to the existing stockholders (for purposes of this discussion of dilution, we are including ATL shareholders who receive shares of our Common Stock or CDIs representing those shares in the Reorganization as "existing stockholders"). Net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the shares of Common Stock outstanding. As of September 30, 2024, ATL had a historical net tangible book value of $2.0 million, or $0.09 per ordinary share of ATL, based on 21,139,816 ordinary shares of ATL issued and outstanding as of such date. This historical net tangible book value per ordinary share represents ATL's total tangible assets (which is ATL's total assets less intangible assets, net and deferred offering costs), less ATL's total liabilities, divided by the total number of ordinary shares of ATL outstanding as of September 30, 2024.

Our pro forma net tangible book value as of September 30, 2024, was $6.9 million, or $0.31 per share of Common Stock. Pro forma net tangible book value represents our total tangible assets (which is our total assets less intangible assets, net and deferred offering costs), less our total liabilities, after giving effect, immediately prior to the closing of this offering, to the Reorganization and assuming the Convertible Note Conversion as if they had occurred on September 30, 2024. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares of Common Stock outstanding as of September 30, 2024, giving effect to the Reorganization and assuming the Convertible Note Conversion.

After giving effect to the Reorganization and assuming the Convertible Note Conversion as if each had occurred on September 30, 2024 and giving further effect to the sale and issuance by us of 14,800,000 shares of our Common Stock in this offering at the initial public offering price of $6.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2024 would be $87.6 million, or $2.37 per share. This represents an immediate increase in pro forma net tangible book value to our existing stockholders (including legacy ATL shareholders who will be holders of our Common Stock and/or CDIs following the Reorganization) of $2.06 per share and an immediate dilution to new investors of $3.63 per share. Dilution per share to new investors represents the difference between the price per share to be paid by new investors for the shares of Common Stock sold in this offering and the pro forma as adjusted net tangible book value per share immediately after this offering.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$6.00
Historical net tangible book value per share as of September 30, 2024	$0.09	
Increase in historical net tangible book value per share as of September 30, 2024 attributable to the Reorganization and assumed Convertible Note Conversion	0.22	
Pro forma net tangible book value per share as of September 30, 2024	0.31	
Increase in pro forma net tangible book value per share attributable to new investors in this offering	2.06	
Pro forma as adjusted net tangible book value per share immediately after this offering		2.37
Dilution per share to new investors in this offering		$3.63

The dilution information discussed above is illustrative and will change based on the other terms of the Reorganization and the number of shares issued as a result of any actual conversions of the Convertible

Notes. For the purposes of the illustrative dilution information discussed above, we have included proceeds of $4,956,750 as a result of the First Drawdown of the Convertible Notes issued on November 7, 2024, and have assumed 950,044 shares of Common Stock will be converted using a conversion rate based on $6.00 per share, which is the initial public offering price.

If the underwriters' option to purchase additional shares is exercised in full, the pro forma as adjusted net tangible book value per share of our Common Stock would be $2.55 per share, and the dilution to new investors in this offering would be $3.45 per share, based on the initial public offering price of $6.00 per share.

The following table summarizes, as of September 30, 2024, on a pro forma as adjusted basis, the number of shares of Common Stock purchased from us, the total consideration paid, or to be paid, and the weighted-average price per share paid, or to be paid, by existing stockholders and by the new investors in this offering, at the initial public offering price of $6.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us and after giving effect to the Reorganization and the assumed Convertible Note Conversion. For purposes of the following table, we have included (i) shares distributed pursuant to the Reorganization as shares purchased by existing stockholders at an assumed average price of $12.76 per share reflecting the historical contributions paid by investors; and (ii) shares issued in the assumed Convertible Note Conversion as shares purchased by existing stockholders at an assumed price of $6.00 per share, the initial public offering price per share in this offering.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	22,089,860	60%	$275,442,737	76%	$ 12.47
New investors in this offering	14,800,000	40%	$ 88,800,000	24%	$ 6.00
Total	36,889,860	100%	$364,242,737	100%	$ 9.87

The above table assumes no exercise of the underwriters' option to purchase additional shares. If the underwriters' option to purchase additional shares were exercised in full, our existing stockholders would own 56% and our new investors in this offering would own 44% of the total number of shares of our Common Stock outstanding upon completion of this offering and after giving effect to the Reorganization and the assumed Convertible Note Conversion.

To the extent that stock options are exercised, new stock options are issued under the Equity Plan or we issue additional shares of Common Stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The foregoing tables and calculations are based on 21,139,816 ordinary shares of ATL outstanding as of September 30, 2024, and:

- excludes 6,118,807 shares issuable upon exercise of options to purchase ATL ordinary shares and 49,388 warrants for the purchase of ATL ordinary shares during the period from September 30, 2024 to 12:00 pm (AEDT) on the business day prior to the record date for the Scheme, as such exercise would increase the number of shares of our Common Stock distributed in the Reorganization;
- excludes 5,163,023 shares of our Common Stock that will be available for future equity awards under the Equity Plan (which includes an annual evergreen increase) and became effective upon the execution of the underwriting agreement for this offering.
- gives effect to the initial public offering price of $6.00 per share;
- gives effect to completion of the Reorganization and the distribution of 21,139,816 shares of our Common Stock in connection therewith;
- gives effect to the filing of our Second Amended and Restated Certificate of Incorporation and the adoption of our Amended and Restated Bylaws immediately prior to the completion of the Reorganization and the closing of this offering;

- assumes no conversion of the Convertible Notes;
- assumes no exercise of the outstanding options of ATL following September 30, 2024; and
- assumes no exercise by the underwriters of their option to purchase additional shares of our Common Stock.

To the extent any outstanding options or other rights are exercised, or we issue additional equity or convertible securities in the future, there will be further dilution to new investors.

BUSINESS

Overview

We are a structural heart company committed to discovering, developing and commercializing innovative medical devices designed to improve the quality of life for patients with aortic stenosis. Our lead product, the DurAVR® THV system, represents a unique product opportunity in a new THV class of single-piece heart valves, for the treatment of aortic stenosis. Our DurAVR® THV system consists of a single-piece, biomimetic valve made with our proprietary ADAPT® tissue-enhancing technology and deployed with our ComASUR® balloon-expandable delivery system. ADAPT® is our proprietary anti-calcification tissue shaping technology that is designed to reengineer xenograft tissue into a pure, single-piece collagen bioscaffold. Our proprietary ADAPT® tissue has been clinically demonstrated to be calcium free for up to 10 years post-procedure, according to *Performance of the ADAPT-Treated CardioCel® Scaffold in Pediatric Patients With Congenital Cardiac Anomalies: Medium to Long-Term Outcomes*, published by William Neethling et. al., and has been distributed for use in over 55,000 patients globally in other indications. Our ComASUR® balloon-expandable delivery system, which was developed in consultation with physicians, is designed to provide precise alignment with the heart's native commissures to achieve accurate placement of the DurAVR® THV system.

We clinically developed our DurAVR® THV system over several years with significant physician input with the goal of addressing hemodynamic limitations of the current standard-of-care products. To date, a total of 73 patients have been treated with the DurAVR® THV system across the United States, Canada and Europe. In November 2021, we commenced our FIH study at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia.

Aortic valve stenosis is one of the most common and serious valvular heart diseases. It is fatal in approximately 50% of patients if left untreated after two years, and no pharmacotherapy is available to treat this disease. Aortic stenosis causes a narrowing of the heart's aortic valve, which reduces or blocks the amount of blood flowing from the heart to the body's largest artery, the aorta, and from there to the rest of the body. Minimally-invasive TAVR, which the FDA initially approved in 2011 for high surgical risk patients, has emerged as an alternative to open-heart surgery. In 2019, the FDA also approved TAVR for use in low-risk surgical patients. These low-risk surgical patients are often younger persons within the geriatric population that require heart valves with longer durability and pre-disease hemodynamics for an improved quality of life. More generally, patients with aortic valve stenosis are now being diagnosed at a younger age. Yet, according to a publication in The Journal of American Medical Association, only 15-20% of severe aortic stenosis cases are treated today.

While previous generations of TAVRs were designed for older, high risk, less-active patients, our DurAVR® THV system is designed to be a solution for all patients, including both older, less-active patients and younger patients. DurAVR® THV is a single-piece valve with a novel biomimetic design that aims to replicate the normal blood flow of a healthy human aortic valve as compared to traditional three-piece aortic valves. In our FIH study, we have observed promising results in relation to hemodynamics, laminar flow and exercise capacity. When compared to a healthy aortic valve, our DurAVR® THV system showed no significant difference in aortic flow.

In addition, our DurAVR® THV system has been developed with the aim to increase durability and last longer than traditional three-piece designs through the use of our ADAPT® anti-calcification tissue including a molded single piece of tissue designed to mimic the performance of a pre-disease human aortic valve, which we believe can result in improved hemodynamics as compared to traditional three-piece designs. These designs and features cumulatively aim to provide a better quality of life as compared to the current standard of care associated with traditional three-piece designs. We intend to test these features in the Pivotal Trial against commercially approved TAVR devices.

The design and scope of the Pivotal Trial will be finalized following completion of our submission to the FDA and receipt of feedback from the FDA. The purpose of the Pivotal Trial will be to demonstrate non-inferiority of the DurAVR® THV system compared with commercially available TAVR systems for treatment of subjects with severe calcific aortic stenosis. We anticipate that the design of the Pivotal Trial will be a prospective, randomized, controlled multicenter, international study wherein subjects will be

randomized to receive either TAVR using the DurAVR® THV system or TAVR using any commercially available and approved THV from competitors. We anticipate that the subjects will include a broad array of risk profiles. We anticipate that subjects with a failed surgical bioprosthesis in need of a ViV TAVR will be enrolled in a separate parallel registry.

In November 2022, we received approval from the FDA to commence an EFS IDE clinical study to treat 15 patients with severe aortic stenosis using the DurAVR® THV system in up to seven heart valve centers across the United States. Building on data obtained in the FIH study, this study has now completed enrollment of 15 patients. At the 30 days post-procedure, patients had a mean effective orifice area ("EOA") of 2.2 cm^2, mean pressure gradient ("MPG") of 7.5 mmHg and Doppler velocity index ("DVI") of 0.64. No paravalvular leaks were observed; however, there was one subject with pre-existing significant conduction abnormalities who received a pacemaker. Furthermore, no mortality, disabling stroke, life-threatening bleeding, or reinterventions were reported at 30 days post-procedure. Follow-up for the last patient is expected after the date of this prospectus in the second half of December 2024. As of the date of this prospectus, some, but not all patient follow-up data, has been obtained, and the Company is not in a position to comment on such data.

In July 2023, our DurAVR® THV system was used for the first time in a ViV procedure, which was performed at the Institut de Cardiologie de Montréal in Canada under a Special Access Program ("SAP"), which allows for the use of a non-commercial device for a specific patient where there is a clinical case that the approved device will not work. In August 2023, a second Canadian patient was successfully implanted with the DurAVR® THV system in a ViV procedure. As of June 2024, we have now treated six ViV patients in Canada with our DurAVR® THV system through the SAP.

In addition, the FDA determined on March 24, 2023 that approval of an IDE supplement is not required to manufacture the DurAVR® valve for investigational use in clinical trials at our facility in a suburb of Minneapolis, Minnesota. We are currently planning to submit an IDE for the DurAVR® THV system Pivotal Trial to the FDA by Q1 of 2025. If we obtain approval from the FDA, we intend to perform site activation and seek IRB approval for commencement of the study at each site. Subject to the foregoing, we anticipate enrollment to begin in the third quarter of 2025. Such a trial would be designed to provide the primary clinical evidence on which the FDA could base a decision for Pre-Market Approval that is required for commercialization of the DurAVR® THV system in the United States.

We are a development stage company and have incurred net losses in each year since inception; however, we believe that we have significant growth potential in a large, underpenetrated and growing market. Since the inception of the TAVR procedure, the annual volume of TAVR procedures in the United States has increased significantly year-over-year, with an estimated 73,000 patients having undergone a TAVR procedure in the United States in 2019 according to the TVT Registry. According to FMI, the total global market opportunity for TAVR in relation to severe aortic stenosis and in relation to ViV procedures is expected to reach $9.9 billion and $2.5 billion, respectively, in 2028. The key specific markets that our Company is initially targeting are North America and Europe due to these markets accounting for the majority of the above global opportunity. FMI indicated that the North American and European markets averaged 53% and 38% of the global market share, respectively, during the period 2016 to 2023. FMI forecasts that the market opportunity in relation to severe aortic stenosis for North America and Europe will reach $5.5 billion and $3.7 billion, respectively, in 2028; and the market opportunity in relation to ViV procedures is forecast to reach $1.5 billion and $0.8 billion, respectively, in 2028. To calculate these future market values, FMI has relied on actual data from 2023 collated from a variety of published sources and key medical experts and applied a projected Compound Annual Growth Rate ("CAGR") of 14.9% for the global market, 16.2% for the North American market, and 14.0% for the European market. A non-exhaustive list of factors that may impact these forecast calculations include key players' historic growth; companies and manufacturers working together to develop new, affordable and timesaving technologies; new product launches and approvals; rising demand for THV replacement; availability and cost of products; growing investment in healthcare expenditure; and increased regulatory focus on patient safety and reimbursement policies. In addition, we expect the TAVR market to benefit from general trends, including an aging population, earlier diagnosis of aortic stenosis, increased incidence of obesity and diabetes (which contribute to heart disease), as well as the broader patient populations' desire to pursue a more active lifestyle.

Our innovation-focused R&D practice is driven by rapid technological advancement and significant input from leading interventional cardiologists and cardiac surgeons. As a company that is primarily in the development phase, we currently generate small amounts of revenue and income which are insufficient to cover our investment in research, development and operational activities resulting in recurring net operating losses, incurred since inception. We, like other development stage medical device companies, experience challenges in implementing our business strategy due to limited resources and a smaller capital base as we prioritize product development, minimize the period to the commencement of commercial sales, ensure our focus on quality as well as scale our operations. The development and commercialization of new medical devices is highly competitive. Those competitors may have substantial market share, substantially greater capital resources and established relationships with the structural heart community potentially creating barriers to adoption of our technology. Our success will partly be based on our ability to educate the market about the benefits of our disruptive technology including current unmet clinical needs compared to commercially available devices as well as how we plan to capture market share post commercialization.

We are dedicated to developing technological enhancements and new indications for existing products, and less invasive and novel technologies to address unmet patient needs. That dedication leads to our initiation and participation in clinical trials that seek to prove our pipeline is safe and effective as the demand for clinical and economic evidence remains high.

From time to time, we enter into strategic agreements aimed at enhancing our business operations and profitability. For example, in April 2023, we invested in, and entered a development agreement with, v2vmedtech, which develops an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation.

Competitive Strengths

We believe the continued growth of our company will be driven by the following competitive strengths:

- ***Novel Biomimetic design***. DurAVR® is a novel "biomimetic" THV system. It is designed to mimic the normal anatomy with a more "human like" valve design. Novel molding of the leaflets allows for a more even coaptation area delivering larger EOAs and lower MPGs.
- ***Significant clinical results to date in European and U.S. studies***. We have made significant progress in advancing clinical trials, which we believe are delivering strong results and are bringing us closer to potentially achieving regulatory approvals for our DurAVR® THV system. We believe our FIH study at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia, and our EFS study represent key steps on our pathway to ultimately support an IDE to undertake the Pivotal Trial of our DurAVR® THV system.
- ***Highly innovative physician-led R&D structure***. Our DurAVR® THV system and our ComASUR® delivery system have both been developed with considerable input from leading interventional cardiologists and cardiac surgeons. We believe our emphasis on involving physicians in the R&D process allows us to better serve the needs of patients and physicians alike.
- ***Strong intellectual property position***. We rely on a combination of intellectual property assets to protect our innovative technology and our brand. This includes our strong patent portfolio, which includes 35 issued patents, 13 of which were issued in 2023, and over 50 pending patent applications, in the United States and in other countries.
- ***Industry experienced executive team***. Our management team and members of our Board of Directors have extensive experience in the medical technology and health care industries. We believe that our team's diverse experiences and track record in the medical industry will assist our efforts to obtain regulatory approval of our products in the United States and continue to grow our business.

Market Opportunity

According to the World Bank, the total population over 65 in the United States and the European Union was approximately 165.0 million as of 2022. According to FMI, the total global market opportunity for TAVR in relation to severe aortic stenosis and in relation to ViV procedures is expected to reach $9.9 billion and $2.5 billion, respectively, in 2028. The key specific markets that our Company is initially targeting

are North America and Europe due to these markets accounting for the majority of the above global opportunity. FMI indicated that the North American and European markets averaged 53% and 38% of the global market share, respectively, during the period 2016 to 2023. FMI forecasts that the market opportunity in relation to severe aortic stenosis for North America and Europe will reach $5.5 billion and $3.7 billion, respectively, in 2028; and the market opportunity in relation to ViV procedures is forecast to reach $1.5 billion and $0.8 billion, respectively, in 2028. To calculate these future market values, FMI has relied on actual data from 2023 collated from a variety of published sources and key medical experts and applied a projected Compound Annual Growth Rate ("CAGR") of 14.9% for the global market, 16.2% for the North American market, and 14.0% for the European market. A non-exhaustive list of factors that may impact these forecast calculations include key players' historic growth; companies and manufacturers working together to develop new, affordable and timesaving technologies; new product launches and approvals; rising demand for THV replacement; availability and cost of products; growing investment in healthcare expenditure; and increased regulatory focus on patient safety and reimbursement policies. In addition, we expect the TAVR market to benefit from general trends, including an aging population, earlier diagnosis of aortic stenosis, increased incidence of obesity and diabetes (which contribute to heart disease), as well as the broader patient populations' desire to pursue a more active lifestyle.

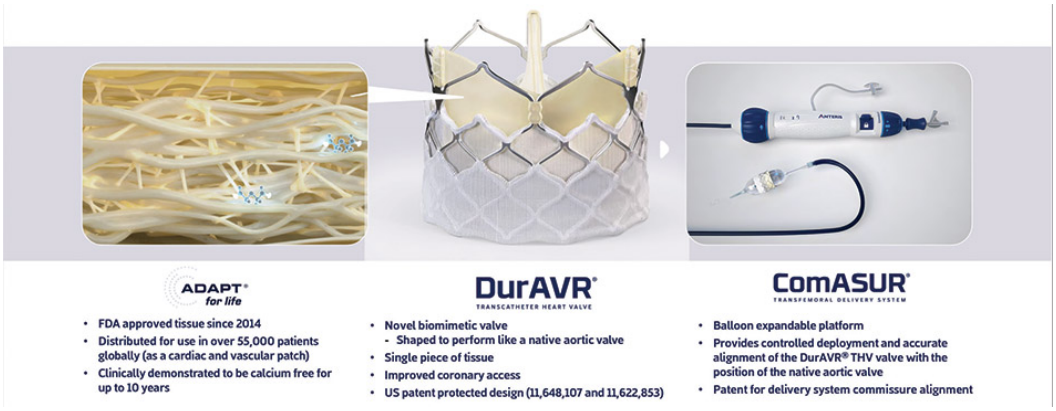
Since the inception of the TAVR procedure, the annual volume of TAVR procedures in the United States has increased significantly year-over-year, with an estimated 73,000 patients having undergone a TAVR procedure in the United States in 2019 according to the TVT Registry. We believe that the rising geriatric population and the growing cardiovascular device market provides us with a clear business opportunity. The use of healthcare services is significantly higher among older people.

DurAVR® THV's single-piece native shaped biomimetic design replicates the performance of a healthy human aortic valve, and is designed to restore normal blood flow as compared to traditional three-piece transcatheter valves, either balloon expandable or self-expanding, which do not restore normal aortic flow. We believe this design, in combination with the ADAPT® tissue technology, has the potential to allow the DurAVR® THV system to last longer than traditional three-piece aortic valves, which have multiple leaflets sewn together that may lead to compromised durability.

Our Product Candidates

Our DurAVR® THV, which employs our ADAPT® anti-calcification tissue and is deployed using our ComASUR® delivery system, is currently in clinical development.

DurAVR® Transcatheter Heart Valve System



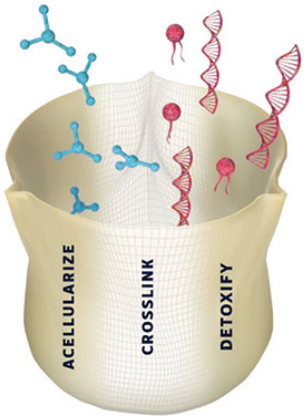
Our DurAVR® THV is a novel transcatheter aortic valve for the treatment of aortic stenosis that is shaped to mimic the performance of a healthy human aortic valve. Our DurAVR® THV system has been designed with considerable input from some of the world's leading interventional cardiologists and cardiac surgeons. DurAVR® THV's single-piece design mimics the native anatomy of a human aortic valve, as

compared to traditional three-piece aortic valves. In addition, our DurAVR® THV system has been developed with the aim to increase durability and last longer than traditional three-piece designs through the use of our ADAPT® anti-calcification tissue including a molded single piece of tissue designed to mimic the performance of a pre-disease human aortic valve, which we believe can result in improved hemodynamics as compared to traditional three-piece designs. These designs and features cumulatively aim to provide a better quality of life compared to the current standard of care associated with traditional three-piece designs. We intend to test these features in the Pivotal Trial against commercially approved TAVR devices.

The DurAVR® THV system has the following attributes:

- it is the first transcatheter aortic valve to use a patented construction of a molded single piece of bioengineered tissue (our ADAPT® anti-calcification tissue with molded leaflets (see "— *ADAPT® Anti-Calcification tissue*"));
- it has fewer sutures and seams when compared with conventional valves, thereby preserving tissue integrity with the intent to reduce calcification risk to extend valve durability;
- it is uniquely shaped to emulate the performance of a healthy human valve and produce long leaflet coaptation, laminar flows and near-normal hemodynamics;
- it has large open cells in the stent frame to improve coronary access; and
- it utilizes the ComASUR® balloon expandable delivery system (see "— *ComASUR® Delivery System*") for controlled deployment and accurate placement.

ADAPT® Anti-Calcification Tissue



The ADAPT® tissue engineering process is an anti-calcification preparation that transforms xenograft tissue (bovine pericardium) into durable bioscaffolds that are used to mimic human tissue for surgical repair in multiple settings, including aortic valve replacement. The outcome of the ADAPT® tissue engineering process is a novel, acellular, biostable and non-calcifying biomaterial.

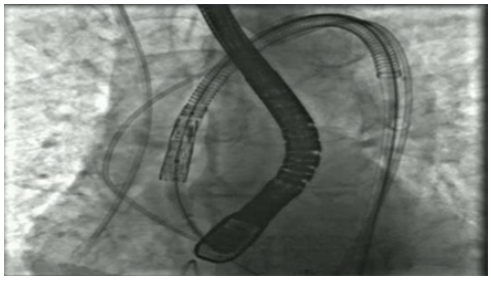
The ADAPT® tissue engineering process involves multiple steps to transform bovine pericardium into a durable bioprosthetic material. Bovine spongiform encephalopathy-free bovine pericardium is decellularized

to remove all cellular antigens that initiate an immune response. The material is then crosslinked to enable maintenance and stabilization of strength and elasticity to improve mechanical resistance. The cytotoxicity is further reduced using detoxification and sterilization processes and anti-calcification methodology to remove and bind aldehydes and enable safe storage in a non-glutaraldehyde solution. Post-implantation, ADAPT® tissue provides a scaffold for cell migration to create the optimal environment. Migrated cells can stimulate site-specific remodeling and repair and enable the formation of new blood vessels.

Our proprietary ADAPT® tissue has been clinically demonstrated to be calcium-free for up to 10 years post-procedure, according to *Performance of the ADAPT-Treated CardioCel® Scaffold in Pediatric Patients With Congenital Cardiac Anomalies: Medium to Long-Term Outcomes*, published by William Neethling et. al., and it has been distributed for use in over 55,000 patients globally in other indications. Our ComASUR® balloon-expandable delivery system, which was developed in consultation with physicians, is designed to provide precise alignment with the heart's native commissures to achieve accurate placement of the DurAVR® THV system.

To meet the need for a durable TAVR, made from ADAPT® tissue scaffold, we have created DurAVR® THV, which is a biomimetic single piece valve with optimal hemodynamic and durability properties. Based on published clinical data in several peer-reviewed journals, including The Journal of Thoracic and Cardiovascular Surgery, the Expert Review of Medical Devices, and Interactive Cardiovascular and Thoracic Surgery, ADAPT® has been observed to offer potentially significant improvements compared with other widely available commercial processes adopted by healthcare providers, including with respect to bio-compatibility, durability, strength, pliability, functionality and controlled remodeling.

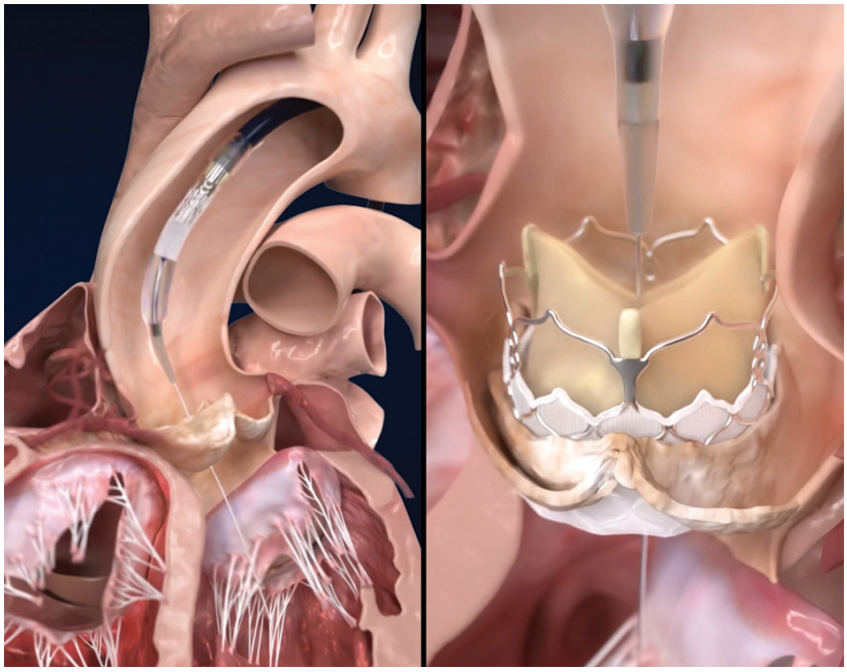
ComASUR® Delivery System



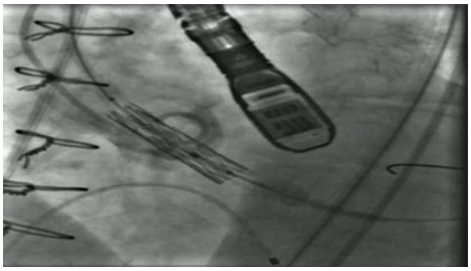
Our ComASUR® delivery system is a physician-developed balloon expandable delivery system that contains a reinforced steerable catheter for a precise deflection through the heart anatomy in a controlled manner to avoid damage to the aorta. The delivery system provides controlled deployment and accurate placement of our DurAVR® THV. Our ComASUR® delivery system is designed to achieve precise alignment with the heart's native commissures to achieve ideal valve positioning.

Within the ComASUR® delivery system, we have rotational control of the DurAVR® valve with the native commissures. This allows for commissure alignment, which is not achieved consistently in competitive

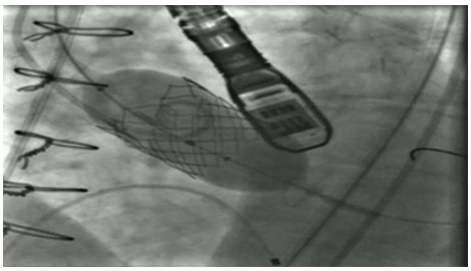
delivery systems. This feature positions the TAVR valve leaflets exactly in line with the anatomical orientation of the recipient's native valve leaflets. We have a patent pending for this system.



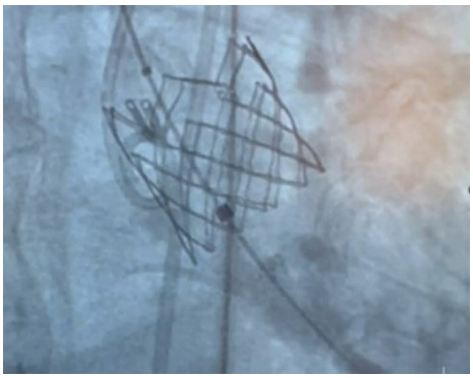
The ComASUR® delivery system provides even balloon expansion for the accurate placement of the DurAVR® THV system as well as ease of use. Under fluoroscopic guidance the physician precisely aligns the DurAVR® THV system with the native annulus before deployment in the following manner:



First, the balloon starts out as collapsed.



The balloon is then expanded and the DurAVR® THV is deployed.



Finally, the balloon is deflated and removed.

Clinical Results and Trials

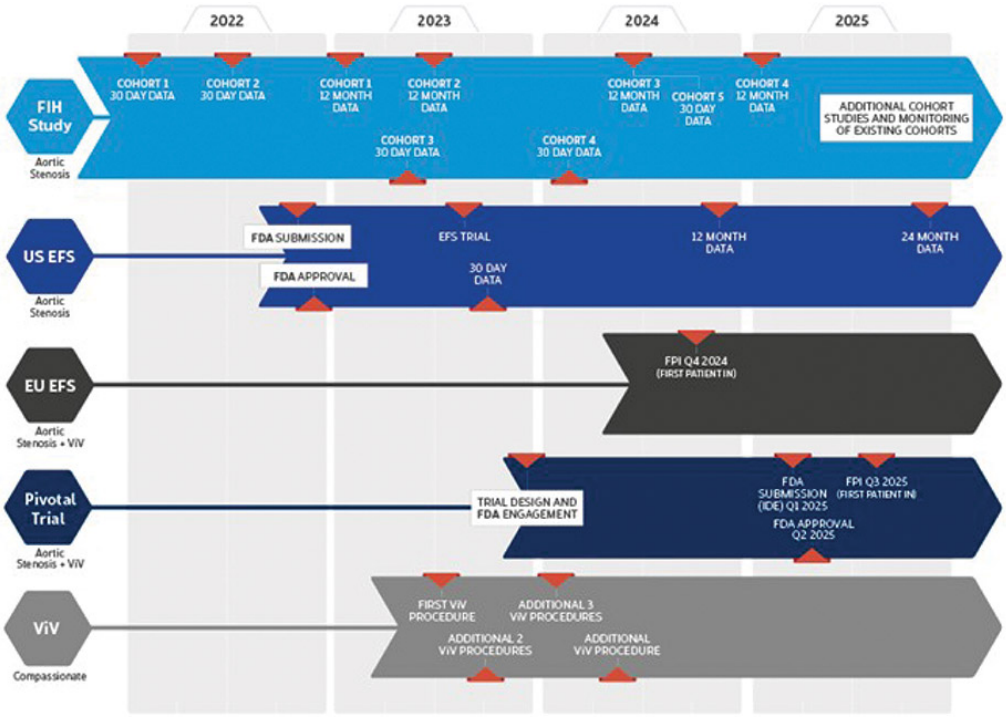
We have made significant progress in advancing clinical trials of our DurAVR® THV system. Thus far clinical development of our DurAVR® THV system has consisted of our ongoing FIH study carried out at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia and the U.S. FDA approved EFS, which builds upon the clinical data obtained in the FIH study thus far and is critical to achieving Pre-Market Approval in the United States. We have a total of 66 patients that have benefited from the implantation of the DurAVR® THV system in Georgia and the United States. In addition, the DurAVR® THV system has been implanted in compassionate ViV cases in Canada (six) and Europe (one).

Key Metrics in Clinical Trials

We believe the key hemodynamic metrics assessed in the DurAVR® THV FIH and EFS trials are:

- EOA, which refers to the smallest cross-sectional area of the aortic valve opening that is available for blood flow. Patients with severe aortic stenosis typically have an EOA of ≤ 1 cm^2. Post-TAVR, EOA is expected to increase. A larger EOA indicates a larger orifice the blood passes through, which reduces the work the left ventricle must do to pump blood through the valve.
- MPG, which refers to the average pressure across the aortic valve between the left ventricle and aorta. Patients with severe aortic stenosis have an MPG ≥ 40 mmHg. Post-TAVR MPG is expected to decrease, which indicates that the left ventricle is not working as hard to pump blood through the aortic valve.
- DVI refers to the index that expresses the EOA as a proportion of valve area, with DVI representing the physical ratio of a patient's aortic valve area to the left ventricular outflow tract area. DVI is a useful metric for assessing aortic prosthetic valve function as well as screening for aortic stenosis. A higher DVI indicates improved blood flow through the aortic valve. DVI is independent of the flow state (like MPG) and diameter (like EOA).

The following graphic shows the timelines and certain key anticipated dates for each of the FIH study, EFS and ViV procedures as well as ongoing activities as we aim to secure approval from the FDA to undertake the Pivotal Trial:



First-In-Human Study

In November 2021, we commenced our FIH study at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia. Since the inception of our FIH study, a total of 51 patients have benefited from the implantation of our DurAVR® THV system at this clinic across six cohorts, including one compassionate case (outside of the study). Patient outcomes are formally measured at both 30 days and 12 months post-procedure.

The scope of the study was to evaluate the safety and feasibility of the DurAVR® THV system in the treatment of subjects with symptomatic severe aortic stenosis. The study was designed to be a prospective, non-randomized, single-arm, single-center study, with the performance endpoints immediately after the procedure including the correct positioning of a single DurAVR® bioprosthetic heart valve into the proper anatomical location and hemodynamic performance. The safety endpoints of the study assessed at 30 days and one year post procedure include all-cause mortality, myocardial infarction, stroke (disabling), and life-threatening bleeding. The study enrollment process was not restrictive to any age parameters, however the ages of study subjects enrolled to date have ranged between 59 and 87.

Due to its nature as a FIH feasibility study, the primary endpoints of the study are not structured for statistical differences to historical controls, but rather to demonstrate functional capabilities. We believe that the sample size will allow investigators to make a qualitative assessment of the safety of DurAVR® THV in the population studied. Thus far, we have observed promising results in relation to patient hemodynamics, laminar flow and exercise capacity. In addition, as noted by Dr. P. Garg (Norwich University Hospital, United Kingdom), the first five patients underwent Cardiac Magnetic Resonance, which incorporated two-dimensional phase contrast at the level of the ascending aorta, at six months to investigate the aortic flow physiology post-DurAVR® THV implantation. Aortic flow characteristics were assessed through the measurement of aortic FD and aortic systolic FRR. The average FD of a healthy aortic valve was 10% while the average FRR of a healthy aortic valve was 1%. The results of the first five patients who received

the DurAVR® THV were compared with those of five age/height/weight-matched controls with healthy native aortic valves. DurAVR® THV recipients had comparable flow displacement (14% versus 10%; p=0.453) and flow reversal ratio (4% versus 1%; p=0.328) as compared to the healthy controls.

Furthermore, during the study, the ComASUR® delivery system component of our DurAVR® THV system has performed as expected, allowing for accurate valve placement.

Cohort 1

Our initial patient cohort consisted of five patients, each of whom were implanted with our DurAVR® THV system with no valve-related complications. These patients were observed to have stable, improved valve function with strong safety results at 12-month follow-up. We observed increased average EOA by 311% at 30 days (average EOA at baseline of 0.5 cm^2 and average EOA at 30 days of 2.05 cm^2) and by 294% at 12 months post-procedure from baseline (average EOA at 12 months of 1.96 cm^2). We also observed reduced average MPG across the valve by 87% at 30 days (MPG at baseline of 58.8 mmHg and MPG at 30 days of 7.54 mmHg) and by 85% at 12 months from baseline (MPG at 12 months of 8.82 mmHg). We observed increased DVI of 212% with stable hemodynamics from baseline (average DVI at baseline of 0.18 and average DVI at 30 days of 0.56), and then an increase of 202% from baseline to 12 months (average DVI of 0.54). Furthermore, no mortality (from any cause), disabling stroke, life-threatening bleeding, myocardial infarction or device-related complications were reported at 12 months. Lastly, the 6-minute walk test distance ("6MWTD") measuring patient exercise capacity after aortic valve replacement improved by 21% from baseline (average 6MWTD at baseline of 224.60 meters and average 6MWTD at 30 days of 271.60 meters), with a 44% improvement from baseline to results at 12 months post-procedure (average 6MWTD at 12 months of 323.50 meters).

Cohort 2

Our second patient cohort consisted of eight patients, each of whom were implanted with our DurAVR® THV system in May 2022 with no valve-related complications. In this cohort we observed increased average EOA by 164% at 30 days (average EOA at baseline of 0.75 cm^2 and average EOA at 30 days of 1.98 cm^2) and by 165% at 12 months post-procedure from baseline (average EOA at 12 months of 1.99 cm^2). We also observed reduced average MPG across the valve by 79% at 30 days (average MPG at baseline of 46.84 mmHg and average MPG at 30 days of 9.94 mmHg) and by 80% at 12 months from baseline (average MPG at 12 months of 9.51 mmHg). We have observed a 146% increased DVI at 30 days with stable hemodynamics from baseline (average DVI at baseline of 0.21 and average DVI at 30 days of 0.51), and a 169% increased average DVI at 12 months (average DVI of 0.56). Furthermore, no valve-related mortality, disabling stroke, life-threatening bleeding, myocardial infarction or valve-related complications were reported at 12 months post-procedure. Lastly, the 6MWTD measuring patient exercise capacity after aortic valve replacement improved by 20% from baseline (average 6MWTD at baseline of 234.88 meters and average 6MTWD at 30 days of 282.38 meters), with a 27% improvement from the baseline result and the 12 months post-procedure (average 6MWTD at 12 months of 297.43 meters).

Cohort 3

We enrolled seven participants in our third cohort in April 2023, each of whom were implanted with our DurAVR® THV with no valve-related complications. In this cohort we observed increased average EOA by 170% from baseline, as observed at 30 days and at 12 months post-procedure (average EOA at baseline of 0.77 cm^2, average EOA at 30 days of 2.09 cm^2 and average EOA at 12 months of 2.09 cm^2). We also observed average reduced MPG across the valve by 87% at 30 days from baseline (average MPG at baseline of 57.14 mmHg and average MPG at 30 days of 7.53 mmHg) and by 85% at 12 months from baseline (average MPG at 12 months of 8.61 mmHg). We observed a 173% increased DVI at 30 days with stable hemodynamics from baseline (average DVI at baseline of 0.22 and average DVI at 30 days of 0.59), and then an increase of 159% from baseline to 12 months (average DVI of 0.57). Furthermore, no mortality (from any cause), disabling stroke, life-threatening bleeding, myocardial infarction or valve-related complications were reported at 12 months. Lastly, the 6MWTD measuring patient exercise capacity after aortic valve replacement improved by 28% from baseline at 30 days post-procedure (average 6MWTD at baseline of

174.57 meters and average 6MWTD at 30 days of 222.71 meters). To date, only partial results are available for the 6MWTD at 12 months post-procedure.

Cohort 4

Our fourth patient cohort consists of eight patients, each of which were implanted with our DurAVR® THV system in December 2023 with no valve-related complications. In this cohort we observed increased average EOA by 165% from baseline (average EOA at baseline of 0.9 cm² and average EOA at 30 days of 2.39 cm²), as observed at 30 days post-procedure. We also observed reduced MPG across the valve by 85% from baseline (average MPG at baseline of 43.25 mmHg and average MPG at 30 days of 6.41 mmHg), as observed at 30 days post-procedure. We observed an increase in DVI from baseline of 170% (average DVI at baseline of 0.23 and average DVI at 30 days of 0.62). Furthermore, no mortality (from any cause), disabling stroke, life-threatening bleeding, myocardial infarction or valve-related complications were reported at 30 days post-procedure. Lastly, the 6MWTD measuring patient exercise capacity after aortic valve replacement improved by 14% from baseline at 30 days post-procedure (average 6MWTD at baseline of 241.50 meters and average 6MWTD at 30 days of 275.00 meters).

Cohort 5

Our fifth patient cohort consisted of 13 patients, each of which were successfully implanted with our DurAVR® THV system in April and May 2024 with no valve-related complications. In this cohort we observed at 30 days post-procedure increased average EOA by 208% from baseline (average EOA at baseline of 0.73 cm^2 and average EOA at 30 days of 2.25 cm^2), reduced MPG across the valve by 84% from baseline (average MPG at baseline of 48.23 mmHg and average MPG at 30 days of 7.81 mmHg), and an increase in DVI from baseline at 30 days post-procedure of 180% (average DVI at baseline of 0.22 and average DVI at 30 days of 0.62). Furthermore, no mortality (from any cause), life-threatening bleeding, myocardial infarction or valve-related complications were reported at 30 days post-procedure.

Cohort 6

Our sixth patient cohort consisted of nine patients, which were implanted with our DurAVR® THV system in September 2024. As of the date of this prospectus, some, but not all of the 30-day clinical data for this cohort is available, and the Company is not in a position to provide an update with respect to this data.

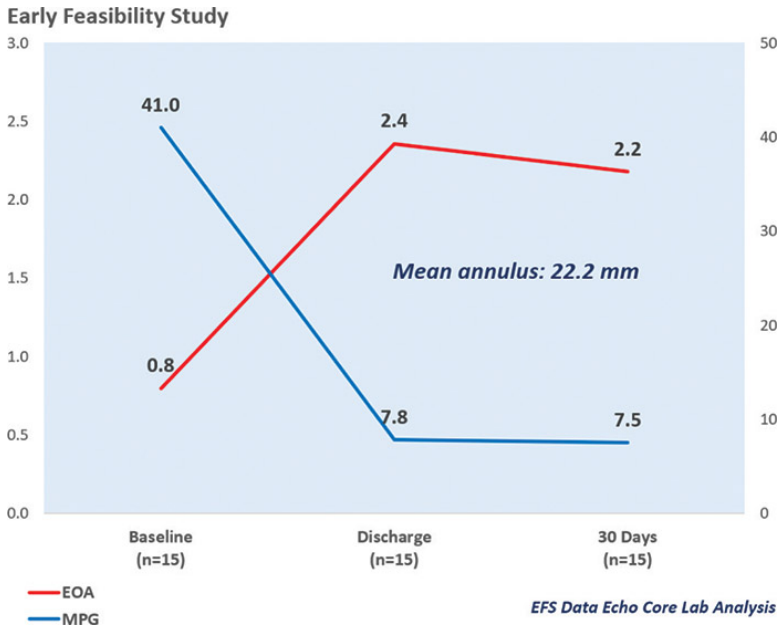
Early Feasibility Study

In November 2022, we received approval with conditions of our EFS IDE application from the FDA to evaluate the safety and feasibility of our DurAVR® THV system in the treatment of patients with symptomatic severe native aortic stenosis. We commenced the EFS in August 2023, enrolling 15 patients at four prominent heart valve centers across the United States. Patient outcomes such as stroke, myocardial infarction, life-threatening bleeds, and all-cause mortality are reported at 30 days and 1-year post implantation. Patients will be followed up to 10 years post-implant. The FDA has categorized DurAVR® in this study as a CMS Category B device, which permits Medicare coverage of the device when a Medicare beneficiary participates in the study.

The primary and key secondary endpoints of this trial include safety and device feasibility assessments such as success of implantation at the anatomically accurate position, and hemodynamic performance assessments, including EOA, mean gradient, aortic regurgitation and DVI.

The EFS demonstrated a 100% precise placement and implant success of our DurAVR® for all 15 patients. At 30 days post-procedure, patients had an increase in average EOA of 172% from baseline (average EOA at baseline of 0.8 cm² and average EOA at 30 days of 2.2 cm²), reduction of MPG of 82% from baseline (average MPG at baseline of 41 mmHg and average MPG at 30 days of 7.5 mmHg) and an increase in DVI of 121% from baseline (average DVI at baseline of 0.28 and average DVI at 30 days of 0.64). No paravalvular leaks were observed; however, there was one subject with pre-existing significant conduction abnormalities who received a pacemaker. Furthermore, no mortality, disabling stroke, life-threatening bleeding, or reinterventions were reported at 30 days post-procedure. 12-month follow up visits

are scheduled to be completed after the date of this prospectus in the second half of December 2024, with analysis and reporting scheduled for the first quarter of 2025. As of the date of this prospectus, some, but not all of the 12-month data, has been obtained, and the Company is not in a position to comment on such data.



We have partnered with IQVIA and the CRF to conduct the EFS. IQVIA is a clinical research organization contracted to provide clinical data monitoring, project and site management, data management, and safety reporting for the EFS. The term of the agreement is until the services for the EFS are completed. CRF provides us with core lab services for the EFS and an independent clinical events committee.

Valve-in-Valve Procedures

In July 2023, DurAVR® THV was used for the first time in a ViV procedure as part of Health Canada's SAP. A ViV procedure is required for patients with a life-threatening situation wherein their current bioprosthetic aortic valve is failing due to calcification or structural deterioration, and a new heart valve must be implanted inside the failing valve. These patients are at high risk for another surgery and require a minimally invasive treatment option. Canada's SAP exists so that life-saving technology not currently available for commercial use in Canada can be provided when no other commercially available alternatives are suitable.

Our participation in the Canadian SAP program is voluntary. There is no formal agreement with Health Canada, other than letters of authorization by Health Canada for the importation and or sale of special access devices. In addition, DurAVR® THV was used for the first time in Sweden as a complex valve-in-valve-in-valve ("ViViV") procedure at the Karolinska Institute hospital. The ViViV procedure involved a 77-year-old male patient with two prior surgically implanted valves, both of which had subsequently failed, who was deemed too high-risk for another surgery. After implantation of DurAVR THV, the patient's MPG was observed to be 20 mmHg (compared to a prior range of 23 to 41 mmHg) and the patient's DVI was observed to be between 0.33 and 0.40 (compared to a prior range of 0.15 to 0.40).

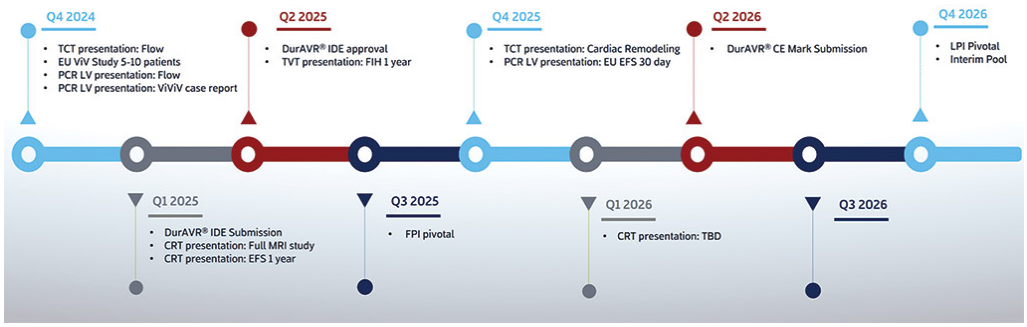
EU Early Feasibility Study

An EU EFS, to evaluate the safety and feasibility of the DurAVR® THV System in the treatment of symptomatic, severe aortic stenosis or failed surgical aortic bioprosthetic valves commenced in December 2024 with the first cases planned to occur after the date of this prospectus in the second half of December

2024 or the first half of January 2025. The EU EFS, anticipated to enroll up to 40 patients, is expected to provide both ViV data in a controlled setting as well as generate further feasibility and safety data in patients with severe aortic stenosis. The data collected from EU sites is expected to be included in future regulatory applications. The EU EFS is subject to a number of approvals and contingencies, and there can be no assurance that such study will commence or be completed on the expected timelines.

Anticipated Milestones

The below image illustrates our anticipated near-term milestones, which are subject to change and which are described in further detail below. These anticipated near-term milestones depend on multiple factors, including, but not limited to, capital allocation, interactions with regulatory authorities, enrollment of patients, timing of our clinical trials and other external events that could influence our operations. There can be no assurance that the achievement of any of these milestones will be achieved on the expected timing or at all, or that the submission of an IDE will necessarily result in our ability to commence the Pivotal Trial or other clinical trials.



Anticipated Milestones in 2024

In December 2024, we commenced an EU EFS, with the first cases planned to occur in the second half of December 2024 or the first half of January 2025, to evaluate the safety and feasibility of the DurAVR® THV System in the treatment of symptomatic, severe aortic stenosis or failed surgical aortic bioprosthetic valves. For further information on the EU EFS, see "*— Our Product Candidates — EU Early Feasibility Study*."

On October 28, 2024, at the Transcatheter Cardiovascular Therapeutics Conference in Washington D.C. Dr Amar Krishnaswamy gave a presentation, titled '*DurAVR® THV System with Biomimetic Leaflet Design: Impact on Flow Dynamics and LV Mass Regression*'. The presentation took place during the '*Innovations in TAVR Systems and New Clinical Updates*' session.

During November 2024, we also expect to present at the PCR London Valves conference. Dr Pankaj Garg is scheduled to give a presentation on November 24, 2024, titled '*DurAVR TAVI: biomimetic design restores flow and leads to significant left ventricular mass regression — MRI study*'. The presentation is scheduled to take place during the '*TAVI Hotline 1*' session. Dr Andreas Ruck is scheduled to give a presentation on November 24, 2024, titled '*DurAVR THV ViViV case: How to achieve optimal gradients in limited space*'. The presentation will take place during the '*Featured cases — TAVI-in-TAVI (Part 1)*' session.

Anticipated Milestones in 2025

We expect to complete our IDE submission in the first quarter of 2025. If we receive FDA approval of the IDE submission, which we anticipate could occur as early as the second quarter of 2025, we would expect to begin the Pivotal Trial in the third quarter of 2025. There can be no assurance that the FDA will approve our IDE submission or that such submission will result in our ability to commence the Pivotal Trial.

We also expect to continue to present at industry conferences throughout the year, including at the Cardiovascular Research Technologies conference on the one-year data from the EFS and a full magnetic resonance imaging study, at the Transcatheter Cardiovascular Therapeutics conference on cardiac remodeling, and at the PCR London Valves conference on the EU EFS, which commenced in December 2024 with the first cases planned to occur in the second half of December 2024 or the first half of January 2025.

Anticipated Milestones in 2026

We expect to continue presenting at industry conferences in 2026, including at the Cardiovascular Research Technologies conference in the first quarter of 2026. We also expect to submit DurAVR® THV for CE marking, which, if received, will indicate that it has been deemed to meet EU safety, health and environmental protection requirements.

Further clinical presentations are planned at scientific symposia and educational forums specializing in structural heart and interventional cardiovascular medicine through 2026.

In the fourth quarter of 2026, we anticipate the last patient to be enrolled into our Pivotal Trial. The Company is exploring the ability to provide Interim Pool data during the fourth quarter of 2026, however this is yet to be confirmed.

License Agreements

CardioCel™ and VascuCel™ Patch Business

We previously deployed our proprietary ADAPT® tissue in our CardioCel™ and VascuCel™ products. CardioCel™ is an advanced cardiovascular scaffold designed to repair and treat a range of cardiovascular and vascular defects. CardioCel™ is used as a patch in great vessel repair, peripheral vascular reconstruction and suture line buttressing. On October 11, 2019, we sold the distribution and manufacturing rights, including the CardioCel™ and VascuCel™ trademarks, to LeMaitre Vascular Inc. (“LeMaitre”) for cash proceeds of $14.2 million, and a further $1.6 million was subsequently received. An additional $2.0 million (less the associated regulatory approval costs incurred by LeMaitre, which are capped at EUR 0.6 million) remains as a contingent receivable (the “LeMaitre Contingent Receivable”). The sale included an exclusive intellectual property license to use our propriety ADAPT® tissue limited to the cardiovascular patch field of use granted to LeMaitre.

Concurrent with such sale, we entered into a transition services agreement (the “Transition Services Agreement”) with LeMaitre pursuant to which we manufacture and sell CardioCel™ and VascuCel™ products to LeMaitre in exchange for a price currently ranging between AUD$200 and AUD$1,400 per product. This Transition Services Agreement has a current term through January 2025, at which time LeMaitre will manufacture the product. The Transition Services Agreement may be terminated by either us or LeMaitre for cause upon the other party's default or if the other party becomes insolvent, and may be terminated by LeMaitre at its convenience upon 90 days' prior written notice to us.

Pursuant to the Transition Services Agreement, LeMaitre is responsible for seeking regulatory approvals for CardioCel™ and VascuCel™ under the European Union Medical Device Regulation (“EUMDR”), with the associated costs being borne by LeMaitre and deductible from the LeMaitre Contingent Receivable due to us upon receipt of approvals under the EUMDR. We have fulfilled the necessary requirements to be able to continue to supply CardioCel™ and VascuCel™ during the updated EUMDR transition period ending on December 31, 2027. The timing of the EUMDR review and approval of these products is primarily managed by LeMaitre but is required to be completed by December 31, 2027.

Until January 2025, we remain the legal manufacturer for CardioCel™ and VascuCel™ products sold by LeMaitre in the Asia Pacific region, Europe, North Africa, Middle East region, including Bahrain, Hong Kong, Indonesia, Israel, South Korea, Kuwait, Lebanon, Malaysia, Philippines, Qatar, Saudi Arabia, Singapore, Thailand, Turkey, United Arab Emirates, the United Kingdom, United States and Vietnam. The CardioCel™ and VascuCel™ medical device license for Canada is held by LeMaitre, which sells its own version of CardioCel™ and VascuCel™.

We have received cash proceeds of $12.8 million through September 30, 2024 from manufacturing the CardioCel™ and VascuCel™ products for LeMaitre, pursuant to the Transition Services Agreement.

License Agreement

We are party to that certain License Agreement, dated as of October 11, 2019, by and between us and LeMaitre (the "License Agreement"), pursuant to which we granted to LeMaitre an exclusive, limited, fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable right and license under and to patents and technology in the fields of (i) patches for cardiac repair or replacement (excluding catheter-delivered repair or catheter-delivered replacement devices), (ii) conduits formed from flat patches for cardiac repair or replacement; and (iii) vascular repair or replacement (the "Exclusive Fields"). In addition, pursuant to the License Agreement, we granted LeMaitre a non-exclusive, limited, fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable right and license under and to patents and technology in the fields of patches for surgical leaflet repair or replacement (excluding catheter delivered repair or catheter delivered replacement). Pursuant to the License Agreement, LeMaitre also granted us: (i) a non-exclusive, fully paid-up, royalty-free, limited, revocable, terminable, non-transferable, non-sublicensable right and license under and to the licensed patents and licensed technology in the Exclusive Fields solely for the purpose of manufacturing products for and on behalf of LeMaitre under the Transition Services Agreement during the term of the Transition Services Agreement, and (ii) a non-exclusive, fully paid up, royalty-free, limited, worldwide perpetual license to use and reproduce any clinical data generated by LeMaitre and pertaining to the products developed under the License Agreement. Consideration under the License Agreement consisted of a one-time upfront payment of $8.0 million from LeMaitre to us. All intellectual property licensed under the License Agreement will be owned by us, but improvements by each party shall be owned by the party that conceived, invented and reduced to practice such improvements. The License Agreement has an indefinite term unless terminated by LeMaitre. We do not have the right to terminate the License Agreement; however, LeMaitre is permitted to terminate on 90 days' notice.

4C Medical Technologies

On August 30, 2017, and as further amended, we entered into a supply and license agreement (as amended, the "4C Agreement") with 4C Medical Technologies, Inc. ("4C"), a medical technology company that develops medical devices for the treatment of cardiovascular valve disease. Under the terms of the 4C Agreement, we supply and sell ADAPT® tissue to 4C, to be used in 4C's production of medical devices related to mitral valves and tricuspid human heart valves and granted a limited license to our related sterilization methods only in connection with use of ADAPT® tissue by 4C in its production of medical devices.

Sales under the 4C Agreement are made pursuant to individual purchase orders at a price per unit based on anticipated annual volume. There are no minimum purchase commitments under the 4C Agreement.

During the term of the 4C Agreement, our supply of ADAPT® tissue to 4C is exclusive, meaning that we agree not to develop, manufacture, or sell certain ADAPT® tissue-based products in the mitral valve or tricuspid valve field other than for 4C without prior written approval. We have received $8.4 million in proceeds through September 30, 2024 under the 4C Agreement relating to the sale and supply of ADAPT® tissue-based products to 4C and granting 4C a worldwide license to use our sterilization method in connection with those supplied ADAPT® tissue-based products.

Pursuant to the 4C Agreement, we also granted to 4C a limited, revocable and royalty free license to use certain of our trademarks for marketing purposes for 4C's medical devices that use ADAPT® tissue. On October 14, 2019, in light of the transaction with LeMaitre, we revoked 4C's license to the CardioCel™ trademark only. We retained our intellectual property rights existing at the time of the 4C Agreement (except for limited licenses granted to 4C in effect during the term of the 4C Agreement), including new intellectual property rights relating to our tissue products developed either solely by us or jointly by us and 4C. The last-to-expire patent related to the intellectual property covered by the 4C Agreement is scheduled to expire between July 2032 and August 2032.

The initial term of the 4C Agreement expires on June 1, 2025, at which time it will automatically renew for successive one-year terms. Either we or 4C may terminate the 4C Agreement upon 180 days written notice

to the other party at the end of the initial term or any renewal term or in the event of an uncured breach or if the other party becomes insolvent, files a petition for bankruptcy or upon the occurrence of similar events.

Collaborations

v2vmedtech

On April 18, 2023, we purchased 30% of the equity capital stock of v2vmedtech, pursuant to a contribution and stock purchase agreement (the "Stock Purchase Agreement"), and concurrently contributed $0.2 million and entered into a series of agreements (collectively, the "v2v Agreements") with v2vmedtech. v2vmedtech has a license agreement with Columbia University to develop an innovative heart valve repair device utilizing a transcatheter edge-to-edge repair method for a minimally invasive treatment of mitral and tricuspid valve regurgitation, also known as leaky valve.

Under the terms of the v2v Agreements, we agreed to provide certain development services to v2vmedtech in exchange for equity in v2vmedtech. Pursuant to the v2v Agreements, we provide engineering, clinical, regulatory, marketing, and executive management resources, but excluding medical and chief medical officer services, in connection with v2vmedtech's development of these valve repair devices. We are responsible for developing products and preparing regulatory filings. All costs and expenses incurred by us directly related to the development of devices constitute development contributions under the v2v Agreements, for which we are solely responsible. These contributions are to be provided over five stages linked to key development and regulatory requirements for the device for transcatheter edge-to-edge repair of the mitral valve ("TEER Product").

Stage 1 is the development of a preferred concept for the TEER Product, during which we will provide analytical, engineering and product development services for the TEER product, gather and document preliminary or critical product requirements, create product specifications, design at least one concept to meet that product specification, and provide initial prototypes. During this stage, v2vmedtech will also establish a separate medical advisory board (the "v2v Advisory Board"). Stage 1 will conclude with a design review with non-Anteris members of v2vmedtech, prior to proceeding to Stage 2. The research and development contributions (excluding general and administration expenses) paid by us under Stage 1 were $2.2 million.

Stage 2 involves manufacturing and testing prototypes of the preferred concept to finalize the TEER Product design for concept lock. This stage may include additional engineering and product development services to modify the preferred concept of the TEER Product at our sole discretion. Before we make a decision to advance to Stage 3, a design review with non-Anteris members of v2vmedtech will be conducted and their feedback will be considered. In addition, to advance to Stage 3, the TEER Product must meet all established criteria in our quality system. The research and development contributions (excluding general and administration expenses) paid by us as set out in the Development Agreement under Stage 2 are expected to be $0.4 million to $0.8 million.

Stage 3 involves non-clinical bench lab testing of the TEER Product, in our discretion. Before we make a decision to advance to Stage 4, a design review with non-Anteris members of v2vmedtech will be conducted and their feedback will be considered. The research and development contributions (excluding general and administration expenses) paid by us as set out in the Development Agreement under Stage 3 are expected to be $0.8 million to $1.8 million.

Stage 4 involves pre-clinical acute and chronic studies of the TEER Product in animals to support regulatory submissions, which will be undertaken in our discretion. Before we make a decision to advance to Stage 5, a design review with non-Anteris members of v2vmedtech will be conducted and their feedback will be considered. Approval from v2vmedtech's board of directors may be required before proceeding to Stage 5. The research and development contributions (excluding general and administration expenses) paid by us as set out in the Development Agreement under Stage 4 are expected to be $0.7 million to $1.6 million.

Stage 5 is the first use of the TEER Product in a first-in-human study in one cohort of patients anywhere in the world. During this stage, v2vmedtech will enter into agreements with the sites and practitioners performing the first-in-human study services and must maintain appropriate insurance.

A review of endpoints and resulting data from the first-in-human study will be conducted by us and by appropriate non-Anteris members of v2vmedtech in order to determine the success of the first-in-human study. The research and development contributions (excluding general and administration expenses) paid by us under Stage 5 as set out in the Development Agreement are expected to be $1.0 million to $2.2 million.

During Stages 2 through 5, we may solicit input from the v2v Advisory Board and will coordinate, facilitate and participate in meetings of the v2v Advisory Board. We are generally permitted to use our own employees, resources, lab facilities and other internal resources during the five development stages.

We have an option to terminate our activities for v2vmedtech, subject to certain break rights. These break rights allow us to discontinue additional development contributions subject to a fee of $0.2 million during Stage 1 and incrementally increasing by $0.2 million for each stage of development to a maximum $1.0 million break fee in Stage 5. We will also pay all customary corporate, operational, and legal costs ("operational contributions") of v2vmedtech up to an amount determined by the board of directors of v2vmedtech each year. After the earlier of the completion of Stage 5 or the incurrence of $10.0 million of development contributions and operational contributions, our ownership stake in v2vmedtech will be increased from 30% to between 58% and 60%.

v2vmedtech owns all intellectual property rights to the technology and data developed (the "Developed Technology and Data") pursuant to the v2v Agreements. However, under the terms of the v2v Agreements, v2vmedtech grants us a perpetual and exclusive license to the Developed Technology and Data for medical device applications other than leaky valve devices. As v2vmedtech is a development company, there is no revenue currently generated by this entity.

The v2v Agreements will expire one year after completion of Stage 5. We may terminate the v2v Agreements upon exercise of our break rights under the Stock Purchase Agreement and payment of the applicable break fee or upon a material breach by v2vmedtech. v2vmedtech may terminate the v2v Agreements once we no longer own any shares of v2vmedtech's issued and outstanding capital stock or upon its exercise of its break rights under the Stock Purchase Agreement or the exercise of certain rights it holds under the Stock Purchase Agreement. We and v2vmedtech may terminate the v2v Agreements upon an event of insolvency or a material breach by the other party.

Development is currently in Stage 2 and has reached concept lock on the clips and coupler. Timing for a FIH trial cannot be reasonably determined at this time as it is contingent on successful completion of further stages of research and development, including the design, prototyping and testing, preclinical testing and completion of regulatory submissions. The timing to complete these activities is influenced by the v2v Agreements, which state that the development agreement can be terminated if certain expenditure amounts, development milestones or regulatory approvals are not incurred or achieved from March 31, 2027 and onwards. The total amount paid by us under the v2v Agreements as of September 30, 2024 was $3.4 million.

Ear Science Institute Australia

On December 5, 2022, we entered into a material development agreement (the "ESIA Agreement") with the Ear Science Institute Australia ("ESIA"), pursuant to which we have the right to use ESIA's silk-based material to create a proprietary silk-based technology for human cardiovascular applications and develop a synthetic heart valve substitute for clinical use (together, the "ESIA New Technology"). We are investigating applying the ESIA New Technology to our DurAVR® THV system design. The ESIA Agreement has a two-year term and may be terminated by us for convenience upon 30 days written notice to ESIA and upon our payment of a termination fee equal to all non-cancellable expenses incurred and all reasonable expenses paid in advance by ESIA. The ESIA Agreement may also be terminated for cause under certain circumstances. We do not receive any revenue from ESIA pursuant to the ESIA Agreement.

Under the terms of the ESIA Agreement, we will own all intellectual property rights in the ESIA New Technology to the extent it relies on our own intellectual property rights or involves heart valves, but will share the development costs with ESIA. Furthermore, we will have the option for a period of 12 months, upon expiration of the ESIA Agreement, to negotiate an exclusive license to use certain technology owned by the ESIA to the extent necessary to further develop and commercialize the ESIA New Technology.

Additionally, the ESIA New Technology cannot be used either for commercial purposes or on humans during the term of the ESIA Agreement.

As of September 30, 2024, we had paid an aggregate of $0.2 million to ESIA under the ESIA Agreement.

Single Source Suppliers

Aran Biomedical

We are party to a supply and quality agreement (the "Aran Supply Agreement"), dated November 16, 2021, with Aran Biomedical Teoranta ("Aran") pursuant to which Aran supplies us with certain knitted materials from time to time pursuant to one or more purchase orders and in accordance with reasonable quality requirements provided by us. The Aran Supply Agreement has an initial term of five years and renews thereafter for successive one-year terms upon mutual written agreement of the parties. Either us or Aran may terminate the Aran Supply Agreement upon an uncured material breach.

Harvey Industries Group

We have entered into a supply and quality agreement (the "Harvey Supply Agreement") with Harvey Industries Group Pty Ltd ("Harvey"), a supplier of animal derived materials for therapeutic applications. Under the Harvey Supply Agreement, Harvey supplies us with bovine pericardia used in the manufacturing of our products pursuant to orders placed by us. We have the ability to reject any product that does not meet the applicable specifications. The Harvey Supply Agreement expires in May 2026, but may be extended by mutual agreement between us and Harvey. If the Harvey Supply Agreement is not extended, Harvey will continue to supply us with bovine pericardia for an additional four months after the expiration of the Harvey Supply Agreement upon our request. We may terminate the Harvey Supply Agreement without cause upon 90 days written notice, and Harvey may terminate the Harvey Supply Agreement with 12 months written notice. Either us or Harvey may terminate the Harvey Supply Agreement for cause upon an uncured breach or a non-remediable breach.

NPX Medical

We are party to a services agreement (the "NPX Services Agreement"), dated March 25, 2020, and subsequently amended on February 21, 2021 and March 24, 2024, with NPX Medical, LLC ("NPX"), pursuant to which NPX provides certain engineering and manufacturing services to us as requested by us in purchase orders from time to time. NPX also provides certain product development services to us under the NPX Services Agreement. The NPX Services Agreement had an original expiration date of March 25, 2021 and renews automatically for successive one-year terms unless terminated. Either party to the NPX Services Agreement may terminate the agreement without cause upon 30 days written notice to the other party or for cause upon an uncured material breach of the NPX Services Agreement.

We are also party to a quality agreement with NPX (the "NPX Quality Agreement"), dated February 11, 2021, which provides for certain quality requirements for the products manufactured for us by NPX, as specified by us in purchase orders made under the NPX Services Agreement. The NPX Quality Agreement will remain in effect as long as the NPX Services Agreement is in effect.

Switchback Medical

We were party to a master services agreement (the "Switchback Master Services Agreement"), dated June 1, 2021 with Switchback Medical, LLC ("Switchback"), under which Switchback provided us with various development and manufacturing services, including engineering and testing services, pursuant to purchase orders made by us from time to time. We also granted Switchback a limited, exclusive, revocable, non-sublicensable, fully paid-up, royalty-free license to certain of our intellectual property to be used solely for the purpose of manufacturing products during the term of the Switchback Master Services Agreement. We retained all rights, title and interest in the results of any testing services, reports or data generated or provided by Switchback and to any developed intellectual property. The Switchback Master Services Agreement expired on June 1, 2024, however, we are negotiating a new agreement with Switchback and expect to finalize such agreement in the near term.

Taurus Engineering and Manufacturing

We are party to a supplier quality agreement (the "Taurus Supplier Agreement"), dated February 15, 2024, with Taurus Engineering and Manufacturing, Inc. ("Taurus"), under which Taurus provides us with certain manufacturing services and supplies us with raw materials in accordance with specified quality requirements and other specifications. Taurus is not an exclusive supplier to us for the materials that it supplies, but under the terms of the Taurus Supplier Agreement, Taurus may not supply anyone other than us with the materials covered by the Taurus Supplier Agreement. The Taurus Supplier Agreement has a two-year term and is scheduled to expire on the later of February 15, 2026 or the term of any supply agreement entered into under the Taurus Supplier Agreement, unless earlier terminated. Anteris may terminate the Taurus Supplier Agreement upon a change in control of Taurus.

Other Agreements

CRF

We are party to a Combined Bioinformatics Master Services Agreement, dated September 1, 2021, with CRF (the "CRF MSA"). Pursuant to the CRF MSA, CRF is engaged on a per project basis to perform independent analyses and provide interpretations on various types of medical data and information, provide comprehensive data coordination and analysis center ("DCAC") services, manage clinical events and data monitoring committees, and health economics and outcomes research ("HEOR"). Data and other research and results generated or produced by CRF concerning core lab and HEOR activities pursuant to the CRF MSA is jointly owned by us and CRF. The data and other research and results generated or produced by CRF concerning DCAC activities pursuant to the CRF MSA is owned by us. Payment terms under the CRF MSA are set forth in work orders for discrete tasks. The original term of the CRF MSA was through December 31, 2022, and has automatically renewed for subsequent annual terms, with the current term expiring on December 31, 2024. Either party to the CRF MSA may provide notice of termination of the CRF MSA for the subsequent annual period or upon 60 days' notice.

QMED

We have agreed to be bound by General Terms and Conditions with QMED, pursuant to which QMED provides certain services to us in accordance with individual service agreements (the "Service Agreements"). Pursuant to the Service Agreements first entered into on July 8, 2024, QMED has agreed to provide us with clinical trial submission support for the EU, including the provision of life science services in the areas of regulatory affairs, training, quality assurance and control, clinical trial consultancy and legal representation. Payment terms and term lengths for discrete tasks and services are set forth in individual Service Agreements. Under the General Terms and Conditions, we may terminate the Service Agreements at our discretion by providing 30 days' notice, or upon ten days' notice and payment of a 15% termination fee. Either we or QMED may terminate the Service Agreements upon default or an uncured material breach.

IQVIA

We are party to a Master Services Agreement, dated October 5, 2021 (the "IQVIA-Anteris MSA"). Pursuant to the IQVIA-Anteris MSA, IQVIA and their affiliates provide services to us for individual studies or projects pursuant to individual work orders. These services may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, project management, pharmacovigilance, central laboratory services, clinical pharmacology services, electrocardiogram services, services utilizing certain of IQVIA's technology, medical device services, and other services as may be mutually agreed to. The IQVIA-Anteris MSA has an initial term of five years. We may terminate the IQVIA-Anteris MSA without cause upon 60 days' written notice. Either party may terminate the IQVIA-Anteris MSA for cause with 30 days' written notice upon an uncured material breach.

Competition

We compete in the cardiovascular device market, and in particular the TAVR market. These markets are characterized by rapid change resulting from technological advances, innovations and scientific

discoveries. Our products face a mix of competitors ranging from large manufacturers with multiple business lines to small manufacturers offering a limited selection of products. In addition, we face competition from providers of other medical therapies, such as pharmaceutical companies. Our primary competitors include Edwards Lifesciences Corporation and Medtronic plc. Currently, no competitor has a single piece tissue TAVR commercially available or has publicly disclosed that a single piece tissue TAVR is in development.

Major shifts in industry market share have occurred in connection with product corrective actions, physician advisories, safety alerts, results of clinical trials to support superiority claims, and publications about products, reflecting the importance of product quality, product efficacy and quality systems in the medical technology industry. In the current environment of managed care, economically motivated customers, consolidation among healthcare providers, increased competition, declining reimbursement rates, and national and provincial tender pricing, competitively priced product offerings are essential to our business. In order to compete effectively, we must continue to create or acquire advanced technology, incorporate this technology into proprietary products, obtain regulatory approvals in a timely manner, maintain high-quality manufacturing processes, and successfully market these products.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights in the United States and other markets. U.S. federal registrations for trademarks can remain in force in perpetuity, provided the mark is still being used in commerce and the maintenance/renewal filings are made as required by the sixth year after registration, by the tenth year after registration, and every ten years thereafter.

As of October 31, 2024, we owned a total of 48 active patents expiring between 2025 and 2042, and 55 pending patent applications.

In the category of prosthetic heart valve devices, we are the sole owner of eight active U.S. patents, four pending U.S. patent applications, six active Australian patents, three pending Australian patent applications, one pending Patent Cooperation Treaty (“PCT”) application, 15 active patents in other countries, and 31 pending applications in other countries. These patents and pending applications are directed to features that are expected to provide competitive advantages such as: a novel process for production of calcification resistant cross-linked biomaterials for the prosthetic valve; three-dimensional molded heart valve leaflets made of cross-linked biomaterial that mimic the performance of a native heart valve designed to provide enhanced performance characteristics such as low mean pressure gradient, low leaflet stress, large open area, high coaptation area and high duration in an open state, to name a few; a prosthetic heart valve that has localized protective covering members that prevent direct contact between the valve and the stent frame to enhance the durability and longevity of the prosthetic valve when the valve is in an open state; and attachment of the biomaterial valve to the stent frame in a novel manner that reduces stresses on the biomaterial of the prosthetic valve.

The below table summarizes our patents and patent applications for prosthetic heart valves:

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Prosthetic Heart Valves	11622853	Utility	USA	2042
Prosthetic Heart Valves	11903827	Utility	USA	2042
Prosthetic Heart Valves	18/410,796	Utility	USA	To be determined.
Prosthetic Heart Valves	PCT/US2023/033817	Utility	PCT	To be determined.
An Implant Biomaterial and Method	9205172	Utility	USA	2032
An Implant Biomaterial and Method	2005318938	Utility	AUSTRALIA	2025
An Implant Biomaterial and Method	PI0519285-4	Utility	BRAZIL	2025
An Implant Biomaterial and Method	1835948	Utility	SWITZERLAND	2025
An Implant Biomaterial and Method	101128225	Utility	CHINA	2025
An Implant Biomaterial and Method	1835948	Utility	GERMANY	2025
An Implant Biomaterial and Method	1835948	Utility	FRANCE	2025
An Implant Biomaterial and Method	1835948	Utility	UK	2025
An Implant Biomaterial and Method	1835948	Utility	IRELAND	2025
An Implant Biomaterial and Method	5208513	Utility	JAPAN	2025
An Implant Biomaterial and Method	300805	Utility	MEXICO	2025
An Implant Biomaterial and Method	1835948	Utility	NETHERLANDS	2025
Calcification Resistant Biomaterial Produced by Treating with an Alcohol Prior to Cross-linking	2591882	Utility	CANADA	2025
Replacement Heart Valve with Reduced Suturing	11648107	Utility	USA	2038
Replacement Heart Valve with Reduced Suturing	18/130,676	Utility	USA	To be determined.
Replacement Heart Valve with Reduced Suturing	2018353854	Utility	AUSTRALIA	2038
Replacement Heart Valve with Reduced Suturing	2023210649	Utility	AUSTRALIA	To be determined.
Replacement Heart Valve with Reduced Suturing	BR112020007850-6	Utility	BRAZIL	To be determined.
Replacement Heart Valve with Reduced Suturing	201880076903.4	Utility	CHINA	To be determined.
Replacement Heart Valve with Reduced Suturing	202310418412.6	Utility	CHINA	To be determined.
Replacement Heart Valve with Reduced Suturing	18779534.9	Utility	EPO	To be determined.
Replacement Heart Valve with Reduced Suturing	23168310.3	Utility	EPO	To be determined.
Replacement Heart Valve with Reduced Suturing	62020018549.9	Utility	HONG KONG	To be determined.
Replacement Heart Valve with Reduced Suturing	42024087452.9	Utility	HONG KONG	To be determined.
Replacement Heart Valve with Reduced Suturing	274054	Utility	ISRAEL	To be determined.
Replacement Heart Valve with Reduced Suturing	531059	Utility	INDIA	2038
Replacement Heart Valve with Reduced Suturing	7393005	Utility	JAPAN	2038

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Replacement Heart Valve with Reduced Suturing	2023-086917	Utility	JAPAN	To be determined.
Replacement Heart Valve with Reduced Suturing	10-2609690	Utility	SOUTH KOREA	2038
Replacement Heart Valve with Reduced Suturing	412797	Utility	MEXICO	To be determined.
Heart Valve with Gathered Sealing Region	11925549	Utility	USA	2039
Heart Valve with Gathered Sealing Region	2019269738	Utility	AUSTRALIA	To be determined.
Heart Valve with Gathered Sealing Region	19802943.1	Utility	EPO	To be determined.
Replacement Heart Valve Assembly with a Valve Loaded Distally from a Stent	11678982	Utility	USA	2039
Replacement Heart Valve Assembly with a Valve Loaded Distally from a Stent	2019269741	Utility	AUSTRALIA	2039
Replacement Heart Valve Assembly with a Valve Loaded Distally from a Stent	19803212.0	Utility	EPO	To be determined.
Inverted Heart Valve for Transcatheter Valve Replacement	11666439	Utility	USA	2040
Inverted Heart Valve for Transcatheter Valve Replacement	2019269740	Utility	AUSTRALIA	2039
Inverted Heart Valve for Transcatheter Valve Replacement	19804425.7	Utility	EPO	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	11877927	Utility	USA	2041
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	18/014,886	Utility	USA	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	2021303413	Utility	AUSTRALIA	2041
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	2023216763	Utility	AUSTRALIA	2041
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	BR112023000271-0	Utility	BRAZIL	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	3184933	Utility	CANADA	To be determined.

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	202180048307.7	Utility	CHINA	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	21836892.6	Utility	EPO	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	62023077198.7	Utility	HONG KONG	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	299561	Utility	ISRAEL	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	202347007545	Utility	INDIA	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	10-2023-7004190	Utility	SOUTH KOREA	To be determined.
Expandable Frame for Improved Hemodynamic Performance of Transcatheter Replacement Heart Valve	MX/a/2023/000407	Utility	MEXICO	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	18/014,888	Utility	USA	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	2021305174	Utility	AUSTRALIA	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	BR112023000299-0	Utility	BRAZIL	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	3184935	Utility	CANADA	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	202180048354.1	Utility	CHINA	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	21838933.6	Utility	EPO	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	299562	Utility	ISRAEL	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	202347007482	Utility	INDIA	To be determined.

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	10-2023-7004191	Utility	SOUTH KOREA	To be determined.
Exteriorly Mounted Tissue on Expandable Frame for Improved Hemodynamic Performance	MX/a/2023/000428	Utility	MEXICO	To be determined.
Replacement Heart Valve for Transcatheter Repair of Native Valve	2023-501161	Utility	JAPAN	To be determined.
Replacement Heart Valve for Transcatheter Repair of Native Valve	2023-501162	Utility	JAPAN	To be determined.

In the category of delivery systems for the prosthetic heart valve devices, we are the sole owner of one active U.S. patent, six pending U.S. patent applications, one pending Australian patent application, three pending PCT applications, and three pending applications in other countries. These patents and pending applications are directed to features that are expected to provide competitive advantages such as: controllable and predictable commissural alignment; a balloon folding technique that mitigates valve rotations during expansion; a single-use valve crimping device; and a delivery catheter hard stop member made of a braided metal material that provides improved trackability, effective expansion of the delivery sheath during advancement, and increased longitudinal compressive strength that serves to maintain the longitudinal position of the prosthetic heart valve on the balloon member.

The below table summarizes our patents and patent applications for delivery systems:

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Systems and Methods for Predictable Commissural Alignment of a Replacement Heart Valve	11883286	Utility	USA	2042
Systems and Methods for Predictable Commissural Alignment of a Replacement Heart Valve	18/393,475	Utility	USA	To be determined.
Systems and Methods for Predictable Commissural Alignment of a Replacement Heart Valve	2022311775	Utility	AUSTRALIA	To be determined.
Systems and Methods for Predictable Commissural Alignment of a Replacement Heart Valve	3225731	Utility	CANADA	To be determined.
Systems and Methods for Predictable Commissural Alignment of a Replacement Heart Valve	22842742.3	Utility	EPO	To be determined.
Systems and Methods for Predictable Commissural Alignment of a Replacement Heart Valve	2024-501568	Utility	JAPAN	To be determined.
Medical Device Delivery System Handle	29/893,247	Design	USA	To be determined.
Medical Device Delivery Systems	63/554,666	Utility	USA	To be determined.
Medical Device Delivery Systems	18/669,999	Utility	USA	To be determined.
Medical Device Delivery Systems	PCT/US2024/030345	Utility	PCT	To be determined.
Commissural Alignment Balloon for Transcatheter Procedures	18/674,597	Utility	USA	To be determined.
Commissural Alignment Balloon for Transcatheter Procedures	PCT/US2024/031120	Utility	PCT	To be determined.
Prosthetic Valve Crimping Devices	18/901,345	Utility	USA	To be determined.
Prosthetic Valve Crimping Devices	PCT/US2024/049245	Utility	PCT	To be determined.

In the category of sterilization and storage of the prosthetic heart valve devices, we are the sole owner of two active U.S. patents, one active Australian patent, seven active patents in other countries, and one pending application in other countries. These patents and pending applications are directed to features that are expected to provide competitive advantages such as a novel process for sterilizing the valve made of collagen-containing implantable biomaterials and storage thereafter.

The below table summarizes our patents and patent applications for sterilization and storage:

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Sterilization Process	10758642	Utility	USA	2032
Sterilization Process	12048778	Utility	USA	2032
Sterilization Process	2012334826	Utility	AUSTRALIA	2032
Sterilization Process	201910022873.5	Utility	CHINA	To be determined.
Sterilization Process	5338815	Utility	INDIA	2032
Sterilization Process	6203738	Utility	JAPAN	2032
Sterilization Process	10-2149227	Utility	SOUTH KOREA	2032
Sterilization Process	400526	Utility	MEXICO	2032
Sterilization Process	MY-184479-A	Utility	MALAYSIA	2032
Method for Sterilizing and Storing a Biomaterial and Container	BR112014011089-1	Utility	BRAZIL	2032
Sterilization of Collagen-Containing Implantable Biomaterials	2855138	Utility	CANADA	2032

In the category of packaging, we are the sole owners of two active U.S. patents, one pending U.S. patent application, two active Australian patents, one pending PCT application, and five active patents in other countries. These patents and pending applications are directed to features that are expected to provide competitive advantages such as a packaging design that includes integrated components and mechanisms for preparing and mounting the valve on the delivery catheter system to make the clinician's valve preparation process more efficient and user-friendly.

The below table summarizes our patents and patent applications for packaging:

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Sterilized Packaging System for Catheter	10926058	Utility	USA	2038
Sterilized Packaging System for Catheter	11752297	Utility	USA	2038
Sterilized Packaging System for Catheter	2018304128	Utility	AUSTRALIA	2038
Sterilized Packaging System for Catheter	2021204333	Utility	AUSTRALIA	2038
Sterilized Packaging System for Catheter	BR112020001067-7	Utility	BRAZIL	2038
Sterilized Packaging System for Catheter	ZL201880056134.1	Utility	CHINA	2038
Sterilized Packaging System for Catheter	272082	Utility	ISRAEL	2038
Sterilized Packaging System for Catheter	7048118	Utility	JAPAN	2038

Title	Patent or Appln. No.	Patent Type	Jurisdiction	Expiry Year
Sterilized Packaging System for Catheter	102351567	Utility	SOUTH KOREA	2038
Medical Device Packaging Systems	18/669,086	Utility	USA	To be determined.
Medical Device Packaging Systems	PCT/US2024/030253	Utility	PCT	To be determined.

We have trademark registrations for several of our most material marks, including “ADAPT,” “ADAPT FOR LIFE”, “ANTERIS”, “ComASUR”, “DurAVR”, and “GYNECEL”. Our filing for the “ANTERIS” mark in India is pending. Our trademarks were obtained between 2006 and 2024. Nearly all of our United States trademarks are federal trademarks.

We operate in an industry characterized by extensive patent litigation. Patent litigation may result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products.

We undertake reasonable measures to protect our patent rights, including monitoring the products of our competitors for possible infringement of our patents. Protecting our intellectual property rights is important to us, and we plan to continue to maintain and defend our rights regarding our intellectual property. Additionally, we are a party to license agreements with various third parties pursuant to which we have obtained, for varying terms, the exclusive or non-exclusive rights to certain patents held by such third parties in consideration for cross-licensing rights and/or royalty payments. We have also licensed certain patent rights to others.

Manufacturing and Supply

R&D Overview

The market in which we participate is subject to rapid technological advances and innovations. We believe that constant improvement of existing products and introduction of new products is necessary to maintain positioning within the market. We remain committed to developing technological enhancements and new indications for existing products, and less invasive and new technologies to address unmet patient needs.

We utilize our extensive R&D capabilities to create pioneering therapeutics and technologies for innovative medical device solutions. Our R&D efforts primarily concentrate on advancing our core DurAVR® THV system technology and exploring additional applications for the heart. This system includes DurAVR® THV, the ComASUR® delivery system, a disposable crimper, and an expandable access sheath. In the year ended December 31, 2023 and the nine months ended September 30, 2024, our expenditures were $30.1 million and $36.2 million, respectively. We do not consider these components to be separate projects and do not maintain and evaluate R&D costs by project. In addition, in the year ended December 31, 2023 and the nine months ended September 30, 2024, we invested $0.8 million and $1.9 million, respectively, in R&D expenditures related to v2vmedtech. This investment reinforces our dedication to innovation and our efforts to bring about significant advancements in healthcare. To date, we have not engaged in significant customer or government-sponsored research.

Third-Party Manufacturers

Our product development relies on third-party manufacturers. This reliance may lead to various types of operational risks. A limited number of manufacturers follow the FDA’s and European Union’s cGMP regulations. Failure of our third-party manufacturers in following the cGMP or other regulatory requirements may result in delays in the availability of products for commercial use or clinical study.

Government Regulation

U.S. FDA Regulation of Medical Devices

Our products are regulated as medical devices in the United States. Accordingly, our products and operations are subject to extensive and ongoing regulation by the FDA under the FDCA, as well as under

other federal, state and local regulatory authorities in the United States, and under foreign regulatory authorities for medical devices. For devices intended for commercial distribution in the United States, the FDA regulates product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance to assure their safety and effectiveness for their intended uses.

Unless an exemption applies, each new medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting a Section 510(k) clearance, de novo classification, or Pre-Market Approval application. Additionally, each significant modification to a 510(k)-cleared or de novo classified device will require a new submission prior to marketing, and each modification that affects the safety and effectiveness of a device with an approved Pre-Market Approval application will require a new Pre-Market Approval application or supplement. The 510(k) clearance, de novo classification and Pre-Market Approval processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees unless a waiver or exemption is available.

FDA classifies medical devices into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of FDA's current good manufacturing practices for devices, as reflected in the Quality System Regulation ("QSR"), establishment registration and device listing, reporting of adverse events and malfunctions, reporting of corrections and removals, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I devices are exempt from the premarket notification requirements.

Class II devices are those that are subject to the FDA's general controls and any other special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, product-specific FDA guidance documents, special labeling requirements and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA through the 510(k) premarket notification process, although some Class II devices are exempt from such requirement.

Under the 510(k) premarket notification process, a medical device manufacturer provides the FDA with a premarket notification that it intends to begin commercializing a product and demonstrates to the FDA that the product is substantially equivalent to another legally marketed predicate device. To be found substantially equivalent to a predicate device, the device must be for the same intended use and have either the same technological characteristics as the predicate or different technological characteristics that do not raise different questions of safety or effectiveness. In some cases, the submission must include data from clinical studies in order to demonstrate substantial equivalence to a predicate device. Commercialization may commence when the FDA issues a clearance letter finding such substantial equivalence.

Class III devices include devices deemed by the FDA to pose the greatest risk. Class III devices include those devices that (i) cannot be classified into Class I or Class II because insufficient information exists to determine that general and special controls would provide a reasonable assurance of safety and effectiveness, and (ii) are intended for uses that are life-supporting, life-sustaining, of substantial importance in preventing impairment in human health, or present a potential unreasonable risk of illness or injury.

Additionally, novel devices that lack a predicate device to which they can demonstrate substantial equivalence via the 510(k) premarket notification process are automatically classified into Class III, unless the manufacturer can demonstrate that the device should be classified into Class I or II via the de novo classification process, discussed below. Devices placed in Class III require approval of a Pre-Market Approval application, which contains valid scientific evidence demonstrating a reasonable assurance of the safety and effectiveness of the device for its intended use. The Pre-Market Approval process is generally more costly and time consuming than the 510(k) premarket notification process or the de novo classification

process. A Pre-Market Approval application typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information, labeling, and financial disclosure information for the clinical investigators in device studies.

Under the FDCA, medical devices such as the DurAVR® THV system are regulated by the FDA Center for Devices and Radiological Health ("CDRH"). Accordingly, CDRH reviews 510(k)s, de novo requests, and PMAs for clearance or approval.

CardioCel™, VascuCel™ and ADAPT® are pericardial tissue products and are Class II medical devices. CardioCel™ was cleared for marketing by the FDA on January 30, 2014 as a Class II device. A modified version of CardioCel™ was cleared for marketing by the FDA on April 28, 2017. VascuCel™ (another modified version of CardioCel™) was cleared for marketing by the FDA on October 14, 2016. ADAPT® tissue was cleared for marketing by the FDA on April 3, 2020.

Replacement heart valves, including the DurAVR® THV, are Class III medical devices. Additionally, because the ComASUR® delivery system is required for use of the DurAVR® THV, the ComASUR® delivery system will be regulated as a component of the DurAVR® THV Class III device (as part of the overall system). Accordingly, the ComASUR® delivery system will be reviewed under any PMA submitted for the DurAVR® THV.

As noted above, if a novel device lacks a predicate device to which it can demonstrate substantial equivalence via that 510(k) process, it is automatically classified into Class III, which means it requires a Pre-Market Approval application. However, under the de novo classification process, a manufacturer that believes its novel device is actually low- to moderate-risk can request the classification of the novel device into Class I or Class II. To obtain de novo classification, the manufacturer must demonstrate that when general controls, or general controls and special controls, are applied, the probable benefits to health from using the device outweigh probable risks of such use, and that a significant portion of the target population will have clinically significant results from use of the device. If a device is de novo classified into Class I or Class II, it becomes a legally marketed predicate device to which future devices can claim substantial equivalence by submitting a 510(k). The de novo classification process is generally more costly and time consuming than the 510(k) premarket notification process but can be less costly and time consuming than the Pre-Market Approval process. A de novo classification request typically includes information similar to that required in a Pre-Market Approval application, plus a recommendation for the proposed classification (Class I or Class II) and, if the device is proposed to be classified into Class II, any proposed special controls.

Obtaining FDA marketing clearance or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data. Our DurAVR® THV system is classified as a Class III device for which we expect to submit a Pre-Market Approval application upon completion of the currently contemplated pivotal clinical trial.

Investigational Device Exemption ("IDE") Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require IDE approval. An IDE authorizes distribution of devices that lack Pre-Market Approval, de novo classification or 510(k) clearance for clinical evaluation purposes. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE if certain requirements are satisfied, including but not limited to obtaining IRB approval for the study, obtaining informed consent from study subjects, and complying with certain recordkeeping and reporting requirements. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal, biocompatibilty and laboratory testing results, showing that it is safe to test the device in humans and that the clinical test protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of test subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA, the study protocol and informed consent documents are approved by appropriate IRBs at the clinical trial sites, and informed consent from study subjects has been obtained. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and

although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

All non-exempt clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA and other applicable authorities.

The results of clinical trials may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a Pre-Market Approval application, for numerous reasons, including the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- device malfunctions occur in unexpected ways, with unexpected frequency, or with potential adverse consequences;
- side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar Pre-Market Approvals or clearance of new or similar 510(k)s or de novo classification requests, or result in the imposition of new requirements or testing;
- IRBs and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- the FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

As discussed above under "*Clinical Results and Studies — Early Feasibility Study*," the FDA approved our commencement of the EFS IDE study for our DurAVR® THV system pursuant to an IDE application.

The Pre-Market Approval Process

Following receipt of a Pre-Market Approval application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the Pre-Market Approval application. If it is sufficiently complete, the FDA will accept the application for filing and begin the substantive review. The FDA, by statute and by regulation, has 180 days to review a filed Pre-Market Approval application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies within the submission communicated by the FDA. The issuance of a deficiency letter automatically stops the FDA 180-day review clock. The FDA considers a Pre-Market Approval or Pre-Market Approval supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a Pre-Market Approval application, an FDA advisory committee may review the Pre-Market Approval application at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a Pre-Market Approval application, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes for the device. Overall, the FDA review of a Pre-Market Approval application generally takes between one and two years but may take significantly longer. The FDA can delay, limit or deny approval of a Pre-Market Approval application for many reasons, including:

- the device may not be shown to be safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements;
- the proposed labeling is found to be false or misleading;
- the device is not shown to conform to a required performance standard; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a Pre-Market Approval application is favorable, the FDA will issue either an approval letter or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the Pre-Market Approval application. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a Pre-Market Approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a Pre-Market Approval application or manufacturing facilities is not favorable, then the FDA will deny the Pre-Market Approval application or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the Pre-Market Approval application may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the Pre-Market Approval application, or the Pre-Market Approval application is withdrawn and resubmitted when the data are available. The Pre-Market Approval process can be expensive, uncertain and lengthy, and a number of devices for which the FDA Pre-Market Approval has been sought by other companies have never been approved by the FDA for marketing.

New Pre-Market Approval applications or Pre-Market Approval supplements generally are required for modifications to an approved device that could affect the safety or effectiveness of an approved device, including modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of the device that has been approved through the Pre-Market Approval process. Pre-Market Approval supplements often require submission of the same type of information as an initial Pre-Market Approval application, except that the supplement is limited to information needed to support any changes from the device covered

by the approved Pre-Market Approval application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a Pre-Market Approval application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance. The applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification or de novo classification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a Pre-Market Approval application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. Modifications to the manufacturing process, labeling and design for a device which has received approval through the Pre-Market Approval process generally require submission of a new Pre-Market Approval application or Pre-Market Approval supplement prior to marketing.

Ongoing Regulation by the FDA

Even after the FDA permits a device to be marketed, numerous regulatory requirements apply, including:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation, and other quality assurance procedures during the manufacturing process;
- labeling regulations, advertising and promotion requirements, restrictions on sale, distribution or use of a device, each including the FDA general prohibition against the promotion of products for any uses other than those cleared or approved by the FDA, which are commonly known as “off label” uses;
- medical device reporting regulations requiring that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- any order from FDA to repair, replace or refund a device;
- product export requirements;
- device tracking requirements; and
- post-market study and surveillance requirements.

If a device receives 510(k) clearance or de novo classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or possibly a Pre-Market Approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with the manufacturer’s determination not to seek a new 510(k) clearance, the FDA may retroactively require the manufacturer to seek 510(k) clearance or possibly a Pre-Market Approval. The FDA could also require us to cease marketing and distribution and/or to recall the modified device until 510(k) clearance or a Pre-Market Approval is obtained. Also, in these circumstances, we may be subject to more significant actions, including regulatory fines and penalties.

Some changes to an approved Pre-Market Approval device, including changes in indications, labeling, or manufacturing processes or facilities, among others, generally require submission and FDA approval of a

new Pre-Market Approval application or Pre-Market Approval supplement, as appropriate, before the change can be implemented. Supplements to a Pre-Market Approval application often require the submission of the same type of information required for an original Pre-Market Approval application, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original Pre-Market Approval. The FDA generally uses the same procedures and actions in reviewing Pre-Market Approval supplements as it does in reviewing original Pre-Market Approval applications, although some Pre-Market Approval supplements may be approved more quickly, such as supplements describing certain modifications in the manufacturing process that do not affect the specifications of the device.

FDA regulations require us to register as a medical device manufacturer with the FDA. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. Furthermore, the FDA requires us to comply with various FDA regulations regarding labeling. Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA or other regulatory authorities. When the FDA conducts an inspection, the investigators will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or Form FDA 483. If we receive a notice of inspectional observations or deficiencies from the FDA following an inspection, we would be required to respond in writing, and would be required to undertake corrective and/or preventive or other actions in order to address the FDA's or other regulators' concerns. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions described below.

Additionally, some states have enacted laws and regulations governing the manufacture, sale, marketing or distribution of medical devices. These laws and regulations may also require medical device manufacturers and/or distributors doing business within multiple states to register or apply for state licenses. These laws and regulations could also subject our facility to state inspection on a routine basis for compliance with any applicable state requirements.

Failure by us or by our suppliers to comply with applicable federal or state regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures, including for repairs, replacements, or refunds of devices;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in reviewing, or refusal to clear or approve, submissions or applications for new products or modifications to existing products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA approvals or clearances that have already been granted; and
- criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation or regulations, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA or other regulatory authorities.

Regulation of Medical Devices Outside the United States

Outside of the United States, the regulation of medical devices is also complex. In Europe, for instance, products are subject to extensive regulatory requirements. In 2021, a new regulatory scheme for medical

devices, the MDR, became effective in EU member states. The MDR requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained, and used in accordance with their intended purpose. The MDR has significant requirements for many medical devices, including requirements for clinical evidence and documentation, device identification and traceability, registration of economic operators throughout the distribution chain and post-market surveillance. In some regions, the level of government regulation of medical devices is increasing, which can lengthen time to market and increase registration and approval costs. In many countries, the national health or social security organizations require products to be qualified before they can be marketed and considered eligible for reimbursement.

In many instances, global regulatory agencies have come together in an attempt to harmonize medical device regulatory requirements. In 2011, the regulatory agencies of the United States, Canada, Brazil, Australia and Japan came together and established the International Medical Device Regulators Forum (the "IMDRF"). The IMDRF continues to grow and now has a management committee of regulatory agency representatives from 11 countries and affiliate members representing seven countries. One example of the IMDRF harmonizing medical device regulatory requirements is the Medical Device Single Audit Program, whereby a medical device manufacturer can have a single Quality Management System audit of their facility which covers the regulatory requirements of Australia, Brazil, Canada, Japan and the United States. Instead of having periodic quality inspections from regulators of each of these countries, a single comprehensive inspection is performed.

Other regional groups working to harmonize regulatory requirements are the Asia-Pacific Economic Cooperation group, Global Harmonization Working Party and African Medical Devices Forum. While regulatory requirements are constantly evolving, regulatory agencies recognize the impact and are attempting to harmonize their efforts.

While the list of regulated countries continues to grow, many of the regulated countries leverage device approvals from the US or Europe, meaning that the testing and clinical studies required to satisfy device safety and efficacy requirements of the US and Europe, often carry over to other geographies.

Other U.S. Regulatory Matters

Medical device companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Manufacturing, sales, promotion, third-party payor reimbursement and other activities following product clearance or approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the CMS, other divisions of the Department of Health and Human Services ("DHHS"), the Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. For example, in the United States, sales, marketing, participation in government health care programs or contracts with third-party payors, and scientific and educational programs also must comply with state and federal fraud and abuse, anti-kickback, false claims, transparency, government price reporting, anti-corruption, and health information privacy and security laws and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services. These laws include the following:

- U.S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The federal Anti-Kickback Statute (the "Anti-Kickback Statute") is particularly relevant because of its broad applicability. The Anti-Kickback Statute makes it illegal for any person, including a prescription medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular medical device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Almost any financial arrangement with a healthcare provider, patient or customer could implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain arrangements if specific requirements are met.

- Another fraud and abuse law that may be implicated by ownership and compensation arrangements with health care professionals or their families is the Physician Self-Referral Law, commonly referred to as the "Stark Law". The Stark Law prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. While the Stark Law generally only provides to those entities that provide "designated health services" and submit claims for such services, it may nonetheless be implicated by certain ownership or compensation arrangements with health care professionals or family members. Individual states have corollaries to the federal Stark law that may also apply and may be more expansive or impose additional requirements.
- Another development affecting the medical technology industry is the increased use of the federal Civil False Claims Act (the "False Claims Act") and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. In recent years, the number of suits brought against healthcare companies by private individuals has increased dramatically. The federal civil and criminal false claims acts prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Additionally, some states have insurance fraud provisions that apply to commercial payors or all payors under insurance laws that have similar whistleblower or relator provisions (e.g., Insurance Fraud Prevention Act for California).
- The Civil Monetary Penalty Act of 1981 ("CMP") allows the DHHS Office of Inspector General to seek civil monetary penalties and sometimes exclusion from participation in the government health care programs for a wide variety of conduct. For example, the CMP and implementing regulations impose penalties against any person or entity that is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Other conduct that may result in violation of the CMP is offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.
- The Health Insurance Portability and Accountability Act ("HIPAA") prohibits executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. While HIPAA applies only to covered entities, which generally does not include device manufacturers, HIPAA and HITECH impose those same obligations to business associates under contractual terms. HIPAA may also still apply directly to the manufacturer depending on the scope and nature of data sharing arrangement or other contracting arrangements. In addition to HIPAA and its accompanying regulations, device manufacturers may be subject to additional state consumer and privacy laws which may be more expansive or restrictive on the use and protection of patient and consumer data.
- The FDCA prohibits the adulteration or misbranding of medical devices. Medical device manufacturers may also be subject to state corollaries to the FDCA.
- The federal Physician Payment Sunshine Act and its implementing regulations, which require applicable manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS and DHHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any

foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

- Analogous state and foreign laws and regulations, such as state anti-kickback, anti-referral, and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require certain medical device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require applicable manufacturers to disclose or report certain information related to payments and other transfers of value to health care professionals and entities or sales, marketing, pricing, clinical trials, marketing expenditures and activities, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

U.S. Health Care Reform

Changes in healthcare policy in the United States could increase our costs and subject us to additional regulatory requirements that may interrupt the development and the commercialization of our current and future products. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage for the procedures associated with the use of our products impose stringent requirements for pre-approval and reimbursement or result in lower reimbursement for those procedures. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products or from reimbursement received from the use of our products. Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement and coverage for our current and future products.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to disclose and/or reduce health care costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Federal and state regulators are also prioritizing costs and charge transparency initiatives, including rebate programs, that may impact our ability to charge and collect payment for our products or charging and collection activities for services that use our products. Other initiatives currently on the healthcare reform agenda include value-based care initiatives, which will impact medical device sales and contracting models, and therefore, product pricing. However, such health policy priorities are consistently evolving and subject to change under shifting political conditions and leadership. As such, depending on policy priorities, current and future health care reform legislation and policies could have a material adverse effect on our business and financial condition given the potential impact to the availability and demand for our products. Notably, we will be impacted by the reimbursement coverage eligibility and rate schedules set by CMS for both our products and for services and procedures involving our products. For example, on June 21, 2019, CMS issued a National Coverage Determination for Transcatheter Aortic Valve Replacement which informed Medicare Administrative Contractors of coverage requirements for the procedure. Current coverage and reimbursement levels are subject to ongoing analysis and could change, thus having an adverse effect on market demand and our pricing flexibility.

Data Privacy & Security Laws

Numerous state, federal and foreign laws govern health privacy, consumer protection, and other use of individually identifiable information. This includes the collection, dissemination, use, access to, confidentiality and security of personal information and health-related information. In the United States, numerous

federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. Notably, the Office for Civil Rights at DHHS has expanded the application of HIPAA to regulated entities' use of tracking technologies that collect and analyze information about how users interact with regulated entities' websites or mobile applications. In addition, certain state and non-U.S. laws and regulations, such as the California Consumer Privacy Act, the California Privacy Rights Act and the EU General Data Protection Regulation, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws or regulations, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Human Capital

Overview

As of October 31, 2024, we had approximately 138 full time equivalent employees. We have never experienced a work stoppage or interruption due to labor disputes. We believe our relations with our employees are good.

Employee Talent and Retention

Our business and future operating results depend in significant part upon the continued contributions of our key personnel, including qualified personnel with medical device and tissue processing experience, and senior management with experience in the medical device or tissue processing space, many of whom would be difficult to replace. Our business and future operating results depend in significant part on our ability to attract and retain qualified management, operations, processing, marketing, sales, and support personnel for our operations.

We have programs and processes in place to help ensure that our compensation, benefits programs, and work environment attract and retain such personnel, and we strive to enhance those programs and processes to respond to the increasingly competitive market for talent. We also strive to offer competitive equitable pay, comprehensive benefits, and services that retain and meet the varying needs of our employees. The principal purposes of our equity and cash incentive plans and non-officer incentive plans are to attract, retain, motivate, and reward our employees.

Culture

Fostering and maintaining a strong and collaborative culture is a key strategic focus. We also have ethics and compliance policies that are designed to instill a commitment to ethical behavior and legal compliance across our company. Employees are encouraged to approach their supervisors if they believe violations of policies have occurred. Employees are also able to confidentially and anonymously report any such violations through an online form. Furthermore, the company has a whistleblower policy whereby employees are able to submit an anonymous disclosure either by email or web form.

We aim to hire based on our AORTIC (Accountability, Objectivity, Respect, Teamwork, Integrity, Courage) values and continuously build our culture around those values. Employees are encouraged to present culture building activities that promote collaboration and inclusivity.

Diversity and Inclusion

We believe that a culture of diversity and inclusion enables us to create, develop, and fully leverage the strengths of our workforce to achieve our business objectives. As of October 31, 2024, approximately 52% of our global employees identify as female. We strive to provide equal opportunity to all applicants and

employees, including those from diverse backgrounds. We believe that bringing together different perspectives and experiences is fundamental to innovation.

Training and Development

We are committed to the learning and development of all global team members by offering training programs. The goals of the training programs are to highlight and boost our company culture, empower employees to add knowledge and skills, increase their job satisfaction and increase team productivity with behaviors that help us succeed on our mission together. Such programs include educational workshops, department-led knowledge-based training (i.e., quality systems, safety, simulation demonstrations), leadership development cohorts, AORTIC values skill building, and new hire onboarding.

Health and Safety

We are committed to providing a safe working environment compliant with all relevant and applicable laws. We maintain our commitment to a safe working environment by routinely conducting assessments of the workplace in order to detect, assess and respond to identified hazards or risks; giving preference to removing any hazards or risks in order to prevent injury, illness or incidents from occurring; and striving to reduce the likelihood of the risk or hazard occurring and its severity, where we are unable to eliminate the risk entirely. We have processes to report all work-related injuries, illness and near-misses to management.

Responsibilities of employees and managers are to create and maintain a safe working environment by reporting any unsafe conditions or potential hazards immediately for assessment and remediation; following all safe work method statements, safe travel practices, procedures, instructions, rules legislation and laws relating to workplace health and safety; treating all breaches of workplace health and safety standards seriously and taking appropriate action; and providing adequate information, instruction, training and supervision to enable our employees to perform their roles effectively and safely.

Employee Engagement

We solicit anonymous employee feedback to assess employee satisfaction and engagement and to identify opportunities for development through a third-party provider. Employee feedback is also gathered through surveys, the employee review process, pulse surveys, and exit interviews.

Corporate History

ATL is an Australian public company originally registered in Western Australia, Australia that was incorporated in 1999. ATL's ordinary shares were admitted for official quotation on the ASX on March 24, 2004.

The Company was incorporated in the State of Delaware on January 29, 2024 for the purposes of effecting the Reorganization. The Company is a global company with its principal executive offices located at Toowong Tower, Level 3, Suite 302, 9 Sherwood Road, Toowong, QLD 4066, Australia, and other key locations located at 860 Blue Gentian Road, Suite 340, Eagan, Minnesota 55121 as well as two other sites in Minnesota and sites in Western Australia, Australia and Geneva, Switzerland. The Company's telephone number is +61 7 3152 3200. Additional information can be found on our website address: *www.anteristech.com*. Information contained on, or that is accessible through, the website does not constitute part of this prospectus and we do not incorporate any such information into this prospectus. The Company has included its website address in this prospectus solely as an inactive textual reference.

Prior to completion of this offering, the Company will receive all of the issued and outstanding shares of ATL pursuant to the Scheme. Contemporaneously with implementation of the Scheme, ATL will also cancel all existing options it has on issue in exchange for the Company issuing replacement options to acquire Common Stock pursuant to the Option Scheme. The Scheme was approved by ATL's shareholders at a general meeting of shareholders, which was held on December 3, 2024. The Option Scheme was approved by ATL's optionholders at a general meeting of optionholders held on the same day. ATL obtained approval of the Scheme and the Option Scheme by the Supreme Court of Queensland on December 4, 2024. All conditions precedent to the Scheme and Option Scheme, other than the closing of this offering, have been satisfied.

Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." We expect that the Company's CDIs will commence trading on an ordinary settlement basis on the ASX one trading day following the closing of this offering under the symbol "AVR." Concurrent with the closing of this offering, ATL will de-list its securities from the ASX.

Pursuant to the Reorganization, the Company will issue to the shareholders of ATL either one share Common Stock for every ordinary share of ATL or one CDI for every one ordinary share of ATL, in each case, as held on the Scheme record date. Eligible shareholders of ATL (being those whose residence at the record date of the Scheme is in Australia, New Zealand, Hong Kong, Singapore, Israel, Belgium, Canada, Denmark, Germany, Ireland, the Netherlands, Sweden, Switzerland or the United States) will receive CDIs by default. In order to receive Common Stock, eligible shareholders were required to complete and submit an election form to ATL's registry no later than 5:00 pm (AEDT) on December 5, 2024. Ineligible shareholders will not receive CDIs or shares of Common Stock but will instead receive the proceeds from the sale of the CDIs to which they would otherwise be entitled by a broker appointed by ATL. Small Shareholders will have the CDIs to which they would otherwise be entitled under the Scheme instead issued to, and sold by, a broker appointed by ATL, with the net proceeds from the sale remitted to the relevant ATL shareholder, unless the Small Shareholder notified ATL's registry that they wished to receive CDIs or Common Stock by no later than 5:00 pm (AEDT) on December 5, 2024. The appointed broker will sell the CDIs in accordance with the terms of a sale facility agreement and will remit the proceeds to ineligible shareholders and Small Shareholders (other than those Small Shareholders who opt out). Additionally, pursuant to the Option Scheme, each outstanding option to acquire ordinary shares of ATL will be cancelled, and the Company will issue replacement options representing the right to acquire shares of Common Stock on the basis of one replacement option for every one existing ATL option held.

Following completion of the Reorganization, ATL's ordinary shares will be de-listed from the ASX and ATL will become a wholly-owned subsidiary of the Company.

Facilities

The locations and uses of our material properties are as follows:

Location of Facility	Lease expiry date
11600-11628 96th Avenue North, Maple Grove, MN 55369[(1)]	December 31, 2025
26 Harris Road, Malaga WA 6090, Australia	July 31, 2026[(2)]

(1) Predominantly used for research and development, manufacturing of the DurAVR® valve and regulatory compliance teams.

(2) The Company has the right to extend to July 31, 2031.

All properties are leased or subleased. Our properties are well maintained, are in good operating condition, and are suitable for current requirements. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

Legal Proceedings

In the ordinary course of our operations, and from time-to-time, we are party to various claims and lawsuits. Currently, we are not party to any material legal proceedings, and no such proceedings are, to management's knowledge, threatened against us.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") summarizes the significant factors affecting the operating results, financial condition and liquidity, and cash flows of our company for the nine months ended September 30, 2024 and 2023 and the years ended December 31, 2023 and 2022. The discussion is based on the historical financial statements of ATL. The Company was incorporated under the laws of the state of Delaware to become the holding company of our business pursuant to the Reorganization. Prior to completion of the Reorganization, the Company will have had no business or operations and, following completion of the Reorganization, the business and operations of the Company will consist solely of the business and operations of ATL and its subsidiaries. Accordingly, financial information for the Company and a discussion and analysis of its results of operations and financial condition for the period of its operation prior to the Reorganization would not be meaningful and is not presented, and references to the "Company," "we," "us," and "our" are references to ATL, its wholly-owned subsidiaries, and entities for which ATL has a controlling financial interest, unless otherwise specified. Following the Reorganization, the historical financial statements of ATL will be our financial statements as a continuation of the predecessor, and our future financial statements will consolidate ATL as an operating subsidiary. This MD&A should be read in conjunction with ATL's consolidated financial statements, the accompanying notes to consolidated financial statements and other financial information included in this prospectus. Except for historical information, the matters discussed in this MD&A contain various forward-looking statements that involve risks and uncertainties and are based upon judgments concerning various factors beyond our control. Our actual results could differ materially from those anticipated in these forward-looking statements. You should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section of this prospectus titled "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a structural heart company committed to discovering, developing and commercializing innovative medical devices designed to improve the quality of life for patients with aortic stenosis. Our lead product, the DurAVR® THV system, represents a unique product opportunity in a new THV class of single-piece heart valves, for the treatment of aortic stenosis. Our DurAVR® THV system consists of a single-piece, biomimetic valve made with our proprietary ADAPT® tissue-enhancing technology and deployed with our ComASUR® balloon-expandable delivery system. ADAPT® is our proprietary anti-calcification tissue shaping technology that is designed to reengineer xenograft tissue into a pure, single-piece collagen bioscaffold. Our proprietary ADAPT® tissue has been clinically demonstrated to be calcium free for up to 10 years post-procedure, according to *Performance of the ADAPT-Treated CardioCel® Scaffold in Pediatric Patients With Congenital Cardiac Anomalies: Medium to Long-Term Outcomes*, published by William Neethling et. al., and has been distributed for use in over 55,000 patients globally in other indications. Our ComASUR® balloon-expandable delivery system, which was developed in consultation with physicians, is designed to provide precise alignment with the heart's native commissures to achieve accurate placement of the DurAVR® THV system.

We clinically developed our DurAVR® THV system over several years with significant physician input with the goal of addressing hemodynamic limitations of the current standard-of-care products. To date, a total of 73 patients have been treated with the DurAVR® THV system across the United States, Canada and Europe. In November 2021, we commenced our FIH study at the Tbilisi Heart and Vascular Clinic in Tbilisi, Georgia.

Aortic valve stenosis is one of the most common and serious valvular heart diseases. It is fatal in approximately 50% of patients if left untreated after two years, and no pharmacotherapy is available to treat this disease. Aortic stenosis causes a narrowing of the heart's aortic valve, which reduces or blocks the amount of blood flowing from the heart to the body's largest artery, the aorta, and from there to the rest of the body. Minimally-invasive TAVR, which the FDA initially approved in 2011 for high surgical risk patients, has emerged as an alternative to open-heart surgery. In 2019, the FDA also approved TAVR for use in low-risk surgical patients. These low-risk surgical patients are often younger persons within the geriatric

population that require heart valves with longer durability and pre-disease hemodynamics for an improved quality of life. More generally, patients with aortic valve stenosis are now being diagnosed at a younger age.

While previous generations of TAVRs were designed for older, high risk, less-active patients, our DurAVR® THV system is designed to be a solution for all patients, including both older, less-active patients and younger patients. DurAVR® THV is a single-piece valve with a novel biomimetic design that aims to replicate the normal blood flow of a healthy human aortic valve as compared to traditional three-piece aortic valves. In our FIH study, we have observed promising results in relation to hemodynamics, laminar flow and exercise capacity. In addition, our DurAVR® THV system has been developed with the aim to increase durability and last longer than traditional three-piece designs through the use of our ADAPT® anti-calcification tissue including a molded single piece of tissue designed to mimic the performance of a pre-disease human aortic valve, which we believe can result in improved hemodynamics as compared to traditional three-piece designs. These designs and features cumulatively aim to provide a better quality of life as compared to the current standard of care associated with traditional three-piece designs. We intend to test these features in the Pivotal Trial against commercially approved TAVR devices.

The design and scope of the Pivotal Trial will be finalized following completion of our submission to the FDA and receipt of feedback from the FDA. The purpose of the Pivotal Trial will be to demonstrate non-inferiority of the DurAVR® THV system compared with commercially available TAVR systems for treatment of subjects with severe calcific aortic stenosis. We anticipate that the design of the Pivotal Trial will be a prospective, randomized, controlled multicenter, international study wherein subjects will be randomized to receive either TAVR using the DurAVR® THV system or TAVR using any commercially available and approved THV from competitors. We anticipate that the subjects will include a broad array of risk profiles. We anticipate that subjects with a failed surgical bioprosthesis in need of a ViV TAVR will be enrolled in a separate parallel registry.

In November 2022, we received approval from the FDA to commence an EFS to treat 15 patients with severe aortic stenosis using the DurAVR® THV system in up to seven heart valve centers across the United States. Building on data obtained in the FIH study, this study has now completed enrollment of all patients. At the 30 days post-procedure, patients had a mean EOA of 2.2 cm^2, MPG of 7.5 mmHg and DVI of 0.64. No paravalvular leaks were observed; however, there was one subject with pre-existing significant conduction abnormalities who received a pacemaker. Furthermore, no mortality, disabling stroke, life-threatening bleeding, or reinterventions were reported at 30 days post-procedure.

In July 2023, our DurAVR® THV system was used for the first time in a ViV procedure, which was performed at the Institut de Cardiologie de Montréal in Canada under a SAP, which allows for the use of a non-commercial device for a specific patient where there is a clinical case that the approved device will not work. In August 2023, a second Canadian patient was successfully implanted with the DurAVR® THV system in a ViV procedure. As of July 2024, we have now treated six ViV patients in Canada with our DurAVR® THV system through the special access protocol and our system was also used in one ViViV patient in Europe. All patients to date have achieved better MPG than what was seen with their original replacement valve in this difficult to treat population.

In addition, the FDA determined on March 24, 2023 that approval of an IDE supplement is not required to manufacture the DurAVR® valve for investigational use in clinical trials at our facility in a suburb of Minneapolis, Minnesota. We are currently planning to submit an IDE for the DurAVR® THV system Pivotal Trial to the FDA by Q1 of 2025. If we obtain approval from the FDA, we intend to perform site activation and seek IRB approval for commencement of the study at each site. Subject to the foregoing, we anticipate enrollment to begin in the third quarter of 2025. Such a trial would be designed to provide the primary clinical evidence on which the FDA could base a decision for Pre-Market Approval that is required for commercialization of the DurAVR® THV system in the United States.

We are a development stage company and have incurred net losses in each year since inception, however, we believe that we have significant growth potential in a large, underpenetrated and growing market. Since the inception of the TAVR procedure, the annual volume of TAVR procedures in the United States has increased significantly year-over-year, with an estimated 73,000 patients having undergone a TAVR procedure in the United States in 2019 according to the TVT Registry. According to FMI, the total global market opportunity for TAVR in relation to severe aortic stenosis and in relation to ViV procedures is expected

to reach $9.9 billion and $2.5 billion, respectively, in 2028. The key specific markets that our Company is initially targeting are North America and Europe due to these markets accounting for the majority of the above global opportunity. FMI indicated that the North American and European markets averaged 53% and 38% of the global market share, respectively, during the period 2016 to 2023. FMI forecasts that the market opportunity in relation to severe aortic stenosis for North America and Europe to reach $5.5 billion and $3.7 billion, respectively, in 2028; and the market opportunity in relation to ViV procedures is forecast to reach $1.5 billion and $0.8 billion, respectively, in 2028. To calculate these future market values, FMI has relied on actual data from 2023 collated from a variety of published sources and key medical experts and applied a projected Compound Annual Growth Rate ("CAGR") of 14.9% for the global market, 16.2% for the North American market, and 14.0% for the European market. A non-exhaustive list of factors that may impact these forecast calculations include key players' historic growth; companies and manufacturers working together to develop new, affordable and timesaving technologies; new product launches and approvals; rising demand for THV replacement; availability and cost of products; growing investment in healthcare expenditure; and increased regulatory focus on patient safety and reimbursement policies. In addition, we expect the TAVR market to benefit from general trends, including an aging population, earlier diagnosis of aortic stenosis, increased incidence of obesity and diabetes (which contribute to heart disease), as well as the broader patient populations' desire to pursue a more active lifestyle.

Our innovation-focused R&D practice is driven by rapid technological advancement and significant input from leading interventional cardiologists and cardiac surgeons. As a company that is primarily in the development phase, we currently generate small amounts of revenue and income which are insufficient to cover our investment in research, development and operational activities resulting in recurring net operating losses, incurred since inception. We, like other development stage medical device companies, experience challenges in implementing our business strategy due to limited resources and a smaller capital base as we prioritize product development, minimize the period to the commencement of commercial sales, ensure our focus on quality as well as scale our operations. The development and commercialization of new medical devices is highly competitive. Those competitors may have substantial market share, substantially greater capital resources and established relationships with the structural heart community potentially creating barriers to adoption of our technology. Our success will partly be based on our ability to educate the market about the benefits of our disruptive technology including current unmet clinical needs compared to commercially available devices as well as how we plan to capture market share post commercialization.

From time to time, we enter into strategic agreements aimed at enhancing our business operations and profitability. For example, in April 2023, we invested in, and entered a development agreement with, v2vmedtech, which develops an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation.

ATL, which prior to the closing of this offering will become a wholly-owned subsidiary of the Company as a result of the Reorganization, is an Australian public company originally registered in Western Australia, Australia that was incorporated in June 1999. The Company was incorporated in the State of Delaware on January 29, 2024 for the purposes of effecting the Reorganization. The Company is a global company with its principal executive offices located at Toowong Tower, Level 3, Suite 302, 9 Sherwood Road, Toowong, QLD 4066, Australia, and other key locations located at 860 Blue Gentian Road, Suite 340, Eagan, Minnesota 55121 as well as two other sites in Minnesota and sites in Western Australia, Australia and Geneva, Switzerland. The Company's telephone number is +61 7 3152 3200. Additional information can be found on our website address: *www.anteristech.com*. Information contained on, or that is accessible through, the website does not constitute part of this prospectus and we do not incorporate any such information into this prospectus. The Company has included its website address in this prospectus solely as an inactive textual reference.

Financial Overview

As a development-stage company, we have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future and there can be no assurance that we will ever achieve or maintain profitability.

We expect expenses for our research, clinical validation, development, design, manufacturing and marketing will increase and, as a result, we will need additional capital to fund our operations. Any future

funding could involve a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Any failure to raise capital or enter into such other arrangements as and when needed could have a negative impact on our financial condition and our ability to market our products.

In an effort to preserve our liquidity while remaining positioned to capitalize on the substantial market opportunity which we believe exists for us in the TAVR market, we have implemented significant cost reduction initiatives across our operations effective from October 2024. This includes reducing the cost of materials that are integrated into our products, including packaging costs, the costs of our research and development activities and our selling, general and administrative costs (excluding the costs associated with the Reorganization and this offering). Furthermore, we have reviewed and reduced our projected headcount for future periods and included significant reductions in costs that we had previously projected for our upcoming trials, including manufacturing builds and patient enrollment costs. We believe that, as a result of these cost reduction initiatives, our operating expenses will be significantly reduced from those that we had previously anticipated for future periods.

Principles of Consolidation and Operating Segments

The consolidated financial statements include the accounts of ATL, its wholly-owned subsidiaries, and entities for which ATL has a controlling financial interest. Intercompany transactions, balances and unrealized gains and losses on transactions between such entities are eliminated.

Our management has determined that the activities of the business as reviewed by the Chief Executive Officer, the chief operating decision maker, are one segment, being the development and commercialization of the ADAPT® platform technology. This is focused on the DurAVR® THV system.

Components of Results of Operations

Revenue and Other Income

We currently derive revenue from the sale of DurAVR® THV regenerative tissue products unrelated to our principal business focus of developing and, if approved, commercializing the DurAVR® THV system. Such sales are made principally to 4C and to LeMaitre, a distributor of medical products, to whom we sold our CardioCel™ and VascuCel™ patch business in 2019 in order to focus on development of our proprietary ADAPT® tissue for the DurAVR® THV system. Under a distribution agreement, we manufacture and sell the CardioCel™ and VascuCel™ products to LeMaitre. Upon expiration of our Transition Services Agreement with LeMaitre in January 2025, we do not expect any future revenue from LeMaitre. In addition, if we do not renew our Supply and License Agreement with 4C, the initial term of which will end on June 1, 2025, we will not receive any future revenue from this party.

We earn other income primarily from tax incentive payments under the Australian Government's Research and Development Tax Incentive Plan for research and development activities conducted in Australia that meet specified regulatory criteria. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than A$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending.

No revenue was earned from our FIH study in Tbilisi, Georgia. In the nine months ended September 30, 2024 and the year ended December 31, 2023, we received reimbursements under the EFS from CMS because the FDA has categorized DurAVR® THV as a Category B device.

Expenses

Our most significant expenses are research and development costs and selling, general and administrative expenses.

Cost of products sold reflects the manufacturing cost from the sale of regenerative tissue products to 4C and to LeMaitre. These expenditures include raw materials and consumables, plus other costs attributable to the manufacturing of these products.

Research and Development Expense

Research and development ("R&D") has been a significant focus for us with investments in the DurAVR® THV system, including the DurAVR® THV, the ComASUR® delivery system, a disposable crimper, and an expandable access sheath, as we advance towards commercial use. These components are collectively managed as part of the overall DurAVR® THV system rather than as separate projects. Since late 2021, when our DurAVR® THV delivery system was first used in human trials in Tbilisi, Georgia, R&D efforts have focused on incorporating feedback from the early clinical trial and progressing towards commercialization. These costs have included, among others, preclinical studies, design iterations, lab services, clinical data monitoring, project and site management, travel, data management and safety of the study.

Going Concern

Our ability to continue as a going concern is dependent upon securing additional funds. Our ability to access capital may be impacted by various factors including economic conditions, a decline in investor confidence and sub-optimal preclinical or clinical outcomes from trials and studies. A reduced ability to access capital may result in a curtailment of the development of our product portfolio, an extended timeline to commercialization and other operational impacts.

We believe that we have the ability to raise additional funds. Notwithstanding the above factors, we are dependent upon continued support from current stockholders to fund our operations. If we do not receive cash inflows, there are material uncertainties as to whether we will be able to continue as a going concern.

The audit report covering the December 31, 2023 and 2022 consolidated financial statements of ATL contains a paragraph that states that ATL's recurring losses from operations and net capital deficiency raise substantial doubt about our ability to continue as a going concern. See Note 3 to the accompanying audited consolidated financial statements.

Results of Operations

Comparison of Nine Months Ended September 30, 2024 and September 30, 2023

The following tables set forth our results of operations for the nine months ended September 30, 2024 and September 30, 2023.

	Nine Months Ended September 30,		
	2024	2023	% Change
	(in U.S. dollars)		
Net Sales	$ 2,166,888	$ 2,190,665	(1)%
Costs and expenses:			
Cost of product sold	(1,229,242)	(1,500,686)	(18)%
Research and development expense	(38,135,103)	(21,254,062)	79%
Selling, general and administrative expense	(19,655,764)	(12,262,458)	60%
Acquired in-process research and development	—	(131,617)	(100)%
Net foreign exchange (losses)/gains	(456,541)	701,571	(165)%
Operating loss	**(57,309,762)**	**(32,256,587)**	**78%**
Other non-operating income, net	637,352	935,808	(32)%
Interest and amortization of debt discount and expense	(39,154)	(52,434)	(25)%
Fair value movement of derivatives and other variable liabilities	(54,486)	39,128	(239)%
Loss on asset acquisition of a variable interest entity	—	(501,247)	(100)%
Loss before income taxes from continuing operations	**(56,766,050)**	**(31,835,332)**	**78%**
Income tax (expense)/benefit	—	—	—
Loss after income tax	**(56,766,050)**	**(31,835,332)**	**78%**

	Nine Months Ended September 30,		
	2024	2023	% Change
	(in U.S. dollars)		
Net income/(loss) attributable to non-controlling interests and redeemable non-controlling interests	149,768	—	(100)%
Loss Attributable to ATL	**(56,915,818)**	**(31,835,332)**	**79%**

Net Sales

Net sales in the first nine months of 2024 were $2.2 million, a decrease of $0.02 million (1%), compared to $2.2 million in the first nine months of 2023, primarily due to lower volume of sales of tissue products in 2024. The reduction in sales was due to an overall lower demand for products sold to LeMaitre and 4C.

Cost of Products Sold

Cost of products sold in the first nine months of 2024 were $1.2 million, a decrease of $0.3 million (18%), compared to $1.5 million in the first nine months of 2023, primarily due to an overall reduced demand and mix of products sold.

Research and Development Expense

Research and development expenses in the first nine months of 2024 were $38.1 million, an increase of $16.8 million (79%), compared to $21.3 million in the first nine months of 2023, primarily due to $12.0 million relating to preparatory activities associated with the Pivotal Trial, including on-going product development, $2.6 million relating to the upscaling of manufacturing capabilities including the expansion of headcount, $1.8 million relating to v2vmedtech development and $1.0 million relating to increased clinical costs including those associated with the enrollment of additional patients. This was partially offset by a reduction in medical affairs of $1.0 million.

Selling, General and Administrative Expense

Selling, general and administrative expenses in the first nine months of 2024 were $19.7 million, an increase of $7.4 million (60%), compared to $12.3 million in the first nine months of 2023, primarily due to $2.8 million relating to the expansion of the work related to the Company's plans to re-domicile, list on the NASDAQ and conduct its initial public offering, $1.8 million relating to the grant of additional stock options and $1.9 million including a 25% increase in headcount in the Corporate departments (including Finance, Human Resources, IT, Marketing, Projects) to support the growth in the Company's operations, and annual wage index increases.

Acquired in-process Research and Development

Acquired in-process research and development in the first nine months of 2023 was $0.1 million primarily due to costs relating to the acquisition of v2vmedtech, including in-process research and development, and we did not have a corresponding charge in the first nine months of 2024.

Net Foreign Exchange (Losses)/Gains

Net foreign exchange losses in the first nine months of 2024 were $0.5 million, a decrease in gains of $1.2 million (165%), compared to $0.7 million of net foreign exchange gains in the first nine months of 2023, primarily due to the change in foreign exchange rates on intercompany and cash balances. In the first nine months of 2024, the U.S. dollar depreciated by 1% relative to the AUD compared to a 5% appreciation in the first nine months of 2023.

Other non-operating income, net

Other non-operating income, net in the first nine months of 2024 was $0.6 million, a decrease of $0.3 million (32%), compared to $0.9 million in the first nine months of 2023, primarily due to the recognition

of the first holdback amount from LeMaitre under the most recent amendment to the License Agreement, signed in September 2023, and we did not have a corresponding entry in the first nine months of 2024. Other non-operating income, net in the first nine months of 2024 also included interest income and government grants relating to Australian Research and Development Tax Incentive.

Loss on Asset Acquisition of a VIE

Loss on asset acquisition of a VIE in the first nine months of 2023 was $0.5 million, primarily due to our determination that v2vmedtech is a VIE and the consolidation of this entity, and we did not have a corresponding loss or gain in the first nine months of 2024.

Loss Before Income Taxes from Continuing Operations

Loss before income taxes from continuing operations in the first nine months of 2024 was $56.8 million, an increase of $24.9 million (78%), compared to $31.8 million in the first nine months of 2023.

Net income attributable to non-controlling interests and redeemable non-controlling interests

Net income attributable to non-controlling interests and redeemable non-controlling interests in the first nine months of 2024 was $0.1 million, which was a 100% increase compared to the prior year due to the acquisition of a VIE in the first nine months of 2023.

Comparison of Years Ended December 31, 2023 and December 31, 2022

The following tables set forth our results of operations for the years ended December 31, 2023, and December 31, 2022.

	Year ended December 31,		
	2023	2022	% Change
	(in U.S. dollars)		
Net sales	$ 2,734,821	$ 3,200,711	(15)%
Costs and expenses:			
Cost of products sold	(1,858,021)	(2,902,328)	(36)%
Research and development expense	(30,889,993)	(17,590,090)	76%
Selling, general and administrative expense	(17,360,629)	(15,439,777)	12%
Acquired in-process research and development	(131,617)	—	(100)%
Net foreign exchange (losses)/gains	(634,459)	1,617,209	(139)%
Operating loss	(48,139,988)	(31,114,275)	55%
Other non-operating income, net	1,935,415	1,456,276	33%
Interest and amortization of debt discount and expense	(67,089)	(648,709)	(90)%
Fair value movement of derivatives	9,512	(257,092)	(104)%
Loss on asset acquisition of a variable interest entity	(501,247)	—	(100)%
Loss before income taxes from continuing operations	(46,763,397)	(30,563,800)	53%
Income tax (expense)/benefit	—	—	—
Loss after income tax	(46,763,397)	(30,563,800)	53%
Net loss attributable to non-controlling interests and redeemable non-controlling interests	(741,556)	—	(100)%
Loss Attributable to ATL	$(46,021,841)	$(30,563,800)	51%

Net Sales

Net sales in 2023 were $2.7 million, a decrease of $0.5 million (15%), compared to $3.2 million in 2022, primarily due to lower volume of sales of regenerative tissue products in 2023. The reduction in sales was primarily due to a lower demand for CardioCel™ and VascuCel™ products that we sell to LeMaitre, which holds distribution rights to these products.

Cost of Products Sold

Cost of products sold in 2023 was $1.9 million, a decrease of $1.0 million (36%), compared to $2.9 million in 2022, primarily due to a decline in sales of the lower-yielding CardioCel™ and VascuCel™ products that we sell to LeMaitre.

Research and Development Expense

Research and development expenses in 2023 were $30.9 million, an increase of $13.3 million (76%) compared to $17.6 million in 2022. This is primarily due to an increase of $5.3 million relating to EFS preparatory activities including on-going product development, an increase of $2.8 million relating to higher clinical costs linked to the enrollment of additional patients, an increase of $3.7 million relating to the upscaling of manufacturing capabilities including headcount growth and $0.8 million relating to the expansion of medical affairs activities.

Selling, General and Administrative Expense

Selling, general and administrative expenses in 2023 were $17.4 million, an increase of $2.0 million (12%) compared to $15.4 million in 2022, primarily due to an expansion of costs related to investor relations activities, increases in insurance costs, increased fees for audit, tax and legal advisors for compliance matters, and increased travel and marketing conference expenses.

Acquired in-process research and development

Acquired in-process research and development expenses in 2023 were $0.1 million, primarily due to costs relating to the acquisition of v2vmedtech, including intangibles.

Net Foreign Exchange (Losses)/Gains

Net foreign exchange losses in 2023 were $0.6 million compared to $1.6 million of net foreign exchange gains in 2022, a change of $2.2 million (139%), primarily due to the change in foreign exchange rate variances between the years on intercompany and cash balances.

Other non-operating income, net

Other non-operating income, net in 2023 was $1.9 million, an increase of $0.5 million (33%) compared to $1.5 million in 2022, primarily due to the recognition of holdback income from a transaction with LeMaitre in 2019, EFS reimbursement income and an increase in interest income on cash held in term deposits, partly offset by a reduction in government grants relating to Australian Research and Development Tax Incentive income.

Interest and amortization of debt discount and expense

Interest and amortization of debt discount and expenses in 2023 were $0.1 million, a decrease of $0.6 million (90%) compared to $0.6 million in 2022, primarily due to a decline in the amortization of debt transaction costs relating to the facility provided by Mercer Street Global Opportunity Fund, LLC ("Mercer").

Loss on asset acquisition of a VIE

Loss on asset acquisition of a VIE in 2023 was $0.5 million compared to $0 in 2022, due to our determination that v2vmedtech is a VIE and the consolidation of this entity.

Loss Before Income Taxes from Continuing Operations

Loss before income taxes from continuing operations was $46.8 million, an increase of $16.2 million (53%) compared to $30.6 million in 2022, primarily due to a decrease in net sales of $0.5 million and increases of $13.3 million in research and development costs, $2.0 million in selling, general and administrative expenses, net foreign exchange losses of $2.2 million and $0.5 million relating to the acquisition of v2vmedtech, partially offset by a decrease of $1.0 million in cost of product sold.

Liquidity and Capital Resources

Capital Requirements and Sources of Liquidity

We have experienced significant recurring operating losses and negative cash flows from operating activities since inception. As of September 30, 2024 and December 31, 2023, we had an accumulated deficit of $257.0 million and $200.1 million, respectively.

In recent years, our operations have mainly been financed through the issuance of capital stock and convertible notes as well as sales of regenerative tissue products and R&D tax incentives from the Australian government. Additional funding has come through interest earned from cash on term deposit. As of September 30, 2024 and December 31, 2023, we had cash and cash equivalents of $10.6 million and $21.1 million, respectively. As of September 30, 2024, we had capital commitments of $1.6 million relating to the lease of properties. We did not have any other material capital expenditure commitments or contingent liabilities as of September 30, 2024. We anticipate that our current cash will be sufficient to fund our operations until December 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations involves risks and uncertainties, and actual results could vary materially. See "— *Going Concern*."

In an effort to preserve our liquidity while remaining positioned to capitalize on the substantial market opportunity which we believe exists for us in the TAVR market, we have implemented significant cost reduction initiatives across our operations effective from October 2024. This includes reducing the cost of materials that are integrated into our products, including packaging costs, the costs of our research and development activities and our selling, general and administrative costs (excluding the costs associated with the Reorganization and this offering). Furthermore, we have reviewed and reduced our projected headcount for future periods and included significant reductions in costs that we had previously projected for our upcoming trials, including manufacturing builds and patient enrollment costs. We believe that, as a result of these cost reduction initiatives, our operating expenses will be significantly reduced from those that we had previously anticipated for future periods.

We anticipate that we will require substantial additional funds in order to achieve our long-term goals and complete the research and development of our current products. We do not expect to generate significant revenue until we obtain regulatory approval to market and sell our products and sales of our products have commenced. We therefore expect to continue to incur substantial losses in the near future. In order to address our short term capital needs, we intend to raise funds through the issuance of our capital stock or other securities.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the scope, results and timing of clinical trials;
- the costs of preparing and completing the Pivotal Trial of our DurAVR® THV system;
- the costs and time required to obtain Pre-Market Approval from the FDA for our DurAVR® THV system; and
- the costs of establishing marketing, sales and distribution capabilities.

We may seek to raise any necessary capital through a combination of public or private equity offerings or debt financings. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we decide to raise capital by issuing equity securities, the issuance of such equity securities may result in dilution to our existing stockholders. See "*Risk Factors — Future equity financings and sales by existing holders could adversely affect the voting power or value of our Common Stock*." We cannot give any assurance that we will be successful in completing any financings or that any such equity or debt financing will be available to us if and when required or on satisfactory terms.

Convertible Note Facility

On October 31, 2024, ATL entered into a secured convertible note facility (the "Convertible Note Facility") with Obsidian Global Partners, LLC ("Obsidian") to provide additional financing to pursue

ATL's strategic objectives, implementation of the Reorganization, and completion of this offering. ATL or the Company (following the implementation of the Schemes) is able to draw up to A$25.0 million (the "Facility Limit") from the Convertible Note Facility, with an initial A$7.5 million drawdown (the "First Drawdown") and subsequent drawdowns (each, a "Drawdown") of A$5.0 million or the remaining balance of the Facility Limit, whichever is lesser. On each drawdown, ATL or the Company (following the implementation of the Schemes) (i) will issue notes to Obsidian that are convertible into ordinary shares of ATL or Common Stock (following the implementation of the Schemes) ("Convertible Notes") and (ii) is required to pay Obsidian a fee of 3% of the drawdown amount. The aggregate face value of the Convertible Notes issued pursuant to a Drawdown will be equal to 115% of the principal amount of the relevant Drawdown. Each Convertible Note will have a face value of $1.15.

In addition, at each Drawdown, ATL or the Company (following the implementation of the Schemes) will issue options to Obsidian, each exercisable into one ordinary share of ATL ("Obsidian Options"), with each Obsidian Option to have a strike price of A$25.00 and a term of three years from the date of issuance. The number of Obsidian Options issued will be such that the aggregate strike price of the Obsidian Options will be equal to 25% of the amount drawn under the relevant Drawdown. For the First Drawdown, this equated to 75,000 Obsidian Options (the "First Tranche Obsidian Options").

The ordinary shares of ATL or the Common Stock (following the implementation of the Schemes) that can be issued on conversion of the Convertible Notes issued under the First Drawdown is limited to an agreed cap of 967,572 shares (the "Initial Drawdown Issue Cap"). To the extent that, based on the price at which Obsidian can convert the Convertible Notes issued under the First Drawdown as set forth below, the number of ordinary shares of ATL or shares of Common Stock (following the implementation of the Schemes) issued on conversion would exceed the Initial Drawdown Issue Cap, ATL or the Company (following the implementation of the Schemes) will be required to redeem the relevant Convertible Notes in cash in lieu of issuing such shares, to the extent such issuance would exceed the Initial Drawdown Issue Cap.

The issuance of First Tranche Obsidian Options is subject to ATL obtaining shareholder approval for the grant of such options. If shareholder approval is not obtained, ATL or the Company (following the implementation of the Schemes) must pay A$300,000 to Obsidian. If the Schemes are implemented, ATL or the Company may elect to make this cash payment in lieu of issuing the First Tranche Obsidian Options.

Any further Drawdowns under the Convertible Note Facility can only be made by agreement between ATL or the Company (following the implementation of the Schemes) and Obsidian (including agreement as to the drawdown amount, Drawdown date, and any cap on the number of ordinary shares of ATL or shares of Common Stock (following the implementation of the Schemes) into which the Convertible Notes to be issued may convert) and may require approval from ATL's shareholders or the Company's stockholders (following the implementation of the Schemes).

In connection with the Convertible Note Facility, Obsidian will be granted a senior-ranking security interest over all of ATL's assets.

ATL or the Company (following the implementation of the Schemes) is permitted to repay the Convertible Notes in cash, whether in full or in part, at any time. Any such cash repayment of the Convertible Notes will be at the following premiums to the face value of the relevant Convertible Notes:

- if repayment is made prior to January 15, 2025 — 0% premium to the Convertible Note's face value;
- if repayment is made between January 16, 2025 to June 30, 2025 — 5% premium to the Convertible Note's face value; and
- if repayment is made on or after July 1, 2025 — 10% premium to the Convertible Note's face value.

The Convertible Notes will mature 24 months from the date of their issuance, at which time they will be either repaid in full by the Company or ATL, as applicable, or, at Obsidian's election, may be converted into ordinary shares of ATL or Common Stock, as applicable, in an amount equal to the face value of the Convertible Notes being converted divided by the relevant conversion price at the time of the conversion (the "Conversion Price"). Obsidian may not convert the Convertible Notes prior to January 15, 2025. The Conversion Price will be the lesser of:

- A$20.00, which is to be adjusted to the price at which shares of Common Stock are sold in this offering unless the Convertible Note Facility is repaid prior to completion of this offering; and
- 90% of the average of seven daily volume weighted average price measurements for ATL's ordinary shares or the Company's Common Stock, as applicable, each to be selected by Obsidian, during the 20 trading day period prior to Obsidian providing notice of the conversion of the relevant Convertible Notes.

The Convertible Note Facility is otherwise on terms customary for an agreement of its nature, including events of default, warranties and undertakings.

On November 7, 2024, 4,956,750 Convertible Notes were issued as a result of the First Drawdown.

Cash Flows

The following table summarizes our primary sources and uses of cash for the periods presented:

	Nine Months ended September 30,			Year ended December 31,		
	2024	**2023**	**% Change**	**2023**	**2022**	**% Change**
Net Cash provided by (used in):						
Operating activities	(43,003,689)	(26,718,961)	61%	(34,631,516)	(29,416,702)	18%
Investing activities	(1,916,432)	(2,130,631)	(10)%	(2,581,673)	(992,570)	160%
Financing activities	34,432,692	23,852,094	44%	49,339,774	23,271,389	112%
Effect of exchange rate movements on cash, cash equivalents and restricted cash	16,170	303,281	(95)%	(390,900)	1,035,891	(138)%
Net change in cash, cash equivalents and restricted cash	(10,471,259)	(4,694,217)	123%	11,735,685	(6,101,992)	(292)%

Operating Activities

Net cash used in operating activities during the first nine months of 2024 was $43.0 million, an increase of $16.3 million (61%), compared to $26.7 million in the first nine months of 2023, primarily due to the acceleration of research and development activities in preparation for the Pivotal Trial, an increase in salaries and wages linked to growth in headcount and increased costs due to the expansion of the work related to the Company's plans to re-domicile, list on the NASDAQ and conduct its initial public offering in the first nine months of 2024.

Net cash used in operating activities during 2023 was $34.6 million, an increase of $5.2 million (18%) compared to $29.4 million in 2022, primarily driven by an increase of research and development activities, product development and the process of seeking regulatory approvals to bring our DurAVR® THV technology to market, plus the expansion of our headcount.

Investing Activities

Net cash used in investing activities in the first nine months of 2024 was $1.9 million, a decrease of $0.2 million (10%), compared to $2.1 million in the first nine months of 2023, primarily due to $0.2 million of costs relating to the acquisition of v2vmedtech in the first nine months of 2023. We did not have a corresponding cash outflow in the first nine months of 2024.

Net cash used in investing activities during 2023 was $2.6 million, an increase of $1.6 million (160%) compared to $1.0 million in 2022, primarily due to an increase of $0.8 million in payments for plant and equipment related to equipment purchases for the expansion of facilities in the United States and $0.2 million of costs relating to the acquisition of v2vmedtech. In 2022 we received $0.7 million in deferred proceeds from sale of distribution rights related to the sale of our CardioCel™ and VascuCel™ patch business to LeMaitre in 2019.

Financing Activities

Net cash provided by financing activities in the first nine months of 2024 was $34.4 million, an increase of $10.5 million (44%), compared to $23.9 million in the first nine months of 2023, primarily due

to an increase of $11.0 million in proceeds from share issuances including the exercise of options for new shares in ATL, partly offset by an increase of $0.5 million in related share issue transaction costs.

Net cash provided by financing activities during 2023 was $49.3 million, an increase of $26.1 million (112%) compared to $23.3 million in 2022, and was primarily driven by the receipt of proceeds of $45.6 million from share placements in February and October 2023 plus $7.2 million from the exercise of options over new shares in ATL, partly offset by the payment of $2.7 million for related transaction costs and repayment of $0.8 million of borrowings.

Contractual Obligations and Commitments

Leases

We lease laboratory facilities and offices. The leases typically include options to renew at which time the lease payments are subject to market adjustments and/or set price increases. Extension and termination options are included in a number of the leases to allow for flexibility in terms of corporate growth and managing the assets used in our operations. The leases expire between 2024 and 2029 and some include options to extend. At September 30, 2024, the Company had contractual commitments (on an undiscounted basis) for property leases of $2.0 million, which were recognized at $1.6 million.

Warrants

On October 25, 2017, ATL issued a 7-year warrant to Partners for Growth V, L.P. (“PFG”) for the issue of 4,938,799 ordinary shares in ATL at an exercise price of $0.1731 (A$0.2531) per share (the “Warrant”). The Warrant was reconstructed due to a consolidation of capital of ATL, and currently entitles the holder to be issued 49,388 ordinary shares in ATL at an exercise price of $17.31 (A$25.31) per share. The Warrant expired on October 25, 2024. Upon the expiration of the Warrant, PFG exercised the put option and PFG put the Warrant to ATL for $985,350 (A$1,500,000), which was subsequently paid on October 31, 2024.

Commitments

At September 30, 2024, we had commitments to purchase $0.2 million of plant and equipment.

Off-Balance Sheet Arrangements

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

We have used various accounting policies to prepare the consolidated financial statements in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). Our significant accounting policies and estimates are more fully described in Note 2 to our audited consolidated financial statements.

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the consolidated financial statements and accompanying notes thereto. Management continually evaluates its judgments and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgments, estimates and assumptions on historical experience and on other various factors, including expectations regarding future events that management believes to be reasonable under the circumstances. Actual results could differ from those estimates due to risks and uncertainties and may be material.

Management has discussed the development and selection of these critical accounting estimates with the Audit and Risk Committee and our Board of Directors. In addition, there are other items within our financial statements that require estimation but are not deemed critical. Changes in estimates used in these and other items could have a material impact on our financial statements.

We believe that the following discussion addresses our most critical accounting policies and estimates, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

Going Concern

Our ability to continue as a going concern and fund the path to profitability is dependent upon securing additional funds in the future. The ability to access capital may be impacted by various factors including economic conditions, a decline in investor confidence and/or sub-optimal preclinical or clinical outcomes from trials/studies. A reduced ability to access capital may result in a curtailment of the development activities of the product portfolio, a delayed timeline to commercialization and other operational impacts.

We believe that we have the ability to raise additional funds. Notwithstanding the above factors, as a company moving towards profitability, we are dependent upon continuing support from current shareholders. If we do not receive the forecasted cash inflows, there are material uncertainties as to whether we will be able to continue as a going concern.

Research and Development Tax Incentive Income

Government grants are received under the Australian government's Research and Development Tax Incentive program, such that a percentage of our eligible research and development expenses are reimbursed by the Australian government with the incentive being recognized as other income. Government grants relating to costs incurred are recognized in the consolidated statements of operations over the periods in which the entity recognizes as expenses the related costs for which they are intended to compensate.

The Research and Development Tax incentive income is recognized as income once we are satisfied that we have complied with the conditions attached to the tax incentives and that the tax incentives will be received. Significant judgment is required in determining the amount and timing of recognition, as the grant requirements are complex. The Australian Taxation Office's interpretation of specific expenditures' eligibility may vary, potentially leading to variances to our estimations. In 2023, we recognized an estimated accrual of $0.7 million of research and development tax incentive income relating to the year ended December 31, 2023. This accrual was increased by $0.3 million in the first nine months of 2024.

Stock-Based Payments

Equity-settled stock-based compensation benefits are provided to employees, directors and consultants in exchange for the rendering of services. We measure and recognize compensation expense for all stock-based awards based on estimated fair values determined at grant date. Fair value is determined using Black-Scholes and Monte Carlo models which require various inputs including the exercise price and share price at grant date, plus other highly judgmental assumptions, such as share price volatility, risk-free interest rate, and the expected option term. For options with service conditions, the expense is recognized over the service period. Stock-based compensation expense is recorded net of estimate forfeitures. Forfeitures are estimated at the time of grant and we reassess the probability of vesting at each quarter end and adjust the stock-based compensation expense based on its probability assessment. Judgment is required in estimating which stock options will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations would be impacted.

The following key assumptions were used in valuing stock-based payments:

- Risk-free interest rate was based on Australian government bonds aligned to the life of the securities, with the range being 3.2% – 4.4% (year to December 31, 2023), and 3.6% to 4.5% (first nine months of 2024).
- The expected price volatility range of 55.0% – 75.1% (year to December 31, 2023) and 40.0% to 65.0% (first nine months of 2024) based on our historic volatility and the remaining life of the securities, adjusted for any expected changes to future volatility due to publicly available information.

Consolidation of VIEs

We consolidate a VIE when the reporting entity (a) has an economic interest in another legal entity (known as a "variable interest") that conveys more than insignificant exposure to potential losses of or

benefits from the other legal entity; and (b) has power over the most significant economic activities of the legal entity. There is significant judgment over the analysis to determine whether an entity is a VIE, to determine whether we have a variable interest and to determine whether we are the primary beneficiary of a VIE.

We determined that v2vmedtech is a VIE and that we are the primary beneficiary of v2vmedtech. This determination is based on our having both power over the most significant activities of v2vmedtech, primarily through holding a majority of the positions on v2vmedtech's Board of Directors (although v2v's non-ATL shareholder representative on the v2v Board of Directors presently maintains certain veto rights), controlling the appointment of the chief executive officer and chief financial officer roles, being the exclusive partner to develop v2vmedtech's products, and benefits through equity ownership. A loss on asset acquisition of $0.5 million was recognized as at acquisition date.

New Accounting Standards Not Yet Adopted

New accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and adopted by us as of the specified effective date. If not explicitly addressed otherwise, we believe that the recently issued standards, which have not yet taken effect, will not materially affect our present or near future financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) Improvements to Income Tax Disclosures. ASU 2023-09 intends to enhance income tax disclosures to address investor requests for more information about the tax risks and opportunities present in an entity's worldwide operations. The ASU's two primary enhancements will require further disaggregation for existing disclosures for the effective tax rate reconciliation and income taxes paid. This ASU is effective January 1, 2026 for smaller reporting companies. We have evaluated the effect of adopting this accounting guidance and will include the new required disclosures in future filings as needed.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) Improvements to Reportable Segment Disclosures. ASU 2023-07 enhances segment reporting by expanding the breadth and frequency of segment disclosures required for public entities. The amendments in this ASU notably allow registrants to disclose multiple measures of segment profit or loss and clarify single reportable segment entities must apply Topic 280 in its entirety. This ASU is effective January 1, 2025 for smaller reporting companies. Our company is a single reportable segment entity, so we anticipate that additional disclosures will be required to meet the requirements of ASU 2023-07.

In June 2022, the FASB issued ASU 2022-03, Fair Value Measurement (Topic 820) Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions. ASU 2022-03 clarifies guidance for fair value measurement of an equity security subject to a contractual sale restriction and establishes new disclosure requirements for such equity securities. This ASU is effective January 1, 2025 for smaller reporting companies. We have assessed the impact of adopting this accounting guidance and have determined that it does not materially impact the fair value measurement of our existing equity securities. Nevertheless, we will apply the guidance and incorporate the new required disclosures in future filings as needed.

MANAGEMENT

Information About Our Executive Officers

The following table sets forth as of October 31, 2024 the names and ages of ATL's executive officers, which will be our executive officers following the Reorganization. Biographies for each executive officer are included below the table. There are no family relationships between the executive officers or between any director and any executive officer.

Name	Age	Position
Wayne Paterson	58	Chief Executive Officer and Managing Director
Matthew McDonnell	52	Chief Financial Officer
David St Denis	56	Chief Operating Officer

Wayne Paterson

Wayne Paterson joined ATL in October 2014 as a Non-Executive Director (as defined below), served as the Chair from February 2016 to March 2017, served as the interim Chief Executive Officer commencing in May 2016, and has served as the Chief Executive Officer and Managing Director since March 2017. Mr. Paterson commenced service as Chair of v2vmedtech, which we consider to be a VIE and consolidate in our financial statements, in April 2023. Prior to joining ATL, Mr. Paterson held senior positions at Merck KGaA ("Merck"), a multinational science and technology company, from 2005 to 2013, including as President of Europe, Canada and Australia, President of Emerging Markets, President of Japan and President of Cardiovascular Medicine. From 1999 until 2005, Mr. Paterson served at Roche Pharmaceuticals, a multinational healthcare company, in several senior positions, including as Head of Pharmaceuticals in Roche's South Korean operation and Head of Commercial Operations for Roche China. Mr. Paterson holds an MBA from the University of Southern Queensland and a degree in Business Studies from the Queensland University of Technology. Mr. Paterson previously served as a director of Cepheid Inc (NASDAQ:CHPD) from April 2015 to November 2016. We believe Mr. Paterson's qualifications to serve as a director include his service as our Chief Executive Officer and Managing Director, as his insight into the business and related risks and challenges facing the Company will contribute to the Board and in its understanding of our business and strategy.

Matthew McDonnell

Matthew McDonnell has been ATL's Chief Financial Officer since November 2018 and the Chief Financial Officer of v2vmedtech, which we consider to be a VIE and consolidate in our financial statements, since September 2023. Prior to his appointment as Chief Financial Officer of ATL, Mr. McDonnell worked for KPMG, a global professional services firm, for over 24 years, where he held several senior positions, including 10 years as a partner. He has a broad range of industry experience and corporate governance acumen, having delivered audit, accounting, and advisory services to a broad range of sectors. During his time at KPMG, Mr. McDonnell worked in Australia covering the financial services, transport, industrial markets, health, childcare and energy industries. He has experience in restructurings, acquisitions, divestments, privatizations and other significant financial transactions. Mr. McDonnell also served as a director of the State Library of Queensland where he was the Chair of the Audit and Risk Management Committee for eight years. Mr. McDonnell holds a Bachelor of Economics from Macquarie University. He is an Associate of Chartered Accountants in Australia and New Zealand, a Fellow of the Financial Services Institute of Australasia and a Member of the Australian Institute of Company Directors.

David St Denis

David St Denis has been ATL's Chief Operating Officer since July 2017 and the Chief Executive Officer of v2vmedtech, which we consider to be a VIE and consolidate in our financial statements, since April 2023. Mr. St Denis also served as Chief Financial Officer of v2vmedtech from April 2023 to September 2023. Prior to his appointment as Chief Operating Officer of ATL, Mr. St Denis served as Head of Commercial Operations for Europe and Canada at Merck since 2013, and prior to that, served as Head of Operations for Emerging Markets at Merck since 2008. In addition, Mr. St Denis had held multiple

leadership roles at Millennium Pharmaceuticals, Inc, now Takeda Pharmaceutical Company, from 1996 to 2006, and provided strategic consulting services to such company from 2006 to 2008. Mr. St Denis has a Bachelor of Science from the University of Connecticut, a Master of Arts from Boston University and an MBA in Global Management and International Marketing from Babson College — Franklin W. Olin Graduate School of Business.

Information About our Board of Directors and Board Committees

Board of Directors

Our Board of Directors oversees the management of the business and affairs of the Company and serves as the ultimate decision-making body of the Company, except for those matters reserved to our stockholders. The Board of Directors oversees the Company's management team, to whom it has delegated responsibility for the Company's day-to-day operations. While the Board of Directors' oversight role is broad and may concentrate on different areas from time to time, its primary areas of focus are strategy, oversight, governance and compliance, as well as assessing management.

Our Board of Directors currently consists of four members, as set forth in the table below. In accordance with our Second Amended and Restated Certificate of Incorporation, which will be effective immediately prior to the completion of the Reorganization and the closing of this offering, our Board of Directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I director will be Mr. Seaberg and his term will expire at the annual meeting of stockholders to be held in 2025;
- The Class II director will be Mr. Denaro, and his term will expire at the annual meeting of stockholders to be held in 2026; and
- The Class III directors will be Mr. Paterson and Dr. Gu, and their terms will expire at the annual meeting of stockholders to be held in 2027.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board of Directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws will not limit the number of terms a member may be re-elected as a director.

Our directors bring a range of skills and experience in relevant areas, including finance, international business, leadership, medical technology, biotechnology and mergers and acquisitions. We believe this cross-section of capabilities enables our Board of Directors to help guide our strategic objectives and leading corporate governance practices.

The following table sets forth, as of October 31, 2024, the names and ages of the members our Board of Directors. Biographies of each director are included below the table, except for Mr. Paterson, whose biography is included above under "*Information About Our Executive Officers*".

Name	Age	Current Position
John Seaberg	73	Chairman
Stephen Denaro	63	Director
Wenyi Gu	62	Director
Wayne Paterson	58	Managing Director and Chief Executive Officer

John Seaberg

John Seaberg has been Chairman of the Board of Directors since March 2017 and a director since October 2014. Additionally, Mr. Seaberg has been serving as Board Chair of Preceptis Medical Inc since 2016 and Phraxis Medical Inc since 2009. He was Executive VP at Cedar Point Capital, a broker-dealer focused on healthcare investment, from June 2015 through December 31, 2023. From 2008 until 2012, Mr. Seaberg was Chair of Synovis Inc., a NASDAQ-listed manufacturer of various medical device and bioscaffold tissue products which was acquired by Baxter, and, from 2007 until 2014, was Co-Founder, Chair and Chief Executive Officer of NeoChord Inc., a company commercializing technology developed at the Mayo Clinic for repair of the mitral valve via minimally invasive techniques. From 1996 to 2006, Mr. Seaberg served at Guidant Corp. (subsequently acquired by Boston Scientific Corp.) where he held various executive level positions, including Director of Marketing for Cardiac Rhythm Management, Vice President of Sales for Cardiac Surgery and Vice President of Sales for Cardiac Rhythm Management. In addition, Mr. Seaberg was co-Founder, President and Chief Executive Officer of ACIST Medical, from 1991 to 1995. Mr. Seaberg holds a Bachelor of Arts in Speech Communications from the University of Minnesota and an MBA from the Carlson School of Management, also at the University of Minnesota. We believe that Mr. Seaberg's qualifications to serve as a director include his extensive finance, leadership and industry experience and his tenure as a director of ATL.

Stephen Denaro

Stephen Denaro has been a director since October 2018. Mr. Denaro serves as ATL's Company Secretary, a position he had held since 2018. Mr. Denaro has been providing company secretarial services to other ASX-listed companies since 1994, and serves as a director and sole shareholder of Trio Business Intermediaries Pty Ltd, a business consulting company, specializing in restructuring, corporate governance, directorship and company secretarial services, through which he provides these and other services. Mr. Denaro has over 25 years of experience in mergers and acquisitions, business valuations, accountancy services, and income tax compliance gained from positions as Company Secretary and Chief Financial Officer of various public companies and with major chartered accountancy firms in Australia and the United Kingdom. Mr. Denaro has a Bachelor of Business in Accountancy and a Graduate Diploma in Applied Corporate Governance, and he is a member of the Institute of Chartered Accountants in Australia & New Zealand, and the Australian Institute of Company Directors. We believe that Mr. Denaro's qualifications to serve as a director include his finance and business experience and his experience with ASX-listed companies, including his tenure as Corporate Secretary and a director of ATL.

Dr. Wenyi Gu

Dr. Wenyi Gu has been a director since October 2018. Dr. Gu is currently guest professor with several Chinese institutes and universities. Since January 2017, Dr. Gu has been working as a Research Fellow for the Australian Institute for Bioengineering and Nanotechnology at the University of Queensland. In addition, from April 2021 to March 2023, Dr. Gu was the Chief Scientific Officer of Guangzhou Gillion Biotherapeutics Ltd, a biotechnology company. From 2006 to 2009, he held a Perter Doherty Fellowship and was supported by the National Health and Medical Research Council to work at Harvard Medical School as a visiting research fellow. Dr Gu holds a master's degree in veterinary science and completed his PhD study in biochemistry and molecular biology at Australian National University and later worked at John Curtin Medical School. He also held a Peter Doherty Fellowship (2006-2009) and was supported by the National Health and Medical Research Council to work at Harvard Medical School, Harvard University as a visiting fellow. We believe that Dr. Gu's qualifications to serve as a director include his extensive industry experience and his tenure as a director of ATL.

Director Independence

Our Board of Directors currently consists of four members. Our Board of Directors has determined that Mr. Seaberg and Dr. Gu qualify as independent directors in accordance with the NASDAQ Marketplace Rules (the "NASDAQ Listing Rules"). Mr. Paterson is not considered independent by virtue of his position as Chief Executive Officer of our company. Mr. Denaro is not considered independent by virtue of his position as Company Secretary.

Phase-In of Certain Corporate Governance Requirements

We expect to rely on phase-in provisions under the NASDAQ Listing Rules applicable to the initial composition of our Board of Directors and committees following the completion of our initial public offering. Our Board of Directors has affirmatively determined that Mr. Seaberg and Dr. Gu are independent directors under NASDAQ Listing Rules applicable to the directors serving on our Board of Directors. The Board of Directors has further determined that Mr. Seaberg and Dr. Gu qualify as independent directors under NASDAQ Listing Rules applicable to membership on our Audit and Risk Committee. In addition, the Board of Directors has determined that each of the members of our Audit and Risk Committee is "financially literate" pursuant to the NASDAQ Listing Rules, and that Mr. Denaro is an "audit committee financial expert," as defined in applicable SEC rules, because of his individual extensive financial experience.

At listing, a majority of the members of each of our committees will satisfy the applicable NASDAQ independence requirements. Under applicable NASDAQ Listing Rules, all members must satisfy the applicable NASDAQ independence requirements within one year of the listing of our Common Stock on NASDAQ. In addition, a majority of the directors serving on our Board of Directors will be required to be independent within one year of the listing of our Common Stock on NASDAQ.

Board Committees

Our Board of Directors has three standing committees: the Audit and Risk Committee, the Compensation Committee and the Nominating and Corporate Governance Committee. Each committee is governed by a charter that will be available on our website prior to the completion of the Reorganization.

Audit and Risk Committee

The members of our Audit and Risk Committee consist of Mr. Seaberg, Dr. Gu and Mr. Denaro. Mr. Denaro is the chairperson of our Audit and Risk Committee. Two of the three members of our Audit and Risk Committee meet the requirements for independence under the current NASDAQ Listing Rules and Rule 10A-3 of the Exchange Act. Under applicable NASDAQ Listing Rules, all members must satisfy the applicable requirements for independence within one year of the listing of our Common Stock on NASDAQ. Each member of our Audit and Risk Committee is "financially literate" under NASDAQ Listing Rules. In addition, our Board of Directors has determined that Mr. Denaro is an "audit committee financial expert" within the meaning of the SEC's rules and regulations. This designation does not impose on such director any duties, obligations, or liabilities that are greater than are generally imposed on members of our Audit and Risk Committee and our Board of Directors. Our Audit and Risk Committee is directly responsible for, among other things:

- appointing, retaining, compensating and overseeing the work of our independent registered public accounting firm;
- assessing the independence and performance of the independent registered public accounting firm;
- reviewing with our independent registered public accounting firm the scope and results of the firm's annual audit of our financial statements;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the financial statements that we will file with the SEC;
- pre-approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- reviewing policies and practices related to risk assessment and management;
- reviewing our accounting and financial reporting policies and practices and accounting controls, as well as compliance with legal and regulatory requirements;
- reviewing, overseeing, approving, or disapproving any related-person and related-party transactions;
- reviewing with our management the scope and results of management's evaluation of our disclosure controls and procedures and management's assessment of our internal control over financial reporting, including the related certifications to be included in the periodic reports we will file with the SEC;

- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal controls, or auditing matters, or other ethics or compliance issues;
- reviewing reports from our management and our independent registered public accounting firm on the effectiveness of the internal control, risk management systems and management of material business risks;
- establishing and reviewing our risk management framework, including the risk profile developed by our management covering material risks to our business; and
- reviewing and assessing the effectiveness of our internal controls, policies, programs, guidelines and procedures making up our risk management framework and reporting systems, including in light of any material breakdowns and reports from our management on new or emerging sources of risk; and
- reviewing with our management and recommending to our Board of Directors additional or material amendments to our risk management reporting and governance policies.

Compensation Committee

The members of our Compensation Committee consist of Mr. Denaro, Dr. Gu and Mr. Seaberg. Mr. Seaberg is the chairperson of our Compensation Committee. Each of Mr. Seaberg and Dr. Gu is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act, and meets the requirements for independence under the current NASDAQ Listing Rules. Our Compensation Committee is responsible for, among other things:

- reviewing and approving the compensation of our executive officers, including reviewing and approving corporate goals and objectives with respect to compensation;
- authority to act as an administrator of our equity incentive plans;
- reviewing and approving, or making recommendations to our Board of Directors with respect to, incentive compensation and equity plans;
- reviewing and recommending that our Board of Directors approve the compensation for our non-employee board members; and
- establishing and reviewing general policies relating to compensation and benefits of our employees.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee consist of Mr. Denaro, Dr. Gu and Mr. Seaberg. Mr. Seaberg is the chairperson of our Nominating and Corporate Governance Committee. Mr. Seaberg and Dr. Gu meet the requirements for independence under the current NASDAQ Listing Rules. Our Nominating and Corporate Governance Committee is responsible for, among other things:

- identifying and recommending candidates for membership on our Board of Directors, including the consideration of nominees submitted by stockholders, and on each of our Board of Directors' committees;
- reviewing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the Code of Business Conduct (the "Code of Business Conduct") for directors and executive officers;
- overseeing the process of evaluating the performance of our Board of Directors; and
- assisting our Board of Directors on corporate governance matters.

Additional Board Information

Each committee is at all times authorized under its charter to have direct, independent and confidential access to our other directors, management and personnel to carry out the committee's purposes. Each committee is authorized to conduct or authorize investigations into any matters relating to the purposes, duties or responsibilities of the committee.

Each committee may, in its sole discretion, retain or obtain the advice of legal counsel, compensation or other consultants and other advisers. We must provide for appropriate funding, as determined by each committee, for payment of reasonable compensation to any legal counsel, compensation or other consultant or other adviser retained by the committee.

Corporate Governance Matters

Our Board of Directors believes sound corporate governance processes and practices, as well as high ethical standards, are critical to handling challenges and to achieving business success. We embrace leading governance practices and also conduct ongoing reviews of our governance structure and processes to reflect shareholder input and changing circumstances. Below are highlights of our corporate governance practices and principles.

The Board of Directors has adopted Corporate Governance Guidelines that outline our corporate governance policies and practices, which will be available on our website prior to the completion of the Reorganization.

Code of Business Conduct

We have adopted a written Code of Business Conduct, which applies to all our directors, officers and employees, and will be available on our website prior to the completion of the Reorganization.

The Audit and Risk Committee is responsible for overseeing the Code of Business Conduct and must approve any waivers of the Code of Business Conduct for executive officers and directors. We expect that any amendments to the Code of Business Conduct, or any waivers of its requirements with respect to our executive officers and directors, will be disclosed on our website.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2023, our Non-Executive Directors Messrs. Seaberg and Denaro and Dr. Gu each participated in the deliberations concerning executive compensation for ATL. Other than Mr. Denaro, no member of the Compensation Committee has served as one of our officers or employees at any time. None of our executive officers serve, or in the past fiscal year has served, as a member of the Board of Directors or compensation committee of any other entity that has one or more of its executive officers serving on our Board of Directors or Compensation Committee.

DIRECTOR COMPENSATION

The following table and related footnotes show the compensation paid to the members of our Board of Directors other than Mr. Paterson, who served as our Chief Executive Officer (such directors, the "Non-Executive Directors") during the last completed fiscal year. Where applicable, the table includes compensation paid to our Non-Executive Directors in their capacities as directors of ATL during the last completed fiscal year.

Name	Fees earned or paid in cash ($)[2]	Stock awards ($)[3]	Option awards ($)[3]	Nonequity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other Compensation[4]	Total ($)
John Seaberg	147,000	—	1,200,659	—	—	—	1,347,659
Stephen Denaro	104,545[1]	—	603,023	—	—	7,848	715,416
Wenyi Gu	69,786	—	550,470	—	—	7,848	628,104

(1) Mr. Denaro received $69,786 plus superannuation for directors fees and receives $34,759 annually for Company secretarial services.

(2) The amounts in this column are presented in USD using the average exchange rate for the fiscal year ended December 31, 2023, which was approximately A$1.00 to $0.66.

(3) The values which have been computed in accordance with Financial Accounting Standards Board Codification Topic 781, Compensation — Stock Compensation ("FASB ASC Topic 718") represent (i) the aggregate grant date fair value of option awards granted in 2023, which were $1,077,006 for Mr. Seaberg, $550,470 for Mr. Denaro and $550,470 for Dr. Gu, plus (ii) the incremental value from option award modifications in 2023, which were $123,653 for Mr. Seaberg and $52,553 for Mr. Denaro. Options issued with a grant date fair value in AUD have been translated into USD using the spot exchange rate of approximately A$1.00 to $0.64 as of September 6, 2023, the date of grant. The option award modifications have been translated into USD using the spot exchange rate of approximately A$1.00 to $0.68 as of February 17, 2023, the date that the modification was approved. See Note 19 to ATL's consolidated financial statements for the years ended December 31, 2023 appearing elsewhere in this prospectus regarding assumptions underlying the valuation of option awards. As of December 31, 2023, our Non-Executive Directors held the following outstanding equity awards: Mr. Seaberg — 60,000 options exercisable at $7.66, 80,000 options exercisable at $8.86, 157,500 options exercisable at $16.42; Mr. Denaro — 25,000 options exercisable at $7.66, 40,000 options exercisable at $8.86, 80,500 options exercisable at $16.42; and Dr. Gu — 40,000 options exercisable at $8.86, 80,500 options exercisable at $16.42. The exercise prices which are designated in AUD have been converted using the spot exchange rate for the fiscal year ended December 31, 2023, which was approximately A$1.00 to $0.68.

(4) The amounts in this column are presented in USD using the average exchange rate for the fiscal year ended December 31, 2023, which was approximately A$1.00 to $0.66. All other compensation amounts relate to superannuation entitlements.

The Non-Executive Directors receive directors' cash fees and options. As of January 1, 2024 through to the completion of the Reorganization, the chairperson receives a fixed cash fee of $152,145 per annum and the other Non-Executive Directors receive a fixed cash fee of $74,334 per annum. In addition, the director serving as the Company Secretary receives an annual fee of A$54,336. The Non-Executive Directors' cash fees are determined within an aggregate directors' fee pool limit, which is periodically recommended for approval by stockholders. Until the completion of the Reorganization, the fee pool limit stands at $478,800 per annum, as approved by stockholders at ATL's 2014 Annual General Meeting. The fees are paid monthly.

The option grants described in the table above will vest in three equal (or broadly equal) tranches over one, two, and three years so long as the recipient continues to serve as a director through each applicable vesting date.

ATL's Australian-based Non-Executive Directors also receive 12% superannuation from July 1, 2024 (previously 11.5%).

Non-Employee Director Compensation Policy

Effective upon the pricing of this offering, the Company will adopt a Non-Employee Director Compensation Policy (the "Director Compensation Policy") to provide for the compensation of non-employee directors for service on our Board of Directors. Each non-employee director will receive an annual cash retainer for their service in each position as denoted below, each of which will be payable in four equal quarterly installments and will be prorated for any portion of a quarter that a non-employee director is not serving in such position on our Board of Directors. Non-employee directors' annual cash retainers will be determined within an aggregate directors' fee pool limit, which is periodically recommended for approval by stockholders and will stand at $2 million per annum, unless increased by approval of stockholders. The annual cash retainers for each applicable position will be:

Board Member	$ 45,000
Non-Executive Board Chair*	$150,000
Lead Independent Director (if appointed)	$ 25,000
Audit Committee Chair**	$ 20,000
Compensation Committee Chair**	$ 15,000
Nominating & Governance Committee Chair**	$ 10,000
Audit Committee Member	$ 10,000
Compensation Committee Member	$ 7,500
Nominating & Governance Committee Member	$ 5,000

* This is the total cash compensation and the Non-Executive Board Chair is not eligible for any additional cash retainers.

** Annual Retainers for Committee chairs will be paid in lieu of, not in addition to, Annual Retainers for Committee members.

Pursuant to the Director Compensation Policy and subject to stockholder approval on a per grant basis in accordance with the rules of the ASX, unless the underlying security which is acquired on exercise of the option or otherwise on satisfaction of right is purchased on-market (as specified in an award agreement), non-employee directors who are elected or appointed to our Board of Directors after the completion of this offering will receive an initial grant of restricted stock units with an aggregate grant date fair value of $250,000, which will vest in three equal annual installments, subject to each non-employee director's continued service through such date. Non-employee directors who serve on our Board of Directors as of the date of any annual stockholder meeting that occurs after the completion of this offering and will continue to serve on our Board of Directors following such annual stockholder meeting will receive, subject to approval on a per grant basis in accordance with the rules of the ASX, unless the underlying security which is acquired on exercise of the option or otherwise on satisfaction of right is purchased on-market (as specified in an award agreement), an annual grant of restricted stock units with an aggregate grant date fair value of $125,000, except for the Non-Executive Board Chair, who will receive $250,000 which will vest on the earlier to occur of the first anniversary of the grant date and the date of our next annual stockholder meeting, subject to each non-employee director's continued service through such date. A non-employee director who has served on our Board of Directors for fewer than six months prior to an annual stockholder meeting will receive a prorated grant of restricted stock units, which will vest on the earlier to occur of the first anniversary of the grant date and the date of our next annual stockholder meeting, subject to such non-employee director's continued service through such date. A non-employee director elected for the first time to our Board of Directors at an annual stockholder meeting will be eligible to receive only an initial grant of restricted stock units.

In addition, in connection with this offering, non-employee directors, other than the Non-Executive Board Chair, will receive a grant of restricted stock units with a target fair value of $250,000 as of the date of the pricing of this offering, and the Non-Executive Chair will receive a grant of restricted stock units with a target fair value of $500,000, each of which is subject to approval by stockholders in accordance with the rules of the ASX and will vest annually over a three year period.

All equity awards held by non-employee directors under the Director Compensation Policy will vest in full upon the consummation of a Change in Control (as such term is defined in the Equity Plan (as defined below)), subject to each non-employee director's continued service through such date.

Pursuant to the Director Compensation Policy, non-employee directors will also be reimbursed for reasonable travel expenses to cover in-person attendance at, and participation in, meetings of our Board of Directors.

EXECUTIVE COMPENSATION

The following is a discussion of compensation arrangements of our named executive officers. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Introduction and Named Executive Officers

We refer to the individuals below as our named executive officers ("NEOs") for the fiscal year ended December 31, 2023:

Name	Position
Named Executive Officers	
Wayne Paterson	Chief Executive Officer and Managing Director
David St Denis	Chief Operating Officer
Matthew McDonnell	Chief Financial Officer

Summary Compensation Table

The following table and related footnotes show the compensation paid to our NEOs during the last completed fiscal year. Where applicable, the table includes compensation paid to our NEOs in their capacities as officers of ATL and its subsidiaries during the fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock awards ($)	Option awards ($)[1]	Nonequity incentive plan compensation[2]	Nonqualified deferred compensation earnings ($)	All other compensation ($)[3]	Total ($)
NEO Compensation									
Wayne Paterson *Chief Executive Officer*	2023	676,381	200,000	—	5,510,065	393,592	—	35,220	6,815,258
David St Denis *Chief Operating Officer*	2023	416,844	20,000	—	3,970,906	249,480	—	35,004	4,692,234
Matthew McDonnell *Chief Financial Officer*	2023	242,330	—	—	1,269,074	105,262	—	20,146	1,636,812

(1) The amounts reported represent the aggregate grant date fair value for the option awards granted in 2023 computed in accordance with FASB ASC Topic 718, plus, for Mr. Paterson, the incremental value from his option award modification in 2023, which was $722,984. Options issued with a grant date fair value in AUD have been translated into USD using the spot exchange rate as of the dates of grant as follows: the grants on September 6, 2023 for which the exchange rate was approximately A$1.00 to $0.64; the modification of Mr. Paterson's 2020 option used the spot exchange rate of approximately A$1.00 to $0.68 on the date that the modification was approved by stockholders; and the Share Price Performance Units issued which have been remeasured at reporting date have been translated using the year-end spot exchange rate, which was approximately A$1.00 to $0.68.

(2) The Non-equity incentive plan compensation bonus, which has been accrued at year-end, has been translated using the spot exchange rate, which was approximately A$1.00 to $0.68.

(3) The amounts disclosed as "all other compensation" set out above for Messrs. Paterson and St Denis include amounts related to health and other benefit related payments in the amounts of $25,320 for Mr. Paterson and $25,104 for Mr. St Denis. The amounts disclosed as "all other compensation" set out above for Mr. McDonnell includes $19,635 of superannuation payments. All such payments are presented in USD using exchange rates prevailing at the dates of the transactions, which averaged over the year to approximately A$1.00 to $0.66.

Employment and Service Agreements

ATL has entered into service agreements with the NEOs that generally contain standard terms and conditions for agreements of this nature, including confidentiality, restraint on competition and intellectual property provisions, as applicable. These agreements may be terminated by notice by either party or

earlier in the event of certain breaches of the terms and conditions. There are no fixed term agreements. The periods of notice required to terminate the contracts and the severance provided under the contracts are described below.

Under the terms of Mr. Paterson's service agreement, three months' notice is required for either party to terminate the agreement. If Mr. Paterson is terminated without cause (as defined in Mr. Paterson's service agreement), Mr. Paterson is entitled to three months of base salary paid over the notice period plus nine months of base salary paid after Mr. Paterson's termination date.

Under the terms of Mr. St Denis' service agreement, twelve months' notice is required for either party to terminate the agreement. If Mr. St Denis is terminated other than by summary dismissal (as described in Mr. St Denis's service agreement), Mr. St Denis may work twelve months or in lieu of working twelve months, Mr. St Denis is entitled to twelve months of base salary paid over the notice period.

Under the terms of Mr. McDonnell's service agreement, three months' notice is required for either party to terminate the agreement. If Mr. McDonnell is terminated other than by summary dismissal (as described in Mr. McDonnell's service agreement), Mr. McDonnell may work three months or in lieu of working three months, Mr. McDonnell is entitled to three months of base salary paid over the notice period.

All service agreements entered into by ATL with NEOs will be revised and will become the obligations of the Company in connection with the Reorganization.

Revised Executive Employment Agreements

Effective as of the completion of the Reorganization, the Company (or ATL, as applicable) will enter into revised employment agreements with the NEOs. The material terms of the revised employment agreements are described below.

Mr. Paterson's revised executive employment agreement (the "Paterson Agreement") provides that Mr. Paterson will serve as the Chief Executive Officer of the Company and will be nominated to serve on our Board of Directors. Mr. Paterson's base salary will be $725,000, subject to annual review by our Board of Directors for increase. Mr. Paterson will also be entitled to receive an annual incentive bonus with a target opportunity of up to 100% of his base salary, a long-term incentive compensation award with a total target fair value of $6,000,000 in connection with this offering, and, starting with the 2026 calendar year, annual long-term incentive compensation awards with a total target grant value of $4,000,000. The Paterson Agreement may be terminated by the Company without "cause" or by Mr. Paterson without "good reason" (as each term is defined in the Paterson Agreement) upon six months' written notice to the other party or by Mr. Paterson for "good reason" by giving notice to the Company of the existence of a "good reason" trigger within sixty days of its occurrence, the Company failing to cure the trigger within the following thirty days, and Mr. Paterson terminating his employment within thirty days of the end of the cure period. If the Company terminates Mr. Paterson's employment without "cause" or Mr. Paterson terminates employment for "good reason", Mr. Paterson will receive the following compensation and benefits, subject to his executing and not revoking a release of claims against the Company and its affiliates: the Company will continue to pay Mr. Paterson his base salary for twelve months, Mr. Paterson will be entitled to receive a pro-rata portion of his annual bonus for the year of termination based on actual achievement of the applicable performance metrics, any outstanding equity awards that vest solely based on continuous service will be earned on a pro-rata basis, and any outstanding performance-based equity awards will be earned on a pro-rata basis, subject to the achievement of the applicable performance metrics, and the Company will reimburse Mr. Paterson for COBRA premium payments for twelve months (or until Mr. Paterson becomes eligible for coverage under another medical plan, whichever occurs first). Mr. Paterson will also be entitled to participate in the Company's employee benefit plans, programs and policies for senior executives. The Paterson Agreement includes customary non-competition, non-solicitation, intellectual property, and confidentiality provisions.

Mr. St Denis' revised executive employment agreement (the "St Denis Agreement") provides that Mr. St Denis will serve as the Chief Operations Officer of the Company. Mr. St Denis' base salary will be $475,000, subject to annual review by the Company for increase. Mr. St Denis will also be entitled to receive an annual incentive bonus with a target opportunity of up to 80% of his base salary, a long-term incentive

compensation award with a total target fair value of $3,000,000 in connection with this offering, and, starting with the 2026 calendar year, annual long-term incentive compensation awards with a total target grant value of $2,000,000. The St Denis Agreement may be terminated by the Company without "cause" or by Mr. St Denis upon three months' written notice to the other party. If the Company terminates Mr. St Denis' employment without "cause", subject to Mr. St Denis executing and not revoking a release of claims against the Company and its affiliates, the Company will continue to pay Mr. St Denis his base salary for nine months and will reimburse Mr. St Denis for COBRA premium payments for nine months (or until Mr. St Denis becomes eligible for coverage under another medical plan, whichever occurs first). Mr. St Denis will also be provided a cellphone and will be entitled to participate in the Company's employee benefit plans, programs and policies for senior executives. The St Denis Agreement includes customary non-competition, non-solicitation, intellectual property, and confidentiality provisions.

Mr. McDonnell's contract of employment (the "McDonnell Contract"), which supersedes and replaces all prior agreements related to Mr. McDonnell's employment, provides that Mr. McDonnell will serve as the Chief Financial Officer of the Company. Mr. McDonnell's base salary will be $250,800, converted using the spot exchange rate of approximately A$1.00 to $0.66 on November 1, 2024 and excluding superannuation. Mr. McDonnell will also be entitled to receive an annual incentive bonus of up to 60% of his base salary, a long-term incentive compensation award with a total target fair value of $500,000 in connection with this offering, and, starting with the 2026 calendar year, annual long-term incentive compensation awards with a total target grant value of $500,000. Either party may terminate the employment relationship generally upon three months' written notice to the other party; however, the Company will be required to provide an additional week's notice if he is over 45 years old and has provided continuous service for at least five years. The McDonnell Contract includes non-competition, non-solicitation, intellectual property, and confidentiality provisions.

Short-Term Incentive Compensation

Compensation for individuals is linked to our performance as well as the performance and contribution of the individual. Incentive payments are dependent on defined corporate and individual key performance targets being met. Incentive payments for the Chief Executive Officer and for our broader company are at the discretion of the Board of Directors and the Compensation Committee.

The Compensation Committee believes the setting of key corporate and individual key performance targets which are aligned to the corporate strategy, will drive the development, performance and position of our company. The Compensation Committee expects that this will drive increased stockholder returns going forward.

The NEOs' short-term incentive ("STI") bonus performance targets are based on a percentage of their base salaries with the actual incentive dependent on certain company and individual performance conditions being satisfied. STI opportunity targets are based on adjusted EBITDA (earnings before interest, tax, depreciation and amortization), capital position targets and achievement of strategic objectives. Strategic targets include measures linked to the advancement of the TAVR program, including the EFS.

Name	Principal Position	Target STI Bonus %
Wayne Paterson	Chief Executive Officer and Managing Director	100% of base salary
David St Denis	Chief Operating Officer	80% of base salary
Matthew McDonnell	Chief Financial Officer	60% of base salary

During 2023, in addition to an STI cash bonus, Mr. Paterson was awarded a cash bonus of $200,000 for his performance in relation to capital raise activities.

The Board of Directors and Compensation Committee increased Mr. St Denis' STI cash bonus above the maximum possible outcome primarily as a result of his achievements and efforts in relation to the overall EFS trial including the various milestones leading up to it. In addition, Mr. St Denis was awarded a bonus of $20,000 in relation to the achievement of completing the enrollment in the EFS.

Executive Equity-Based Compensation

During 2023, ATL granted options to its directors and officers, including Messrs. Paterson, St Denis, and McDonnell, pursuant to the Incentive Plan (as defined below). Equity settled share options are issued with exercise prices determined by the Board of Directors. There are no performance conditions on options issued other than remaining employed by ATL until the vesting dates, generally over a three-year period. In addition, Mr. Paterson has also received equity settled share options that had performance hurdles linked to share price increases and tenure.

In September 2023, ATL granted 700,000 options to Mr. Paterson which vest in three equal tranches over one, two, and three years subject to Mr. Paterson being employed by ATL through each vesting date. The options will automatically vest, to the extent not already vested, in the event of a change in control. The exercise price of $15.37 has been translated from AUD using the spot exchange rate, as of the date of issue, which was approximately A$1.00 to $0.64.

In June 2024, following the approval by shareholders at the Annual General Meeting on May 29, 2024, ATL issued 475,000 options with an exercise price of $15.34 per share to directors (Mr. Seaberg 75,000 options; Mr. Paterson 300,000 options, Mr. Denaro 50,000 options and Dr. Gu 50,000 options). The quoted exercise prices have been translated from AUD using the spot exchange rate, as of the date of issue, which was approximately A$1.00 to $0.67.

ATL also grants Share Price Performance Units (the "SPP Units") to officers. Employees may receive cash post-vesting that is based on positive increases in the price of ATL's ordinary shares from the base price specified at grant date.

In September 2023, ATL granted SPP Units to Mr. McDonnell, which will vest in three equal tranches over three years subject to Mr. McDonnell being employed by ATL through each vesting date. The SPP Units can be accelerated at the discretion of the administrator in the event of a change in control. The base price of the SPP Units issued was $16.42. The cash payments will be determined by considering the rise in share price from the base price specified at grant date to the vesting date.

In November 2023, ATL granted SPP Units to Mr. St Denis, which vest subject to the satisfaction of service or performance conditions. The first tranche vests upon ATL's share price reaching $41.04, the second tranche vests upon ATL's share price reaching $51.30, and there is no share price requirement for the third tranche, which vests after three years of service. The SPP Units for the first and second tranche vest and become exercisable on the earlier of the achievement of the specified share price hurdles for ten consecutive trading days and the completion of three years of service. If the share price hurdles for the first and second tranche are not achieved, the options vest after three years of service. The base price of the SPP Units issued was $16.42. The units will vest, to the extent not already vested, in the event of a change in control. The cash payments will be determined by considering the rise in share price from the base price specified at grant date to the exercise date.

The above quoted exercise prices, base prices and share price hurdles have been translated from AUD using the year-end spot exchange rate which was approximately A$1.00 to $0.68 on December 31, 2023.

Equity Compensation Plans

Incentive Plans for Directors including the CEO

ATL has a long-term incentive plan for directors, including the Chief Executive Officer, under which they may receive ordinary shares, options or rights. ATL has granted options to its Directors and the Chief Executive Officer subject to the satisfaction of service-based conditions, and in some cases, performance hurdles which, when satisfied, allow eligible participants to receive vested options which are exercisable over shares. Awards of options have been approved by a majority of votes at a shareholder meeting.

An option confers a right to acquire a share during the exercise period, subject to the satisfaction of any vesting conditions, the payment of the exercise price for the option set out in the offer, and otherwise in the manner required by the Board of Directors and specified by the offer.

2017 Employee Incentive Plan

ATL has a long-term incentive plan known as the Admedus Ltd (now known as "n/k/a" ATL) Employee Long Term Incentive Plan (the "2017 Incentive Plan"), which was approved by shareholders in November 2017. Certain eligible participants (which include employees, including any executive director, of Admedus Ltd (n/k/a ATL) or a subsidiary, or any other person so designated by Admedus Ltd's (n/k/a ATL) Board of Directors) under the 2017 Incentive Plan may receive ordinary shares, options or rights.

The vesting of shares, options or rights may be subject to the satisfaction of service-based conditions and performance hurdles which, when satisfied, will allow eligible participants to receive shares or vested options or rights which are exercisable over shares. Awards of fully paid ordinary shares, options, performance rights and share appreciation rights can be made under the 2017 Incentive Plan.

An option confers a right to acquire a share during the exercise period, subject to the satisfaction of any vesting conditions, the payment of the exercise price for the option set out in the offer, and otherwise in the manner required by Admedus Ltd's (n/k/a ATL) Board of Directors and specified by the offer. A right confers an entitlement to be issued, transferred or allocated one share after the vesting date, subject to any disposal restrictions, the satisfaction of the vesting conditions, and any other requirements contained in the offer. Admedus Ltd's (n/k/a ATL) Board of Directors may decide, in its absolute discretion, that rights or options may be satisfied in cash rather than shares by payment to the participant of the cash equivalent value less any exercise price, provided such discretion was stated in the letter inviting the relevant employee to apply for a grant of such securities. Admedus Ltd's (n/k/a ATL) Board of Directors may generally accelerate the vesting of awards upon a change in control at its discretion.

Admedus Ltd's (n/k/a ATL) Board of Directors may amend, supplement or revoke the 2017 Incentive Plan in any manner it decides subject to Rule 12.1 of the 2017 Incentive Plan, which prohibits Admedus Ltd's (n/k/a ATL) Board of Directors from making any amendment to the 2017 Incentive Plan that would have the effect of materially adversely affecting or prejudicing the rights of any participant holding awards. Admedus Ltd's (n/k/a ATL) Board of Directors must not grant shares, options and rights under the 2017 Incentive Plan if the number of shares that could be exercised in aggregate would exceed 5% of the total number of ordinary shares on issue at the date of the invitation to apply for a grant or at the date of the grant.

2020 Employee Incentive Plan

ATL has a long-term incentive plan known as the Employee Incentive Plan (the "2020 Incentive Plan"). Certain eligible participants (which include employees, including any executive director, of ATL or a subsidiary, or any other person so designated by our Board of Directors) under the 2020 Incentive Plan may receive ordinary shares, options or rights.

The vesting of shares, options or rights may be subject to the satisfaction of service-based conditions and performance hurdles which, when satisfied, will allow eligible participants to receive shares or vested options or rights which are exercisable over shares. Awards of fully paid ordinary shares, options, performance rights and share appreciation rights can be made under the 2020 Incentive Plan.

An option confers a right to acquire a share during the exercise period, subject to the satisfaction of any vesting conditions, the payment of the exercise price for the option set out in the offer, and otherwise in the manner required by our Board of Directors and specified by the offer. A right confers an entitlement to be issued, transferred or allocated one share after the vesting date, subject to any disposal restrictions, the satisfaction of the vesting conditions, and any other requirements contained in the offer. Our Board of Directors may decide, in its absolute discretion to substitute the issue, transfer of allocation of these securities for the payment of a cash amount, provided such discretion was stated in the letter inviting the relevant employee to apply for a grant of such securities. Our Board of Directors may generally accelerate the vesting of awards upon a change in control at its discretion.

Our Board of Directors may amend, supplement or revoke the 2020 Incentive Plan in any manner it decides subject to Rule 12.1 of the 2020 Incentive Plan, which prohibits our Board of Directors from making any amendment to the 2020 Incentive Plan that would have the effect of materially adversely affecting or prejudicing the rights of any participant holding awards. Our Board of Directors must not grant shares, options and rights under the 2020 Incentive Plan if the number of shares that could be exercised in aggregate

would exceed 5% of the total number of ordinary shares on issue at the date of the invitation to apply for a grant or at the date of the grant.

The 2017 Incentive Plan and 2020 Incentive Plan will be assigned by ATL to the Company in connection with the Reorganization.

Anteris Technologies Global Corp. Equity Incentive Plan (New)

In connection with the Reorganization, the Company has adopted the Anteris Technologies Global Corp. Equity Incentive Plan (the "Equity Plan") for purposes of granting options in the Company and other awards based on the shares of the Company to employees and other service providers of the Company. The following is a summary of the material terms of the Equity Plan, which is qualified in its entirety by reference to the full text of the Equity Plan, which is filed as an exhibit to the registration statement of which this prospectus forms a part and incorporated herein by reference. No further grants will be made under the 2017 Incentive Plan or the 2020 Incentive Plan following the completion of this offering.

Purpose of the Equity Plan

The purpose of the Equity Plan is to permit award grants to non-employee directors, officers and other employees of the Company and its subsidiaries, and certain consultants to the Company and its subsidiaries, and to provide to such persons incentives and rewards for service and/or performance.

Administration of the Equity Plan

The Equity Plan will be administered by the Compensation Committee of our Board of Directors or a subcommittee thereof (the "Administrator"). The Compensation Committee is comprised of "non-employee directors" for purposes of Rule 16b-3 under the Exchange Act. The Administrator has the power to interpret and construe the Equity Plan and is authorized to take any action it determines in its sole discretion to be appropriate, subject to the express limitations contained in the Equity Plan.

Number of Authorized Shares

The aggregate number of shares of Common Stock which may be issued or transferred pursuant to awards granted under the Equity Plan will not exceed, in the aggregate, 5,163,023 shares of Common Stock (the "Share Limit"). The Share Limit will be increased by 5% of the total number of issued and outstanding shares of Common Stock on a fully-diluted basis on the last day of the preceding fiscal year on the first day of each fiscal year, for a period of ten years commencing in the first fiscal year following the effective date of the Equity Plan. The aggregate number of shares of Common Stock actually issued or transferred by the Company upon the exercise of incentive stock options will not exceed 4,312,777 shares of Common Stock, which limit will increase by 5% of the total number of issued and outstanding shares of Common Stock on the last day of the preceding fiscal year on the first day of each fiscal year, for a period of ten years commencing in the first fiscal year following the effective date of the Equity Plan.

The maximum number of shares subject to awards granted on or following the Effective Date during a single calendar year to any non-employee director, taken together with any cash fees paid to such non-employee director during the fiscal year, may not exceed $750,000 in total value (calculating the value of any such awards based on the fair value of such awards as of their approval effectiveness date); provided, that such calendar year limit shall be $1,000,000 for (i) the non-executive chair of our Board of Directors and (ii) a new non-employee director during his or her first year of service on our Board of Directors.

In the event of certain changes in the capitalization of the Company, the Administrator will adjust the number and kind of shares of Common Stock available for issuance under the Equity Plan and all awards shall be adjusted as the Committee, in its sole discretion, determines is equitably required. Except as described below, shares subject to an award under the Equity Plan that are cancelled, forfeited, expire, or become unexercisable without having been exercised in full will be available for subsequent awards under the Equity Plan. Shares withheld in payment of the exercise price of an option or withholding taxes related to an award will be returned to the Share Limit for future grants of awards under the Equity Plan and will not reduce the Share Limit.

Any references in the Equity Plan and this summary to "shares of Common Stock" may be read as a reference to a CDI or shares of Common Stock as the context reasonably requires, unless the contrary intention is expressly stated in the Equity Plan.

Eligibility and Participation

Eligibility to participate in the Equity Plan is generally limited to employees, consultants, directors, and officers of the Company or any subsidiary. Grants of awards over CDIs may only be granted to Australian employees of the Company or a subsidiary who are not U.S. taxpayers.

Types of Awards under the Equity Plan

The Equity Plan authorizes the Administrator to grant awards, individually or collectively, to recipients in any of the following forms, subject to such terms, conditions and provisions as the Administrator may determine to be necessary or desirable:

- Option rights;
- Appreciation rights;
- Restricted stock;
- Restricted stock units ("RSUs");
- Cash incentive awards;
- Performance shares;
- Performance units ("PSUs"); and
- Other equity-based awards.

Term of Awards

The term of each award will be determined by the Administrator and stated in the award agreement. In the case of option rights and appreciation rights, the term may not exceed ten years from the grant date or such shorter term as may be provided in the award agreement.

Option Rights

Option rights entitle the option holder to purchase shares of Common Stock at a price established by the Administrator. The Administrator will determine the terms of the option rights, including the vesting and other conditions that must be satisfied for the vesting and exercisability of such awards.

Exercise Price

The Administrator will determine the exercise price of each option right at the date of grant, which price may not be less than 100% of the fair market value of the underlying shares on the date of grant. The Equity Plan prohibits the reduction of the exercise price of option rights without stockholder approval, other than in connection with a change in the Company's capitalization.

Exercise of Option Rights

An option holder may exercise his or her option rights by delivering notice of the number of option rights that are being exercised accompanied by payment in full of the applicable exercise price, in such form and pursuant to such procedures as the Company may designate from time to time, and may consist of any method of payment by the award agreement and the Equity Plan.

Appreciation Rights

Appreciation rights entitle the holder to receive from the Company an amount determined by the Committee, which will be expressed as a percentage of the excess of the market value per share of Common

Stock on the date when an appreciation right is exercised over the base price provided for with respect to the appreciation right at the time of exercise. The Administrator will determine the terms of the appreciation rights, including the vesting and other conditions that must be satisfied for the vesting and exercisability of such awards.

Base Price

The Administrator will determine the base price of each appreciation right at the date of grant, which price may not be less than 100% of the fair market value of the underlying shares on the date of grant. The Equity Plan prohibits the reduction of the base price of appreciation rights without stockholder approval, other than in connection with a change in the Company's capitalization.

Stock Awards

Stock awards, including restricted stock, RSUs, cash incentive awards, performance shares, PSUs, and other equity-based awards,may be granted under the Equity Plan. These stock awards may be denominated in shares or units payable in shares of Common Stock (e.g., RSUs), and may be settled in cash, shares, or a combination of cash and shares. Dividend equivalents, which represent a right to receive the equivalent value of dividends paid on shares of Common Stock, may be granted in connection with RSUs, performance shares, and PSUs. The Administrator will determine the terms of stock awards, including the vesting and other conditions that must be satisfied for the vesting of such awards.

Tax Withholding

The Administrator may require a recipient to remit and will have the right to deduct or withhold an amount sufficient to satisfy applicable withholding tax requirements with respect to any award granted under the Equity Plan.

Change in Control

The effect, if any, of certain transactions described in the Equity Plan constituting a change in control of the Company on any awards outstanding at the time immediately prior to such change in control may be specifically set forth in the corresponding award agreement, or if no such treatment is specified, then the Administrator will determine the effect of such transaction on any outstanding awards in accordance with the Equity Plan.

Termination and Amendment of the Equity Plan

Our Board of Directors may at any time amend the Equity Plan, subject to any required stockholder approval and any required consent from participants to the extent required under the Equity Plan or by applicable law. Our Board of Directors may terminate the Equity Plan at any time; provided, however, that such termination will not affect the rights of holders of outstanding awards granted under the Equity Plan or their successors.

Term of Equity Plan

The Equity Plan became effective in connection with the pricing of this offering, and will continue in effect until terminated through a resolution by our Board of Directors, provided that the termination of the Equity Plan will not affect awards then outstanding, and the terms and conditions of the Equity Plan shall continue to apply to such awards. No grant will be made under the Equity Plan on or after the tenth anniversary of the effective date of the Equity Plan.

Outstanding Equity Awards at Fiscal Year End

In connection with the Reorganization and the distribution of our Common Stock, our directors and NEOs will receive CDIs or shares of Common Stock with respect to the ATL ordinary shares they own in the same manner as other ATL shareholders. Where the ATL ordinary shares held by our directors and NEOs prior to the Reorganization and distribution of our Common Stock are subject to vesting requirements,

restrictions on transfer or other similar conditions, the CDIs or shares of Common Stock they receive pursuant to the Reorganization will continue to be subject to substantially equivalent requirements, restrictions and conditions.

In cases where a director or officer of the Company was a director or officer of ATL prior to the Reorganization, we will cancel each of the outstanding options to acquire ordinary shares of ATL held by the director or officer and issue replacement options representing the right to acquire shares of our Common Stock on the basis of one replacement option for every one existing ATL option held. Each replacement option will be vested to the same extent and have the same terms as the existing ATL options held (provided that any references in the existing terms to ATL will be deemed to be references to the Company), except that in connection with issuance of replacement options, the exercise price and number of shares of Common Stock issuable pursuant to each option will be adjusted as appropriate to preserve (but not increase) the economic value of the award to its recipient.

The following table sets forth the outstanding equity awards held by our NEOs as of December 31, 2023.

	Option awards[3]					Stock awards[4]	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option Exercise Price ($)[1]	Option Expiration Date[2]	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
Wayne Paterson	14,358	—	—	25.31	12/31/2027	—	—
	31,890	—	—	4.04	5/15/2029	—	—
	233,000	—	117,000	7.66	3/20/2025	—	—
	27,482	13,740	—	6.48	6/13/2027	—	—
	172,519	86,259	—	8.86	6/13/2027	—	—
	—	700,000	—	16.42	9/15/2028	—	—
David St Denis	5,430	—	—	25.31	12/31/2027	—	—
	40,000	20,000	—	6.07	9/23/2026	—	—
	66,668	133,332	—	8.86	6/13/2027	—	—
	—	—	—	—	—	700,000	3,799,563
Matthew McDonnell	2,001	—	—	4.65	7/12/2029	—	—
	40,000	20,000	—	6.07	9/23/2026	—	—
	16,668	33,332	—	8.86	6/13/2027	—	—
	—	—	—	—	—	350,000[5]	1,048,815

(1) All options are issued in AUD. The exercise prices and share price hurdles have been translated using the year-end spot exchange rate which was approximately A$1.00 to $0.68.

(2) Options vest in three equal tranches over one, two, and three years subject to the option holder being employed by ATL through each vesting date.

(3) The options vest in three tranches following the completion of at least 12, 18 and 24 months service with an increase in the closing share price to $11.49, $15.32 and $22.98 respectively. 117,000 options awarded to Mr. Paterson on March 20, 2020 will vest when ATL's share price reaches $22.98. ATL's Board of Directors exercised its discretion to extend the period to achieve the share price hurdle by an additional 12 months, being 48 months since the date of issue, or March 19, 2024. The share price hurdle was not met by the expiry date, so the options were cancelled subsequent to the year-end.

(4) Stock awards include SPP Units. Employees may receive cash post-vesting that is based on positive increases in the price of ATL's ordinary shares from the base price specified at grant date.

(5) 116,666 of the SPP rights held by Mr. McDonnell were forfeited and cancelled in September 2024 as the share price on the vesting date was less than the base price.

The following table shows the vesting schedule for all unexercisable options, as at December 31, 2023. Unless otherwise noted, approximately one-third of each grant vests on each anniversary of the date of grant over a three-year period, generally subject to continued service.

Name	Grant Date	2024	2025	2026
Wayne Paterson	3/20/2020	117,000[1]	—	—
	5/25/2022	13,740	—	—
	5/25/2022	86,259	—	—
	9/6/2023	233,333	233,333	233,334
Matthew McDonnell	9/23/2021	20,000	—	—
	9/17/2022	16,666	16,666	—
David St Denis	9/23/2021	20,000	—	—
	9/17/2022	66,666	66,666	—

(1) The options were only exercisable when ATL's share price reached $22.98. The share price hurdle was not reached by the expiry date of March 19, 2024 so the options did not vest.

Amended Options

In connection with the Reorganization, options to purchase ATL ordinary shares that were outstanding immediately prior to the consummation of the Reorganization will be amended. The amended options will be options to acquire shares of Common Stock. The amended options will be subject to substantially similar provisions applicable to the options to purchase ATL ordinary shares, including the vesting conditions and option term, except that the number of shares of Common Stock issuable pursuant to each option will be equal to the number of ATL ordinary shares multiplied by the conversion ratio, and the exercise price of the amended options will be equal to the exercise price of the cancelled options divided by the conversion ratio.

New Equity Awards

In connection with this offering, each NEO will receive an award of restricted stock units under the Equity Plan, which will vest annually over a three year period. Vesting of such awards will accelerate upon a termination of employment following a change in control. The target grant value for such awards as of the date of pricing of this offering will be: for Mr. Paterson, $6,000,000; for Mr. St Denis, $3,000,000; and for Mr. McDonnell, $500,000, and Mr. Paterson's award is subject to stockholder approval in accordance with the rules of the ASX.

Retirement Plan

Australian employees are entitled to contributions to defined contribution plans (superannuation) at 12% of the participant's annual eligible gross salary and wages (post July 1, 2024) subject to certain contribution caps. The rate has increased by 0.5% annually for the past three years. U.S. employees receive 3% of gross income as an employer contribution limited by the eligible compensation threshold.

Health Benefit Plan

ATL provides a health benefit plan to U.S.-based NEOs.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

Other than executive compensation arrangements described elsewhere in this prospectus (See "*Executive Compensation*") and those transactions contemplated by the Reorganization, since January 1, 2022, there have been no transactions, and there currently are no proposed transactions in which the Company was or is to be a participant and in which any related person has or will have a direct or indirect material interest involving the lesser of $120,000 or one percent (1%) of the average of our total assets as of the end of last three completed fiscal years. A related person is any executive officer, director, nominee for director or holder of 5% or more of our Common Stock, or an immediate family member of any of those persons.

We have a written related-party transaction policy, to be effective immediately prior to the effectiveness of the Reorganization, that applies to our executive officers, directors, director nominees, holders of more than 5% of any class of our voting securities and any member of the immediate family of, and any entity affiliated with, any of the foregoing persons. Such persons will not be permitted to enter into a related-party transaction with us without the prior consent of our Audit and Risk Committee, or other independent members of our Board of Directors in the event it is inappropriate for our Audit and Risk Committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, director nominee, principal stockholder, or any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 or one percent (1%) of the average of our total assets as of the end of last three completed fiscal years must first be presented to our Audit and Risk Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit and Risk Committee will consider the relevant facts and circumstances available and deemed relevant to our Audit and Risk Committee, including, but not limited to, the commercial reasonableness of the terms of the transaction and the materiality and character of the related party's direct or indirect interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

In connection with the Reorganization, our directors and executive officers will receive CDIs or shares of Common Stock with respect to ATL ordinary shares they own in the same manner as other ATL shareholders. The following table presents certain information with respect to (i) ATL's ordinary shares as of November 29, 2024, (ii) shares of our Common Stock (including shares represented by CDIs) after giving effect to the Reorganization and this offering, assuming no exercise of the underwriters' option to purchase additional shares and (iii) shares of the Company's Common Stock (including shares represented by CDIs) after giving effect to the Reorganization and this offering, assuming the underwriters exercise their option to purchase additional shares in full, beneficially owned by:

- each of our NEOs;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person known to us to be the beneficial owner of more than 5% of the outstanding ordinary shares of ATL.

ATL's ordinary shares will be converted upon completion of the Reorganization into shares of our Common Stock at a ratio of one share of Common Stock for every one ATL ordinary share held. Immediately following the completion of the Reorganization and this offering, 35,939,816 shares of our Common Stock will be issued and outstanding, including shares of Common Stock represented by CDIs, based on the 21,139,816 shares of Common Stock issued in connection with the Reorganization and 14,800,000 shares sold in this offering.

The percentage of beneficial ownership prior to the Reorganization and this offering is based on 21,139,816 ordinary shares of ATL outstanding as of November 29, 2024. The percentage of beneficial ownership giving effect to the Reorganization and after this offering, assuming no exercise of the underwriters' option to purchase additional shares, is based on 35,939,816 shares of Common Stock to be outstanding as of the completion of this offering, after giving effect to the sale by us of 14,800,000 shares of Common Stock at the initial public offering price of $6.00 per share. The percentage of beneficial ownership giving effect to the Reorganization and after this offering, assuming the underwriters exercise their option to purchase additional shares in full, is based on 38,159,816 shares of Common Stock to be outstanding after giving effect to the sale by us of 17,020,000 shares of Common Stock at the initial public offering price of $6.00 per share.

The amounts and percentages of Common Stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or to direct the voting of such security, or "investment power," which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has the right to acquire beneficial ownership within 60 days. Under these rules more than one person may be deemed a beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all ATL ordinary shares or shares of Common Stock that they beneficially own, subject to community property laws where applicable.

Share ownership information of our directors and executive officers is as of November 29, 2024. The number of ATL Ordinary Shares are based on quantities disclosed in the most recent substantial holding notices given to the Company and ASX under the *Corporation Act 2001* plus quantities reported in ATL's share and option registers. Unless otherwise indicated below, the address for each person or entity listed below is Toowong Tower, Level 3, Suite 302, 9 Sherwood Road, Toowong, QLD 4066, Australia.

Name of Beneficial Owner	Securities Beneficially Owned Before the Reorganization and this Offering (Assuming Full Exercise of the Vested Options)		Securities Beneficially Owned After the Reorganization and this Offering (Assuming No Exercise of the Option to Purchase Additional Shares)		Securities Beneficially Owned After the Reorganization and this Offering (Assuming Full Exercise of the Option to Purchase Additional Shares)	
	ATL Ordinary Shares	Percentage	Shares of Common Stock[1]	Percentage	Shares of Common Stock[1]	Percentage
Directors and NEOs						
J. Seaberg[2]	188,358	*	188,358	*	188,358	*
W. Paterson[2]	837,082	3.8%	837,082	2.3%	837,082	2.1%
S. Denaro[3]	90,555	*	90,555	*	90,555	*
W. Gu	66,833	*	66,833	*	66,833	*
D. St Denis[2]	198,764	*	198,764	*	198,764	*
M. McDonnell[4]	95,335	*	95,335	*	95,335	*
All directors and executive officers as a group (six persons)	1,476,927	6.5%	1,476,927	4.0%	1,476,927	3.7%
Five Percent Stockholders						
L1 Capital Pty Ltd[6]	4,356,485	20.2%	4,356,485	12.0%	4,356,485	11.3%
Perceptive Advisors LLC[5]	2,440,000	11.4%	2,440,000	6.7%	2,440,000	6.3%
Stephen Silver	1,413,481	6.5%	1,413,481	3.9%	1,413,481	3.6%
Sio Capital Management, LLC[7]	1,114,005	5.3%	1,114,005	3.1%	1,114,005	2.9%

* Represents beneficial ownership of less than 1% of the outstanding ordinary shares or shares of Common Stock, as applicable.

(1) Includes shares of Common Stock that may be represented by CDIs.

(2) The address is 860 Blue Gentian Road, Suite 340, Eagan, Minnesota 55121.

(3) Includes 83,333 shares issuable upon exercise of vested options held by Sloane Pty Ltd as Trustee for the Denaro Family Trust and 7,222 shares held by Citicorp Nominees Pty Limited. Mr. Denaro serves as the director and sole shareholder of Sloane Pty Ltd, which Mr. Denaro is deemed to beneficially own.

(4) Includes 95,335 shares issuable upon exercise of vested options held by Quadroo Pty Ltd, as Trustee for the McDonnell Family Trust. Mr. McDonnell and Mrs. McDonnell serve as directors of Quadroo Pty Ltd and share voting and investment power over such shares.

(5) The address for Perceptive Advisors LLC is 51 Astor Place, 10th Floor, New York, NY 10003.

(6) The address for L1 Capital Pty Ltd is Level 45, 101 Collins Street, Melbourne, VIC 3000 Australia.

(7) The address for Sio Capital Management, LLC is 600 Third Avenue, 2nd Floor, New York, NY 10016.

DESCRIPTION OF CAPITAL STOCK

Description of Capital Stock

The following description of our capital stock is a summary. The complete text of forms of our Second Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, which will be effective immediately prior to the completion of the Reorganization and the closing of this offering, are each included as exhibits to the registration statement of which this prospectus forms a part and are incorporated by reference herein. Our authorized share capital is divided into 400,000,000 shares of Common Stock, par value of $0.0001 per share, and 40,000,000 shares of preferred stock, par value of $0.0001 per share ("Preferred Stock"). Immediately after the completion of the Reorganization and this offering, there will be 35,939,816 shares of our Common Stock issued and outstanding held by 3,662 record holders. As of immediately after the completion of the Reorganization, we expect that no shares of Preferred Stock will be issued and outstanding. The actual number of stockholders will be considerably greater than the number of stockholders of record and will include stockholders who are beneficial owners but whose CDIs or shares of Common Stock are held in street name by brokers and other nominees.

Common Stock

Except as otherwise required by law, as provided in our Second Amended and Restated Certificate of Incorporation or as provided in the resolution or resolutions, if any, adopted by our Board of Directors with respect to any series of the Preferred Stock, the holders of our Common Stock will exclusively possess all voting power. Each holder of shares of Common Stock will be entitled to one vote for each share held by such holder. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. Subject to the rights of holders of any series of outstanding Preferred Stock, holders of shares of our Common Stock will have equal rights of participation in the dividends and other distributions in cash, stock or property of the Company when, as and if declared thereon by our Board of Directors from time to time out of assets or funds legally available therefor and will have equal rights to receive the assets and funds of the Company available for distribution to stockholders in the event of any liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary.

CDIs

CDIs will confer the beneficial ownership of our Common Stock on each CDI holder, with the legal title to such securities held by an Australian depositary entity, CHESS Depositary Nominees Pty Limited (the "Depositary Nominee"), which is a wholly-owned subsidiary of ASX Limited, being the operator of the ASX. The Depositary Nominee will be the registered holder of those shares of our Common Stock held for the benefit of the holders of CDIs. The Depositary Nominee does not charge a fee for providing this service. Each CDI will represent an interest in one share of our Common Stock. Holders of CDIs will not hold the legal title to the underlying shares of our Common Stock to which the CDIs relate, as the legal title will be held by the Depositary Nominee. Each holder of CDIs will, however, have a beneficial interest in the underlying shares in our Common Stock. Each holder of CDIs that elects to vote at a stockholder meeting will be entitled to one vote for every one CDI held by such holder. In order to vote at a stockholder meeting, a CDI holder may:

- instruct the Depositary Nominee, as legal owner of the shares of Common Stock, to vote the Common Stock represented by their CDIs to vote the shares of our Common Stock represented by their CDIs in a particular manner. A voting instruction form will be sent to holders of CDIs and must be completed and returned to the share registry for the CDIs prior to a record date fixed for the relevant meeting, or the CDI Voting Instruction Receipt Time, which is notified to CDI holders in the voting instructions included in a notice of meeting;
- inform us that they wish to appoint themselves or a third party as the Depositary Nominee's proxy with respect to our shares of Common Stock underlying the holder's CDIs for the purposes of attending and voting at the meeting. The instruction form must be completed and returned to the share registry for the CDI prior to the CDI Voting Instruction Receipt Time; or

- convert their CDIs into shares of our Common Stock and vote those shares at the meeting. The conversion must be undertaken prior to a record date fixed by the Board of Directors for determining the entitlement of stockholders to attend and vote at the meeting. If the holder later wishes to sell their investment on the ASX, it would first be necessary to convert those shares of Common Stock back to CDIs. Further details on the conversion process are set out below.

Voting instruction forms and details of these alternatives are included in each notice of meeting sent to CDI holders by the Company.

Conversion of CDIs to Shares of Common Stock

CDI holders may at any time convert their CDIs to a holding of shares of Common Stock by instructing the share registry for the CDIs, either:

- Directly in the case of CDIs held on the issuer sponsored sub-register operated by the Company (holders of CDIs will be provided with a CDI issuance request form to return to the share registry for the CDIs); or
- Through their "sponsoring participant" (usually their broker) in the case of CDIs which are held on the CHESS sub-register (in this case, the sponsoring broker will arrange for completion of the relevant form and its return to the share registry for the CDIs).

In both cases, once the share registry for the CDIs has been notified, it will arrange the transfer of the relevant number of shares of Common Stock from the Depositary Nominee into the name of the CDI holder in book entry form or, if requested, deliver the relevant shares of Common Stock to their Depository Trust Company participant in the U.S. Central Securities Depositary. The share registry for the CDIs will not charge a fee for the conversion (although a fee may be payable by market participants). Holding shares of Common Stock will, however, prevent a person from selling their shares of Common Stock on the ASX, as only CDIs can be traded on that market.

Conversion of Shares of Common Stock to CDIs

Shares of Common Stock may be converted into CDIs and traded on the ASX. Holders of shares of Common Stock may at any time convert those shares to CDIs by contacting our transfer agent. The underlying shares of Common Stock will be transferred to the Depositary Nominee, and CDIs (and a holding statement for the corresponding CDIs) will be issued to the relevant security holder. No trading in the CDIs may take place on the ASX until this conversion.

Our transfer agent will not charge a fee to a holder of shares of Common Stock seeking to convert their shares of Common Stock to CDIs, although a fee may be payable by market participants.

In either case, it is expected that each of the above processes will be completed within 24 hours, provided that our transfer agent is in receipt of a duly completed and valid request form. No guarantee can, however, be given about the time required for this conversion to take place.

Dividends and Other Stockholder Entitlements

Holders of CDIs will be entitled to receive all the direct economic benefits and other entitlements in relation to the underlying shares of Common Stock that are held by the Depositary Nominee, including dividends and other entitlements that attach to the underlying shares of Common Stock.

It is possible that marginal differences may exist between the resulting entitlement of a holder of CDIs and the entitlements that would have accrued if a holder of CDIs held their holding directly as shares of Common Stock. The marginal difference in treatment may exist because any fractional entitlement arising in respect of the Depositary Nominee's holding of shares of Common Stock is rounded up by only one (i.e., on the basis of a single consolidated holding) while, if holders of CDIs were treated as though they held shares of Common Stock directly, fractional entitlements arising in respect of each CDI holder's indirect holding of shares of Common Stock would be rounded up individually, which would generally lead to a greater aggregate rounding up of the interests held by CDI holders. We will, however, be required by the

ASX Settlement Rules to minimize any such differences where legally permissible. If a cash dividend or any other cash distribution is declared in a currency other than Australian dollars, we currently intend to convert that dividend or other cash distribution to which a holder of CDIs is entitled to Australian dollars and distribute it to the relevant holder of CDIs in accordance with their entitlement.

Due to the need to convert dividends from U.S. dollars to Australian dollars in the above mentioned circumstances, holders of CDIs may potentially be advantaged or disadvantaged by exchange rate fluctuations, depending on whether the Australian dollar weakens or strengthens against the U.S. dollar during the period between the resolution to pay a dividend and conversion into Australian dollars.

Takeovers

If a takeover bid is made in respect of any of our Common Stock of which the Depositary Nominee is the registered holder, the Depositary Nominee will be prohibited from accepting the offer made under the takeover bid except to the extent that acceptance is authorized by the CDI holders in respect of the shares of Common Stock represented by their holding of CDIs.

The Depositary Nominee must accept a takeover offer in respect of shares of Common Stock represented by a holding of CDIs if the relevant holder of CDIs instructs it to do so and must notify the entity making the takeover bid of the acceptance.

Preferred Stock

Our Board of Directors will be authorized to provide, out of the unissued shares of Preferred Stock, for one or more series of Preferred Stock and, with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof, of the shares of such series, as are stated in the resolution or resolutions providing for the issuance of such series adopted by the Board of Directors. The authority of the Board of Directors with respect to each series of Preferred Stock will include determination of the following:

- the designation of the series;
- the number of shares of the series;
- the dividend rate or rates on the shares of that series, whether dividends will be cumulative and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series;
- whether the series will have voting rights in addition to the voting rights provided by law and, if so, the terms of such voting rights;
- whether the series will have conversion privileges and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the Board of Directors determines;
- whether or not the shares of that series will be redeemable, in whole or in part, at the option of the Company or the holder thereof and, if made subject to such redemption, the terms and conditions of such redemption, including the date or dates upon or after which they will be redeemable, and the amount per share payable in case of redemptions, which amount may vary under different conditions and at different redemption rates;
- the terms and amount of any sinking fund provided for the purchase or redemption of the shares of such series;
- the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Company, and the relative rights of priority, if any, of payment of shares of that series;

- the restrictions, if any, on the issue or reissue of any additional Preferred Stock; and
- any other relative rights, preferences and limitations of that series.

Classified Board of Directors

In accordance with our Second Amended and Restated Certificate of Incorporation, which will be effective immediately prior to the closing of this offering, our Board of Directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our Board of Directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Listing

Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." We currently expect that our CDIs will commence trading on the ASX one trading day following the closing of this offering under the symbol "AVR."

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock will be Computershare Trust Company, N.A.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our Common Stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our Common Stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our Common Stock.

This discussion is limited to Non-U.S. Holders that hold our Common Stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our Common Stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our Common Stock under the constructive sale provisions of the Code;
- persons who hold or receive our Common Stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our Common Stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our Common Stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our Common Stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "U.S. persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

Distributions

As described in the section titled "*Dividend Policy*," we do not anticipate declaring or paying dividends to holders of our Common Stock in the foreseeable future. However, if we do make distributions of cash or property on our Common Stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its Common Stock, but not below zero. Any excess will be treated as capital gain and will be treated as described in the subsection titled "— *Sale or Other Taxable Disposition*" below.

Subject to the discussions below regarding effectively connected income, backup withholding and FATCA, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption from withholding, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below regarding backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our Common Stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);

- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our Common Stock constitutes a U.S. real property interest ("USRPI") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our Common Stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our Common Stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our Common Stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market and such Non-U.S. Holder owned, actually and constructively, 5% or less of our Common Stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our Common Stock will not be subject to backup withholding, provided the Non-U.S. Holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our Common Stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our Common Stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a U.S. person or the holder otherwise establishes an exemption. Proceeds of a disposition of our Common Stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or "FATCA") on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may

be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our Common Stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial U.S. owners" (as defined in the Code) or furnishes identifying information regarding each substantial U.S. owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified U.S. persons" or "U.S. owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the U.S. governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our Common Stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our Common Stock, the preamble to proposed Treasury Regulations eliminates FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our Common Stock.

SHARES ELIGIBLE FOR FUTURE SALE

Market for the Registrant's Equity

Prior to this offering, there has been no public market for our Common Stock. We cannot predict with certainty the effect, if any, that market sales of CDIs or shares of Common Stock or the availability of CDIs or shares of Common Stock for sale will have on the market price prevailing from time to time. The sale of substantial amounts of CDIs or shares of Common Stock in the public market or the perception that such sales could occur could adversely affect the prevailing market price of CDIs or shares of Common Stock and our ability to raise equity capital in the future.

ATL's ordinary shares currently trade on the ASX under the trading symbol "AVR." The shares will be delisted and will cease trading upon the completion of the Reorganization. Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." We expect that our CDIs will commence trading on the ASX on an ordinary settlement basis one trading day following the completion of this offering under the symbol "AVR." There can be no assurance that an active U.S. trading market for our Common Stock will develop.

Upon completion of the Reorganization and this offering, we will have 35,939,816 shares of Common Stock outstanding (including 20,360,496 shares of Common Stock represented by CDIs), assuming no exercise of the underwriters' option to purchase additional shares, held by 3,662 record holders. Based on elections made or expected to be made by holders of ATL ordinary shares in connection with the Reorganization, 20,360,496 of our outstanding shares of Common Stock as of the completion of the Reorganization will be represented by CDIs. Of these shares, 35,895,402 or 99.9% of shares of our Common Stock if the underwriters exercise their option to purchase additional shares in full, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 44,414 shares of Common Stock outstanding will be "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act, which rules are summarized below.

Upon completion of the Reorganization, which is being conducted in reliance upon the exemption from registration provided under Section 3(a)(10) of the Securities Act, we will issue to the shareholders of ATL either one share of Common Stock for every ordinary share of ATL or one CDI for every one ordinary share of ATL, in each case, as held on the Scheme record date. Eligible shareholders of ATL (being those whose residence at the Scheme record date is in Australia, New Zealand, Hong Kong, Singapore, Israel, Belgium, Canada, Denmark, Germany, Ireland, the Netherlands, Sweden, Switzerland or the United States) will receive CDIs by default. In order to receive Common Stock, eligible shareholders were required to complete and submit an election form to ATL's registry no later than 5:00 pm (AEDT) on December 5, 2024. Ineligible shareholders will not receive CDIs or shares of Common Stock but will instead receive the proceeds from the sale of the CDIs to which they would otherwise be entitled by a broker appointed by ATL. Small Shareholders will have the CDIs to which they would otherwise be entitled under the Scheme instead issued to, and sold by, a broker appointed by ATL, with the net proceeds from the sale remitted to the relevant ATL shareholder, unless the Small Shareholder notified ATL's registry that they wish to receive CDIs or Common Stock by no later than 5:00 pm (AEDT) on December 5, 2024. The appointed broker will sell the CDIs in accordance with the terms of a sale facility agreement and will remit the proceeds to ineligible shareholders and Small Shareholders (other than those Small Shareholders who opt out). Additionally, pursuant to the Option Scheme, each outstanding option to acquire ordinary shares of ATL will be cancelled, and the Company will issue replacement options representing the right to acquire shares of Common Stock on the basis of one replacement option for every one existing ATL option held.

Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, a person (or persons whose shares of Common Stock are required to be aggregated) who is an affiliate of the Company is entitled to, subject to any applicable lock-up agreement as described below, sell in any three-month period a number of shares of Common Stock that does not exceed the greater of:

- 1% of the number of shares of Common Stock then outstanding, including shares represented by CDIs, which is expected to equal 359,399 shares immediately after completion of the Reorganization and after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume in the shares of Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such a sale;

except that, in the case of restricted securities, at least six months have elapsed since the later of the date such shares were acquired from us or any of our affiliates.

Sales by our affiliates under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Under Rule 144, a person (or persons whose shares are required to be aggregated) who is not deemed to have been an affiliate of ours at any time during the 90 days preceding a sale, and who holds shares of Common Stock that are restricted securities, may sell such shares provided that at least six months have elapsed since the later of the date such shares were acquired from us or from any of our affiliates and subject to the availability of current information about us. If at least one year has elapsed since the later of the date such shares were acquired from us or from any of our affiliates, such non-affiliate of ours may sell such shares without restriction under Rule 144.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, any of our employees, officers, directors or consultants who purchased or receive shares from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701, or other contract to resell such shares in reliance upon Rule 144, but without compliance with the notice, manner of sale, public information requirements, or volume limitation provisions of Rule 144. Subject to any applicable lock-up agreements, Rule 701 provides that persons who are our "affiliates" as defined in Rule 144 during the immediately preceding 90 days may resell those shares beginning 90 days after the date of this prospectus without complying with the minimum holding period requirements under Rule 144 and that persons who are not our affiliates may sell such shares in reliance on Rule 144 beginning 90 days after the date of this prospectus without complying with the minimum holding period, public information, volume limitation or notice requirements of Rule 144.

The SEC has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Lock-Up Agreements

In connection with this offering, we, our directors, officers and certain of our securityholders have agreed with the underwriters that for a period of 180 days after the date of this prospectus, among other things and subject to certain exceptions more fully described under the section titled "*Underwriting*," not to sell or otherwise transfer or dispose of any of our securities during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior consent of TD Securities (USA) LLC and Barclays Capital Inc. See the section titled "*Underwriting*" for additional information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our Common Stock subject to options outstanding as well as reserved for future issuance under our Equity Plans. We expect to file the registration statements shortly after completion of the Reorganization. The registration statements will become effective immediately upon filing and will permit the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144 applicable to affiliates and any lock-up agreement described above.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated December 12, 2024, among us and TD Securities (USA) LLC, Barclays Capital Inc. and Cantor Fitzgerald & Co, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of Common Stock shown opposite its name below:

Underwriter	Number of Shares
TD Securities (USA) LLC	5,920,000
Barclays Capital Inc.	4,884,000
Cantor Fitzgerald & Co.	2,664,000
Lake Street Capital Markets, LLC	1,332,000
Total	14,800,000

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of Common Stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the Common Stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the Common Stock, that you will be able to sell any of the Common Stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the Common Stock subject to their acceptance of the Common Stock from us and subject to prior sale. Sales of any shares of common stock may be made by affiliates of the underwriters. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Bell Potter Securities Limited is acting as financial advisor in connection with the offering. Bell Potter Securities Limited is not acting as an underwriter of this offering.

Commission and Expenses

The underwriters have advised us that they propose to offer the Common Stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $0.2520 per share of Common Stock. After the offering, the initial public offering price and concession may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	$6.00	$6.00	$88,800,000	$102,120,000
Underwriting discounts and commissions paid by us	$0.42	$0.42	$ 6,216,000	$ 7,148,400
Proceeds to us, before expenses	$5.58	$5.58	$82,584,000	$ 94,971,600

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $2.6 million, which includes the reimbursement of the underwriters for their counsel fees and other expenses related to this offering of up to $364,630. In accordance with Financial Industry Regulatory Authority, Inc. Rule 5110 these reimbursed fees and expenses are deemed underwriting compensation for this offering.

Determination of Offering Price

Prior to this offering, while the ordinary shares of ATL (which will become a subsidiary of the Company following completion of the Reorganization) have been traded on the ASX since March 2004, there has been no public market on a U.S. national securities exchange for ATL's ordinary shares in the United States, and there has not been a public market for our Common Stock. Consequently, the initial public offering price for our Common Stock was determined by negotiations between us and the representatives. Among the factors considered in these negotiations were prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the Common Stock will trade in the public market subsequent to the offering or that an active trading market for the Common Stock will develop and continue after the offering.

Listing

Our Common Stock has been approved for listing on NASDAQ under the symbol "AVR." We expect that our CDIs will commence trading on the ASX on an ordinary settlement basis one trading day following the completion of this offering under the symbol "AVR".

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 2,220,000 shares of Common Stock from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above.

No Sales of Similar Securities

We, our officers, directors and certain of our securityholders, have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act;
- otherwise dispose of any shares of Common Stock, options or warrants to acquire Common Stock, or securities exchangeable or exercisable for or convertible into shares of Common Stock currently or hereafter owned either of record or beneficially; or

- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of TD Securities (USA) LLC and Barclays Capital Inc.

This restriction terminates after the close of trading of the Common Stock on and including the 180th day after the date of this prospectus.

TD Securities (USA) LLC and Barclays Capital Inc. may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of Common Stock prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the Common Stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our Common Stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our Common Stock or purchasing shares of our Common Stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of Common Stock available for purchase in the open market as compared to the price at which they may purchase Common Stock through the option to purchase additional Common Stock.

"Naked" short sales are sales in excess of the option to purchase additional shares of our Common Stock. The underwriters must close out any naked short position by purchasing Common Stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our Common Stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of Common Stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the Common Stock. A syndicate covering transaction is the bid for or the purchase of shares of Common Stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our Common Stock or preventing or retarding a decline in the market price of our Common Stock. As a result, the price of our Common Stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the Common Stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our Common Stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our Common Stock on NASDAQ in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our Common Stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of Common Stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the Common Stock offered hereby. Any such short positions could adversely affect future trading prices of the Common Stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission ("ASIC"), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to persons who are "sophisticated investors" in accordance with section 708(8) of the Corporations Act, or to persons where the offer or invitation to that person otherwise does not require disclosure in accordance with Chapter 6D.2 of the Corporations Act ("Exempt Investors").

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in

compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

Canada

(A) Resale Restrictions

The distribution of shares of Common Stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta, British Columbia, Manitoba, New Brunswick and Nova Scotia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of Common Stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the Common Stock.

(B) Representations of Canadian Purchasers

By purchasing shares of Common Stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of Common Stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106 — Prospectus Exemptions or Section 73.3(1) of the Securities Act (Ontario), as applicable;
- the purchaser is a "permitted client" as defined in National Instrument 31-103 — Registration Requirements, Exemptions and Ongoing Registrant Obligations;
- where required by law, the purchaser is purchasing as principal and not as agent; and
- the purchaser has reviewed the text above under "— *(A) Resale Restrictions*".

(C) Conflicts of Interest

Canadian purchasers are hereby notified that each of the underwriters is relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 — Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these shares of Common Stock in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

(E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of shares of Common Stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of Common Stock in their particular circumstances and about the eligibility of the shares of Common Stock for investment by the purchaser under relevant Canadian legislation.

European Economic Area

In relation to each Member State of the European Economic Area (each, a "Relevant State"), no shares of Common Stock have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of Common Stock which have been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares of Common Stock may be offered to the public in that Relevant State at any time:

a) to any legal entity which is a "qualified investor" as defined under Article 2 of the Prospectus Regulation;

b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer;

c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of the shares of Common Stock shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression "offer to the public" in relation to the shares of Common Stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of Common Stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of Common Stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Hong Kong

No shares of Common Stock have been offered or sold, and no shares of Common Stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (the "SFO"), and any rules made under the SFO; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong (the "CO"), or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the shares of Common Stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of Common Stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under the SFO.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the shares of Common Stock may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of Common Stock will be required, and is deemed by the acquisition of the shares of Common Stock, to confirm that he is aware of the restriction on offers of the shares of Common Stock described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any shares of Common Stock in circumstances that contravene any such restrictions.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the "Securities Law"), and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of Common Stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum (the "Addendum"), to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50.0 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended) ("FIEL"), and the underwriters will not offer or sell any shares of Common Stock, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the Common Stock may not be circulated or distributed, nor may the Common Stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of Common Stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b) trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of Common Stock pursuant to an offer made under Section 275 of the SFA except:

   i. to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

   ii. where no consideration is or will be given for the transfer;

   iii. where the transfer is by operation of law;

iv. as specified in Section 276(7) of the SFA; or

v. as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The shares of Common Stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the "SIX"), or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority ("FINMA"), and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (the "CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

No shares of Common Stock have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares of Common Stock which has been approved by the Financial Conduct Authority, except that the shares of Common Stock may be offered to the public in the United Kingdom at any time:

a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (the "FSMA"),

provided that no such offer of the shares of Common Stock shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares of Common Stock in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of Common Stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of Common Stock and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

New Zealand

The shares of Common Stock offered hereby have not been offered or sold, and will not be offered or sold, directly or indirectly in New Zealand and no offering materials or advertisements have been or will be distributed in relation to any offer of shares in New Zealand, in each case other than:

- to persons whose principal business is the investment of money or who, in the course of and for the purposes of their business, habitually invest money;
- to persons who in all the circumstances can properly be regarded as having been selected otherwise than as members of the public;

- to persons who are each required to pay a minimum subscription price of at least NZ$500,000 for the shares before the allotment of those shares (disregarding any amounts payable, or paid, out of money lent by the issuer or any associated person of the issuer); or
- in other circumstances where there is no contravention of the Securities Act 1978 of New Zealand (or any statutory modification or reenactment of, or statutory substitution for, the Securities Act 1978 of New Zealand).

LEGAL MATTERS

The validity of the issuance of the shares of Common Stock offered hereby will be passed upon for Anteris Technologies Global Corp. by Jones Day. Covington & Burling LLP, New York, New York, is U.S. counsel to the underwriters in connection with this offering and Allens, Australia is Australian counsel to the underwriters.

EXPERTS

The consolidated financial statements of Anteris Technologies Ltd and subsidiaries as of December 31, 2023 and 2022, and for each of the years in the two year period ended December 31, 2023, have been included herein and in the prospectus in reliance upon the report of KPMG, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The audit report covering the December 31, 2023 and 2022 consolidated financial statements of Anteris Technologies Ltd contain an explanatory paragraph that states that Anteris Technologies Ltd and subsidiaries' recurring losses from operations and net capital deficiency raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements of Anteris Technologies Ltd do not include any adjustments that might result from the outcome of that uncertainty.

The financial statements of Anteris Technologies Global Corp. as of September 30, 2024 and for the period from January 29, 2024 to September 30, 2024, have been included herein and in the prospectus in reliance upon the report of KPMG, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

Certain market data in this prospectus is attributed to a report prepared for us by FMI and is included on reliance upon the authority of that firm as an expert, although FMI has not independently verified the material provided to it by any outside sources relied upon in producing such report. This information has been included with the consent of FMI and FMI has authorized that portions of the prospectus be attributed to it.

LIMITATION ON INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S LIABILITY

The liability of KPMG, in relation to the performance of their professional services provided to Anteris Technologies Ltd including, without limitation, KPMG's audits of Anteris Technologies Ltd's consolidated financial statements described above, is limited under the Chartered Accountants in Australia and New Zealand (NSW) Scheme approved by the New South Wales Professional Standards Council or such other applicable scheme approved pursuant to the Professional Standards Act 1994 (NSW) (the "Professional Standards Act"), including the Treasury Legislation Amendment (Professional Standards) Act (the "Accountants Scheme"). Specifically, the Accountants Scheme limits the liability of KPMG to a maximum amount of A$75.0 million. The Accountants Scheme does not limit liability for breach of trust, fraud or dishonesty. The Professional Standards Act and the Accountants Scheme have not been subject to relevant judicial consideration and, therefore, how the limitations will be applied by courts and the effect of the limitations on the enforcement of foreign judgments is untested.

Anteris Technologies Ltd does not have an indemnification agreement with KPMG, the auditors of Anteris Technologies Ltd that, under FRC 602.02.f.i, would result in KPMG not being considered independent for the purpose of certifying the financial statements. Any such indemnification agreement would be regarded as against public policy and unenforceable under U.S. securities laws.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the Common Stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to the Company and our Common Stock, reference is made to the registration statement and the exhibits and any schedules filed therewith. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance, if such contract or document is

filed as an exhibit, reference is made to the copy of such contract or other document filed as an exhibit to the registration statement, each statement being qualified in all respects by such reference. Our SEC filings will also be available to the public from commercial document retrieval services and at the website maintained by the SEC at *www.sec.gov*.

As a result of the offering, we will be required to file periodic reports and other information with the SEC. We also maintain a website at *www.anteristech.com*, at which, following this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Information contained on, or that is accessible through, any website referenced in this prospectus does not constitute a part of this prospectus and we do not incorporate any such information into this prospectus or the registration statement of which it forms a part. Any such website address has been included in this prospectus solely as an inactive textual reference.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Anteris Technologies Ltd:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Anteris Technologies Ltd and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has suffered losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (U.S.) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG

We have served as the Company's auditor since 2022.

Brisbane, Australia
13 May 2024

ANTERIS TECHNOLOGIES LTD

CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in US dollars, except share quantities)

	Note	YEARS ENDED DECEMBER 31, 2023 $	2022 $
Net sales	4	2,734,821	3,200,711
Costs and expenses:			
Cost of products sold		(1,858,021)	(2,902,328)
Research and development expense		(30,889,993)	(17,590,090)
Selling, general and administrative expense	5	(17,360,629)	(15,439,777)
Acquired in-process research and development	20	(131,617)	—
Net foreign exchange (losses)/gains		(634,549)	1,617,209
Operating loss		(48,139,988)	(31,114,275)
Other non-operating income, net	4	1,935,415	1,456,276
Interest and amortization of debt discount and expense	5	(67,089)	(648,709)
Fair value movement of derivatives	15	9,512	(257,092)
Loss on asset acquisition of a variable interest entity	20	(501,247)	—
Loss before income taxes from continuing operations		(46,763,397)	(30,563,800)
Income tax (expense)/benefit	6	—	—
Loss after income tax		(46,763,397)	(30,563,800)
Net loss attributable to non-controlling interests and redeemable non-controlling interests		(741,556)	—
Loss Attributable to Anteris Technologies Ltd		(46,021,841)	(30,563,800)
Share information			
Basic and diluted loss per share ($ per share)	18	2.95	2.29
Basic and diluted weighted average shares outstanding	18	15,605,878	13,362,583

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Amounts in US dollars)

	YEARS ENDED DECEMBER 31,	
	2023 $	2022 $
Loss after income tax	(46,763,397)	(30,563,800)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments	381,929	(2,185,789)
Other comprehensive loss for the year, net of tax	381,929	(2,185,789)
Total comprehensive loss	(46,381,468)	(32,749,589)

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONSOLIDATED BALANCE SHEETS
(Amounts in US dollars, except share quantities)

	Note	DECEMBER 31, 2023 $	2022 $
ASSETS			
Current Assets			
Cash and cash equivalents	7	21,088,875	9,353,190
Accounts receivable from customers, net of allowances		407,556	440,926
Inventories	8	442,348	355,624
Prepaid expenses		845,129	1,016,295
Other current assets	12	1,437,826	1,073,640
Total Current Assets		24,221,734	12,239,675
Non-Current Assets			
Plant and equipment, net	9	4,034,636	2,271,793
Operating lease right-of-use assets	10	1,443,655	866,684
Intangible assets, net	11	410,146	607,354
Other assets	12	417,269	—
Total Non-Current Assets		6,305,706	3,745,831
TOTAL ASSETS		30,527,440	15,985,506
LIABILITIES			
Current Liabilities			
Accounts payable		3,139,140	1,726,872
Accrued and other liabilities	13	4,725,540	2,868,849
Current portion of operating lease liabilities	10	659,802	469,131
Current portion of debt obligations	14	931,802	980,394
Total Current Liabilities		9,456,284	6,045,246
Non-Current Liabilities			
Operating lease liabilities	10	922,656	431,083
Long-term debt obligations	14	97,961	8,695
Other liabilities	13	1,152,466	467,260
Total Non-Current Liabilities		2,173,083	907,038
TOTAL LIABILITIES		11,629,367	6,952,284
COMMITMENTS AND CONTINGENCIES	23		
SHAREHOLDERS' EQUITY			
Ordinary shares, 17,820,149 and 13,901,883 shares issued and outstanding, respectively[(1)]	17	217,327,489	169,789,200
Additional paid in capital		11,625,608	3,256,299
Accumulated other comprehensive loss	21	(9,555,376)	(9,937,305)
Accumulated Deficit		(200,096,813)	(154,074,972)
TOTAL SHAREHOLDERS' EQUITY		19,300,908	9,033,222
Non-controlling interests		(402,835)	—
TOTAL EQUITY		18,898,073	9,033,222
TOTAL LIABILITIES AND EQUITY		30,527,440	15,985,506

(1) Under the Australian *Corporations Act 2001*, companies are not required to maintain authorized capital or assign a par value to their issued shares

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(Amounts in US dollars, except share quantities)

	Ordinary shares		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity	Non-controlling interests	Total Equity
	Shares Quantity	Shares $	$	$	$	$	$	$
Balance at December 31, 2021	11,093,845	141,468,341	319,282	(7,751,516)	(123,511,172)	10,524,935	—	10,524,935
Loss after income tax	—	—	—	—	(30,563,800)	(30,563,800)	—	(30,563,800)
Other comprehensive loss	—	—	—	(2,185,789)	—	(2,185,789)	—	(2,185,789)
Ordinary shares issued	2,808,038	28,320,859	—	—	—	28,320,859	—	28,320,859
Stock-based compensation	—	—	2,937,017	—	—	2,937,017	—	2,937,017
Balance at December 31, 2022	13,901,883	169,789,200	3,256,299	(9,937,305)	(154,074,972)	9,033,222	—	9,033,222
Loss after income tax	—	—	—	—	(46,021,841)	(46,021,841)	(741,556)	(46,763,397)
Other comprehensive loss	—	—	—	381,929	—	381,929	—	381,929
Ordinary shares issued	3,918,266	47,538,289	—	—	—	47,538,289	—	47,538,289
Acquisition of subsidiary	—	—	—	—	—	—	338,721	338,721
Stock-based compensation	—	—	8,369,309	—	—	8,369,309	—	8,369,309
Balance at December 31, 2023	17,820,149	217,327,489	11,625,608	(9,555,376)	(200,096,813)	19,300,908	(402,835)	18,898,073

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in US dollars)

	Note	YEARS ENDED DECEMBER 31, 2023 $	2022 $
CASH FLOWS FROM OPERATING ACTIVITIES			
Loss after income tax		(46,763,397)	(30,563,800)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		1,157,723	774,077
Equity-settled stock-based compensation		5,759,775	2,937,017
Acquired in-process research and development		131,617	—
Loss on asset acquisition of a variable interest entity		501,247	—
Non-cash financing costs		—	538,604
Fair value movement of derivatives		(9,512)	257,092
Net foreign exchange losses/(gains)		634,549	(1,617,209)
Other items		(29,761)	4,370
Change in operating assets and liabilities:			
Accounts receivable, prepayments and other assets		(345,011)	(533,796)
Inventories		(86,725)	194,196
Accounts payable, accrued and other liabilities		4,417,979	(1,407,253)
NET CASH USED IN OPERATING ACTIVITIES		(34,631,516)	(29,416,702)
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisition of plant and equipment		(2,388,264)	(1,574,766)
Acquisition of intangibles		(6,644)	(91,223)
Acquisition of subsidiary	20	(213,000)	—
Proceeds from sale of distribution rights		—	670,000
Proceeds from sale of plant and equipment		26,235	3,419
NET CASH USED IN INVESTING ACTIVITIES		(2,581,673)	(992,570)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from share issues		52,823,026	25,298,089
Share issue transaction costs		(2,675,203)	(1,051,246)
Repayment of debt		(763,030)	(936,090)
Principal payments under finance lease obligations		(45,019)	(39,364)
NET CASH PROVIDED BY FINANCING ACTIVITIES		49,339,774	23,271,389
Effect of exchange rate movements on cash, cash equivalents and restricted cash		(390,900)	1,035,891
CASH, CASH EQUIVALENTS AND RESTRICTED CASH			
Net change during the year		11,735,685	(6,101,992)
Balance at beginning of year		9,353,190	15,455,182
Balance at end of year	7	21,088,875	9,353,190

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEAR ENDED DECEMBER 31, 2023

1. DESCRIPTION OF BUSINESS

Anteris Technologies Ltd's ("Anteris," "Company", "we," "us," or "our") principal activities consist of:

- Continued research and development ("R&D") of Structural Heart products. Products under development include DurAVR®, a transcatheter heart valve ("THV") for the treatment of aortic stenosis.
- The manufacture and sale of proprietary ADAPT® tissue products.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This note provides a list of the significant accounting policies adopted in the preparation of these consolidated financial statements. The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP"). These policies have been consistently applied to all the years presented, unless otherwise stated.

(a) Principles of consolidation

The consolidated financial statements include the accounts of Anteris Technologies Ltd, its wholly-owned subsidiaries, entities for which the Company has a controlling financial interest, as well as any variable interest entities ("VIEs") for which Anteris Technologies Ltd has been determined to be the primary beneficiary. Anteris Technologies Ltd and its subsidiaries together are referred to in these financial statements as the 'Group'.

Subsidiaries are all those entities over which the Group has control. Control is the power to govern the financial and operating policies of an entity. All subsidiaries of Anteris Technologies Ltd have a reporting year end of December 31, 2023.

Intercompany transactions, balances and unrealized gains or losses on transactions between entities in the Group are eliminated.

(b) Use of estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts in the consolidated financial statements and accompanying notes. Management continually evaluates its judgments and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgments, estimates and assumptions on historical experience and on other various factors, including expectations of future events that management believes to be reasonable under the circumstances. Actual results could differ from those estimates due to risks and uncertainties and may be material.

Management has discussed the development and selection of these critical accounting estimates with the Audit and Risk Management Committee and the Board of Directors. In addition, there are other items within the financial statements that require estimation but are not deemed critical as defined above. Changes in estimates used in these and other items could have a material impact on the financial statements.

Significant items subject to such estimates and assumptions include, but are not limited to the following:

- Going concern: The Directors assess whether the Company and the Group will be able to continue as a going concern and therefore, whether they will realize their assets and extinguish their liabilities in the normal course of business and at the amounts stated in this financial report. In the event that opportunities do not eventuate there are material uncertainties as to whether they will be able to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

- Timing of recognition of the Research and Development Tax incentive income: Significant judgment is required in determining the amount and timing of recognition of the research and development tax incentive asset. As the grant requirements are complex, the Group performs detailed analysis over eligible expenditure based on the criteria set by the relevant taxation authorities and assesses whether there is reasonable assurance that the research and development tax incentive grant will be received.
- Stock-based compensation fair value inputs: Fair value is determined using Black-Scholes and Monte Carlo models which require various inputs including the exercise price and share price at grant date, plus other highly judgmental assumptions, such as share price volatility, risk-free interest rate, and the expected option term.
- Consolidation of variable interest entities: The Company consolidates a VIE when the reporting entity (a) has an economic interest in another legal entity (known as a "variable interest") that conveys more than insignificant exposure to potential losses of or benefits from the other legal entity; and (b) has power over the most significant economic activities of the legal entity. There is significant judgment over the analysis to determine whether an entity is a VIE, to determine whether the Company has a variable interest and to determine whether the Company is the primary beneficiary of a VIE.

(c) Foreign currency translation

The financial statements are presented in United States dollars, which is Anteris Technologies Ltd's reporting currency.

Foreign currency transactions

Foreign currency transactions are translated using the average monthly currency exchange rates in effect during the period. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are included as operating income or expense in the consolidated statements of operations.

Conversion to presentation currency

The assets and liabilities of non-U.S. dollar functional currency entities are translated into U.S. dollars using period-end exchange rates, and the revenues and expenses of those entities are translated into U.S. dollars using the average exchange rates, which approximates the rate at the date of the transaction. Equity accounts are translated at historical rates, except for the change in retained earnings during the year, which is the result of the income statement translation process. The cumulative translation adjustments associated with the net assets of foreign subsidiaries are recorded in accumulated other comprehensive loss in the consolidated statements of comprehensive loss and shareholders' equity.

The determination of the functional and reporting currency of each Group company is based on the primary currency in which the Group company operates. Anteris Technologies Ltd's functional currency is Australian Dollars (AUD), and the significant Anteris subsidiaries have U.S. dollar (USD or $), Swiss Franc (CHF) and AUD functional currencies.

(d) Revenue and Other income

Sale of goods

Revenue from the sale of goods, which is primarily ADAPT® tissue, is recognized at a point in time when the performance obligation is satisfied, typically being upon delivery to the customer's premises when

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

control of the goods transfers to the customer. Revenue is recognized at an amount which reflects the consideration to which the Group expects to be entitled in exchange for those goods.

The Company generates its revenue from direct product sales and typically does not have any significant unusual payment terms beyond 30 days in its contracts with customers.

The Company offers volume rebates to certain customers, with these volume rebates being recorded as a reduction to sales. The amount of sales rebates are estimated based on contracted rebate terms, projected sales and historical experience.

Revenue recognition is determined by considering sales rebates and returns, which are assessed through sales terms, historical data, and trend analysis. When estimating rebates, the Company takes into account factors such as the stated rebate rates, trending volumes and other relevant information. Adjustments to rebates and returns reserves are recorded by the Company as either revenue increases or decreases. The Company offers warranties on its tissue and valves that they conform to the specifications, fit for their intended purpose, and do not have material defects.

Taxes assessed by a governmental authority that are both imposed on specific revenue producing transactions and collected by the Company from customers (for example, sales, use, value added, and some excise taxes) are not included in revenue.

Shipping costs to move products from the Company's premises to the customer's premises, are included in "Selling, General and Administrative Expenses." Handling costs, which are costs incurred to store at the Company's premises, move, and prepare products for shipment, are included in "Cost of products sold."

Interest income

Interest income is recognized as interest accrues using the effective interest method. This is a method of calculating the amortized cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts contractual future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

Other income

Other income is recognized when it is received or when the right to receive payment is established.

Research and development tax incentive income

Government grants are received under the Australian government's Research and Development Tax Incentive program, such that a percentage of eligible research and development expenses are reimbursed by the Australian government with the incentive being recognized as other income. Government grants relating to costs incurred are recognized in the consolidated statements of operations over the periods in which the entity recognizes as expenses the related costs for which they are intended to compensate.

The Research and Development Tax incentive income is recognized as income once the Group is satisfied that the Group has complied with the conditions attached to the tax incentives and that the tax incentives will be received. The value is estimated based on an assessment of actual and budgeted eligible research and development expenditure data for the period. Significant judgment is required in determining the amount and timing of recognition, as the grant requirements are complex.

(e) Cash and cash equivalents

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of change in value.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(f) Accounts receivable and other financing receivables

Accounts receivable are amounts due from customers for direct product sales in the ordinary course of business. They are generally due for settlement within 30 days and therefore all classified as current. Accounts receivable are recognized initially at the amount of consideration that is unconditional. The Company holds the accounts receivable with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost less impairment allowances.

An allowance is maintained for estimated losses in the collection of accounts receivable based on customer-specific analysis. The allowance is assessed by considering factors including the recent sales experience, the aging of receivables and historical collection rates. Uncollectible amounts are written-off against the allowance when it is determined that a customer account is uncollectible. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Company, and a failure to make contractual payments for a period greater than 120 days past due. Subsequent recoveries on amounts previously written off are credited against the same line item.

Other receivables are recognized at amortized cost, less any expected loss allowance.

(g) Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realizable value on a weighted average cost formula. Cost comprises direct materials and delivery costs, direct labor, import duties and other taxes, plus an appropriate proportion of variable and fixed overhead expenditure based on normal operating capacity. Costs of purchased inventory are determined after deducting rebates and discounts received or receivable.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

The Company recognizes an inventory reserve to recognize write-downs recorded against the carrying value of inventories for items that are obsolete, damaged, nearing its expiration date, or slow-moving.

(h) Plant and equipment

Recognition and measurement

Plant and equipment is stated at historical cost less accumulated depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Additions and improvements that extend the lives of the assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred.

Costs incurred in acquiring software and licences that will contribute to future period financial benefits through revenue generation and/or cost reduction are capitalised to software and systems. Costs capitalised include external direct costs of materials and services.

An item of plant and equipment is derecognized upon disposal or when there is no future economic benefit to the Group. Gains and losses between the carrying amount and the disposal proceeds are taken to the Consolidated statements of operations. The Company assesses plant and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Depreciation

Depreciation is calculated on a straight-line basis to write off the net cost of each item of plant and equipment over their expected useful lives. Leasehold improvements and plant and equipment under lease are depreciated over the unexpired period of the lease or the estimated useful life of the assets, whichever is shorter.

The residual values, useful lives and depreciation methods are reviewed, and adjusted if appropriate, at each reporting date.

Impairment of Long-lived assets

The Group assesses impairment of long-lived assets at each reporting date by evaluating conditions specific to the Group and to the asset or asset group that may lead to impairment. If an impairment trigger exists and the review indicates that the assets will not be fully recoverable based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. For the purposes of identifying and measuring impairment, long-lived assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

(i) Leases

The Company's lease agreements include leases accounted for as operating leases and those accounted for as finance leases. Finance lease right-of-use assets are included in plant and equipment, net, and finance lease liabilities are included in current debt obligations and long-term debt on the consolidated balance sheets.

The Group leases laboratory facilities and offices through operating leases. The Group leases IT equipment through finance leases.

See note 10 for further information.

Anteris is not a lessor in any lease arrangement.

Anteris as the Lessee

At inception of a contract, the Group assesses whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

At the lease commencement date, the Group recognizes a right-of-use ("ROU") asset (the right to use the leased item) and a corresponding lease liability, except for short term leases. Anteris have made an accounting policy election to apply the short-term lease election to all classes of underlying assets, being those leases which have a term of 12 months or less. The Group recognizes the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

The Company determines the lease term as the noncancellable period of the lease, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option.

Lease liabilities

For operating and finance leases, the lease liability is initially measured at the present value of the unpaid lease payments at the lease commencement date.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Lease liabilities are subsequently measured by reducing the balance to reflect the principal lease repayments made and increasing the carrying amount by the interest on the lease liability. The Group is required to remeasure the lease liability and make an adjustment to the right of use asset in the following instances:

- the term of the lease has been modified or there has been a change in the assessment of a purchase option being exercised, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate;
- a lease contract is modified, and the lease modification is not accounted for as a separate lease, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate; and
- the lease payments are adjusted due to changes in the index or a change in expected payment under a guaranteed residual value, in which cases the lease liability is remeasured by discounting the revised lease payments using the initial discount rate. However, if a change in lease payments is due to a change in a floating interest rate, a revised discount rate is used.

Lease liabilities which will be repaid within twelve months are recognized as current and the liabilities which will be repaid in excess of twelve months are recognized as non-current liabilities.

Lessees are required to discount future lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. Generally, for operating leases, the Group cannot determine the interest rate implicit in the lease because it does not have access to the lessor's estimated residual value or the amount of the lessor's deferred initial direct costs. Therefore, the Group generally uses its incremental borrowing rate as the discount rate for the lease. The incremental borrowing rate is the rate of interest that the Group would have to pay to borrow an amount equal to the lease payments in a similar economic environment and on a collateralized basis over a similar term.

Right of Use assets

The ROU asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred, less any lease incentives received.

For finance leases, the ROU asset is subsequently depreciated using the straight-line method from the commencement date to the end of the lease term. Any remeasurement of the lease liability is also applied against the right-of-use asset value.

For operating leases, the ROU asset is subsequently measured at the amount of the remeasured lease liability, adjusted for the remaining balance of any lease incentives, accrued or prepaid rents. The carrying amount of the ROU asset approximates the present value of the remaining benefits to the Group at each measurement date.

Extension and termination options

Extension and termination options are included in a number of property operating leases across the group and are an area of judgment. In determining the lease term, management considers all facts and circumstances that create an economic incentive to exercise an extension option, or not exercise a termination option. Extension options (or periods after termination options) are only included in the lease term if the lease is reasonably certain to be extended (or not terminated).

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(j) Intangibles

Intangible assets acquired as part of a business combination, other than goodwill, are initially measured at their fair value at the date of the acquisition. Intangible assets acquired separately are initially recognized at cost. Finite life intangible assets are subsequently measured at cost less amortization and any impairment.

The method and useful lives of finite life intangible assets are reviewed at each reporting period. Changes in the expected pattern of consumption or useful life are accounted for prospectively by changing the amortization method or period.

The Group holds finite life intangible assets which are amortized on a straight-line basis with estimated useful lives.

The Group holds intellectual property relating to the ADAPT® tissue engineering technology which was recognized based on an external valuation via a business combination. It is being amortized on a straight-line basis over the period of its expected benefit, being 14 years.

Significant costs associated with the registration of patents and trademarks are deferred and amortized on a straight-line basis over the period of their expected benefit. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States and Australia, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country.

In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

Impairment of intangible assets

Intangible assets with finite lives are tested for impairment when an event occurs or circumstances change that would indicate the carrying amount of the assets or asset group may be impaired. If an impairment trigger exists, the recoverable amount of the asset is determined. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit, and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved.

(k) Derivative financial instruments

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Accounting Standards Codification ("ASC") 815 *Derivatives and Hedging*. The accounting treatment of derivative financial instruments requires that the Company record embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. Conversion options are recorded as a discount to the host instrument and are amortized as amortization of debt discount on the consolidated statements of operations over the life of the underlying instrument.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Derivative instrument liabilities are classified in the balance sheet as current or non-current liabilities based on whether or not net-cash settlement of the derivative instrument is expected within twelve months of the balance sheet date.

Derivative financial instruments are recognized at fair value and on a gross basis in the consolidated balance sheets. Since the Company does not elect to apply hedge accounting, the gains and losses on the fair value movements of the derivative financial instruments are recognized in the Consolidated statements of operations.

(l) Debt obligations

Interest-bearing debt obligations

Debt obligations are initially recognized at fair value, net of transaction costs incurred. Debt obligations are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in the Consolidated statements of operations over the period of the borrowings using the effective interest method.

Warrant liabilities

Warrants are freestanding derivatives which meet the definition of a liability pursuant to ASC 480 *Distinguishing Liabilities from Equity,* with changes in fair value recognized in profit or loss.

(m) Income taxes

Income taxes are accounted for under the asset and liability method.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those deferred tax assets and liabilities are expected to be recovered or settled. A valuation allowance is provided to reduce deferred tax assets to the amount that is more likely than not to be realized. Deferred taxes, including valuation allowances, are determined separately for each tax-paying component in each jurisdiction. The factors used to assess the likelihood of realization are future reversals of existing taxable temporary differences, carryback availability, both historical experience and the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Unrecognized tax benefits

The Group recognizes the effect of income tax positions only if those positions are more likely than not (greater than 50% likelihood) of being sustained upon examination by the taxing authorities, based on the technical merits of the position. Where the Group expects a tax position to be sustained, it recognizes the tax benefit as the largest amount that has a greater than 50% likelihood of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

The Group is subject to income taxes in the jurisdictions in which it operates. Significant judgment is required in determining unrecognized tax benefits. The Group records liabilities or makes other adjustments for unrecognized tax benefits based on the Group's current understanding of the tax law. Where the final tax outcome of these matters is different from the carrying amounts, such differences will impact current and

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

deferred taxes in the period in which such determination is made. The Group has not recorded any unrecognized tax benefits at December 31, 2023.

Inherent in determining the income tax amounts, including the valuation allowance, are judgments regarding business plans, tax planning opportunities and expectations about future outcomes. Realization of certain deferred tax assets is dependent upon generating sufficient taxable income in the appropriate jurisdiction prior to the expiration of the carryforward periods. Currently, management has recognized a valuation allowance for the amount of the deferred tax assets not supported by future reversals of existing taxable temporary differences as management believes that it is more likely than not that those deferred tax assets will not be realized.

(n) Stock-based payments

Equity-settled stock-based compensation benefits are provided to employees, directors and consultants in exchange for the rendering of services. Cash-settled stock-based payment transactions provide employees with the right to cash payments upon the satisfaction of vesting conditions.

The Company measures and recognizes compensation expense for all stock-based awards based on estimated fair values determined at grant date.

The fair value of the cash-settled stock-based obligation is recognized as an expense on a straight line basis over the requisite service period, with a corresponding increase in liabilities. Upon satisfaction of the vesting conditions attached to the rights, the provision becomes a payable. The liability is remeasured at each reporting date and at settlement date based on the fair value of the rights. Any changes in the liability are recognized in profit or loss.

If equity-settled awards are modified, an additional expense is recognized, over the remaining vesting period, for any modification that increases the total fair value of the stock-based compensation benefit as at the date of modification.

Employee service-based stock options

Anteris offers employees service-based stock options in the Company as it believes that the grant of these awards to employees assists with attracting, motivating and aligning the interest of employees with those of its shareholders.

Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period) on a straight-line basis. Forfeitures are estimated at the time of grant and the Company reassesses the probability of vesting at each quarter end and adjusts the stock-based compensation expense based on its probability assessment. Upon exercise of stock options, the Company issues ordinary shares.

Director stock options

The directors have been awarded service-based stock options with the same terms and conditions as the above-mentioned employee service-based stock options. The treatment of these stock options is consistent with the employee stock options.

The directors have also been issued stock options which in addition to the service-based conditions, contain target share price market conditions. The fair value of these options is determined using the Monte Carlo option pricing model which takes into consideration the market conditions. Compensation cost is recognized provided that the service is rendered, regardless of when, if ever, the market condition is satisfied.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The fair value of the award is recognized as an expense over the longer of the requisite service period and the derived service period for the market condition.

Stock options and shares issued to external consultants

On occasion, the Company has granted options or shares to external consultants as consideration for services provided. Awards granted to non-employees are measured at the grant date by estimating the fair value of the equity instruments to be issued in exchange for goods or services received. The expense is recognized in the same manner as if the Company had paid cash for the services.

Fair value estimates

Fair value is determined using Black-Scholes and Monte Carlo models which require various inputs including the exercise price and share price at grant date, plus other highly judgmental assumptions, such as share price volatility, risk-free interest rate, and the expected option term. For options with service conditions, the expense is recognized over the service period. Stock-based compensation expense is recorded net of estimate forfeitures. Judgment is required in estimating which stock options will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and the results of operations would be impacted.

(o) Earnings/Loss per share

Basic earnings (or loss) per share is computed by dividing net profit/loss by the weighted-average ordinary shares outstanding during the period. Diluted earnings/loss per share is computed based on the weighted-average ordinary shares outstanding plus the effect of dilutive potential ordinary shares outstanding during the period calculated using the treasury stock method. Dilutive potential ordinary shares include employee equity stock options, non-vested shares, and similar equity instruments granted by the Company. Potential ordinary share equivalents have been excluded where their inclusion would be anti-dilutive.

(p) Fair value measurement

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either in the principal market; or in the absence of a principal market, in the most advantageous market.

Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Assets and liabilities measured at fair value are classified, into three levels, using a fair value hierarchy that reflects the significance of the inputs used in making the measurements:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities
- Level 3: Unobservable inputs for the asset or liability

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Classifications are reviewed each reporting date and transfers between levels are determined based on a reassessment of the lowest level input that is significant to the fair value measurement.

For recurring and non-recurring fair value measurements, external valuers may be used when internal expertise is either not available or when the valuation is deemed to be significant. External valuers are selected based on market knowledge and reputation. Where there is a significant change in fair value of an asset or liability from one period to another, an analysis is undertaken, which includes a verification of the major inputs applied in the latest valuation and a comparison, where applicable, with external sources of data.

(q) Other liabilities

The Company records a liability in the consolidated financial statements where it is probable that a liability has been incurred, and the amount may be reasonably estimated. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed.

Lease asset retirement obligation

The lease asset retirement obligation relates to the removing of leasehold improvements including laboratories, clean rooms and office spaces and returning the premises to their original condition in accordance with the lease agreements. The calculation of this obligation requires assumptions such as application of closure dates and cost estimates. The amount recognized for each site is periodically reviewed and updated based on the facts and circumstances available at the time.

(r) Employee benefits

Liabilities for employment benefits, which include wages and salaries, bonuses, post-employment benefits, annual leave and long-term service benefits expected to be settled within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

The liability for annual leave and long-term service benefits not expected to be settled within 12 months of the reporting date are measured as the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on national government bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

Defined contribution savings plans

Contributions to defined contribution plans are expensed in the period in which they are incurred.

Australian employees are entitled to contributions to defined contribution plans (superannuation) at 11.5% of the participant's annual eligible compensation (post July 1, 2023) subject to certain contribution caps. The rate has increased by 0.5% annually for the past three years.

The Company's employees in the United States are eligible to participate in a qualified defined contribution plan. Employees receive 3% employer contributions limited by the eligible compensation threshold.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(s) Research and development expenses

Research and development expenses are recognized in the Consolidated statements of operations in the period in which they are incurred. Research and development costs include costs of research, engineering, and technical activities to develop a new product or service or make significant improvement to an existing product or manufacturing process. Research and development costs also include pre-approval regulatory and clinical trial expenses. Research and development costs also include expenses associated with the purchase of intellectual property relating to a particular research and development project that has no alternative future uses, costs of inventory in jurisdictions where regulatory approval from regulatory authorities has not yet been obtained, services and supplies associated with clinical studies, registries and sponsored research. These costs include direct salary and employee benefit-related costs for research and development personnel, costs for materials used and costs for outside services.

(t) Asset Acquisition

The Company evaluates acquisitions of entities or assets to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If this screen criteria is met, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets.

In an asset acquisition, the cost allocated to in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date. The Company recognizes assets acquired and liabilities assumed in asset acquisitions, including contingent assets and liabilities and non-controlling interests ("NCI") in the acquired assets at their estimated fair values as of the date of acquisition.

(u) Variable Interest Entities

Under the ASC 810 *Consolidation* ("ASC 810"), when the Company obtains an economic interest in an entity, it evaluates the entity to determine if it should be deemed a VIE, and, if so, whether the Company is the primary beneficiary and is therefore required to consolidate the VIE, based on significant judgment whether the Company (i) has the power to direct the activities that most significantly impact the economic performance of the VIE and (ii) has the obligation to absorb losses or the right to receive benefits of the VIE that could potentially be significant to the VIE.

On an ongoing basis, the Company re-evaluates the VIE assessment based on potential changes in facts and circumstances, including but not limited to, the shareholder loans to the entity and the execution of any future significant agreements between the entity and its shareholders and/or other third parties.

(v) Segment reporting

Segment information is presented using a management approach, meaning that segment information is provided on the same basis as information is used for internal reporting purposes by the chief operating decision maker ("CODM") which is the CEO, who makes key strategic decisions. The CODM is responsible for the allocation of resources and assessing the performance of the Group. Management has determined that the activities of the business as reviewed by the CODM are one segment, being the development and commercialization of the ADAPT® platform technology. This is focused on the DurAVR® Transcatheter Heart Valve System.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(w) Recently Adopted Accounting Standards

For fiscal year 2023, there were no newly adopted accounting standards that had a material impact to the consolidated financial statements.

(x) New Accounting Standards Not Yet Adopted

New accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and adopted by the Company as of the specified effective date. If not explicitly addressed otherwise, the Company believes that the recently issued standards, which have not yet taken effect, will not materially affect its present or near future financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740) Improvements to Income Tax Disclosures*. ASU 2023-09 intends to enhance income tax disclosures to address investor requests for more information about the tax risks and opportunities present in an entity's worldwide operations. The ASU's two primary enhancements will require further disaggregation for existing disclosures for the effective tax rate reconciliation and income taxes paid. This ASU is effective January 1, 2026 for certain emerging growth companies. The Company has evaluated the effect of adopting this accounting guidance and will include the new required disclosures in future filings as needed.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280) Improvements to Reportable Segment Disclosures.* ASU 2023-07 enhances segment reporting by expanding the breadth and frequency of segment disclosures required for public entities. The amendments in this ASU notably allow registrants to disclose multiple measures of segment profit or loss and clarify single reportable segment entities must apply Topic 280 in its entirety. This ASU is effective January 1, 2025 for smaller reporting companies. The Company is a single reportable segment entity, so it is anticipated that additional disclosures will be required to meet the requirements of ASU 2023-07.

In September 2022, the FASB issued ASU 2022-04, *Liabilities — Supplier Finance Programs (Subtopic 405-50) Disclosure of Supplier Finance Program Obligations.* The ASU requires that a buyer in a supplier finance program disclose sufficient information about the program to allow a user of financial statements to understand the program's nature, activity during the period, changes from period to period, and potential magnitude. This ASU is effective January 1, 2024 for smaller reporting companies. The Company has evaluated the effect of adopting this accounting guidance and will include the new required disclosures in future filings as needed.

In June 2022, the FASB issued ASU 2022-03*, Fair Value Measurement (Topic 820) Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions.* ASU 2022-03 clarifies guidance for fair value measurement of an equity security subject to a contractual sale restriction and establishes new disclosure requirements for such equity securities. This ASU is effective January 1, 2025 for smaller reporting companies. The Company has assessed the impact of adopting this accounting guidance and has determined that it does not materially impact the fair value measurement of the Company's existing equity securities. Nevertheless, the Company will apply the guidance and incorporate the new required disclosures in future filings as needed.

3. GOING CONCERN

The consolidated financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and realisation of assets and discharges of liabilities in the ordinary course of business. As disclosed in the financial statements, the Group incurred a net loss of $46,763,397 and had net cash outflows from operating activities of $34,631,516 for the financial year ended December 31, 2023. As at that date, the Group had a cash balance of $21,088,875.

3. GOING CONCERN (continued)

The Group has been investing in research and development activities associated with the continuing development and proposed commercialization of DurAVR® THV, as well as continuing to invest in R&D. In the year ended December 31, 2023, amounts invested in R&D activities and general operations exceeded cash inflows associated with sales of CardioCel™ and VascuCel™ products tissue products plus R&D tax incentives from the Australian government. The Company generated proceeds of $52,823,026 from the issue of equity securities (before transaction costs).

The Group anticipates that additional funds will need to be generated in order to achieve the Group's long-term goals and complete the research and development of current products. The Group does not expect to generate significant revenue until after regulatory approvals to commercially sell DurAVR® THV have been obtained and sales have commenced. The Group therefore expects to continue incurring substantial losses in the near future.

To become and remain profitable, the Group has commenced conducting clinical trials and obtaining regulatory approvals with the aim of commercializing, manufacturing and supplying products, including DurAVR® THV, that generate significant revenue. For medtech devices, including DurAVR® THV, this will require the Group to obtain further relevant regulatory approvals, successfully complete product clinical trials, develop and expand quality management systems, obtain regulatory approval post completion of clinical trials, expand manufacturing and distribution capabilities and comply with ongoing post-market regulatory requirements.

Prior to achieving commercialization, the Group will periodically require capital infusion through the issuance of ordinary shares, debt instruments, or other securities that can be converted into ordinary shares. The future success of the Company is dependent on its ability to attract additional capital and ultimately, upon its ability to develop future profitable operations. There can be no assurance that the Company will be successful in obtaining such financing, or that it will attain positive cash flow from operations. If the Group is unable to obtain adequate capital resources to fund operations, it may be necessary to delay, scale back or eliminate some or all of its operations, which may have a material adverse effect on the business, results of operations and its ability to operate as a going concern. However, the Group has established a track record of successfully raising new capital and debt facilities. This includes completing an equity capital raise of $21.4 million before costs in Q4 2023 and $14.7 million before costs in Q2 2024.

The above conditions give rise to substantial doubt as to whether the Group will be able to continue as a going concern for one year from the issuance date of these financial statements.

The Directors and management believe that the going concern basis of preparation is appropriate for the reasons outlined above.

Should the Group be unable to continue as a going concern, it may be required to realize its assets and extinguish its liabilities other than in the ordinary course of business, and at amounts that differ from those stated in the financial statements. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts or classification of liabilities and appropriate disclosures that may be necessary should the Group be unable to continue as a going concern.

4. NET SALES AND OTHER NON-OPERATING INCOME, NET

	2023 $	2022 $
Net sales		
Net sales from contracts with customers, at a point in time ADAPT® business	2,734,821	3,200,711
Total net sales	2,734,821	3,200,711
Other non-operating income, net		
Government grants[(1)]	717,331	1,243,839
LeMaitre holdback income[(2)]	434,014	—
Early Feasibility Study ("EFS") income[(3)]	300,000	—
Interest income	428,059	210,382
Sundry income	56,011	2,055
Total other income	1,935,415	1,456,276

(1) In 2023, Government grants consists of $697,531 Research and Development Tax Incentive income accrued relating to the year ended December 31, 2023 plus $19,800 Research and Development Tax Incentive income recognized relating to the year ended December 31, 2022. In 2022, Government grants consisted of $950,889 Research and Development Tax Incentive income relating to the year ended December 31, 2022, plus $277,435 Research and Development Tax Incentive income recognized relating to the year ended December 31, 2021; and a Growth grant of $15,515.

(2) In 2019, the Group sold the distribution rights to its CardioCel™ and VascuCel™ product range to LeMaitre Vascular, Inc. ("LeMaitre"). The agreement provided that Anteris was entitled to an earn-out payable upon receipt of product approval under European Medical Devices Directorate Regulation. Historically, the income had not been virtually certain to be received. In 2023, the agreement was amended and Anteris is entitled to 33% of the holdback amount less eligible deductions by 26 January 2025 if LeMaitre does not obtain the regulatory approvals for either the CardioCel™ and VascuCel® by January 11, 2025. The first instalment has been recognized as a non-current receivable as at December 31, 2023. Refer to note 23.

(3) Early Feasibility Study income generated while assessing the feasibility and viability of the DurAVR® THV device is measured at the fair value of the consideration received or receivable.

5. EXPENSES

The below tables provide additional information regarding the Group's expenses.

	2023 $	2022 $
Depreciation and amortization		
Depreciation of plant and equipment	953,704	573,924
Amortization of Intangibles	204,019	200,153
	1,157,723	774,077
Interest and amortization of debt discount and expense		
Interest and finance charges	35,033	27,762
Interest expense on lease liabilities	3,440	5,639

5. EXPENSES (continued)

	2023 $	2022 $
Amortization of debt transaction costs	—	538,604
Unwind discount on liabilities	28,616	76,704
	67,089	648,709
Selling, general and administrative expense ("SG&A")		
SG&A employee expenses	6,051,393	5,119,005
Stock-based payment expenses	3,810,577	2,045,997
Consultancy and legal fees	3,002,134	4,327,150
IT and telecommunications	711,614	896,417
Marketing and promotional expenses	1,086,200	806,278
Insurance	840,747	643,877
Depreciation and amortization	314,931	226,353
Travel and entertainment	480,051	467,188
Other expenses	1,062,982	907,512
	17,360,629	15,439,777

Defined contribution savings plans

Australian employees are entitled to contributions to defined contribution plans (superannuation) at 11.5% of the participant's annual eligible gross salary and wages (post July 1, 2023) subject to certain contribution caps. The rate has increased by 0.5% annually for the past three years. United States employees receive 3% of gross income as an employer contribution limited by the eligible compensation threshold.

The net expense related to these plans was $565,249 and $452,910 in fiscal years 2023 and 2022, respectively.

6. INCOME TAX

(a) Income tax expense/(benefit)

No income tax expense/(benefit) has been recognized because the Group has historically incurred operating losses and maintains a valuation allowance against its deferred tax assets not supported by future reversals of existing taxable temporary differences.

The components of the loss/(income) before income taxes from continuing operations, based on tax jurisdiction, are as follows:

	2023 $	2022 $
United States	35,850,720	21,489,743
Australia	11,077,540	8,522,855
Other international	(164,863)	551,202
Loss/(income) before income taxes from continuing operations	46,763,397	30,563,800

6. INCOME TAX (continued)

(b) Deferred Tax Assets and Liabilities

Deferred tax assets and liabilities are attributable to the following:

	2023 $	2022 $
Deferred tax assets		
Accrued and other liabilities	1,177,830	581,395
Share issue costs	338,353	288,277
Intangible assets	108,775	132,325
Other capitalized costs	100,927	274,216
Stock-based payments	1,582,846	498,571
Operating lease liabilities	318,929	169,832
Capitalized R&D	4,362,381	1,636,646
Other	35,305	—
Tax credit carryforwards	1,355,946	1,343,071
Operating loss carryforwards	28,209,419	22,691,706
Total deferred tax assets	37,590,711	27,616,039
Deferred tax liabilities		
Plant and equipment	(12,374)	(130,592)
Operating lease right-of-use assets	(310,386)	(143,009)
Accounts receivable from customers, net of allowances	(23,916)	—
Prepaid expenses	(91,500)	—
Other	(20,972)	(643,225)
Total deferred tax liabilities	(459,148)	(916,826)
Total net deferred tax assets (prior to valuation allowance)	37,131,563	26,699,213
Valuation allowance	(37,131,563)	(26,699,213)
Net deferred tax assets	—	—

The valuation allowance of $37,131,563 as at December 31, 2023 and $26,699,213 at December 31, 2022 reduces deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the net operating loss carryforwards of the Group as management does not believe that it is more likely than not that these net operating losses will be utilized. The increase in the valuation allowance is primarily related to the additional net operating losses and capitalized R&D recorded during the fiscal year.

The portion of the valuation allowance for deferred tax assets for which subsequently recognized tax benefits would be applied directly to contributed capital was $2,136,683 in 2023 and $1,654,367 in 2022.

6. INCOME TAX (continued)

(c) Operating loss carryforwards

Information about net operating and capital loss carryforwards at December 31, 2023 is summarized as follows:

	Balance at December 31, 2023 $
Australian net operating and capital loss carryforwards	53,582,708
United States federal net operating loss carryforwards	64,374,522
United States state net operating loss carryforwards	—
Other net operating loss carryforwards	8,564,139
Total	126,521,369

Included within the Australian carryforwards disclosed above, the Australian tax consolidated group has $5,202,557 of transferred losses at December 31, 2023, which are subject to loss recoupment testing and their available fraction which limits the annual rate at which losses may be claimed by the parent entity.

The Group's operating loss carryforwards are subject to examination with taxing authorities specific to each geography in which they were incurred and the filing and finalization of income tax returns. The actual operating loss carryforwards available on filing of these returns may be different. The operating loss carryforwards may not be realizable in whole or in part due to the generation of significant future income being dependent on obtaining the necessary regulatory approvals, which are not in place as of December 31, 2023.

At December 31, 2023, the Company had $126,521,369 of operating loss carryforwards in the United States, Australia and other international jurisdictions, of which $108,414,974 carryforward indefinitely, with the remaining $18,106,395 due to expire during fiscal years 2024 through to 2037 if not used.

The Group files income tax returns in a number of jurisdictions including the United States, Australia, Switzerland and Singapore. Income tax returns for all jurisdictions have been filed for the period ended December 31, 2022. With limited exceptions, all years prior to 2019 in Australia and 2020 in the United States are no longer subject to examination by taxation authorities.

Operating loss carryforwards

The operating loss carryforwards, including the year they are scheduled to expire, are set out below:

Financial Year Ending December 31:	Net operating loss carry forward $
2024	1,601,219
2025	1,159,433
2026	850,357
2027	1,455,156
2028	1,887,869
2034	933,120
2035	2,762,531

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEAR ENDED DECEMBER 31, 2023

6. INCOME TAX (continued)

Financial Year Ending December 31:	Net operating loss carry forward $
2036	3,820,598
2037	3,636,112
Indefinite	108,414,974
Total	126,521,369

(d) Tax credit carryforwards

Tax credit carryforwards for the period are summarized as follows:

	Balance at December 31, 2023 $
Australian research expenditure tax credits	1,355,946
Total	1,355,946

Tax credit carryforwards will carry forward indefinitely and are not subject to expiration.

(e) Effective income tax rate varied from the Australian statutory income tax rate

The Company's reported income tax expense varied from the amount of income tax expense that would result from applying the Australian statutory income tax rate, the income tax rate of the parent entity's country of domicile, as follows:

	2023	2022
Australian statutory income tax rate	25%	25%
Income tax (benefit) at the statutory income tax rate	(11,690,849)	(7,640,950)
Increase / (decrease) in income tax expense resulting from:		
Non-deductible other expenses	288,926	348,736
Non-deductible stock based payments	222,300	136,472
Non-assessable income	(291,671)	(304,236)
Non-deductible R&D expenditure	427,289	559,503
Loss on acquisition of subsidiary	101,227	—
Foreign statutory income tax rate differential	1,419,639	751,791
Change in valuation allowance	9,523,139	6,148,684
Reported income tax expense	—	—

The 25% tax rate used is the Australian corporate tax rate. The basis for using this rate is that the registered office of the parent entity is based in Australia.

Current tax expense includes an income tax benefit of $148,926 and $6,004 in 2023 and 2022, respectively, for the realization of operating loss carryforwards for which a valuation allowance has been previously applied against the related deferred tax asset.

7. CASH, CASH EQUIVALENTS AND RESTRICTED CASH

(a) Reconciliation of Cash, Cash equivalents and Restricted Cash reported in the balance sheet

	2023 $	2022 $
Cash at bank	13,012,497	9,293,057
Short term deposits	8,014,722	—
Short term deposits (restricted cash)	61,656	60,133
Cash and cash equivalents	21,088,875	9,353,190
Total Cash, Cash equivalents and Restricted Cash shown in the Consolidated Statements of cash flows	21,088,875	9,353,190

Amounts included in restricted cash primarily represent funds placed in escrow related to operating leases. The Company holds the funds in short term deposits.

(b) Supplemental Cash Flow information

	2023 $	2022 $
Cash received during the year for:		
Research and development tax incentive	909,973	1,010,895
Cash paid during the year for:		
Interest	38,473	33,401
Operating cash flows from operating leases	699,245	561,881
Non-cash investing and financing transactions		
Right-of-use assets obtained in exchange for new finance lease liabilities	4,687	—
Options issued to consultant for services provided	2,623,926	—
Conversion of convertible notes to equity instrument	—	2,848,338

8. INVENTORIES

	2023 $	2022 $
Raw materials – at cost	262,130	268,109
Work in progress – at cost	53,531	82,229
Finished goods – at cost	126,687	5,286
	442,348	355,624
Inventory reserve	—	—
	442,348	355,624

9. PLANT AND EQUIPMENT

	Estimated Useful Lives	2023 $	2022 $
Plant and equipment	3 – 10 years	7,081,723	4,843,874
Capital work in progress		492,273	—
Information technology equipment, under finance lease	2 – 5 years	42,855	76,579
Motor vehicle, under finance lease	10 years	—	46,423
		7,616,851	4,966,876
Less accumulated depreciation		(3,582,215)	(2,695,083)
		4,034,636	2,271,793

10. LEASES

The Company's lease agreements include leases accounted for as operating leases and those accounted for as finance leases. Finance lease right-of-use assets are included in plant and equipment, net. Finance lease liabilities are included in current debt obligations and long-term debt on the consolidated balance sheets. This note provides information for leases where the group is a lessee.

The Group leases laboratory facilities and offices through operating leases. These leases typically include lease options to renew the lease at which time the lease payments are renegotiated to reflect market rentals. Extension and termination options are included in a number of the property leases to allow for flexibility in terms of corporate growth and managing the assets used in the Group's operations.

The Group leases IT equipment through finance leases with contract terms of 2-5 years. In order to extend the leases, both parties must agree.

The Company recognizes variable lease payments not included in its lease liabilities in the period in which the obligation for those payments is incurred. Short term and variable lease payments for fiscal year 2023 and 2022 were not material.

The below table discloses the balance sheet information relating to the Group's leases:

	Balance sheet Classification	2023 $	2022 $
Finance leases			
Right-of-use assets	Plant and equipment	42,855	123,002
Current liability	Current debt obligations	9,119	43,878
Non-current liability	Long-term debt	4,120	8,695
Operating leases			
Right-of-use assets	Operating lease right-of-use assets	1,443,655	866,684
Current liability	Current Operating lease liabilities	659,802	469,131
Non-current liability	Non-current Operating lease liabilities	922,656	431,083

The weighted-average remaining lease terms the Group's operating leases was 2.2 years with weighted-average discounts of 14.8% for both 2023 and 2022.

10. LEASES (continued)

The following table summarizes the components of total lease costs:

	2023 $	2022 $
Finance lease cost		
Amortization of right-of-use assets	20,970	45,387
Interest on lease liabilities	3,440	5,639
	24,410	51,026
Operating lease cost	689,721	566,616
Total lease cost	714,131	617,642

The following table summarizes the cash paid for amounts included in the measurement of lease liabilities:

	2023 $	2022 $
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from finance leases	3,440	5,639
Operating cash flows from operating leases	699,245	561,881
Financing cash flows from finance leases	45,019	39,364

The following table summarizes the right-of-use assets obtained in exchange for lease liabilities and as a result of lease modifications:

	2023 $	2022 $
Right-of-use assets obtained in exchange for new finance lease liabilities	4,687	—
Right-of-use assets obtained in exchange for new operating lease liabilities	108,706	232,018
Non-cash changes related to lease modifications	932,438	491,181

The following table summarizes the maturities of the Company's leases at December 31, 2023. The amounts disclosed in the table are the contractual undiscounted cash flows. It is not expected that the cash flows included in the below maturity analysis could occur significantly earlier, or at significantly different amounts.

Fiscal Year	Finance Leases $	Operating Leases $
2024	10,251	844,461
2025	4,083	803,300
2026	435	208,805
2027	—	—
2028	—	—
Thereafter	—	—
Total expected lease payments	14,769	1,856,566
Less imputed interest	(1,530)	(274,108)
Total lease liabilities	13,239	1,582,458

11. INTANGIBLE ASSETS

The following table summarizes the gross carrying amounts and accumulated amortization of intangible assets:

	Patents $	Software $	Intellectual property $	Total $
DECEMBER 31, 2022				
Cost	269,284	98,170	2,371,274	2,738,728
Accumulated amortization	(188,673)	(15,942)	(1,926,759)	(2,131,374)
Net carrying value	80,611	82,228	444,515	607,354
DECEMBER 31, 2023				
Cost	271,862	105,695	2,393,979	2,771,536
Accumulated amortization	(202,323)	(43,281)	(2,115,786)	(2,361,390)
Net carrying value	69,539	62,414	278,193	410,146

Amortization expense

Refer to note 5 for the amortization expense recognized during the years ended December 31, 2023 and 2022.

Estimated aggregate amortization expense by fiscal year based on the current carrying value and remaining estimated useful lives of finite-lived intangible assets at December 31, 2023 is as follows:

Fiscal Year	Amortization expense $
2024	210,442
2025	140,393
2026	15,933
2027	10,623
2028	6,071

12. OTHER ASSETS

	2023 $	2022 $
Current		
Research and development tax incentive	713,943	950,889
Lease incentive receivable	114,445	—
Other receivables	609,438	122,751
	1,437,826	1,073,640
Non-current		
Holdback receivable, LeMaitre Vascular, Inc. (refer to note 23)	417,269	—
	417,269	—

13. ACCRUED AND OTHER LIABILITIES

	2023 $	2022 $
Current		
Accrued liabilities	3,874,673	2,231,834
Employee compensation and withholdings	728,796	637,015
Cash-settled stock-based payment provision	122,071	—
	4,725,540	2,868,849
Non-current		
Employee compensation and retirement benefits	48,157	30,742
Lease asset retirement obligation	471,161	436,518
Cash-settled stock-based payment provision	633,148	—
	1,152,466	467,260

Lease asset retirement obligation

The lease asset retirement obligation relates to the removing of leasehold improvements including laboratories, clean rooms and office spaces and returning the premises to their original condition in accordance with the lease agreements. The calculation of this obligation requires assumptions such as application of closure dates and cost estimates. The amount recognized for each site is periodically reviewed and updated based on the facts and circumstances available at the time. Changes to the estimated future costs for sites are recognized in the balance sheet by adjusting the asset and the liability. Reductions in the obligation that exceed the carrying amount of the asset will be recognized in profit or loss.

The following table provides a reconciliation of the beginning and ending balances of the lease asset retirement obligation:

	$
Balance at January 1, 2023	436,518
Accretion expense	34,643
Revisions in estimated cash flows	—
Balance at December 31, 2023	471,161

Cash-settled stock-based payment provision

Refer to note 19 *Stock-based payments*.

14. DEBT OBLIGATIONS

	2023 $	2022 $
Current		
Finance lease liabilities	9,119	43,878
Warrant liabilities	922,683	936,516
Current debt obligations	931,802	980,394

14. DEBT OBLIGATIONS (continued)

	2023 $	2022 $
Non-current		
Finance lease liabilities	4,120	8,695
Other variable liabilities	93,841	—
Non-current debt obligations	97,961	8,695

Warrant liabilities

In conjunction with receiving a loan facility from Partners For Growth ("PFG") in October 2017, Anteris Technologies Ltd issued PFG a 7-year warrant for the issue of 49,388 ordinary shares in the Company at an exercise price of $17.31 (AUD25.31) per share. The warrant expires on October 25, 2024. The holder of the warrant also has the option to put the warrant to the Company for $1,026,000 (AUD1,500,000) on expiry or on the occurrence of certain events. Both these components need to be considered when determining the valuation of the warrant.

The value of the call option component of the warrant in relation to the issue of the shares has been determined using a Black-Scholes pricing model that incorporates a share price hurdle. The share price hurdle reflects the fact the call option will only be exercised in circumstances where the value that can be derived from exercising the call option exceeds the value that can be derived from the put option. The value of the put option is primarily determined having regard to a discounted cash flow methodology to calculate its risk-adjusted present value. Refer to note 16 for inputs used to determine the fair value of the warrants at each reporting date.

The key judgemental inputs, being volatility and the put option discount rate, used in the measurement of the fair values at each reporting date are set out in note 16.

Other variable liabilities

The agreement with v2vmedtech, inc. ("v2v") (refer note 20) included non-current liabilities which are dependent on the entity's future activities. The non-current liabilities include anti-dilution rights of $34,342 which are valued taking into account the protection these rights offer the licensor of a pending patent related to the IPR&D against future dilution and incorporate the v2v company valuation. At acquisition, the anti-dilution rights were valued at $68,342.

Other variable liabilities include contingent consideration. Contingent consideration is related to removable clips and is contingent on (i) the relevant design being incorporated into the first generation of devices developed by v2v or (ii) v2v having reasonably demonstrated an intent and plans to use removable clips in future iterations of the devices. Contingent consideration is payable in the form of additional shares in an amount equal to a three percent equity interest in v2v, on a fully diluted basis. If the criterion is met, the contingent consideration will not be paid until device has achieved First-In-Human studies. At acquisition, the contingent consideration was valued at $12,801. Subsequent changes in the estimated future cash flows are adjusted through the profit or loss.

Supplier financing arrangements

During the year ended December 31, 2023, the Group entered a supplier financing arrangement to fund insurance premiums. Under the arrangement, the insurance premiums are paid directly by the financier and Anteris recognizes a financing cash outflow for the repayment of the borrowing. At the time of initial recognition, an asset recognized in Other assets) and a corresponding debt obligation is recognized

14. DEBT OBLIGATIONS (continued)

representing both the future insurance benefits and the obligation to repay respectively. The asset is subsequently expensed on a straight-line basis over the period of the insurance term. As of December 31, 2023, the liability had been fully paid. The supplier obligation arranged by and paid directly by the financier totalled $763,030.

Contractual obligations

The Company's financing arrangements consisted of the following:

		December 31, 2023		December 31, 2022	
	Maturity by Fiscal Year	Amount	Effective interest rate	Amount	Effective interest rate
Finance lease obligations	2024 – 2026	13,239	13.0%	52,573	7.6%

The table below summarizes the contractual maturities of the Group's debt, excluding deferred financing costs and debt discounts, net. The amounts disclosed in the table are the contractual undiscounted cash flows.

Fiscal Year	$
2024	10,251
2025	4,083
2026	435
Total	14,769

The holder of the warrant has the option to put the warrant to the Company for $1,026,000 (AUD1,500,000) on the expiry date, October 25, 2024. The present value of the put option forming part of the warrant was $922,683 and $936,516 as of December 31, 2023 and 2022, respectively, using a discount rate of 14.75% and 14.75%, respectively.

15. DERIVATIVES

The following tables summarize the balance sheet classification and fair value of derivative instruments included in the consolidated balance sheets. The Company has not designated any derivatives as hedging instruments. The fair value amounts are presented on a gross basis and are segregated by type of contract.

	Derivative liabilities	
	Balance sheet classification	Fair value $
December 31, 2023		
Derivatives not designated as hedging instruments		
Warrant liabilities	Current debt obligations	922,683
Other variable liabilities	Non-current debt obligations	93,841
Total derivatives at December 31, 2023		1,016,524
December 31, 2022		
Derivatives not designated as hedging instruments		
Warrant liabilities	Current debt obligations	936,516
Total derivatives at December 31, 2022		936,516

15. DERIVATIVES (continued)

Information regarding the terms of the warrant liability and derivative liabilities are disclosed in note 14. The inputs and assumptions used in determining the fair value of these derivatives are disclosed in note 16.

The Company has elected to present the fair value of derivatives within the consolidated balance sheets on a gross basis, even when the derivative transactions may otherwise qualify for net presentation.

The gains and losses recognized for derivative liabilities not designated as hedging instruments are recognized in the consolidated statements of operations as "Fair value movement of derivatives" and are summarized in the following table:

	2023 $	2022 $
Warrant liabilities	22,210	(132,374)
Other variable liabilities	(12,698)	—
Convertible note embedded derivative	—	(124,718)
Total gain/(loss) recognized for derivatives	9,512	(257,092)

16. FAIR VALUE MEASUREMENT

The consolidated financial statements include financial instruments for which the fair value of such instruments may differ from the amounts reflected on a historical cost basis. Financial instruments consist of cash deposits, accounts and other receivables, accounts payable, accrued liabilities and debt obligations. The carrying value of these financial instruments generally approximates fair value due to their short-term nature.

Fair value hierarchy

The following table summarizes the Group's financial assets and liabilities, measured or disclosed at fair value, using a three-level hierarchy, based on the lowest level of input that is significant to the fair value measurement. The carrying amounts of other financial assets and liabilities not measured at fair value approximate their fair values.

	Note	Level 1 $	Level 2 $	Level 3 $	Total $
December 31, 2023					
Liabilities					
Warrant	14	—	—	922,683	922,683
Other variable liabilities	14	—	—	93,841	93,841
Total liabilities		—	—	1,016,524	1,016,524
December 31, 2022					
Liabilities					
Warrant liabilities	14	—	—	936,516	936,516
Total liabilities		—	—	936,516	936,516

16. FAIR VALUE MEASUREMENT (continued)

	Warrant liabilities $	Other variable liabilities $
Balance as of January 1, 2022	878,265	—
Mark to market adjustment	58,251	—
Balance as of December 31, 2022	936,516	—
Issuance	—	81,143
Mark to market adjustment	(13,833)	12,698
Balance as of December 31, 2023	922,683	93,841

Fair value of warrant liabilities — Level 3

The warrant is valued using a Black-Scholes model that incorporates a share price hurdle and a discounted cashflow methodology. The inputs used in the measurement of the fair values of the warrant liabilities (translated using year-end exchange rates) are detailed below. No reasonable change in the unobservable inputs would result in a significant change to the fair value of the warrant liabilities.

	2023	2022
Fair value per warrant	$18.68	$18.96
Assumptions used:		
Share price	$13.75	$16.70
Exercise price (AUD25.31)	$17.31	$17.15
Share price hurdle (AUD55.68)	$38.08	$37.72
Expected volatility	55%	70%
Time to maturity	0.82 years	1.82 years
Risk-free interest rate	3.69%	3.41%
Exercise price of the put option (AUD30.37)	$20.77	$20.58
Put option discount rate	14.75%	14.75%

17. EQUITY

(a) Ordinary shares

	2023 Number	2022 Number	2023 $	2022 $
Ordinary shares, Fully paid	**17,820,149**	13,901,883	**217,327,489**	169,789,200

Under the *Corporations Act 2001*, Australian companies are not required to have authorized capital or par value in respect of its issued shares. Ordinary shares listed on the Australian Securities Exchange ("ASX") are designated in AUD.

All ordinary shares rank equally. Holders of these shares are entitled to dividends as declared from time to time and are entitled to one vote per share at general meetings of the Company.

The timing, declaration, and payment of future dividends to holders of the Company's ordinary shares is at the discretion of the Company's Board of Directors. Under the Australian Corporations Act, a dividend may only be paid if Anteris' assets exceed its liabilities immediately before the dividend is declared and the

17. EQUITY (continued)

excess is sufficient for the payment of the dividend, the payment of the dividend is fair and reasonable to Anteris' shareholders as a whole and the payment of the dividend does not materially prejudice Anteris' ability to pay its creditors. The Company is currently in a loss position and had not declared a dividend.

On a return of assets, whether on liquidation or otherwise:

- Option holders are not entitled to any participation in the assets or profits of the Company.
- The warrant holder is entitled to either the excess of the fair value of the shares over their exercise price or the exchange put price of $1,026,000 (AUD1,500,000).

(b) Movements in Ordinary shares

Details	Date	Notes	No. shares	AUD per share	USD equivalent per share	$
Balance	**December 31, 2021**		**11,093,845**			**141,468,341**
Exercise of unlisted EIP options		(i)	3,672	4.96	3.54	12,989
Exercise of unlisted options		(ii)	646,152	10.00	7.19	4,647,149
Exercise of unlisted options		(ii)	70,834	11.50	8.12	575,512
Share placement		(iii)	1,840,000	15.00	10.90	20,062,440
Exercise of convertible notes		(v)	116,883	15.10	10.58	1,236,689
Exercise of convertible notes		(v)	71,571	20.60	14.77	1,056,823
Exercise of convertible notes		(v)	58,926	26.60	18.50	1,090,305
Transaction costs						(361,048)
Balance	**December 31, 2022**		**13,901,883**			**169,789,200**
Exercise of unlisted EIP options		(i)	168	8.19	5.48	920
Exercise of unlisted options		(ii)	160,250	10.00	6.56	1,051,976
Exercise of unlisted options		(ii)	134,364	11.50	7.75	1,041,290
Exercise of unlisted options		(ii)	500,000	15.00	10.12	5,061,000
Share placement		(iii)	1,454,167	24.00	16.65	24,210,136
Share placement		(iii)	4,167	24.00	15.59	64,955
Share placement		(iii)	1,664,150	20.00	12.86	21,392,749
Share placement to consultant		(iv)	1,000	21.50	14.39	14,392
Transaction costs		(vi)				(5,299,129)
Balance	**December 31, 2023**		**17,820,149**			**217,327,489**

(i) Exercise of unlisted EIP options

During the years ended December 31, 2023 and 2022, unlisted options issued under the Anteris Employee Incentive Plan were exercised. These options had various exercise prices and expiry dates with weighted average exercise prices of $5.48 and $3.54 per share, respectively (translated using the exchange rates on the dates of issue).

17. EQUITY (continued)

(ii) Exercise of unlisted options

During the year ended December 31, 2023, external investors exercised the following options:

- 160,250 unlisted options were exercised for $6.56 equivalent per share (AUD10.00) raising $1,051,976.
- 134,364 unlisted options were exercised for $7.75 equivalent per share (AUD11.50) raising $1,041,290.
- 500,000 unlisted options were exercised for $10.12 equivalent per share (AUD15.00) raising $5,061,000.

During the year ended December 31, 2022, external investors exercised the following options:

- 646,152 unlisted options were exercised for $7.19 equivalent per share (AUD10.00) raising $4,647,149.
- 70,834 unlisted options were exercised for $8.12 equivalent per share (AUD11.50) raising $575,512.

(iii) Share placements

On February 15, 2023, 1,454,167 new shares and 1,454,167 free-attaching options were issued to various sophisticated and professional investors for total consideration of $24,210,136. The consideration received for both the shares and free-attaching options has been reflected as an increase in share capital.

On May 31, 2023, 4,167 new shares and 4,167 free-attaching options were issued to Wayne Paterson, the Company's CEO and Managing Director, for consideration of $64,955, which is on the same terms as other investors who participated in the February 15, 2023 capital raise. Shareholder approval was obtained at the Company's Annual General Meeting on May 29, 2023.

On November 2, 2023 and November 16, 2023, a total of 1,664,150 new shares were issued to various sophisticated and professional investors for total consideration of $21,392,749.

On March 2, 2022, 1,840,000 new shares were issued to Perceptive Life Sciences Master Fund, Ltd at $10.90 equivalent per share (AUD15.00) for total consideration of $20,062,440.

(iv) Share placement to consultant

On April 17, 2023, 1,000 shares were issued as compensation for expert advisory services received. No amounts were payable for the issue of the ordinary shares.

(v) Exercise of convertible notes

The conversion prices were set at 90% of the volume weighted average price of the shares for the five trading days on the ASX immediately prior to issue of a relevant conversion notice. The dollar per share figures disclosed in the Movements in Ordinary shares table (prior page) are the share prices on the dates of issue as the equity instruments are recognized at fair value in share capital when issued.

Immediately prior to settlement of the convertible note the derivative is remeasured to fair value, and the change in value recognized in the consolidated statements of operations as fair value movement of derivatives.

17. EQUITY (continued)

On May 17, 2022, 116,883 new shares were issued to Mercer Street Global Opportunity Fund ("Mercer") upon conversion of 1,620,000 convertible notes using a conversion price of $9.71 equivalent per share (AUD13.86).

On June 1, 2022, 71,571 new shares were issued to Mercer upon conversion of 1,080,000 convertible notes using a conversion price of $10.82 equivalent per share (AUD15.09).

On August 1, 2022, 58,926 new shares were issued to Mercer upon conversion of 1,350,000 convertible notes using a conversion price of $15.94 equivalent per share (AUD22.91). The remaining portion of the third tranche of convertible notes with a face value of $936,090 was repaid in cash on August 3, 2022.

(vi) Transaction costs

Transaction costs include cash payments and options granted for legal, share issuance services, and lead manager services provided.

18. LOSS PER SHARE

The below table presents the computation of basic and diluted loss per share:

		2023	2022
Loss for the year, attributable to the owners of the Company	$	46,021,841	30,563,800
Weighted average number of shares outstanding: used in the denominator in calculating basic and diluted loss per share	Number	15,605,878	13,362,583
Basic and diluted loss per share	$	2.95	2.29

As of December 31, 2023 and 2022, there were outstanding stock options and warrants for the purchase of 6,075,996 and 3,894,726 shares, respectively, which were not included in the calculation of diluted earnings per share given that the potential shares are anti-dilutive. Details of the terms and conditions of these instruments are disclosed in notes 13, 14 and 19.

Details of the issues of ordinary shares that occurred since reporting date are included in note 26.

19. STOCK-BASED COMPENSATION

(a) Stock Options

Stock options issued by the Company to employees, directors and consultants have been described below. Each option, when exercised, entitle the holder to subscribe for and be allotted one share in the capital of the Company.

Employee service-based stock options

The Anteris Employee Incentive Plan (the "EIP") was approved by shareholders. Eligible employees can participate in the Plan. Anteris believes that the grant of these awards to employees assists with attracting, motivating and aligning the interest of employees with those of its shareholders.

The key terms of the EIP include:

– All options have an AUD base currency;

19. STOCK-BASED COMPENSATION (continued)

- Options are issued to selected eligible employees for nil cost;
- The allotment of options is at the discretion of the Board of Directors;
- The exercise price of the options are determined by the Board of Directors in its absolute discretion. Generally, the exercise price is determined with reference to the 5-day volume-weighted average price of the Company's listed shares (VWAP);
- Options vest in three equal tranches over 1, 2 and 3 years subject to the holder still being employed by the Group;
- Options expire 5 years after the grant date under the current plan, and 10 years under the former plan;
- All options expire on the earlier of their expiry date or 90 days after the termination of the individual's employment;
- Options are unlisted and not transferable unless the Directors in their absolute discretion agree to a transfer;
- Options carry no dividend rights or voting rights; and
- If a change of control event occurs prior to the vesting of an award, then the Board of Directors may, determine in its absolute discretion the treatment of the participant's unvested awards and the timing of such treatment.

There is no restriction on the number of shares authorized for awards of equity instruments. For the purposes of the ASX listing rules, at the Company's Annual General Meeting held on May 25, 2022, shareholders approved the issue of 678,680 EIP options in the three years following the date of the meeting without using the Company's 15% placement capacity allowed under the ASX listing rules. Additionally, the number of equity instruments which can be issued in reliance on the exemptions set out in the Australian Corporations Act or ASIC Class Order 14/1000 is limited by the requirement that offers made pursuant to those exemptions in the previous three years cannot exceed 5% of the issued capital of the Company (which, as at December 31, 2023, was 891,007 shares) (subject to certain carve-outs), and the remaining capacity pursuant to those exemptions was 285,788 EIP securities as at December 31, 2023.

The Company uses the Black-Scholes option pricing model ("Black-Scholes model") to determine the fair value of stock options at the grant date. The fair value of stock options under the Black-Scholes model requires management to make assumptions regarding projected employee stock option exercise behaviors, expected price volatility of the underlying share, the expected dividend yield and the risk-free interest rate for the term of the option.

Director stock Options

On September 15, 2023 following approval by shareholders at an Extraordinary General Meeting held on September 6, 2023, the Company issued 1,018,500 options with an exercise price of $15.37 equivalent (AUD24.00) per share to the following Directors relating to the 2023 financial year:

- John Seaberg (Chair) — 157,500 options
- Wayne Paterson (CEO and Managing Director) — 700,000 options
- Stephen Denaro (Non-Executive Director and Company Secretary) — 80,500 options
- Wenyi Gu (Non-Executive Director) — 80,500 options

19. STOCK-BASED COMPENSATION (continued)

The above Director stock options expire after 5 years, vest in three tranches on the completion of at least 12, 24 and 36 months of service commencing from the date of issue. These options were not awarded as part of the existing Employee Incentive Plan. There were no performance conditions attached to the Director options issued. These options were valued using the Black-Scholes model.

On June 13, 2022 following approval by shareholders at the Annual General Meeting on May 25, 2022, the Company issued:

A. 418,778 options with an exercise price of $9.21 equivalent (AUD12.96) per share to the following Directors relating to the 2022 financial year:
   - John Seaberg (Chair) — 80,000 options
   - Wayne Paterson (CEO and Managing Director) — 258,778 options
   - Stephen Denaro (Non-Executive Director and Company Secretary) — 40,000 options
   - Wenyi Gu (Non-Executive Director) — 40,000 options

B. 41,222 options with an exercise price of $6.74 equivalent (AUD9.48) per share to Wayne Paterson (CEO and Managing Director) relating to his performance during the year ended December 31, 2021.

The above Director stock options expire after 5 years, vest in three tranches on the completion of at least 12, 24 and 36 months of service commencing January 1, 2022. These options were not awarded as part of the existing Employee Incentive Plan. These options were valued using the Black-Scholes model.

Modification of Director Options

In 2020, the Company issued 350,000 options to Wayne Paterson (CEO and Managing Director), 60,000 options to John Seaberg (Chairman) and 25,000 options to Stephen Denaro (Non-Executive Director and Company Secretary) at an exercise price of $7.66 (AUD11.20) which only vested upon the completion of at least 12, 18 and 24 months service and the achievement of corresponding performance hurdles related to increases in the Company's share price. During the 2022 year, 289,500 of the 435,000 options vested upon achievement of share price performance hurdles. The remaining options were only exercisable if the Company's share price reached $22.98 (AUD33.60) for at least 10 out of 20 sequential trading days.

On February 17, 2023, the Board of Directors exercised their discretion to extend the period to achieve the share price hurdle, by an additional 12 months, from March 19, 2023 to March 19, 2024. The incremental fair value of these options was $6.18 per option, resulting in an increased fair value of $899,576. The value was expensed at the date of the modification.

Notwithstanding any other terms and conditions of the Options, if a change of control event occurs in relation to the Company, any unvested options on issue will vest. Due to the performance conditions attached, the options were valued under the Monte Carlo simulation model.

Shares and Options Granted to Consultants

The Company issued 1,000 shares as compensation for expert advisory services received. No amounts were payable for the issue of the ordinary shares.

The Company granted 500,000 options as consideration for lead manager services and underwriting services provided, with the value of the issues being recognized as an equity transaction cost.

19. STOCK-BASED COMPENSATION (continued)

Share Price Performance Rights (Cash-settled)

During the year ended December 31, 2023, the Company established a Share Price Performance Plan ("SPP") which provides employees with the right to receive cash payments calculated by considering the rise in Anteris' share price from the base price specified at grant date. The SPP rights expire after 5 years. There are two types of arrangements:

- Service based conditions: employees have the right to receive cash payments after 1, 2 and 3 years from the grant date subject to the holder still being employed by the Group. The cash payments are calculated by considering the rise in Anteris' share price from the base price specified at grant date to the vesting date.
- Service and performance conditions: the SPP rights are divided into three equal tranches which vest and become exercisable on the earlier of the achievement of specified share price hurdles and the completion of 3 years of service. The cash payments are calculated by considering the rise in Anteris' share price from the base price specified at grant date to the exercise date.

(b) Stock option activity

The exercise prices for all stock-based compensation is based in AUD, therefore all of disclosures within this note using foreign exchange rates on the dates that the options, rights or shares were granted, vested or forfeited. Year-end amounts are translated using the foreign exchange rate on that date.

Service-based stock options

The number and weighted-average exercise prices of service-based stock options (EIP and director options), excluding those with share price performance hurdles, under stock-based payment arrangements were as follows:

	Number of options	Weighted-average exercise price	Weighted-average Remaining Contractual Term (in years)	Aggregate Intrinsic Value $
Outstanding at January 1, 2023	1,142,124	AUD 12.71 / USD 8.61		
Granted during the year	1,032,300	AUD 23.96 / USD 15.35		
Forfeited during the year	(14,581)	AUD 16.34 / USD 11.18		
Exercised during the year	(168)	AUD 8.19 / USD 5.48		
Expired during the year	—			
Outstanding at December 31, 2023	2,159,675	AUD 18.07 / USD 12.36	3.9	5,453,273
Expected to vest at December 31, 2023	1,488,244	AUD 20.37 / USD 13.93	2.0	2,158,928
Exercisable at December 31, 2023	653,475	AUD 12.79 / USD 8.75	2.0	3,270,661

A change of control event is a non-market condition which has not been taken into consideration in the valuation of the options. A change of control event was not considered probable at December 31, 2023.

19. STOCK-BASED COMPENSATION (continued)

The following table summarizes the status of Anteris' non-vested service-based stock options:

	Number of options	Weighted-average exercise price
Non-vested at December 31, 2022	839,369	AUD 12.42 / USD 8.42
Granted	1,032,300	AUD 23.96 / USD 15.35
Vested	(351,555)	AUD 12.15 / USD 8.05
Forfeited	(13,914)	AUD 16.69 / USD 11.43
Non-vested at December 31, 2023	1,506,200	AUD 20.36 / USD 13.92

As of December 31, 2023, there was $8,075,197 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted. That cost is expected to be recognized over a weighted-average period of 1.5 years.

Stock options with share price performance hurdles

The number and weighted-average exercise prices of stock options with share price performance hurdles issued to the Directors under stock-based payment arrangements were as follows:

	Number of options	Weighted-average exercise price	Weighted-average Remaining Contractual Term (in years)	Aggregate Intrinsic Value $
Outstanding at January 1, 2023	435,000	AUD 11.20 / USD 7.59		
Outstanding at December 31, 2023	435,000	AUD 11.20 / USD 7.66	1.8	2,365,443
Expected to vest at December 31, 2023	145,500	AUD 11.20 / USD 7.66	1.8	791,200
Exercisable at December 31, 2023	289,500	AUD 11.20 / USD 7.66	1.8	1,574,243

The remaining 145,500 options were only to vest if the Company's share price reached at least $22.98 (AUD33.60) for a minimum of 10 days within any 20 sequential trading days by March 19, 2024. The share price hurdle was not met by the expiry date and the associated options were cancelled subsequent to year-end.

Stock options issued to consultants

The below table shows the number and weighted-average exercise prices of stock options issued to consultants under stock-based payment arrangements. They contain no vesting conditions.

	Number of options	Weighted-average exercise price	Weighted-average Remaining Contractual Term (in years)	Aggregate Intrinsic Value $
Outstanding at January 1, 2023	795,000	AUD 11.16 / USD 7.56		
Granted during the year	500,000	AUD 29.00 / USD 20.17		
Exercised during the year	(225,000)	AUD 14.11 / USD 9.50		
Outstanding and exercisable at December 31, 2023	1,070,000	AUD 18.88 / USD 12.91	1.4	5,215,500

19. STOCK-BASED COMPENSATION (continued)

Cash-settled stock-based compensation

The following table summarizes the SPP rights activity during the year:

	Number of options	Weighted-average base price	Weighted-average Remaining Contractual Term (in years)	Carrying amount of liabilities $
SPP with service conditions				
Outstanding at January 1, 2023	—			
Granted in September 2023	850,000	AUD 24.00 / USD 15.46		
Outstanding and exercisable at December 31, 2023	850,000	AUD 24.00 / USD 16.42	1.7	377,268
SPP with service and performance conditions				
Outstanding at January 1, 2023	—			
Granted in November 2023	700,000	AUD 24.00 / USD 15.42		
Outstanding and exercisable at December 31, 2023	700,000	AUD 24.00 / USD 16.42	4.7	377,951

Exercises of stock-based compensation options

The following table summarizes the total cash received from the issuance of new shares upon stock option award exercises, the total intrinsic value of options exercised, and the related income tax benefit:

	2023 $	2022 $
Cash proceeds from options exercised	2,137,440	225,749
Intrinsic value of options exercised	804,773	194,535
Income tax benefit related to options exercised	—	—

The weighted-average grant-date fair value of options granted relating to stock-based payments during the year ended 31 December 2023 and 2022 was $6.33 and $9.43, respectively.

(c) Option inputs

Director options

The following table presents the weighted average inputs (based on number of options granted) used in the measurement of the fair values at grant date of the stock-based payments options granted each year. All options are based in AUD.

19. STOCK-BASED COMPENSATION (continued)

	2023	2023 Modification	2022(A)*	2022(B)*
Weighted average fair value per option at grant date (incremental value for modification)	$6.84	$6.18	$7.57	$8.34
Assumptions used:				
Share price at grant date or modification date	AUD 20.80 / USD 13.32	AUD 22.20 / USD 15.19	AUD 17.00 / USD 12.08	AUD 17.00 / USD 12.08
Exercise price (USD equivalent at grant date or modification date)	AUD 24.00 / USD 15.37	AUD 11.20 / USD 7.66	AUD 12.96 / USD 9.21	AUD 9.48 / USD 6.74
Expected volatility	67.3%	65.0%	80.0%	80.0%
Expected life	3.5 years	2.1 years	3.5 years	3.5 years
Expected dividends	Nil	Nil	Nil	Nil
Risk-free interest rate range	3.21% – 4.29%	3.52%	2.75% – 2.85%	2.75% – 2.85%

* (A) and (B): Refer to the "Director stock options" section of note 19(a) for additional details of the options granted.

EIP options

The following table provides the weighted average fair value of options granted to employees during the year and the related assumptions used in the Black-Scholes model. All options are based in AUD.

	EIP 2023	EIP 2022
Weighted average fair value per option at grant date	$7.53	$11.56
Assumptions used:		
Share price at grant date	AUD 21.83 / USD 14.70	AUD 25.21 / USD 16.95
Exercise price (USD equivalent at grant date)	AUD 21.16 / USD 14.23	AUD 13.65 / USD 9.20
Expected volatility	67.3%	75.6%
Expected life	3.5 years	3.4 years
Expected dividends	Nil	Nil
Risk-free interest rate range	3.21% – 4.29%	1.31% – 3.83%

Consultant options

The following table provides the weighted average fair value of options granted to consultants during the year and the related assumptions used in the Black-Scholes model. All option exercise prices are based in AUD.

	Consultant 2023
Weighted average fair value per option at grant date	$5.26
Assumptions used:	
Share price at grant date	AUD 24.04 / USD 16.72
Exercise price (USD equivalent at grant date)	AUD 29.00 / USD 20.17
Expected volatility	64.8%

19. STOCK-BASED COMPENSATION (continued)

	Consultant 2023
Expected life	2.0 years
Expected dividends	Nil
Risk-free interest rate	3.34%

SPP rights

The inputs used in the measurement of the fair values at grant date (date of shared understanding) and reporting date of the SPP rights were as follows:

Service based SPP	Grant date September 19 – 20, 2023	Reporting date December 31, 2023
Weighted average fair value per right	$3.53	$3.00
Share price at measurement date	AUD 20.03 / USD 12.91	AUD 19.15 / USD 13.10
Base price	AUD 24.00 / USD 15.46	AUD 24.00 / USD 16.42
Expected volatility (weighted average)	57.5%	57.5%
Expected life (weighted average)	2.0 years	1.7 years
Risk-free interest rate (based on government bonds)	4.02%	3.66%

Service and performance based SPP	Grant date November 2, 2023	Reporting date December 31, 2023
Weighted average fair value per right	$5.67	$5.40
Share price at measurement date	AUD 20.00 / USD 12.85	AUD 19.15 / USD 13.10
Base price	AUD 24.00 / USD 15.42	AUD 24.00 / USD 16.42
Expected volatility (weighted average)	60.0%	60.0%
Expected life (weighted average)	3.9 years	3.7 years
Risk-free interest rate (based on government bonds)	4.4%	3.8%

(d) Stock-based Compensation expense

The following table presents the components and classification of stock-based compensation expense recognized for stock options issued to employees, directors and consultants:

	2023 $	2022 $
Equity-settled stock-based payments	4,845,807	2,937,017
Modification of equity-settled stock-based payments	899,576	—
Cash-settled stock-based payments (SPP rights)	745,261	—
Shares issued as compensation to consultants	14,392	—
Total stock-based compensation expense	6,505,036	2,937,017
Classification of stock-based compensation expense		
Cost of products sold	4,609	4,288
Research and development expense	2,689,850	886,732
Selling, general and administrative expense	3,810,577	2,045,997

19. STOCK-BASED COMPENSATION (continued)

	2023 $	2022 $
Total stock-based compensation expense	6,505,036	2,937,017
Stock-based compensation capitalized to equity (transaction cost)	2,623,926	—
Income tax benefit	—	—
Total stock-based compensation	9,128,962	2,937,017

20. ACQUISITION OF SUBSIDIARY

On April 18, 2023, the Group entered into a series of agreements with v2vmedtech, inc. ("v2v") to develop an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation. As part of the binding agreements, the Group acquired 30% interest in v2v for consideration of $213,000.

Pursuant to the guidance under ASC 810, the Company determined that v2v is a variable interest entity ("VIE") and that the Company is the primary beneficiary of v2v. This determination is based on the Company having both power over the most significant activities of v2v, primarily through having the right to designate a majority of the board of directors, and benefits through equity ownership. Therefore, the Company consolidated v2v as of December 31, 2023.

The transaction was accounted for as an asset acquisition under ASC 805 *Business Combinations,* as substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable in-process research and development ("IPR&D") asset. In accordance with the accounting for asset acquisitions, an entity that acquires IPR&D assets in an asset acquisition follows the guidance in ASC 730 *Research and Development,* which requires that both tangible and intangible identifiable research and development assets with no alternative future use (in other research and development projects or otherwise) be allocated a portion of the consideration transferred and recorded as research and development expense at the acquisition date. As a result, the Company recorded $131,617 in acquired in-process research and development expense, which represents the acquisition-date fair value of the acquired IPR&D. Further, Subtopic 810-10 requires the primary beneficiary to recognize and measure the assets, liabilities and NCI of the newly consolidated VIE under Subtopic 805-20 as if the acquisition were a business combination. However, because the VIE is not a business, the primary beneficiary is precluded from recognizing certain intangibles and a gain or loss on initial consolidation (unless the primary beneficiary and the VIE are under common control). The net assets of the acquired business along with NCI and the corresponding loss from consolidating v2v is calculated as follows:

The following assets and liabilities have been recognized as a result of the transaction:

	$
Purchase consideration	213,000
Assets	
Acquired in-process research and development	131,617
Total assets	131,617
Liabilities	
Contingent consideration	81,143
Total liabilities	81,143
Net assets	50,474

20. ACQUISITION OF SUBSIDIARY (continued)

	$
Non-controlling interests	338,721
Net identifiable assets, liabilities, less non-controlling interests	(288,247)
Loss on asset acquisition	(501,247)

The Company determined the fair value of the IPR&D asset with the support of a third-party valuation specialist. The acquired IPR&D assets were determined to have no alternative future use. Accordingly, the Company expensed the fair value of the acquired IPR&D assets of $131,617 as "Acquired in-process research and development" in the consolidated statements of operations for the year ended December 31, 2023.

Pursuant to the Shareholder Agreement and subject to certain requirements, the licensor of a pending patent related to the IPR&D was granted anti-dilution rights. These rights grant the licensor the right to 5% of the shares outstanding in v2v on a fully diluted basis. The Company determined the fair value of the anti-dilution rights in the amount of $68,342 with the support of a third-party valuation specialist.

The Stock Purchase Agreement provided Anteris Technologies Corporation with a contractual right to acquire up to a further 27% to 29% interest in v2v following the earlier of the first use of a v2v device in a First-in-human trial or contributions reaching $10,000,000. Anteris was also granted a call option to purchase all remaining issued and outstanding shares of v2v. The option can be exercised at the higher of fair market value and $150,000,000. No value has currently been attributed to this option.

21. ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table presents the components of Accumulated Other Comprehensive Loss:

	Foreign currency translation adjustments $	Total Accumulated Other Comprehensive Loss $
December 31, 2021	7,751,516	7,751,516
Other comprehensive loss – equity adjustment from foreign currency translation	2,185,789	2,185,789
December 31, 2022	9,937,305	9,937,305
Other comprehensive loss – equity adjustment from foreign currency translation	(381,929)	(381,929)
December 31, 2023	9,555,376	9,555,376

No income taxes have been allocated to the translation adjustments.

22. RELATED PARTY TRANSACTIONS

(a) Parent Entity

The legal parent entity within the Group is Anteris Technologies Ltd.

(b) Subsidiaries

The Company may provide letters of support to its subsidiary companies when required.

22. RELATED PARTY TRANSACTIONS (continued)

During the year ended December 31, 2023, the Group acquired an initial 30% stake in v2v, to develop minimally invasive treatment of mitral and tricuspid valve regurgitation. v2v has been recognized as a subsidiary (refer note 20). There have been no other changes in the Company's ownership interests in subsidiaries during the year ended December 31, 2023.

23. COMMITMENTS AND CONTINGENCIES

At December 31, 2023 the Group had no commitments to purchase plant and equipment, as compared to commitments of $839,040 at December 31, 2022.

Anteris is involved in various ongoing proceedings arising in the normal course of business, including proceedings related to product, labor, intellectual property and other matters. No material legal proceedings are currently pending.

Contingent asset

Anteris Technologies Ltd sold the distribution rights to its CardioCel™ and VascuCel™ product portfolio to LeMaitre on October 11, 2019. In addition to the initial proceeds received, the agreement provided for additional payments subject to the achievement of certain milestones. This included an entitlement to receive a holdback amount of $2,000,000 less the associated regulatory approval costs incurred by LeMaitre, subject to approval of the products by the European Medical Devices Directorate Regulation.

The agreement has since been amended and extended with the revised agreement now contracted to conclude in January 2025. Under the revised agreement, LeMaitre is responsible for obtaining regulatory approvals under the European Medical Devices Directorate Regulation. Anteris is entitled to receive a holdback amount of $2,000,000 less the associated regulatory approval costs incurred by LeMaitre (capped at €600,000) payable in the following instalments:

1. Anteris is entitled to 33% of the holdback amount less eligible deductions by January 26, 2025 if LeMaitre do not obtain the regulatory approvals for either the CardioCel™ and VascuCel™ by January 11, 2025. The first instalment has been recognized as a non-current receivable as at December 31, 2023 (note 12).

2. The remaining 67% of the holdback amount will be due on the following basis with the eligible deductions applied on a proportional to those activities:

    a. 75% when LeMaitre receive the CardioCel™ regulatory approval; and

    b. 25% when LeMaitre receive the VascuCel™ regulatory approval.

The second holdback entitlement, which is a contingent receipt, has not been recognized as income as it is not yet considered probable that the contingent event will occur.

Contingent liabilities

The Company records a liability in the consolidated financial statements on an undiscounted basis for loss contingencies related to legal actions when a loss is considered probable and the amount may be reasonably estimated. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required. Estimates of probable losses resulting from litigation and governmental proceedings involving the Company are inherently difficult to predict, particularly when the matters are in early procedural stages with incomplete scientific

23. COMMITMENTS AND CONTINGENCIES (continued)

facts or legal discovery, involve unsubstantiated or indeterminate claims for damages, potentially involve penalties, fines or punitive damages, or could result in a change in business practice.

There were no unrecognized contingent liabilities in relation to the current reporting period.

24. SEGMENT REPORTING

(a) Segment information

The revenue and cost information relating to all of the ADAPT® products including both DurAVR® and regenerative tissue products are regularly reviewed by the CODM on an aggregate basis.

The below segment information is consistent with the information reported by the Group since the Group operates as a single segment, as determined by the CODM.

	2023 $	2022 $
Segment revenue from external customers	2,734,821	3,200,711
Segment profit/(loss)	(46,763,397)	(30,563,800)
Interest income	428,059	210,382
Interest expense	67,089	648,709
Depreciation & amortization	1,157,723	774,077

No detailed asset information by reportable segment has been reported given that the single segment's information is already presented in the consolidated balance sheet. Refer to the consolidated statements of cash flows and note 7(b) for significant non-cash items and total expenditure for additions of long-lived assets.

(b) Geographic information

Segment revenues have been based on the geographic location of the customers taking possession of the products. Geographic long-lived assets are attributed to the country based on the physical location of the assets.

	Revenues		Long-lived assets, net	
	2023 $	2022 $	2023 $	2022 $
Australia	8,437	18,127	1,174,091	866,160
United States	2,255,107	2,442,138	4,042,218	2,051,713
Germany	471,277	740,446	—	—
Switzerland	—	—	183,131	220,604
Sweden	—	—	78,851	—
	2,734,821	3,200,711	5,478,291	3,138,477

(c) Major customers

The Group had two customers that provided greater than 10% of the Group's consolidated revenues during the year ended December 31, 2023, being $1,449,283 and $1,277,101, and had two customers that provided greater than 10% of the Group's consolidated revenues during the year ended December 31, 2022,

24. SEGMENT REPORTING (continued)

being $1,824,622 and $1,369,816. Amounts outstanding from these customers at reporting date was $106,986 and $440,926, as of December 31, 2023 and 2022, respectively.

25. VALUATION AND QUALIFYING ACCOUNTS

		Additions		Deductions			
Description	Balance at beginning of period $	Charged to Costs and Expenses $	Charged to Other Accounts $	Charged to Costs and expenses $	Charged to Other Accounts $	Balance at End of Period $	Net change $
Allowance for doubtful accounts							
Year ended December 31, 2023	—	—	—	—	—	—	—
Year ended December 31, 2022	—	—	—	—	—	—	—
Inventory reserve							
Year ended December 31, 2023	—	—	—	—	—	—	—
Year ended December 31, 2022	—	—	—	—	—	—	—
Deferred tax asset valuation allowance							
Year ended December 31, 2023	26,699,213	9,741,344	909,211	(218,205)	—	37,131,563	10,432,350
Year ended December 31, 2022	22,353,340	6,394,272	—	(245,588)	(1,802,811)	26,699,213	4,345,873

Allowance for doubtful debts

The allowances for doubtful accounts deductions represent accounts receivable which have been written off.

The Company's revenues are primarily derived from two external customers, both of which have no recent history of default. As at December 31, 2023 and 2022, no trade receivables were expected to default.

Inventory reserve

When applicable, the Group maintains reserves for excess or slow-moving inventory, and inventory which is obsolete, damaged, nearing its expiration date, or slow moving. Estimates are made regarding the future recoverability of the costs of these products and record provisions based on historical experience, expiration of sterilization dates and expected future trends. At December 31, 2023 and 2022, it was determined that no provisions for reserves were required.

Deferred tax asset valuation allowance

The deferred tax asset valuation allowances are provided for all deferred tax assets and liabilities that are not be recognized due to insufficient future taxable income.

Amounts charged to other accounts includes valuation allowance movements which are allocated to other comprehensive income as a result of foreign currency translation adjustments.

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE YEAR ENDED DECEMBER 31, 2023

26. SUBSEQUENT EVENTS

Management has evaluated the impact of subsequent events through to May 13, 2024.

Since reporting date, 402,167 unlisted options have been converted into new ordinary shares providing cash proceeds of $2,643,767.

The 145,500 options held by directors which were contingent upon the Company's share price reaching at least $22.98 (AUD33.60) for vesting, were cancelled subsequent to year-end due to the specified performance condition not being met by the predetermined deadline.

On April 17, 2024, the Company issued 1,000,000 new ordinary shares to various sophisticated and professional investors at an issue price of $14.74 (A$23.00) per share, raising $14,738,400 before costs.

ANTERIS TECHNOLOGIES LTD

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In US dollars, except share quantities)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Net sales	768,981	598,984	2,166,888	2,190,665
Costs and expenses:				
Cost of products sold	(443,546)	(555,858)	(1,229,242)	(1,500,686)
Research and development expense	(13,945,791)	(7,702,349)	(38,135,103)	(21,254,062)
Selling, general and administrative expense	(6,976,323)	(3,973,073)	(19,655,764)	(12,262,458)
Acquired in-process research and development	—	—	—	(131,617)
Net foreign exchange (losses)/gains	(1,290,026)	430,880	(456,541)	701,571
Operating loss	(21,886,705)	(11,201,416)	(57,309,762)	(32,256,587)
Other non-operating income, net	123,145	634,144	637,352	935,808
Interest and amortization of debt discount and expense	(11,740)	(25,116)	(39,154)	(52,434)
Fair value movement of derivatives and other variable liabilities	(19,152)	886	(54,486)	39,128
Loss on asset acquisition of a variable interest entity	—	—	—	(501,247)
Loss before income taxes from continuing operations	(21,794,452)	(10,591,502)	(56,766,050)	(31,835,332)
Income tax (expense)/benefit	—	—	—	—
Loss after income tax	(21,794,452)	(10,591,502)	(56,766,050)	(31,835,332)
Net income attributable to noncontrolling interests and redeemable noncontrolling interests	64,198	—	149,768	—
Loss Attributable to Anteris Technologies Ltd	(21,858,650)	(10,591,502)	(56,915,818)	(31,835,332)
Basic and diluted loss per share ($ per share)	1.07	0.68	2.97	2.09
Basic and diluted weighted average shares outstanding	20,513,631	15,587,983	19,144,910	15,221,827

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In US dollars)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Loss after income tax	(21,794,452)	(10,591,502)	(56,766,050)	(31,835,332)
Other comprehensive income/(loss), net of tax:				
Foreign currency translation adjustments	1,468,030	(485,079)	602,158	(1,612,576)
Other comprehensive income/(loss) for the period, net of tax	1,468,030	(485,079)	602,158	(1,612,576)
Total comprehensive loss	(20,326,422)	(11,076,581)	(56,163,892)	(33,447,908)

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In US dollars, except share quantities)

	Note	AS OF SEPTEMBER 30, 2024	AS OF DECEMBER 31, 2023
ASSETS			
Current Assets			
Cash and cash equivalents	5	10,617,616	21,088,875
Accounts receivable from customers, net of allowances		126,020	407,556
Inventories	6	459,603	442,348
Prepaid expenses		1,319,000	845,129
Other current assets	7	2,648,160	1,437,826
Total Current Assets		15,170,399	24,221,734
Non-Current Assets			
Plant and equipment, net		4,379,386	4,034,636
Operating lease right-of-use assets		1,287,892	1,443,655
Intangible assets, net		264,562	410,146
Other assets		—	417,269
Total Non-Current Assets		5,931,840	6,305,706
TOTAL ASSETS		21,102,239	30,527,440
LIABILITIES			
Current Liabilities			
Accounts payable		5,883,557	3,139,140
Accrued and other liabilities	8	8,613,747	4,725,540
Current portion of operating lease liabilities		748,175	659,802
Current portion of debt obligations		1,037,059	931,802
Total Current Liabilities		16,282,538	9,456,284
Non-Current Liabilities			
Operating lease liabilities		860,331	922,656
Long-term debt obligations		55,392	97,961
Other liabilities	8	1,007,503	1,152,466
Total Non-Current Liabilities		1,923,226	2,173,083
TOTAL LIABILITIES		18,205,764	11,629,367
COMMITMENTS AND CONTINGENCIES	16		
SHAREHOLDERS' EQUITY			
Ordinary shares, 21,139,816 and 17,820,149 shares issued and outstanding, respectively[(1)]	12	252,491,184	217,327,489
Additional paid in capital		16,624,207	11,625,608
Accumulated other comprehensive loss		(8,953,218)	(9,555,376)
Accumulated Deficit		(257,012,631)	(200,096,813)
TOTAL SHAREHOLDERS' EQUITY		3,149,542	19,300,908
Noncontrolling interests		(253,067)	(402,835)
TOTAL EQUITY		2,896,475	18,898,073
TOTAL LIABILITIES AND EQUITY		21,102,239	30,527,440

(1) Under the Australian *Corporation Act 2001*, companies are not required to maintain authorized capital or assign a par value to their issued shares

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(Unaudited)
(In US dollars, except share quantities)

	Ordinary shares		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity	Noncontrolling interests	Total Equity
	Quantity	Amount						
Balance at December 31, 2023	17,820,149	217,327,489	11,625,608	(9,555,376)	(200,096,813)	19,300,908	(402,835)	18,898,073
Loss after income tax	—	—	—	—	(16,349,958)	(16,349,958)	197,363	(16,152,595)
Other comprehensive loss	—	—	—	(1,560,465)	—	(1,560,465)	—	(1,560,465)
Ordinary shares issued	275,167	1,710,637	—	—	—	1,710,637	—	1,710,637
Stock-based compensation	—	—	1,499,568	—	—	1,499,568	—	1,499,568
Balance at March 31, 2024	18,095,316	219,038,126	13,125,176	(11,115,841)	(216,446,771)	4,600,690	(205,472)	4,395,218
Loss after income tax	—	—	—	—	(18,707,210)	(18,707,210)	(111,793)	(18,819,003)
Other comprehensive income	—	—	—	694,593	—	694,593	—	694,593
Ordinary shares issued	1,127,000	14,584,694	—	—	—	14,584,694	—	14,584,694
Stock-based compensation	—	—	1,694,712	—	—	1,694,712	—	1,694,712
Balance at June 30, 2024	19,222,316	233,622,820	14,819,888	(10,421,248)	(235,153,981)	2,867,479	(317,265)	2,550,214
Loss after income tax	—	—	—	—	(21,858,650)	(21,858,650)	64,198	(21,794,452)
Other comprehensive income	—	—	—	1,468,030	—	1,468,030	—	1,468,030
Ordinary shares issued	1,917,500	18,868,364	—	—	—	18,868,364	—	18,868,364
Stock-based compensation	—	—	1,804,319	—	—	1,804,319	—	1,804,319
Balance at September 30, 2024	**21,139,816**	**252,491,184**	**16,624,207**	**(8,953,218)**	**(257,012,631)**	**3,149,542**	**(253,067)**	**2,896,475**

	Ordinary shares		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity	Noncontrolling interests	Total Equity
	Quantity	Amount						
Balance at December 31, 2022	13,901,883	169,789,200	3,256,299	(9,937,305)	(154,074,972)	9,033,222	—	9,033,222
Loss after income tax	—	—	—	—	(10,576,865)	(10,576,865)	—	(10,576,865)
Other comprehensive loss	—	—	—	(829,132)	—	(829,132)	—	(829,132)
Ordinary shares issued	1,454,335	20,076,392	—	—	—	20,076,392	—	20,076,392
Stock-based compensation	—	—	4,502,300	—	—	4,502,300	—	4,502,300
Balance at March 31, 2023	15,356,218	189,865,592	7,758,599	(10,766,437)	(164,651,837)	22,205,917	—	22,205,917
Loss after income tax	—	—	—	—	(10,666,965)	(10,666,965)	—	(10,666,965)
Other comprehensive loss	—	—	—	(298,365)	—	(298,365)	—	(298,365)
Ordinary shares issued	164,207	1,166,135	—	—	—	1,166,135	—	1,166,135
Acquisition of subsidiary	—	—	—	—	—	—	338,721	338,721
Stock-based compensation	—	—	1,002,439	—	—	1,002,439	—	1,002,439
Balance at June 30, 2023	15,520,425	191,031,727	8,761,038	(11,064,802)	(175,318,802)	13,409,161	338,721	13,747,882
Loss after income tax	—	—	—	—	(10,591,502)	(10,591,502)	—	(10,591,502)
Other comprehensive loss	—	—	—	(485,079)	—	(485,079)	—	(485,079)
Ordinary shares issued	85,574	637,656	—	—	—	637,656	—	637,656
Stock-based compensation	—	—	1,218,419	—	—	1,218,419	—	1,218,419
Balance at September 30, 2023	15,605,999	191,669,383	9,979,457	(11,549,881)	(185,910,304)	4,188,655	338,721	4,527,376

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In US dollars)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss after income tax	(56,766,050)	(31,835,332)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,102,708	863,931
Equity-settled stock-based compensation	5,213,636	4,113,624
Loss on asset acquisition of a variable interest entity	—	501,247
Acquired in-process research and development	—	131,617
Fair value movement of derivatives	54,486	(39,128)
Net foreign exchange gains	456,541	(701,571)
Loss/(gain) on disposal of intangibles / plant and equipment	4,469	(26,235)
Other items	(4,161)	(3,315)
Change in operating assets and liabilities:		
Accounts receivable, prepayments and other assets	(756,547)	(138,777)
Inventories	(17,255)	(40,187)
Accounts payable, accrued and other liabilities	7,708,484	455,165
NET CASH USED IN OPERATING ACTIVITIES	(43,003,689)	(26,718,961)
CASH FLOWS FROM INVESTING ACTIVITIES		
Acquisition of plant and equipment	(1,902,905)	(1,937,222)
Acquisition of intangibles	(13,527)	(6,644)
Acquisition of subsidiary	—	(213,000)
Proceeds from sale of plant and equipment	—	26,235
NET CASH USED IN INVESTING ACTIVITIES	(1,916,432)	(2,130,631)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from share issues	37,060,257	26,051,327
Share issue transaction costs	(2,111,599)	(1,561,610)
Repayment of debt	(507,876)	(596,107)
Principal payments under finance lease obligations	(8,090)	(41,516)
NET CASH PROVIDED BY FINANCING ACTIVITIES	34,432,692	23,852,094
Effect of exchange rate movements on cash, cash equivalents and restricted cash	16,170	303,281
CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Net change during the period	(10,471,259)	(4,694,217)
Balance at beginning of period	21,088,875	9,353,190
Balance at end of period	10,617,616	4,658,973

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

1. DESCRIPTION OF BUSINESS

Anteris Technologies Ltd's ("Anteris" or "Company" or "ATL") principal activities consist of:

- Continued research and development ("R&D") of our new class of biomimetic technology (ADAPT®, DurAVR® Transcatheter Heart Valve ("THV"), ComASUR® Transfemoral Delivery System) to address unmet medical needs in the treatment of aortic stenosis. The DurAVR® THV, with its single piece, native-shaped biomimetic design is built to mimic the performance of a healthy aortic valve and to restore normal laminar (smooth) blood flow. This new class of technology can be used to treat new aortic stenosis patients and to treat aortic stenosis patients with failed valves ("valve-in-valve");
- Generating and compiling data to gain FDA approval to commence the DurAVR® THV, global, pivotal registration study, a key milestone on the path to commercialization; and
- The co-development with v2vmedtech, inc, of an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation (also known as a leaky valve).

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("US GAAP"). These policies have been consistently applied to all the periods presented, unless otherwise stated. The accompanying condensed consolidated financial statements of the Company are unaudited. In the opinion of management, all adjustments necessary for a fair statement of results of operations, cash flows, and financial position have been made. Except as otherwise disclosed, all such adjustments are of a normal recurring nature. The results of operations for the three and nine months ended September 30, 2024 and 2023 are not necessarily indicative of results that may be expected for the full year or any other subsequent interim period.

Unless noted otherwise, all dollar amounts are in United States dollars ("US dollars" or "$"). Some amounts may not reconcile due to rounding.

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Management bases its judgments, estimates and assumptions on historical experience and on other various factors, including expectations of future events that management believe to be reasonable under the circumstances. Actual results could differ from those estimates due to risks and uncertainties.

The accounting policies adopted in the preparation of the condensed consolidated financial statements are consistent with those adopted and disclosed in the Group's financial statements for the year ended December 31, 2023, and therefore these condensed consolidated financial statements do not include all information and footnote disclosures normally included in the annual consolidated financial statements. The financial information included herein should be read in conjunction with the consolidated financial statements and related notes for the year ended December 31, 2023 as included in the Form S-1.

There have been no material changes to the Company's significant accounting policies from those described in the consolidated financial statements for the year ended December 31, 2023 as included in the Form S-1.

(a) Principles of consolidation

The consolidated financial statements include the accounts of Anteris Technologies Ltd, its wholly-owned subsidiaries, entities for which the Company has a controlling financial interest, as well as any

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

variable interest entities ("VIEs") for which Anteris Technologies Ltd has been determined to be the primary beneficiary. Anteris Technologies Ltd and its subsidiaries together are referred to in these financial statements as the 'Group'.

Subsidiaries are all those entities over which the Group has control. Control is the power to govern the financial and operating policies of an entity. All subsidiaries of Anteris Technologies Ltd have a reporting year-end of December 31.

Intercompany transactions, balances and unrealized gains or losses on transactions between entities in the Group are eliminated.

(b) Recently Adopted Accounting Standards

In September 2022, the Financial Accounting Standards Board ("FASB") issued ASU 2022-04, *Liabilities — Supplier Finance Programs (Subtopic 405-50) Disclosure of Supplier Finance Program Obligations.* The ASU requires that a buyer in a supplier finance program disclose sufficient information about the program to allow a user of financial statements to understand the program's nature, activity during the period, changes from period to period, and potential magnitude. This ASU is effective January 1, 2024 for smaller reporting companies. The adoption of ASU 2022-04 on January 1, 2024 resulted in additional disclosures as shown in note 8.

(c) New Accounting Standards Not Yet Adopted

The FASB has issued several new accounting pronouncements during the first nine months of 2024 which the Company has reviewed. Based on this assessment, the Company has determined that there are no new accounting pronouncements issued but not yet adopted that would have a material impact on the Company's financial position, results of operations, or cash flows.

For further details on new accounting pronouncements issued in prior years but not yet adopted, refer to note 2(x) in the consolidated financial statements for the year ended December 31, 2023.

3. GOING CONCERN

The condensed consolidated financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and realization of assets and discharges of liabilities in the ordinary course of business. As disclosed in the financial statements, the Group incurred a net loss of $56,766,050 and had net cash outflows from operating activities of $43,003,689 for the nine months ended September 30, 2024. As at that date, the Group had a cash balance of $10,617,616.

The Group has been investing in research and development activities primarily associated with the continuing development and proposed commercialization of DurAVR® THV. Over the nine months to September 30, 2024, amounts invested in R&D activities and general operations exceeded cash inflows associated with sales of CardioCel™ and VascuCel™ tissue products. The Company generated proceeds of $37,060,257 from the issue of equity securities including the conversion of options (before transaction costs) for the nine months ended September 30, 2024.

The Group anticipates that additional funds will need to be raised in order to achieve the Group's long-term goals and complete the research and development of current products. The Group does not expect to generate significant revenue until after regulatory approvals to commercially sell DurAVR® THV

3. GOING CONCERN (continued)

have been obtained and sales have commenced. The Group therefore expects to continue incurring substantial losses in the near future.

To become and remain profitable, the Group has commenced conducting clinical trials and obtaining regulatory approvals with the aim of commercializing, manufacturing and supplying products, including DurAVR® THV, that generate significant revenue. For medtech devices, including DurAVR® THV, this will require the Group to obtain further relevant regulatory approvals, successfully complete product clinical trials, develop and expand quality management systems, obtain regulatory approval post completion of clinical trials, expand manufacturing and distribution capabilities and comply with ongoing post-market regulatory requirements.

Prior to achieving commercialization, the Group will periodically require capital infusion through the issuance of ordinary shares, debt instruments, or other securities that can be converted into ordinary shares. The future success of the Company is dependent on its ability to attract additional capital and ultimately, upon its ability to develop future profitable operations. There can be no assurance that the Company will be successful in obtaining such financing, or that it will attain positive cash flows from operations. If the Group is unable to obtain adequate capital resources to fund operations, it may be necessary to delay, scale back or eliminate some or all of its operations, which may have a material adverse effect on the business, results of operations and its ability to operate as a going concern. However, the Group has established a track record of successfully raising new capital and debt facilities. This includes completing an equity capital raise of $19,668,000 before costs in July 2024. Following the quarter, on October 31, 2024, ATL entered into a secured convertible note facility with Obsidian Global Partners, LLC which allows ATL to draw up to A$25.0 million (the “Facility Limit”), with an initial A$7.5 million drawdown and subsequent drawdowns (subject to mutual agreement) of A$5.0 million or the remaining balance of the Facility Limit, whichever is lesser (refer to note 18).

The above conditions give rise to substantial doubt as to whether the Group will be able to continue as a going concern for one year from the issuance date of these financial statements.

The Directors and management believe that the going concern basis of preparation is appropriate for the reasons outlined above.

Should the Group be unable to continue as a going concern, it may be required to realize its assets and extinguish its liabilities other than in the ordinary course of business, and at amounts that differ from those stated in the financial statements. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts or classification of liabilities and appropriate disclosures that may be necessary should the Group be unable to continue as a going concern.

4. INCOME TAX

The Company’s provision for interim periods is determined using an estimate of the annual effective tax rate, adjusted for discrete items arising in that period. The Company’s effective tax rate differs from the U.S. statutory tax rate primarily due to valuation allowances on its deferred tax assets as it is more likely than not that some, or all, of the Company’s deferred tax assets will not be realized. There was no income tax benefit for the nine months ended September 30, 2024 and September 30, 2023.

Deferred tax assets and liabilities are determined based upon the differences between the unaudited condensed consolidated financial statements carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards, using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. The Company has provided a full valuation allowance against

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

4. INCOME TAX (continued)

the net deferred tax assets as the Company has determined that it was more likely than not that the Company would not realize the benefits of net deferred tax assets.

5. CASH, CASH EQUIVALENTS AND RESTRICTED CASH

(a) Reconciliation of Cash, Cash equivalents and Restricted Cash reported in the balance sheet

(In US dollars)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Cash at bank	4,740,525	13,012,497
Short term deposits	5,386,340	8,014,722
Short term deposits (restricted cash)	490,751	61,656
Cash and cash equivalents	10,617,616	21,088,875
Total Cash, Cash Equivalents and Restricted Cash shown in the Consolidated Statements of Cash Flows	10,617,616	21,088,875

Amounts included in restricted cash primarily represent funds placed in escrow related to operating leases. The Company holds the funds in short-term deposits.

(b) Supplemental Cash Flow information

	NINE MONTHS ENDED SEPTEMBER 30,	
(In US dollars)	2024	2023
Cash paid during the period for:		
Interest	22,667	34,231
Operating cash flows from operating leases	607,991	498,703
Non-cash investing and financing transactions		
Shares or Options issued to consultant for services provided	430,074	2,623,926
Capital expenditure accruals	231,656	2,077

6. INVENTORIES

(In US dollars)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Raw materials – at cost	272,549	262,130
Work in progress – at cost	62,486	53,531
Finished goods – at cost	124,568	126,687
	459,603	442,348
Inventory reserve	—	—
	459,603	442,348

7. OTHER CURRENT ASSETS

(In US dollars)	Note	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Holdback receivable, LeMaitre Vascular, Inc.	16	431,652	—
Research and development tax incentive		988,843	713,943
Deferred Offering costs		678,576	—
Lease incentive receivable		175,000	114,445
Other receivables		374,089	609,438
		2,648,160	1,437,826

During the quarter, the Group deferred $678,576 of direct, incremental costs which are directly related to a proposed offering of securities.

8. ACCRUED AND OTHER LIABILITIES

(In US dollars)	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Current		
Accrued liabilities	7,723,229	3,874,673
Employee compensation and withholdings	860,227	728,796
Cash-settled stock-based payment provision	30,291	122,071
	8,613,747	4,725,540
Non-current		
Employee compensation and retirement benefits	32,687	48,157
Lease asset retirement obligation	494,618	471,161
Cash-settled stock-based payment provision	480,198	633,148
	1,007,503	1,152,466

9. DEBT OBLIGATIONS

Supplier financing arrangements

The Group utilizes supplier financing arrangements to fund insurance premiums. Under the arrangements, the settlement of the supplier obligation is paid directly by the financier. Anteris pays the financier a set amount per month over an agreed period of 10 months. These repayments are recognized as financing cash outflows. In the event that Anteris defaults on payments to the financier, the financier can cancel the related insurance.

At the time of initial recognition of the supplier financing arrangement, an asset (recognized in Other assets) and a corresponding debt obligation is recognized representing both the future insurance benefits and the obligation to repay the financier respectively. The asset is subsequently expensed on a straight-line basis over the period of the insurance term. No amounts payable to the financier were outstanding at September 30, 2024 or December 31, 2023.

The roll forward of Anteris' outstanding payment obligations to the insurance supplier under this arrangement, are as follows:

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

9. DEBT OBLIGATIONS (continued)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
(In US dollars)	2024	2023	2024	2023
Confirmed obligations outstanding at the beginning of the period	—	—	—	—
Invoices confirmed during the period	—	—	503,875	770,948
Confirmed invoices paid during the period	—	—	(503,875)	(770,948)
Confirmed obligations outstanding at the end of the period	—	—	—	—

10. DERIVATIVES

Warrant liabilities

In conjunction with receiving a loan facility from Partners For Growth ("PFG") in October 2017, Anteris Technologies Ltd issued PFG a 7-year warrant for the issue of 49,388 ordinary shares in the Company at an exercise price of $17.54 (AUD 25.31) per share. The warrant expires on October 25, 2024. The holder of the warrant also has the option to put the warrant to the Company for AUD1,500,000 ($1,039,800) on expiry or on the occurrence of certain events. On October 8, 2024, the Company received notice of PFG's intention to exercise the put option at maturity. Both these components need to be considered when determining the valuation of the warrant.

The value of the call option component of the warrant in relation to the issue of the shares has been determined using a Black-Scholes pricing model that incorporates a share price hurdle. The share price hurdle reflects the expectation that the call option will only be exercised in circumstances where the value that can be derived from exercising the call option exceeds the value that can be derived from the put option. The value of the put option is primarily determined having regard to a discounted cash flow methodology to calculate its risk-adjusted present value. The key judgmental inputs, being volatility and the put option discount rate, used in the measurement of the fair values at each reporting date are set out in note 11.

The following table summarize the balance sheet classification and fair value of derivative instruments included in the condensed consolidated balance sheets. The Company has not designated any derivatives as hedging instruments. The fair value amounts are presented on a gross basis and are segregated by type of contract.

(In US dollars)	Balance sheet classification	Fair value
September 30, 2024		
Derivatives not designated as hedging instruments		
Warrant liabilities	Current debt obligations	1,033,024
December 31, 2023		
Derivatives not designated as hedging instruments		
Warrant liabilities	Current debt obligations	922,683

The gains and losses recognized for derivative liabilities not designated as hedging instruments are recognized in the condensed consolidated statements of operations within the 'Fair value movement of derivatives and other variable liabilities'. The total fair value adjustment recognized for the nine months ended September 30, 2024 and September 30, 2023 was $93,991 loss and $39,128 gain, respectively. The value of

10. DERIVATIVES (continued)

the warrant, which is designated in Australian Dollars ("AUD"), was also impacted by changes in the foreign exchange rate.

11. FAIR VALUE MEASUREMENT

The condensed consolidated financial statements include financial instruments for which the fair value of such instruments may differ from the amounts reflected on a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, accounts payable, accrued liabilities and debt obligations. The carrying value of these financial instruments generally approximates fair value.

Fair value hierarchy

The following table summarizes the Group's financial assets and liabilities, measured and disclosed at fair value, using a three-level hierarchy, based on the lowest level of input that is significant to the fair value measurement. The carrying amounts of other financial assets and liabilities not measured at fair value approximate their fair values.

(In US dollars)	Level 1	Level 2	Level 3	Total
September 30, 2024				
Liabilities				
Warrant liabilities	—	—	1,033,024	1,033,024
Other variable liabilities	—	—	54,336	54,336
Total liabilities	—	—	1,087,360	1,087,360
December 31, 2023				
Liabilities				
Warrant liabilities	—	—	922,683	922,683
Other variable liabilities	—	—	93,841	93,841
Total liabilities	—	—	1,016,524	1,016,524

Changes in the fair value of the level 3 liabilities were as follows:

(In US dollars)	Warrant liabilities	Other variable liabilities
Balance as of December 31, 2023	922,683	93,841
Mark to market adjustment	26,110	(27,803)
Foreign exchange impact	(41,634)	—
Balance as of March 31, 2024	907,159	66,038
Mark to market adjustment	43,938	(6,911)
Foreign exchange impact	12,582	—
Balance as of June 30, 2024	963,679	59,127
Mark to market adjustment	23,943	(4,791)
Foreign exchange impact	45,402	—
Balance as of September 30, 2024	1,033,024	54,336
Balance as of December 31, 2022	936,516	—
Mark to market adjustment	(56,453)	—

ANTERIS TECHNOLOGIES LTD

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024

11. FAIR VALUE MEASUREMENT (continued)

(In US dollars)	Warrant liabilities	Other variable liabilities
Foreign exchange impact	(8,945)	—
Balance as of March 31, 2023	871,118	—
Mark to market adjustment	18,211	—
Foreign exchange impact	(10,839)	—
Balance as of June 30, 2023	878,490	—
Mark to market adjustment	(886)	—
Foreign exchange impact	(22,812)	—
Balance as of September 30, 2023	854,792	—

Fair value of warrant liabilities — Level 3

The warrants have been valued using a Black-Scholes model that incorporates a share price hurdle and a discounted cashflow methodology. The inputs used in the measurement of the fair values of the warrant liabilities (translated using year-end exchange rates) are detailed below. No reasonable change in the unobservable inputs would result in a significant change to the fair value of the warrant liabilities.

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Fair value per warrant	$20.92	$18.68
Assumptions used:		
Share price	$9.22	$13.75
Exercise price (AUD 25.31)	$17.54	$17.31
Share price hurdle (AUD 55.68)	$38.60	$38.08
Expected volatility	45%	55%
Time to maturity	0.07 years	0.82 years
Risk-free interest rate	3.62%	3.69%
Exercise price of the put option (AUD 30.37)	$21.05	$20.77
Put option discount rate	10.00%	14.75%

12. EQUITY

Ordinary shares

For information on the pertinent rights and privileges of the Company's outstanding ordinary shares, refer to Note 17 *Equity* in the audited consolidated financial statements for the year ended December 31, 2023 as included in the Form S-1.

During the nine months ended September 30, 2024:

- In January 2024, 667 unlisted options issued under the Anteris Employee Incentive Plan were exercised raising $3,782. These options had an exercise price of $5.67 equivalent per share (AUD8.60).
- In January 2024, external investors exercised 12,500 unlisted options for $6.70 equivalent per share (AUD10.00) raising $83,788.
- In March 2024, external investors exercised 262,000 unlisted options for $6.59 equivalent per share (AUD10.00) raising $1,726,877.

12. EQUITY (continued)

- In April 2024, external investors exercised 115,000 unlisted options for $6.52 equivalent per share (AUD10.00) raising $750,000.
- In April 2024, 1,000,000 new shares were issued to various sophisticated and professional investors at $14.74 equivalent per share (AUD23.00) for total consideration of $14,738,400.
- In May 2024, external investors exercised 12,000 unlisted options for $6.60 equivalent per share (AUD10.00) raising $79,152.
- In July 2024, 1,875,000 new shares were issued to various sophisticated and professional investors at $10.49 equivalent per share (AUD16.00) for total consideration of $19,668,000.
- In July 2024, 41,000 new shares were issued to a consultant for services provided. The equivalent price per share was $10.49 (AUD16.00).
- In September 2024, external investors exercised 1,500 unlisted options for $6.84 equivalent per share (AUD10.00) raising $10,258.

For the comparable nine-month period ended September 30, 2023:

- In February 2023, 1,454,167 new shares and 1,454,167 free-attaching options were issued to various sophisticated and professional investors for total consideration of $24,210,136. The consideration received for both the shares and free-attaching options has been reflected as an increase in share capital.
- In March 2023, 168 unlisted options issued under the Anteris Employee Incentive Plan were exercised raising $920. These options had a weighted average exercise price of $5.48 equivalent per share (AUD8.19).
- In April 2023, 1,000 shares were issued as compensation for expert advisory services received. No amounts were payable for the issue of the ordinary shares.
- During April to June 2023, 92,000 unlisted options were exercised for $6.68 equivalent per share (AUD10.00) raising $614,991.
- During April to June 2023, 67,040 unlisted options were exercised for $7.80 equivalent per share (AUD11.50) raising $522,669.
- In May 2023, 4,167 new shares and 4,167 free-attaching options were issued to Wayne Paterson, the Company's CEO and Managing Director, for consideration of $64,955, which is on the same terms as other investors who participated in the February 2023 capital raise. Shareholder approval was obtained at the Company's Annual General Meeting on May 29, 2023.
- During July to September 2023, 18,250 unlisted options were exercised for $6.52 equivalent per share (AUD10.00) raising $119,035.
- During July to September 2023, 67,324 unlisted options were exercised for $7.70 equivalent per share (AUD11.50) raising $518,621.

Refer to note 18 for details of the shares issued post period-end.

13. LOSS PER SHARE

The below table presents the computation of basic and diluted loss per share:

		THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
		2024	2023	2024	2023
Loss for the period, attributable to the owners of the Company	$	21,858,650	10,591,502	56,915,818	31,835,332
Weighted average number of shares outstanding: used in the denominator in calculating basic and diluted loss per share	Number	20,513,631	15,587,983	19,144,910	15,221,827
Basic and diluted loss per share	$	1.07	0.68	2.97	2.09
Securities excluded as their inclusion would be anti-dilutive	Number	6,168,195	6,624,495	6,168,195	6,624,495

14. STOCK-BASED COMPENSATION

(a) Stock-based Compensation expense

The following table presents the components and classification of stock-based compensation expense recognized for stock options issued to employees, directors and consultants:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
(In US dollars)	2024	2023	2024	2023
Equity-settled stock-based payments	1,804,319	1,218,419	4,998,599	3,199,656
Modification of equity-settled stock-based payments	—	—	—	899,576
Cash-settled stock-based payments (SPP rights)	(473,816)	77,257	(248,223)	77,257
Shares issued as compensation to consultants	215,037	—	15,307	14,392
Total stock-based compensation expense	1,545,540	1,295,676	4,965,413	4,190,881
Classification of stock-based compensation expense				
Cost of products sold	1,295	1,041	3,338	4,018
Research and development expense	(57,694)	598,531	761,214	1,824,935
Selling, general and administrative expense	1,601,939	696,104	4,200,861	2,361,928
Total stock-based compensation expense	1,545,540	1,295,676	4,965,413	4,190,881
Stock-based compensation capitalized to equity (transaction cost)	215,037	—	215,037	2,623,926
Total stock-based compensation	1,760,577	1,295,676	5,180,450	6,814,807

As of September 30, 2024, there was $7,770,681 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements granted. That cost is expected to be recognized over a weighted-average period of 1.4 years.

14. STOCK-BASED COMPENSATION (continued)

(b) Stock option activity

All stock-based compensation is based in AUD, therefore all disclosures within this note use foreign exchange rates on the dates that the options, rights or shares were granted, vested or forfeited. Period-end amounts are translated using the foreign exchange rate on that date.

Employee options

The number of employee options issued during the nine months ended September 30, 2024 and 2023 was 9,450 and 3,000, respectively. The number of employee options issued during the nine months ended September 30, 2024 and 2023 was 167,950 and 10,050, respectively.

Director stock options

On June 19, 2024, following approval by shareholders at the Annual General Meeting on May 29, 2024, the Company issued 475,000 options with an exercise price of $15.34 equivalent (AUD23.00) per share to the following Directors:

- John Seaberg (Chair) — 75,000 options
- Wayne Paterson (CEO and Managing Director) — 300,000 options
- Stephen Denaro (Non-Executive Director and Company Secretary) — 50,000 options
- Wenyi Gu (Non-Executive Director) — 50,000 options

The above Director share options expire after 5 years and vest in three tranches on the completion of at least 12, 24 and 36 months of service from the date of issue. These options were awarded as part of the existing Employee Incentive Plan.

Modification of Director options

In 2020, the Company issued 350,000 options to Wayne Paterson (CEO and Managing Director), 60,000 options to John Seaberg (Chairman) and 25,000 options to Stephen Denaro (Non-Executive Director and Company Secretary) at an exercise price of $7.66 (AUD 11.20) which only vested upon the completion of at least 12, 18 and 24 months service and the achievement of corresponding performance hurdles related to increases in the Company's share price. During the 2022 year, 289,500 of the 435,000 options vested upon achievement of share price performance hurdles.

On February 17, 2023, the Board of Directors exercised their discretion to extend the period to achieve the share price hurdle of the final tranche, by an additional 12 months, from March 19, 2023 to March 19, 2024. The incremental fair value of these options was $6.18 per option, resulting in an increased fair value of $899,576. The value was expensed at the date of the modification.

The remaining 145,500 options were only to vest if the Company's share price reached at least $22.98 (AUD 33.60) for a minimum of 10 days within any 20 sequential trading days by March 19, 2024. The share price hurdle was not met by the expiry date and the associated options were cancelled on March 20, 2024.

Consultant options and shares

No options were issued to consultants during the three months ended September 30, 2024 and 2023, or the nine months ended September 30, 2024. The number of options issued to consultants during the nine months ended September 30, 2024 was 500,000.

14. STOCK-BASED COMPENSATION (continued)

Cash-settled stock-based compensation

The Share Price Performance Plan ("SPP") provides employees with the right to receive cash payments calculated by considering the rise in Anteris' share price from the base price specified at grant date. No SPP rights were issued during the nine months ended September 30, 2024 and 2023.

On September 13, 2024, 283,332 SPP rights were forfeited and cancelled as the share price on the vesting date was less than the base price.

The carrying amount of the SPP liabilities was $568,330 and $775,219 as of September 30, 2024 and December 31, 2023, respectively.

(c) Shares issued as compensation

During the three and nine months ended September 30, 2024, 41,000 ordinary shares were issued to a consultant as compensation for services received. No shares were issued to consultants during the three months ended September 30, 2023. During the nine months ended September 30, 2023, 1,000 ordinary shares were issued to a consultant as compensation for expert advisory services received. No amounts were payable for the issue of the ordinary shares.

(d) Fair Value Disclosures

Employee options

The following table provides the weighted average fair value of options granted to employees during the periods indicated and the related weighted average assumptions used in the Black-Scholes model.

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Quantity issued during the period	9,450	3,000	167,950	10,050
Weighted average fair value per option at grant date	$4.78	$7.82	$7.50	$8.14
Assumptions used:				
Share price at grant date	AUD 17.05 / USD 11.33	AUD 20.90 / USD 14.20	AUD 22.35 / USD 14.70	AUD 22.84 / USD 15.49
Exercise price (USD equivalent at grant date)	AUD 18.27 / USD 12.12	AUD 20.65 / USD 14.03	AUD 19.28 / USD 12.68	AUD 21.69 / USD 14.70
Expected volatility	52.2%	75.0%	60.9%	69.4%
Expected life	3.5 years	3.5 years	3.5 years	3.5 years
Expected dividends	Nil	Nil	Nil	Nil
Risk-free interest rate range	4.04% – 4.06%	3.79% – 3.82%	3.63% – 4.06%	3.21% – 3.82%

Director options granted

The following table provides the fair value of the stock-based payments options granted to directors during the periods indicated and the weighted average inputs (based on number of options granted) used in the Black-Scholes model.

14. STOCK-BASED COMPENSATION (continued)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Quantity issued during the period	—	1,018,500	475,000	1,018,500
Weighted average fair value per option at grant date	—	$7.24	$4.87	$7.24
Assumptions used:				
Share price at grant date	—	AUD 20.80 / USD 14.09	AUD 18.98 / USD 12.62	AUD 20.80 / USD 14.09
Exercise price (USD equivalent at grant date)	—	AUD 24.00 / USD 16.26	AUD 23.00 / USD 15.29	AUD 24.00 / USD 16.26
Expected volatility	—	75.0%	56.25%	75.0%
Expected life	—	3.5 years	3.5 years	3.5 years
Expected dividends	—	Nil	Nil	Nil
Risk-free interest rate range	—	3.80% – 3.82%	4.07% – 4.08%	3.80% – 3.82%

Modification of director options

The following table provides the incremental fair value of the options modified during the periods indicated and the related assumptions used in the Black-Scholes model.

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Quantity modified during the period	—	—	—	145,500
Incremental fair value per option at modification date	—	—	—	$6.18
Assumptions used:				
Share price at modification date	—	—	—	AUD 22.20 / USD 15.19
Exercise price (USD equivalent at modification date)	—	—	—	AUD 11.20 / USD 7.66
Expected volatility	—	—	—	65.0%
Expected life	—	—	—	2.1 years
Expected dividends	—	—	—	Nil
Risk-free interest rate range	—	—	—	3.52%

Consultant options

The following table provides the weighted average fair value of options granted to consultants during the periods indicated and the related weighted average assumptions used in the Black-Scholes model.

14. STOCK-BASED COMPENSATION (continued)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Quantity issued during the period	—	—	—	500,000
Weighted average fair value per option at grant date	—	—	—	$5.26
Assumptions used:				
Share price at grant date	—	—	—	AUD 24.04 / USD 16.72
Exercise price (USD equivalent at grant date)	—	—	—	AUD 29.00 / USD 20.17
Expected volatility	—	—	—	64.8%
Expected life	—	—	—	2.0 years
Expected dividends	—	—	—	Nil
Risk-free interest rate range	—	—	—	3.34%

SPP rights

The inputs used in the measurement of the fair values at reporting date of the SPP rights were as follows:

Service based SPP	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Weighted average fair value per right	$0.57	$3.00
Share price at measurement date	AUD 12.20 / USD 8.46	AUD 19.15 / USD 13.10
Base price	AUD 24.00 / USD 16.64	AUD 24.00 / USD 16.42
Expected volatility (weighted average)	50.0%	57.5%
Expected life (weighted average)	1.5 years	1.7 years
Risk-free interest rate (weighted average)	3.71%	3.66%

Service and performance based SPP	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Weighted average fair value per right	$2.63	$5.40
Share price at measurement date	AUD 12.20 / USD 8.46	AUD 19.15 / USD 13.10
Base price	AUD 24.00 / USD 16.64	AUD 24.00 / USD 16.42
Expected volatility (weighted average)	57.5%	60.0%
Expected life (weighted average)	3.0 years	3.7 years
Risk-free interest rate (weighted average)	3.56%	3.8%

15. VARIABLE INTEREST ENTITY

At each reporting period, the Company reassesses whether it remains the primary beneficiary for Variable Interest Entities (“VIEs”) consolidated under the VIE model.

On April 18, 2023, the Group entered into a series of agreements with v2vmedtech, inc. (‘v2v’) to develop an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation. As part of the binding agreements, the Group acquired 30% interest in v2v for

15. VARIABLE INTEREST ENTITY (continued)

consideration of $213,000, with the remaining 70% retained by the sellers. The transaction was accounted for as an asset acquisition under ASC 805 *Business Combinations*, as substantially all of the fair value of the gross assets acquired were concentrated in a single identifiable in-process research and development ("IPR&D") asset. In accordance with the accounting for asset acquisitions, an entity that acquires IPR&D assets in an asset acquisition follows the guidance in ASC 730 *Research and Development*, which requires that both tangible and intangible identifiable research and development assets with no alternative future use be allocated a portion of the consideration transferred and recorded as research and development expense at the acquisition date. The Company provides non-reciprocal contributions to fund research and development.

Pursuant to the guidance under ASC 810, the Company determined that v2v is a VIE and that the Company is the primary beneficiary of v2v. This determination is based on the Company having both power over the most significant activities of v2v, primarily through appointing and holding a majority of the board of directors, and benefits through equity ownership. Therefore, the Company consolidated v2v from acquisition date.

The following table presents the assets and liabilities for VIE:

	SEPTEMBER 30, 2024	DECEMBER 31, 2023
Assets		
Other current assets	20,798	25,000
Total assets	20,798	25,000
Liabilities		
Other current liabilities	327,986	25,000
Non-current liabilities	54,336	93,841
Total liabilities	382,322	118,841
Net (liabilities)/assets	(361,524)	(93,841)

Included in other current liabilities is a loan from v2v's parent entity amounting to $20,798 as of September 30, 2024, and $25,000 as of December 31, 2023. This loan has been provided to support v2v's working capital needs. It is unsecured and repayable on demand. This balance is eliminated in the condensed consolidated financial statements. v2v is wholly financed by the Company. The Company contributed $2,097,868 in contributions to v2v to finance its operations during the nine months ended September 30, 2024 with $759,481 of this amount contributed in the three months ended September 30, 2024.

Noncontrolling Interests

Noncontrolling interests represent the equity in a subsidiary not attributable, directly or indirectly, to the parent company. The Group uses the Hypothetical Liquidation at Book Value (HLBV) approach to measure the noncontrolling interests. Under HLBV, the noncontrolling interests are calculated as the amount that would be paid to noncontrolling interest holders upon a hypothetical liquidation of the entity at book value as of the reporting date.

15. VARIABLE INTEREST ENTITY (continued)

The Company recognizes noncontrolling interests related to v2v and provides a roll forward of the noncontrolling interests balance, as follows:

Balance as of December 31, 2023	$(402,835)
Net gain attributable to noncontrolling interests	197,363
Balance as of March 31, 2024	$(205,472)
Net loss attributable to noncontrolling interests	(111,793)
Balance as of June 30, 2024	$(317,265)
Net loss attributable to noncontrolling interests	64,198
Balance as of September 30, 2024	$(253,067)

16. COMMITMENTS AND CONTINGENCIES

At September 30, 2024 the Group had commitments to purchase $209,231 of plant and equipment (December 31, 2023: Nil).

Anteris are involved in various ongoing proceedings, legal actions and claims arising in the normal course of business, including proceedings related to product, labor, intellectual property and other matters. No material legal proceedings are currently pending.

Contingent asset

Anteris Technologies Ltd sold the distribution rights to its CardioCel™ and VascuCel™ product portfolio to LeMaitre Vascular, Inc. (‘LeMaitre’) on October 11, 2019. In addition to the initial proceeds received, the agreement provided for additional payments subject to the achievement of certain milestones. This included an entitlement to receive a holdback amount of $2,000,000 less the associated regulatory approval costs incurred by LeMaitre, subject to approval of the products by the European Union Medical Device Regulation.

The agreement has since been amended and extended with the revised agreement now contracted to conclude in January 2025. Under the revised agreement, LeMaitre is responsible for obtaining regulatory approvals under the European Union Medical Device Regulation. Anteris is entitled to receive a holdback amount of $2,000,000 less the associated regulatory approval costs incurred by LeMaitre (capped at €600,000) payable in the following instalments:

1. Anteris is entitled to 33% of the holdback amount by January 26, 2025 if LeMaitre do not obtain the regulatory approvals for either the CardioCel™ and VascuCel™ by January 11, 2025. The payment will be reduced by 33% of the eligible deductions. The first net instalment was recognized in Other non-operating income during September 2023 with $431,652 recognized in Other current assets as of September 30, 2024.
2. The remaining 67% of the holdback amount will be due on the following basis with the eligible deductions applied proportionally to those activities:
    a. 75% when LeMaitre receive the CardioCel™ regulatory approval; and
    b. 25% when LeMaitre receive the VascuCel™ regulatory approval.

16. COMMITMENTS AND CONTINGENCIES (continued)

This second holdback entitlement, which is a contingent receipt, has not been recognized as income as it is not yet considered probable that the contingent event will occur.

Contingent liabilities

The Company records a liability in the condensed consolidated financial statements on an undiscounted basis for loss contingencies related to legal actions when a loss is considered probable, and the amount may be reasonably estimated. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed. When determining the estimated loss or range of loss, significant judgment is required. Estimates of probable losses resulting from litigation and governmental proceedings involving the Company are inherently difficult to predict, particularly when the matters are in early procedural stages with incomplete scientific facts or legal discovery, involve unsubstantiated or indeterminate claims for damages, potentially involve penalties, fines or punitive damages, or could result in a change in business practice.

There were no unrecognized contingent liabilities in relation to the current reporting period.

17. SEGMENT REPORTING

(a) Description of segments

Segment information is presented using a management approach, meaning that segment information is provided on the same basis as information is used for internal reporting purposes by the chief operating decision maker ("CODM") which is the CEO, who makes key strategic decisions. The CODM is responsible for the allocation of resources and assessing the performance of the Group. Management has determined that the activities of the business as reviewed by the CODM are one segment, being the development and commercialization of the ADAPT® platform technology. This is focused on the DurAVR® Transcatheter Heart Valve System.

(b) Segment information

The revenue and cost information relating to all of the ADAPT® products including both DurAVR® and regenerative tissue products are regularly reviewed by the CODM on an aggregate basis.

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Segment revenue from external customers	768,981	598,984	2,166,888	2,190,665
Segment profit/(loss)	(21,794,452)	(10,591,502)	(56,766,050)	(31,835,332)

No detailed asset information by reportable segment has been reported given that the single segment's information is already presented in the condensed consolidated balance sheet. Refer to the condensed consolidated statements of cash flows for significant non-cash items and total expenditure for additions of long-lived assets.

(c) Geographic information

Segment revenues have been based on the geographic location of the customers taking possession of the products.

17. SEGMENT REPORTING (continued)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
United States	443,648	408,969	1,557,761	1,866,983
Australia	5,714	2,140	13,288	6,608
Germany	319,619	187,875	595,839	317,074
	768,981	598,984	2,166,888	2,190,665

(d) Major customers

The following table summarizes revenues from major customers that individually accounted for 10% or more of the Company's total revenues for the three months and nine months ended September 30, 2024, and 2023:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2024	2023	2024	2023
Customer A	346,946	596,845	1,007,847	1,188,598
Customer B	416,317	—	1,145,753	995,460

Amounts outstanding from these customers was $183,330 and $106,986, as of September 30, 2024 and December 31, 2023, respectively.

18. SUBSEQUENT EVENTS

Management has evaluated the impact of subsequent events through to November 1, 2024.

On October 8, 2024, the Company received notice from PFG reflecting PFG's intention to exercise the put option at maturity of the warrant. The put option was paid on October 31, 2024.

On October 31, 2024, ATL entered into a secured convertible note facility (the "Convertible Note Facility") with Obsidian Global Partners, LLC ("Obsidian") to provide additional financing to pursue ATL's strategic objectives, implementation of the Reorganization, and implementation of this Offering. ATL is able to draw up to A$25.0 million (the "Facility Limit") from the Convertible Note Facility, with an initial A$7.5 million drawdown and subsequent drawdowns (subject to mutual agreement) of A$5.0 million or the remaining balance of the Facility Limit, whichever is lesser. On each drawdown, ATL or the Company (following the implementation of the Schemes) will issue notes to Obsidian that are convertible into ordinary shares of ATL or Common Stock (following the implementation of the Schemes) ("Convertible Notes") and is required to pay Obsidian a fee of 3% of the drawdown amount. The aggregate face value of the Convertible Notes issued pursuant to a Drawdown will be equal to 115% of the principal amount of the relevant Drawdown. Each Convertible Note will have a face value of $1.15. In addition, at each Drawdown, ATL will issue options to Obsidian, each exercisable into one ordinary share of ATL or share of Common Stock (following the implementation of the Schemes) ("Obsidian Options"), with each Obsidian Option to have a strike price of A$25.00 and a term of 3 years from the date of issuance. The number of Obsidian Options issued will be such that the aggregate strike price of the Obsidian Options is equal to 25% of the amount drawn under the relevant drawdown.

Report of Independent Registered Public Accounting Firm

To the Board of Directors of Anteris Technologies Global Corp.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Anteris Technology Global Corp. (the Company) as of September 30, 2024, the related statement of cash flows for the period from January 29, 2024 to September 30, 2024 and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2024 and its cash flows for the period from January 29, 2024 to September 30, 2024 in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

We have served as the Company's auditor since 2024.

/s/ KPMG

Brisbane
November 20, 2024

Anteris Technologies Global Corp.

Balance Sheet as of September 30, 2024
(In US dollars, except share quantities)

	SEPTEMBER 30, 2024
Assets	
Current assets	
Cash and cash equivalents	1
Other receivable	9
Total current assets	10
Total assets	$10
Liabilities and Stockholder's Equity	
Current liabilities	
Payable to Anteris Technologies Corporation (Note 5)	10
Total current liabilities	10
Total liabilities	10
Commitments and contingencies	
Stockholder's equity:	
Common stock, $0.0001 par value, 400,000,000 shares authorized	—
Preferred stock, $0.0001 par value, 40,000,000 shares authorized	
Total stockholder's equity	—
Total liabilities and stockholder's equity	$10

Anteris Technologies Global Corp.

Statement of Cash Flows
(In US dollars)

	JANUARY 29, 2024 to SEPTEMBER 30, 2024
Cash Flows from Operating Activities	
Bank Charge Error	(9)
Net Cash Used in Operating Activities	(9)
Cash Flows from Financing Activities	
Proceeds from Loan	10
Net Cash Provided By Financing Activities	10
Cash and Cash equivalents	
Net change during the period	1
Balance at beginning of period	—
Balance at end of period	$ 1

Anteris Technologies Global Corp.
Notes to the Balance Sheet and Statement of Cash Flows

Note 1: Background and Nature of Operations

Anteris Technologies Global Corp. (the "Company") was incorporated in Delaware on January 29, 2024. The Company was formed for the purpose of reorganizing the operations of Anteris Technologies Ltd ("ATL"), an Australian public company registered in Western Australia, Australia and listed on the Australian Securities Exchange ("ASX"), into a structure whereby the ultimate parent company will be a Delaware corporation, Anteris Technologies Global Corp (the "Reorganization"). The Company is planning to issue its common stock ("Common Stock") in an offering ("Offering"). Prior to completion of this Offering, the Company will receive all the issued and outstanding shares of ATL pursuant to a scheme of arrangement under Australian law between ATL and its shareholders (the "Scheme") under Part 5.1 of the Australian Corporations Act 2001 (Cth) (the "Corporations Act"). Contemporaneously with implementation of the Scheme, ATL will also cancel all existing options it has on issue in exchange for the Company issuing replacement options to acquire Common Stock pursuant to a scheme of arrangement between ATL and its option holders (the "Option Scheme") under Part 5.1 of the Corporations Act. The Company intends to list its Common Stock on The Nasdaq Capital Market ("NASDAQ") under the symbol "AVR" and the Company's CHESS Depositary Interests ("CDIs") over the Common Stock will commence trading on an ordinary settlement basis on the ASX following the completion of this offering under the symbol "AVR." Concurrent with the completion of this offering, ATL will de-list its securities from the ASX. Prior to completion of the Reorganization, the Company will have had no business or operations and following completion of the Reorganization, the business and operations of the Company will consist solely of the business and operations of ATL and its subsidiaries. As a result of the Reorganization, the Company will become the parent company of ATL, and for financial reporting purposes the historical financial statements of ATL will become the historical financial statements of the Company as a continuation of the predecessor.

Note 2: Summary of Significant Accounting Policies

Basis of Presentation

The Balance Sheet and Statement of Cash Flows are presented in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Separate statements of income and comprehensive income and changes in stockholder's equity have not been presented because the entity has had no activities as of September 30, 2024, other than a cash contribution and an incorrect bank charge, which will be refunded.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet. Actual results could differ from those estimates.

Note 3: Stockholder's Equity

The Company's authorized capital stock consists of two classes of capital stock, designated Common Stock and Preferred Stock. The total number of shares of capital stock that the Company is authorized to issue is 440,000,000 shares, consisting of 400,000,000 shares of Common Stock, par value $0.0001 per share, and 40,000,000 shares of Preferred Stock, par value $0.0001 per share. The Company has not issued any shares of Common Stock or Preferred Stock.

Note 4: Liquidity and Capital Resources

The Company has been formed to complete the transactions contemplated by the Share and Option Schemes. Liquidity needs have been satisfied through the support of ATL. The Company has no existing liabilities or obligations, other than a liability to a subsidiary of ATL, and does not plan to incur any expenses prior to the close of the transactions contemplated in the Scheme. Based on the foregoing, management

believes that the Company will have sufficient working capital to meet its needs through the earlier of the completion of the Scheme or one year from this filing.

Note 5: Related Party Transactions

Costs related to incorporation of the Company will be paid by ATL and recorded as an expense of ATL.

In August 2024, the Company received $10 from Anteris Technologies Corporation, a subsidiary of ATL to enable establishment of the Company's bank account. The balance is recognized as a payable and is repayable at the discretion of the Company. There are no formal written agreements governing the terms of the payable..

Note 6: Income Taxes

As of September 30, 2024, the Company is a dormant entity with no operations or taxable income. Consequently, no current or deferred tax provision has been recorded for the period ended September 30, 2024.

The Company did not incur any taxable income or losses, and there are no deferred tax assets or liabilities recognized in the financial statements. Furthermore, the Company does not have any uncertain tax positions or tax-related contingencies requiring disclosure under ASC 740, Income Taxes. The Company remains subject to U.S. federal and state tax filing requirements.

No income tax expense is reported as the Company had no tax-related transactions during the period.

Note 7: Subsequent Events

On November 13, 2024, Wayne Paterson, the Sole Director of the Company, increased the number of directors comprising the entire Board from one director to four directors by appointing three new directors to the Board: John Seaberg, Stephen Denaro and Wenyi Gu.

The Company has evaluated subsequent events through November 20, 2024, the date on which the financial statements was available for issuance.

In October 2024, the bank refunded $9 of bank fees which had been charged in error.

14,800,000 Shares of Common Stock

Joint Book-Running Managers

TD Cowen **Barclays** **Cantor**

Lead Manager

Lake Street

Prospectus

December 12, 2024

Through and including January 6, 2025 (25 days after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect an unsold allotment or subscription.