UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-42437

Anteris Technologies Global Corp.

(Exact name of Registrant as specified in its Charter)

Delaware	**99-1407174**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Toowong Tower, Level 3, Suite 302 **9 Sherwood Road** **Toowong, QLD** **Australia**	
(Address of principal executive offices)	**4066** **(Zip Code)**

Registrant's telephone number, including area code: +61 7 3152 3200

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	AVR	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.

YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☐ NO ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES ☐ NO ☒

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting equity held by non-affiliates as of such date.

The number of shares of Registrant's Common Stock outstanding as of March 12, 2025 was 36,023,796.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to the 2025 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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INTRODUCTION

Prior to the consummation of our initial public offering, we completed a series of reorganization transactions (the "Reorganization"). Unless otherwise indicated or context otherwise requires in this Annual Report on Form 10-K (this "Form 10-K"), all references in this Form 10-K to the "Company," "Anteris," "Anteris®," "we," "us" and "our" refer to Anteris Technologies Ltd ("ATL") prior to the Reorganization and Anteris Technologies Global Corp. ("ATGC") after the Reorganization, and for purposes of this Form 10-K:

- "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 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.

- "Cytotoxicity" 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 ≤ 1 cm^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" refer 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.
- "ViV" refers to valve-in-valve.
- "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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements in this Form 10-K, other than statements of historical facts, 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," "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 ("R&D") 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 R&D expenses; and
- risks facing our operations and intellectual property.

We have based the forward-looking statements contained in this Form 10-K 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 Form 10-K, 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 Form 10-K 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 within this Form 10-K.

You should read this Form 10-K and the documents that we reference in this Form 10-K 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 Form 10-K by these cautionary statements.

This Form 10-K 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, par value $0.0001 per share ("Common Stock"), and CHESS Depository Interests ("CDIs"). All references in this Form 10-K to Common Stock shall include the shares represented by CDIs unless the context suggests otherwise. 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.

CAUTIONARY NOTE REGARDING INDUSTRY AND MARKET DATA

This Form 10-K includes information concerning the Company's industry and the markets in which it operates that is based on information from various sources including public filings, internal company sources, various third-party sources and management estimates. In addition, this Form 10-K 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 Form 10-K 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 Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates included in this Form 10-K. 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.

RISK FACTOR SUMMARY

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 Form 10-K, 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 Form 10-K, together with our other publicly available filings with the Securities and Exchange Commission (the "SEC"), 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. Our business and any investment in our securities involves risks. You should carefully consider the risks described in the section titled "*Risk Factors"* before making a decision to invest in our Common Stock. 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.
- We will require substantial additional future financing and may be unable to raise sufficient capital, which could have a material impact on our R&D 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 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, liquid trading market for our Common Stock may not be maintained.

- 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 (the "Amended and Restated Bylaws") contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

PART I

Item 1. Business.

Overview

Anteris is a structural heart company dedicated to revolutionizing cardiac care by pioneering science-driven and measurable advancements to restore heart valve patients to healthy function. Our lead product, the DurAVR® THV, represents a unique product opportunity in a new THV class of single-piece heart valves, for the treatment of aortic stenosis. Our DurAVR® THV 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.

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. As of January 2025, a total of 83 patients have been treated with the DurAVR® THV 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 United States Food and Drug Administration ("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. Our first in class 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 observed promising results in relation to hemodynamics, laminar flow and exercise capacity. When compared to a healthy aortic valve, our DurAVR® THV showed no significant difference in aortic flow.

In addition, our DurAVR® THV 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 or TAVR using a 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 conditional approval of our United States early feasibility study ("US EFS") EFS investigational device exemption ("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, enrolling 15 patients in four prominent heart valve centers across the United States. At 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. 12-month follow-up visits were completed in December 2024. As of the date of this Form 10-K, some, but not all patient follow-up data, has been obtained, and the Company is not in a position to comment on such data at this time.

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 compassionate 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 is unsuitable. In August 2023, a second Canadian patient was successfully implanted with the DurAVR® THV system in a ViV procedure. As of January 2025, we have now treated seven ViV patients with our DurAVR® THV.

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 the end of quarter one 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 operation, 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.

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 into a development agreement (the "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.

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, first in class, "biomimetic" THV. 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 United States studies***. Anteris has 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 and our ComASUR® balloon expandable 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***. Anteris relies on a combination of intellectual property assets to protect our innovative technology and our brand. This includes our strong patent portfolio, which includes 51 issued patents and 53 pending patent applications, in the United States and in other countries. We also have six pending patent applications through v2vmedtech.

- ***Industry experienced executive team***. Our management team and members of our Board of Directors (our "Board") 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 other territories 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 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 to last longer than traditional three-piece aortic valves, which have multiple leaflets sewn together that may lead to compromised durability.

Our Product Candidates

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



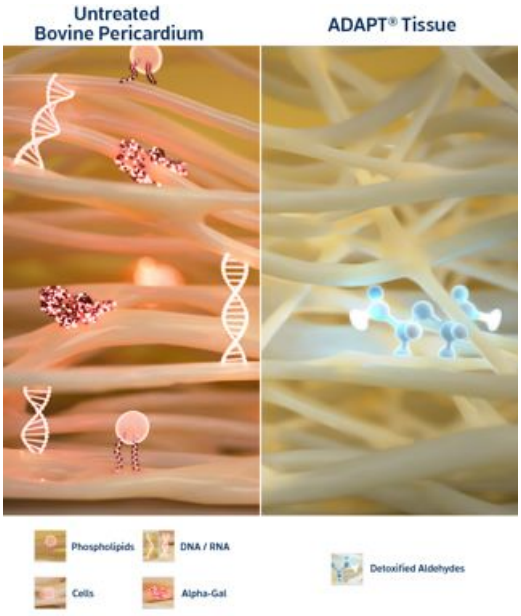
Our DurAVR® THV is a novel transcatheter aortic valve for the treatment of aortic stenosis that is shaped to mimic the performance of a healthy human aortic valve. Our DurAVR® THV system has been designed with considerable input from some of the world's leading interventional cardiologists and cardiac 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 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 restore 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 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.

To meet the need for a durable TAVR, made from ADAPT ® tissue scaffold, we have created DurAVR® THV, which is a first in class, 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.

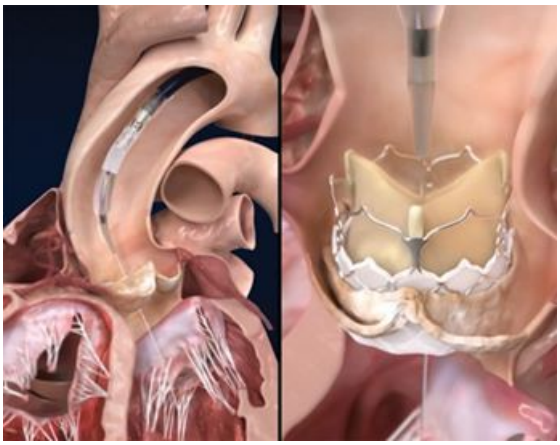
ComASUR® Delivery System



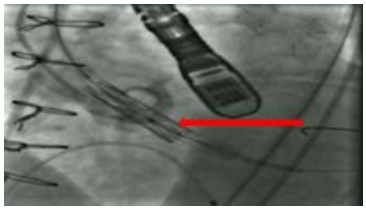
Our ComASUR® delivery system is a physician-developed balloon expandable delivery system that contains a reinforced steerable catheter for a precise deflection through the heart anatomy in a controlled manner to avoid damage to the aorta. This delivery system provides controlled deployment and accurate 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.



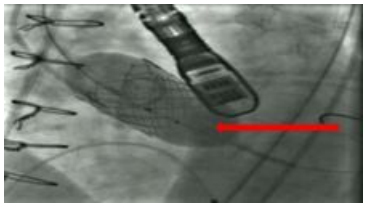
Within the ComASUR® delivery system, we have rotational control of the DurAVR® valve with the native commissures. This allows for commissure alignment, which is not achieved consistently in competitive delivery systems. This feature positions the TAVR valve leaflets exactly in line with the anatomical orientation of the recipient's native valve leaflets. We have a patent pending for this system.



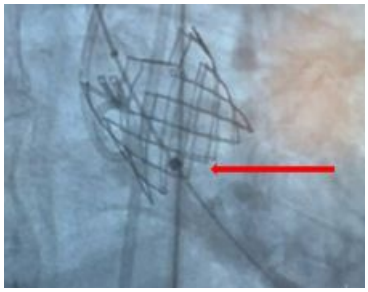
The ComASUR® delivery system provides even balloon expansion for the accurate placement of the DurAVR® THV as well as ease of use. Under fluoroscopic guidance the physician precisely aligns the DurAVR® THV with the native annulus before deployment in the following manner:



First, the balloon starts out as collapsed.



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



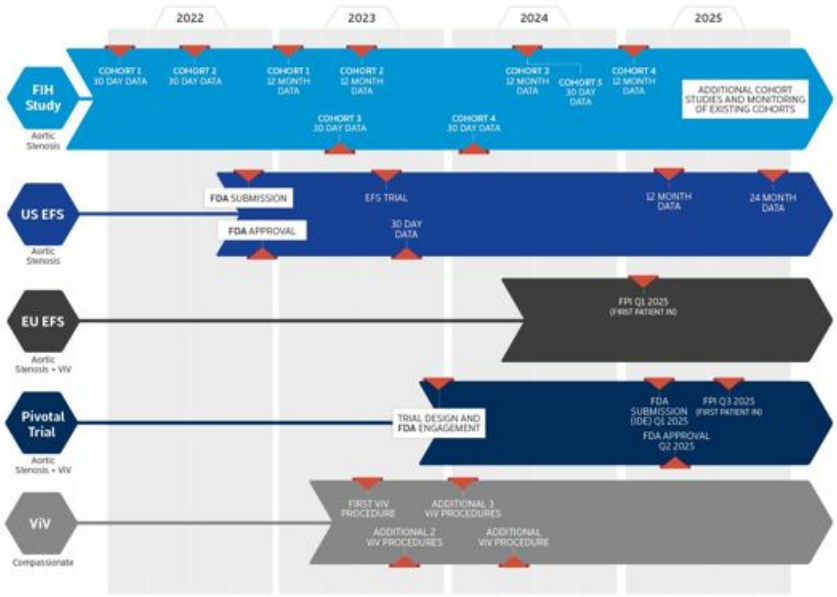
Finally, the balloon is deflated and removed.

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 United States and the 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 75 patients that have benefited from the implantation of the DurAVR® THV in Georgia and the United States. In addition, the DurAVR® THV has been implanted in eight compassionate ViV patients, including one Valve-in-Valve-in-Valve ("ViViV") compassionate procedure.

The preparation for our European Union early feasibility study (our "EU EFS") commenced in December 2024 and the first two subjects were implanted in January 2025.

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 59 patients (including one compassionate case, which was outside of the study) have benefited from the implantation of our DurAVR® THV system at this clinic across seven cohorts. 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 88.

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 six-month 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. The below cohort study results relate only to patients enrolled in the specific cohort and excludes the results of all compassionate cases.

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) and with a 48% improvement from the baseline results and the 12 months post-procedure (average 6MWTD at 12 months of 258.57 meters).

Cohort 4

Our fourth patient cohort consists of eight patients, each of which were implanted with our DurAVR® THV 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 cm^2 and average EOA at 30 days of 2.39 cm^2), 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 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 in September 2024. As of the date of this Form 10-K the 30-day clinical data for this cohort was not available for release, and the Company is not in a position to provide an update with respect to this data at this time.

Cohort 7

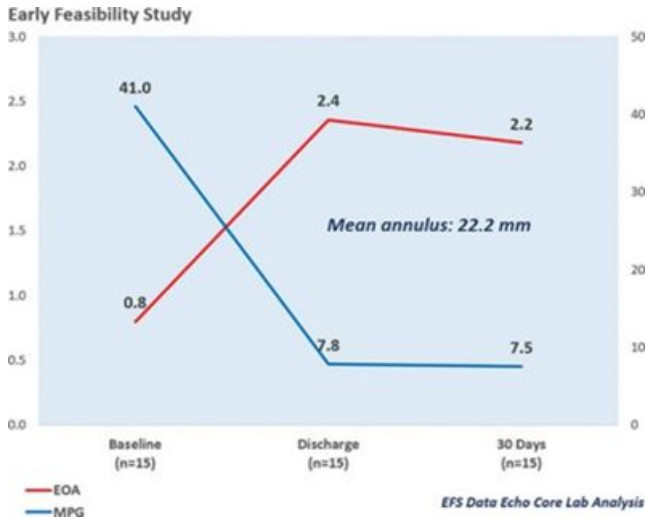
Our seventh patient cohort consisted of eight patients, which were implanted with our DurAVR® THV system in December 2024. As of the date of this Form 10-K, the 30-day clinical data for this cohort was not available for release, and the Company is not in a position to provide an update with respect to this data at this time.

United States 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 the DurAVR® THV in this study as a Centers for Medicare and Medicaid Services ("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 pressure gradient, aortic regurgitation and DVI.

The EFS demonstrated a 100% precise placement and implant success of our DurAVR® THV 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 cm^2 and average EOA at 30 days of 2.2 cm^2), 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 were completed in December, 2024, with analysis and reporting scheduled for the first quarter of 2025. As of the date of this Form 10-K, not all of the 12-month data, has been obtained, and the Company is not in a position to comment on such data at this time.



We have partnered with IQVIA Inc ("IQVIA") and the Cardiovascular Research Foundation ("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 procedure at the Karolinska Institute hospital.

EU Early Feasibility Study

Preparation of our EU EFS commenced in December 2024, with the activation of the first European Union ("EU") investigational site. The first two subjects were implanted in January 2025. The EU EFS plans 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 and is expected to provide ViV data in a controlled setting as well as generate further feasibility and safety data in patients with severe aortic stenosis. The study is anticipated to enroll up to 40 patients with data collected to be included in future regulatory applications.

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. United States 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 December 31, 2024, Anteris owned a total of 51 active patents expiring between 2025 and 2042, and 53 pending patent applications, as further detailed below.

In the category of prosthetic heart valve devices, we are the sole owner of eight active United States patents, four pending United States patent applications, six active Australian patents, three pending Australian patent applications, one pending Patent Cooperation Treaty ("PCT") application, 17 active patents in other countries, and 29 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.

In the category of delivery systems for the prosthetic heart valve devices, we are the sole owner of one active United States patent, six pending United States 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.

In the category of sterilization and storage of the prosthetic heart valve devices, we are the sole owner of two active United States 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.

In the category of packaging, we are the sole owners of two active United States patents, one pending United States 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.

Anteris holds a 30% interest in v2vmedtech. v2vmedtech's intellectual property is directed to implantable medical devices for mitigating heart valve regurgitation. Using a transcatheter deployment technique, one or more clip devices are attached to the leaflets of a patient's mitral or tricuspid heart valve to permanently join together edge portions of the leaflets. This is often referred to as an edge-to-edge repair procedure. As of December 31, 2024, v2vmedtech had six pending patent applications and is the exclusive licensee of two pending patent applications owned by Columbia University.

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" trademark 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.

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 were capped at EUR 0.6 million) has been recognized as a receivable as of December 31, 2024 with LeMaitre confirming receipt of the European Union Medical Device Regulation (Regulation (EU) 2017/745) ("EUMDR") approvals in January 2025. 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 per product currently ranging between Australian dollar ("AUD $") $200 and AUD $1,400 per product. This Transition Services Agreement expired in January 2025, whereupon LeMaitre commenced manufacturing the product.

Until January 2025, we remained the legal manufacturer for CardioCel™ and VascuCel™ products sold by LeMaitre in the Asia Pacific region, North Africa, Middle East region, including Bahrain Kuwait, Lebanon, Israel, Qatar, Saudi Arabia, the United Arab Emirates, Hong Kong, Indonesia, South Korea, Malaysia, Philippines, Singapore, Thailand, Turkey, the United Kingdom, and Vietnam. LeMaitre is in the process of transitioning to become a legal manufacturer for these regions. The CardioCel™ and VascuCel™ medical device license for Canada and the FDA issued 510(k) clearance, is now held by LeMaitre, which sells its own version of CardioCel™ and VascuCel™. LeMaitre has also received a European CE mark under the EUMDR transition period for its version of CardioCel™ and VascuCel™. Under the EUMDR, LeMaitre is able to continue to distribute its remaining inventory of Anteris CardioCel™ and VascuCel™ currently held in LeMaitre's facility in Europe. For further information, refer to the section titled "United States FDA Regulation of Medical Devices."

We have received cash proceeds of $13.4 million through December 31, 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 received $8.4 million in proceeds through December 31, 2024 (life to date) 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 current term of the 4C Agreement expires on June 1, 2026, at which time it 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 and 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 concluded with a design review with non-Anteris members of v2vmedtech, prior to proceeding to Stage 2. The R&D contributions (excluding general and administration expenses) paid by us under Stage 1 were $2.2 million.

Stage 2 involved manufacturing and testing prototypes of the preferred concept to finalize the TEER Product design for concept lock. This stage included 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 R&D 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, at 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 R&D 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 at 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 may be required before proceeding to Stage 5. The R&D 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 R&D 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 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 R&D, 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 of eligible development contributions and operational contributions paid by us under the v2v Agreements as of December 31, 2024 was $3.6 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"). Pursuant to the ESIA Agreement, we investigated applying the ESIA New Technology to our DurAVR® THV design.

Under the terms of the ESIA Agreement, we 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 shared the development costs with ESIA. Furthermore, it contained an option for a period of 12 months, upon expiration of the ESIA Agreement, for Anteris 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.

It was determined that the ESIA material was not commercially viable for Anteris' purposes. The development project under the ESIA Agreement extended beyond the initial December 31, 2024 term of the ESIA Agreement, however the development project, and therefore the agreement, was terminated on February 11, 2025. We did not receive any revenue from ESIA pursuant to the ESIA Agreement.

As of December 31, 2024, we 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") (subsequently acquired by Integer Holdings Corporation) 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, 2025. 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 Consulting A/S ("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 its 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.

Government Regulation

United States 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 ("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 ("PMA"). 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 PMA will require a new PMA 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, 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 PMA, 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 PMA 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 system.

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 PMA. 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 PMA, 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 PMA upon completion of the currently contemplated pivotal clinical trial.

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, biocompatibility 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 PMA, 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.

The Pre-Market Approval Process

Following receipt of a PMA, 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 PMA. 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 PMA, 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 PMA, the FDA may hold an advisory committee meeting to obtain advice related to the safety and effectiveness of the medical devices 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 PMA, 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 PMA application generally takes between one and two years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA 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; or
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA 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 PMA. 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 PMA or manufacturing facilities is not favorable, then the FDA will deny the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA 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 PMAs 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 PMA, except that the supplement is limited to information needed to support ay changes from the device covered by the approved PMA 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 PMA, 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 PMA 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 PMA 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 Device cGMP, 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 PMA or pre-market approval supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA, 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 PMA, 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, namely the EUMDR, became effective in EU Member States subject to a transition period during which some devices that were in conformity with the previous rules could still be placed on the EU market for some time. The EUMDR requires that medical devices may only be placed on the market or put into service if they meet certain pre-established general safety and performance requirements when properly installed, maintained, and used in accordance with their intended purpose. The EUMDR has significant requirements for many medical devices, including requirements for clinical evidence necessary to demonstrate the devices' conformity (and the related documentation), device identification and traceability, registration of devices and of economic operators throughout the distribution chain and post-market surveillance (dealing with the collection and review of the experience gained from devices for the purpose of identifying any for any necessary corrective or preventive actions after they have been placed on the market or put into service). 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 Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as the World Health Organization 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 10 countries as well as the European Union and affiliate members and observers from many other 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 separate 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 United States 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:

- United States 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. Individual states have corollaries to the federal Anti-Kickback Statute that may also apply and may be more expansive or impose additional requirements.

- 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. Individual states have false claims acts with respect to Medicaid spending that may also apply and may be more expansive or impose additional requirements. 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 United States 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. On February 10, 2025, Executive Order "Pausing Foreign Corrupt Practices Act Enforcement to Further American Economic and National Security" was signed, which directs the U.S. attorney general to review and update guidelines and policies related to FCPA enforcement and to cease new FCPA investigations and enforcement actions until a new enforcement policy is implemented.

- 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.

United States Health Care Reform

Changes in healthcare policy in the United States 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 may limit coverage for the procedures associated with the use of our products. Changes in healthcare policy may further reform state and federal legislation and regulations related to 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 and Security

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-United States 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.

Corporate Information

The Company was incorporated in the State of Delaware on January 29, 2024. 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 shall not be deemed incorporated into and is not a part of this Form 10-K.

Initial Public Offering and Reorganization

On December 12, 2024, our registration statement on Form S-1 (File No. 333-283414) (the "Registration Statement") relating to our initial public offering became effective pursuant to which we issued and sold 14,878,481 shares of Common Stock at a public offering price of $6.00 per share. We received net proceeds of $80.1 million, after deducting the underwriting discounts, commissions and offering expenses and giving effect to the exercise of the underwriters' option to purchase additional shares. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

Prior to the consummation of the initial public offering, we completed the Reorganization pursuant to which we received all of the issued and outstanding shares of ATL, which was formerly an Australian public company originally registered in Western Australia, Australia and listed on the ASX, 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 also cancelled all existing options it had on issue in exchange for our 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. As a result of the Reorganization, ATL became a wholly owned subsidiary of our company and the shareholders of ATL immediately prior to the consummation of the initial public company became holders of the either one share of Common Stock for every ordinary share of ATL or one CDI for every one ordinary share of ATL for each share held as of the record date.

In connection with the Reorganization, on December 16, 2024, we issued (i) 21,139,816 shares of Common Stock to shareholders of ATL, 20,360,496 of which are represented by CDIs, pursuant to the Scheme and (ii) 6,118,807 options to purchase shares of Common Stock pursuant to the Option Scheme. The foregoing issuances were made pursuant to an exemption from registration under Section 3(a)(10) of the Securities Act. Each option is exercisable into one share of Common Stock, including as represented by a CDI, upon the payment of the relevant exercise price.

Human Capital

Overview

As of December 31, 2024, we had approximately 136 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 ethics and compliance hotlines and an online form. Furthermore, the company has a whistleblower policy whereby employees are able to submit an anonymous disclosure either by email, web form or our ethics and compliance hotlines.

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.

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.

Available Information

Prior to the Reorganization, regulatory information on the Company was filed with the ASX. Following the Reorganization, the Company files information with both the ASX and the SEC.

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and related amendments, exhibits and other information with the SEC. You may access and read our filings without charge through the SEC's website at www.sec.gov, the ASX's website at www.asx.com.au or through our website at https://anteristech.com/investors/financials.html, as soon as reasonably practicable after such materials are electronically filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") and the ASX Listing Rules. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Form 10-K.

Item 1A. Risk Factors.

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 years ended December 31, 2024 and 2023, we had total losses after income tax of $76.0 million and $46.8 million, respectively, and negative cash flows from operating activities of $61.2 million and $34.6 million, respectively. As of December 31, 2024 and December 31, 2023, we had an accumulated deficit of $276.4 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 system, as well as continuing to invest in R&D. Moreover, there is a substantial risk that we may not be able to complete the development of DurAVR® THV system 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 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 system, 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, 2024 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.

We will require substantial additional future financing and may be unable to raise sufficient capital, which could have a material impact on our R&D 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 system, 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 R&D. To date, we have financed a significant amount of our operations through equity financings, including our initial public offering, and to a lesser extent, through the divestment of business segments and incurrence of indebtedness and convertible 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 R&D 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 R&D 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 continue 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 R&D 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 future 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 system, 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 - United States 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 system 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 lack sufficient resources to timely and completely address applications for regulatory clearance or approval of our products;
- 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 system, 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 R&D 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, including governmental resources availability and allocation, 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 our DurAVR® THV system 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 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 system 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 R&D 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 system. 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, 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;
- CRF, which provides us with core lab services for the EFS and an independent clinical events committee; and
- 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 – Single Source 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 Device cGMP or other applicable laws enforced by the FDA, state regulatory authorities or non-United States 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 R&D activities for a number of years. Our manufacturing and R&D 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 R&D 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 R&D 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 R&D 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 R&D 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 United States 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 United States 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 United States dollar, then, if we decide to convert our Australian dollars into United States dollars for any business purpose, appreciation of the United States dollar against the Australian dollar would have a negative effect on the United States dollar amount available to us. To the extent that we need to convert United States dollars we receive into Australian dollars for our operations, appreciation of the Australian dollar against the United States 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 United States 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 United States 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 United States 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, or change regulatory and policy priorities, each of which could impact how our products are regulated, prevent or delay approval or clearance of devices, 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 United States federal and state governments, to control healthcare costs and, more generally, to reform healthcare systems. The healthcare industry in the United States is subject to fundamental changes due to ongoing federal and state healthcare reform efforts and related political, economic, and regulatory influences, including those from the recent change in presidential administration. 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 United States 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 United States 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 United States 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 United States 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 United States 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 R&D activities in countries where we do not have patent rights, or in countries where R&D 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 United States 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-United States 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 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.

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.

Shares of our Common Stock are listed to trade on Nasdaq in United States dollars and our CDIs are listed to trade on the ASX in Australian dollars, which may result in price variations.

Shares of our Common Stock are listed to trade on Nasdaq in United States dollars and our CDIs are 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. 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, liquid trading market for our Common Stock may not be maintained.

We can provide no assurance that we will be able to maintain an active trading market for our Common Stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling our Common Stock and our ability to acquire other companies, products or technologies by using our Common Stock as consideration.

We do not anticipate paying dividends in the foreseeable future.

ATL (which became a subsidiary of the Company following completion of the Reorganization) did not declare any dividends during fiscal years 2021, 2022, 2023 or 2024 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 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 United States 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 United States 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 United States 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 Jumpstart Our Business Startups Act of 2012 ("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 of 2002 ("Sarbanes-Oxley Act") relating to internal control over financial reporting, reduced disclosure obligations regarding executive compensation in this Form 10-K and our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation. In addition, as a smaller reporting 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 our initial public 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 incur increased costs as a result of operating as a United States listed public company, and our management is 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 United States listed public company, and particularly after we are no longer an "emerging growth company," we incur, and will continue to 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 efforts to comply with the requirements of being a United States public company, and our management and other personnel need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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, 2024 and 2023, 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 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 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 or take other corporate actions, including effecting changes in our management. These provisions include:

- the ability of our Board to issue shares of preferred 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 divided into three classes serving staggered three-year terms, such that not all members of our Board will be elected at one time;
- allowing only our Board to fill director vacancies, which prevents stockholders from being able to fill vacancies on our Board;
- 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 to amend our Amended and Restated Bylaws, which may allow our Board 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 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, 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 authorizes 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 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 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.

We are a holding company and, as such, we will depend on our subsidiaries to support our operations.

We are a holding company and essentially all of our assets are 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 R&D 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 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 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 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 United States net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2024 we had United States federal net operating loss ("NOL") carryforwards of $94.2 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 United States 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.

Our initial public offering in the United States in December 2024 caused an "ownership change." Under this "ownership change," Section 382 of the Code will 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. This "ownership change" is not expected to cause any tax attributes to expire unused. It is possible that any future ownership changes could materially reduce our ability to use our United States 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, 2024, we had Australian net operating and capital loss ("NOCL") carryforwards of $58.4 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 1997. 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.

Our initial public offering in the United States in December 2024 did not cause a failure of the continuity of ownership test. If future issuances and sales of our Common Stock (including certain transactions involving our Common Stock that are outside of our control) did cause a failure of the continuity of ownership test, 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.

Sales of a substantial number of shares of our Common Stock in the public market by our existing stockholders could cause the price of our Common Stock to fall.

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 or the perception that these sales could occur. In addition, the future registration of shares of our Common Stock may cause our stock price to decline, even before such shares are actually sold in the market. We have registered shares of Common Stock that we may issue under our employee equity incentive plans. These shares can be sold freely in the public market upon issuance. We are unable to predict the effect that sales, or the perception that our shares may be available for sale, will have on the prevailing market price of our Common Stock.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

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 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.

We have developed and implemented a risk-based program focused on cybersecurity measures to protect the confidentiality, integrity, and availability of our critical systems and information.

Our cybersecurity risk management is integrated into our overall risk management framework, and shares common methodologies, reporting channels and governance processes that apply across the risk management program to other legal, compliance, strategic, operational, and financial risk areas.

The Audit and Risk Committee periodically reviews and discusses with management the Company's policies and internal controls with respect to cybersecurity. Our Senior Group Technology Manager ("SGTM") (who has over 20 years of experience in information technology roles and holds various industry certifications) reports to the Chief Financial Officer and together report to the Audit and Risk Committee periodically on cyber security matters. The Audit and Risk Committee reports through to the Board.

In addition to the annual security assessment and penetration test, the SGTM utilizes an Endpoint Detection and Response system which acts as Anti-virus and intrusion prevention system and reports all abnormalities to the SGTM. Essential Eight and Center for Internet Security Control Strategies including patch applications, multi-factor authentication, administrative privileges, application hardening and backups are performed internally via a security consultant with regular updates provided to the SGTM. Reported findings and action items are recorded and assigned to personnel for action.

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.

Our cybersecurity risk management program includes:

- periodic risk assessments;
- annual security assessment and penetration testing;
- A third-party Security Operations Center ("SOC") partner to monitor, manage and respond to cybersecurity incidents;

- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- a cyber risk management process for service providers, suppliers, and vendors that have access to our critical systems and information managed through the selection of typically larger well-known providers, which is supplemented by review of contractual arrangements, insurance and information requests;
- cybersecurity awareness training and phishing campaigns for specific employee groups;
- disaster recovery plans/procedures;
- access control and CCTV systems (where appropriate) for the physical protection of Anteris systems; and
- incident response and recovery procedures, for cybersecurity incidents.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled *"Risk Factors - Risks related to our business - Our information technology systems,* or those used by our third-party contract research organizations or other contractors or consultants, may fail or suffer security breaches."

Item 2. Properties.

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 R&D, 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.

Item 3. Legal Proceedings.

In the ordinary course of our operations, and from time-to-time, we are party to various claims and lawsuits. The Company has received a legal claim in connection with an equity raise undertaken in 2024 and the subsequent Nasdaq IPO. Anteris denies the claims and no court proceedings have been filed at this stage. A provision of $1.4 million has been recognized in relation to this claim. Any further developments that could impact this estimate will be assessed in future reporting periods. We are not party to any additional material legal proceedings, and no such proceedings are, to management's knowledge, threatened against us.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

The Common Stock is traded on the Nasdaq Global Market under the symbol "AVR." The CDIs are traded on the ASX under the symbol "AVR."

Holders of Record

As of December 31, 2024, there were 3,669 holders of record of the Common Stock (including Common Stock underlying CDIs). 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.

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 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 may deem relevant.

Equity Compensation Plan Information

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Form 10-K.

Use of Proceeds from our Initial Public Offering

On December 12, 2024, the Registration Statement relating to our initial public offering became effective pursuant to which we issued and sold 14,878,481 shares of Common Stock at a public offering price of $6.00 per share. We received net proceeds of $80.1 million, after deducting the underwriting discounts, commissions and offering expenses and giving effect to the exercise of the underwriters' option to purchase additional shares. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the planned use of proceeds from the initial public offering from that described in the prospectus included in the Registration Statement.

Recent Sales of Unregistered Securities

In connection with the Reorganization, on December 16, 2024, the Company issued (i) 21,139,816 shares of Common Stock to shareholders of ATL, 20,360,496 of which are represented by CDIs, pursuant to the Scheme and (ii) 6,118,807 options to purchase shares of Common Stock pursuant to the Option Scheme. The foregoing issuances were made pursuant to an exemption from registration under Section 3(a)(10) of the Securities Act. Each option is exercisable into one share of Common Stock, including as represented by a CDI, upon the payment of the relevant exercise price.

Issuer Repurchases of Equity Securities

During the quarter ended December 31, 2024, we did not repurchase any equity securities.

Item 6. [Reserved].

Item 7. 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 year ended December 31, 2024. 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 had no business or operations and, following completion of the Reorganization, the business and operations of the Company consists solely of the business and operations of ATGC and its subsidiaries. Our financial statements as of and for the years ended December 31, 2023 and 2024 consolidate, and our future financial statements will consolidate, ATGC as an operating subsidiary. This MD&A should be read in conjunction with our consolidated financial statements, the accompanying notes to consolidated financial statements and other financial information included in this Form 10-K. 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 Form 10-K titled "Cautionary Note Regarding Forward- Looking Statements.

Overview

Anteris is a structural heart company dedicated to revolutionizing cardiac care by pioneering science-driven and measurable advancements to restore heart valve patients to healthy function. 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. As of January 2025, a total of 83 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.

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 will 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 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.

On December 12, 2024, our Registration Statement relating to our initial public offering became effective pursuant to which we issued and sold 14,800,000 shares of Common Stock at a public offering price of $6.00 per share. We received net proceeds of $79.6 million, after deducting the underwriting discounts, commissions and offering expenses. This excludes the underwriters' option to purchase additional shares, which occurred on January 15, 2025, subsequent to the year ended December 31, 2024.

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.

Principles of Consolidation and Operating Segments

The consolidated financial statements include the accounts for our company, our wholly-owned subsidiaries, and entities for which we have a controlling financial interest, and for periods prior to the Reorganization, 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® anti-calcification tissue. 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 regenerative tissue products. 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. The Transition Services Agreement with LeMaitre expired in January 2025. We do not expect to receive any significant future revenues from LeMaitre. The initial term of our Supply and License Agreement with 4C, expires on June 1, 2026, at which time it automatically renews for successive one-year terms.

We earn other income primarily from tax incentive payments under the Australian Government's R&D Tax Incentive Plan for R&D 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 AUD $20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their R&D spending.

No revenue was earned from our FIH study in Tbilisi, Georgia during the year ended December 31, 2024. In 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 R&D 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.

R&D Expense

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 substantial doubt as to whether we will be able to continue as a going concern.

The audit report covering the December 31, 2024 and 2023 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 *Going Concern* to the accompanying audited consolidated financial statements for ATGC for the year ended December 31, 2024.

Results of Operations

Comparison of Years Ended December 31, 2024 and December 31, 2023

The following tables set forth our results of operations for the years ended December 31, 2024, and December 31, 2023 (in thousands, except percentages).

	Year Ended December 31,		
	2024	2023	% Change
Net sales	$ 2,703	$ 2,735	(1)%
Costs and expenses:			
Cost of products sold	(1,437)	(1,858)	(23)%
Research and development expense	(51,451)	(30,890)	67%
Selling, general and administrative expense	(28,187)	(17,361)	62%
Acquired in-process research and development	-	(132)	(100)%
Operating loss	(78,372)	(47,506)	65%
Other non-operating income, net	2,442	1,935	26%
Interest and amortization of debt discount and expense	(47)	(67)	(30)%
Net foreign exchange gains/(losses)	1,440	(635)	(327)%
Debt issuance costs	(465)	-	100%
Loss on debt extinguishment	(904)	-	100%
Fair value movement of derivatives	(61)	10	(710)%
Loss on asset acquisition of a variable interest entity	-	(501)	(100)%
Loss before income taxes from continuing operations	(75,967)	(46,764)	62%
Income tax (expense)/benefit	—	—	—
Loss after income tax	(75,967)	(46,764)	62%
Net income/(loss) attributable to non-controlling interests	324	(742)	144%
Loss Attributable to ATGC	$ (76,291)	$ (46,022)	66%

Net Sales

Net sales in 2024 was $2.7 million, a decrease of $0.03 million (1%), compared to $2.7 million in 2023, primarily due to lower sales volumes of tissue products in 2024.

Cost of Products Sold

Cost of products sold in 2024 was $1.4 million, a decrease of $0.4 million (23%), compared to $1.9 million in 2023, primarily due to a change in the mix of products sold.

R&D Expense

R&D expenses in 2024 were $51.5 million, an increase of $20.6 million (67%) compared to $30.9 million in 2023. This is primarily due to $16.0 million relating to preparatory activities associated with the Pivotal Trial, including on-going product development, $3.9 million relating to the upscaling of manufacturing capabilities including the expansion of headcount, $1.3 million relating to v2vmedtech development and $0.6 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 $1.4 million.

Selling, General and Administrative Expense

Selling, general and administrative expenses in 2024 were $28.2 million, an increase of $10.8 million (62%) compared to $17.4 million in 2023, primarily due to $4.9 million relating to the expansion of the work related our plans to re-domicile, list on Nasdaq and conduct our initial public offering, $1.4 million relating to the grant of additional stock options, $1.4 million relating to a legal claim, and $2.4 million including an increase in headcount in the Corporate departments (including Finance, Human Resources, IT, Marketing) to support the growth in our operations, and annual wage index increases.

Acquired In-Process R&D

Acquired in-process R&D expenses in 2023 was $0.1 million which was for costs relating to the acquisition of v2vmedtech, including in-process research and development. We did not have a corresponding charge in 2024.

Other non-operating income, net

Other non-operating income, net in 2024 was $2.4 million, an increase of $0.5 million (26%) compared to $1.9 million in 2023, primarily due to the recognition of holdback income of $0.9 million from a transaction with LeMaitre in 2019. EFS reimbursement income of $0.3 million was recognized in 2023, and we did not have corresponding income in 2024.

Net Foreign Exchange Gains/(Losses)

Net foreign exchange gains in 2024 were $1.4 million compared to $0.6 million of net foreign exchange losses in 2023, a change of $2.1 million (327%), primarily due to the change in foreign exchange rates on intercompany and cash balances. In 2024, the United States dollar appreciated by 9% relative to the Australian dollar ("AUD $").

Debt Issuance Costs

Debt issuance costs in 2024 was $0.5 million primarily due to the secured convertible note facility entered into during the year. The convertible notes were recognized at fair value through profit or loss which resulted in the costs being expensed when incurred. We did not have a corresponding charge in 2023. See "*Liquidity and Capital Resources — Convertible Note Facility*" for additional details regarding the secured convertible note facility.

Loss on Debt Extinguishment

Loss on debt extinguishment in 2024 was $0.9 million primarily due to settlement of the secured convertible note facility at a loss. We did not have a corresponding charge in 2023.

Loss on Asset Acquisition of a Variable Interest Entity ('VIE")

Loss on asset acquisition of a VIE in 2023 was $0.5 million, as when we acquired v2vmedtech, the consideration paid exceeded the fair value of the net assets acquired. We did not have a corresponding loss or gain in 2024.

Loss Before Income Taxes from Continuing Operations

Loss before income taxes from continuing operations was $76.0 million, an increase of $29.2 million (62%) compared to $46.8 million in 2023.

Net Income/(Loss) Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests ("NCI") was $0.3 million, an increase of $1.1 million (144%) compared to a $0.7 million loss in 2023 primarily due to the use of the hypothetical liquidation at book approach to measure the NCI interest which is impacted by movements in creditors and prepayments.

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 December 31, 2024 and December 31, 2023, we had an accumulated deficit of $276.4 million and $200.1 million, respectively.

In recent years, our operations have mainly been financed through the issuance of capital stock, including in our initial public offering, convertible notes, sales of regenerative tissue products and R&D tax incentives from the Australian government. Additional funding has come through interest earned from cash deposits. As of December 31, 2024 and December 31, 2023, we had cash and cash equivalents of $70.5 million and $21.1 million, respectively. As of December 31, 2024 and December 31, 2023, we had capital commitments of $1.4 million and $1.6 million, respectively, relating to the lease of properties. We did not have any other material capital expenditure commitments or contingent liabilities as of December 31, 2024. We do not believe that our current cash on hand would fund our cash needs for the 12 months following December 31, 2024, and that we will need to access the capital markets and debt markets to fund our cash needs. 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.

We anticipate that we will require substantial additional funds in order to achieve our long-term goals and complete the R&D 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 our initial public offering. We were able to draw up to AUD $25.0 million with an initial AUD $7.5 million drawdown (the "First Drawdown") and subsequent drawdowns (each, a "Drawdown") of AUD $5.0 million or the remaining balance of the Facility Limit, whichever was lesser. On each drawdown, we were required to (i) issue notes convertible into shares of Common Stock ("Convertible Notes") and (ii) pay a fee of 3% of the drawdown amount. The aggregate face value of the Convertible Notes issued pursuant to a Drawdown were equal to 115% of the principal amount of the relevant Drawdown. Each Convertible Note had a face value of $1.15.

In addition, at each Drawdown, we were to issue options, each exercisable into one share of Common Stock ("Obsidian Options"), with each Obsidian Option to have a strike price of $15.92 and a term of three years from the date of issuance. The number of Obsidian Options issued were to be such that the aggregate strike price would 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").

Any further Drawdowns under the Convertible Note Facility could only be made by agreement between us and Obsidian (including agreement as to the drawdown amount, Drawdown date, and any cap on the number of shares of Common Stock into which the Convertible Notes to be issued may convert) and may have required approval from our stockholders.

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

On December 16, 2024, following the closing of our initial public offering and the Reorganization, we received a notice of redemption from Obsidian, requiring that we redeem all outstanding Convertible Notes for cash. Accordingly, on December 19, 2024, we redeemed the outstanding Convertible Notes for an aggregate cash payment of $5.7 million and paid Obsidian an additional $0.2 million in lieu of the First Tranche Obsidian Options (representing AUD $0.3 million converted to United States dollars using the opening spot rate reported by the Reserve Bank of Australia of $0.6367 to AUD $1.00 on December 16, 2024). Upon redemption, no Convertible Notes were outstanding under the Convertible Note Facility.

On February 18, 2025, the Convertible Note Facility was terminated, and the security interest was released.

Cash Flows

The following table summarizes our primary sources and uses of cash for the periods presented (in thousands, except percentages):

	Year Ended December 31,		
	2024	2023	% Change
Net Cash provided by (used in):			
Operating activities	$ (61,241)	$ (34,631)	77%
Investing activities	(2,280)	(2,582)	(12)%
Financing activities	112,833	49,340	129%
Effect of exchange rate movements on cash, cash equivalents and restricted cash	57	(391)	(115)%
Net change in cash, cash equivalents and restricted cash	49,369	11,736	321%

Operating Activities

Net cash used in operating activities during 2024 was $61.2 million, an increase of $26.6 million (77%), compared to $34.6 million in 2023, primarily due to the acceleration of R&D 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 our plans to re-domicile, list on Nasdaq and conduct our initial public offering in 2024.

Investing Activities

Net cash used in investing activities in 2024 was $2.3 million, a decrease of $0.3 million (12%), compared to $2.6 million in 2023, primarily due to $0.2 million of costs relating to the acquisition of v2vmedtech in 2023. We did not have a corresponding cash outflow in 2024.

Financing Activities

Net cash provided by financing activities in 2024 was $112.8 million, an increase of 63.5 million (129%), compared to $49.3 million in 2023, primarily due to an increase of $65.6 million in net proceeds received from share issuances including in our initial public offering and the exercise of options for new shares, plus $5.0 million in proceeds from the issuance of Convertible Notes, partly offset by an increase of $6.9 million in repayments of debt instruments including related costs of issuance.

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 2025 and 2029 and some include options to extend. At December 31, 2024, we had contractual commitments (on an undiscounted basis) for property leases of $1.7 million, which were recognized at $1.4 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 (AUD $0.2531) per share (the "Warrant"). The Warrant was reconstructed due to a consolidation of capital of ATL, and entitled the holder to be issued 49,388 ordinary shares in ATL at an exercise price of $17.31 (AUD $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 $1 million (AUD $1.5 million), which was subsequently paid on October 31, 2024.

Commitments

At December 31, 2024, we had commitments to purchase $0.3 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 ("United States 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 United States 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. 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. 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.

R&D Tax Incentive Income

Government grants are received under the Australian government's R&D Tax Incentive program, such that a percentage of our eligible R&D 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 R&D 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. We recognized income of $1.0 million and $0.7 million in the years ended December 31, 2024 and 2023, respectively, which included estimated accruals of $0.8 million and $0.7 million as of December 31, 2024 and 2023, respectively.

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 3.56% - 4.48% (year to December 31, 2024) and 3.2% - 4.4% (year to December 31, 2023).

- The expected price volatility range of 40.0% - 65.5% (year to December 31, 2024) and 55.0% - 75.1% (year to December 31, 2023) 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 (although v2v's non-ATL shareholder representative on the v2v Board 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 in 2023 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 November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This ASU is effective January 1, 2027. ASU 2024-03 will require us to disclose the amounts of purchases of inventory, employee compensation, depreciation and intangible asset amortization, as applicable, included in certain expense captions in the Consolidated Statements of Operations, as well as qualitatively describe remaining amounts included in those captions. ASU 2024-03 will also require us to disclose both the amount and our definition of selling expenses.

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 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.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in 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 our initial public 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 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 that we provide to our investors 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.

As a smaller reporting company we will present 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

ANTERIS TECHNOLOGIES GLOBAL CORP.

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DECEMBER 31, 2024

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Anteris Technologies Global Corp.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Anteris Technologies Global Corp. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2024, 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 (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 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 2024.
Brisbane, Australia
March 12, 2025

ANTERIS TECHNOLOGIES GLOBAL CORP.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands of US dollars, except share quantities)	Note	YEARS ENDED DECEMBER 31, 2024 $	2023 $
Net sales	4	2,703	2,735
Costs and expenses:			
Cost of products sold		(1,437)	(1,858)
Research and development expense		(51,451)	(30,890)
Selling, general and administrative expense		(28,187)	(17,361)
Acquired in-process research and development		-	(132)
Operating loss		(78,372)	(47,506)
Other non-operating income, net	5	2,442	1,935
Interest and amortization of debt discount and expense		(47)	(67)
Net foreign exchange gains/(losses)		1,440	(635)
Debt issuance costs	11	(465)	-
Loss on debt extinguishment	11	(904)	-
Fair value movement of derivatives		(61)	10
Loss on asset acquisition of a variable interest entity		-	(501)
Loss before income taxes from continuing operations		(75,967)	(46,764)
Income tax (expense)/benefit	6	-	-
Loss after income tax		(75,967)	(46,764)
Net income/(loss) attributable to non-controlling interests		324	(742)
Loss Attributable to Anteris Technologies Global Corp.		(76,291)	(46,022)
Share information			
Basic and diluted loss per share ($ per share)	15	3.68	2.95

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES GLOBAL CORP.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	YEARS ENDED DECEMBER 31,	
	2024	2023
(In thousands of US dollars)	$	$
Loss after income tax	(75,967)	(46,764)
Other comprehensive (income)/loss, net of tax:		
Foreign currency translation adjustments	(1,336)	382
Other comprehensive (income)/loss for the year, net of tax	(1,336)	382
Total comprehensive loss	(77,303)	(46,382)
Total comprehensive loss is attributable to:		
Equity holders of Anteris Technologies Global Corp.	(77,303)	(46,382)
Non-controlling interest	-	-
	(77,303)	(46,382)

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES GLOBAL CORP.

CONSOLIDATED BALANCE SHEETS

(In thousands of US dollars, except share quantities)	Note	DECEMBER 31, 2024 $	DECEMBER 31, 2023 $
ASSETS			
Current Assets			
Cash and cash equivalents		70,458	21,089
Accounts receivable from customers, net of allowances		208	408
Inventories		513	442
Prepaid expenses		640	845
Other current assets	9	2,832	1,438
Total Current Assets		74,651	24,222
Non-Current Assets			
Plant and equipment, net	7	4,774	4,035
Operating lease right-of-use assets, net	8	1,085	1,444
Intangible assets, net		189	410
Other assets	9	-	417
Total Non-Current Assets		6,048	6,306
TOTAL ASSETS		80,699	30,528
LIABILITIES			
Current Liabilities			
Accounts payable		5,889	3,139
Accrued and other liabilities	10	9,921	4,726
Current portion of operating lease liabilities	8	747	660
Current portion of debt obligations	11	3	932
Total Current Liabilities		16,560	9,457
Non-Current Liabilities			
Operating lease liabilities	8	645	923
Long-term debt obligations		-	4
Other liabilities	10	812	1,246
Total Non-Current Liabilities		1,457	2,173
TOTAL LIABILITIES		18,017	11,630
COMMITMENTS AND CONTINGENCIES	20		
STOCKHOLDERS' EQUITY			
Common Stock, $0.0001 par value, 400,000,000 shares authorized, 35,939,816 and 17,820,149 shares issued and outstanding as of December 31, 2024 and 2023, respectively	14	4	2
Preferred stock, $0.0001 par value, 40,000,000 shares authorized		-	-
Additional paid in capital		350,036	228,951
Accumulated other comprehensive loss	18	(10,891)	(9,555)
Accumulated Deficit		(276,388)	(200,097)
TOTAL STOCKHOLDERS' EQUITY		62,761	19,301
Non-controlling interests		(79)	(403)
TOTAL EQUITY		62,682	18,898
TOTAL LIABILITIES AND EQUITY		80,699	30,528

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES GLOBAL CORP.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands of US dollars, except share quantities)

	Common stock							
	Shares Quantity	Par Value $	Additional Paid in Capital $	Accumulated Other Comprehensive Loss $	Accumulated Deficit $	Total Stockholders' Equity $	Non-controlling interests $	Total Equity $
Balance at December 31, 2022	13,901,883	1	173,044	(9,937)	(154,075)	9,033	-	9,033
Loss after income tax	-	-	-	-	(46,022)	(46,022)	(742)	(46,764)
Other comprehensive loss	-	-	-	382	-	382	-	382
Common stock issued	3,918,266	1	47,538	-	-	47,539	-	47,539
Acquisition of subsidiary	-	-	-	-	-	-	339	339
Stock-based compensation	-	-	8,369	-	-	8,369	-	8,369
Balance at December 31, 2023	17,820,149	2	228,951	(9,555)	(200,097)	19,301	(403)	18,898
(Loss)/Gain after income tax	-	-	-	-	(76,291)	(76,291)	324	(75,967)
Other comprehensive loss	-	-	-	(1,336)	-	(1,336)	-	(1,336)
Common stock issued	18,119,667	2	114,781	-	-	114,783	-	114,783
Stock-based compensation	-	-	6,304	-	-	6,304	-	6,304
Balance at December 31, 2024	35,939,816	4	350,036	(10,891)	(276,388)	62,761	(79)	62,682

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES GLOBAL CORP.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands of US dollars)	YEARS ENDED DECEMBER 31, 2024 $	2023 $
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss after income tax	(75,967)	(46,764)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,507	1,158
Equity-settled stock-based compensation	6,519	5,760
Loss on asset acquisition of a variable interest entity	-	501
Acquired in-process research and development	-	132
Loss on debt extinguishment	904	-
Debt issuance costs	465	-
Net foreign exchange (gains)/losses	(1,440)	635
Other items	78	(39)
Change in operating assets and liabilities:		
Accounts receivable, prepayments and other assets	(911)	(345)
Inventories	(71)	(87)
Accounts payable, accrued and other liabilities	7,675	4,418
NET CASH USED IN OPERATING ACTIVITIES	(61,241)	(34,631)
CASH FLOWS FROM INVESTING ACTIVITIES		
Acquisition of plant and equipment	(2,266)	(2,388)
Acquisition of intangibles	(14)	(7)
Acquisition of subsidiary	-	(213)
Proceeds from sale of plant and equipment	-	26
NET CASH USED IN INVESTING ACTIVITIES	(2,280)	(2,582)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of shares	115,727	50,148
Proceeds from issuance of convertible notes	4,957	-
Repayment of debt	(7,186)	(763)
Debt issuance costs paid	(465)	-
Cash settlement of contingent options on debt	(191)	-
Principal payments under finance lease obligations	(9)	(45)
NET CASH PROVIDED BY FINANCING ACTIVITIES	112,833	49,340
Effect of exchange rate movements on cash, cash equivalents and restricted cash	57	(391)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Net change during the year	49,369	11,736
Balance at beginning of year	21,089	9,353
Balance at end of year	70,458	21,089
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash received for research and development tax incentive	962	910
Cash paid for amounts included in the measurement of operating lease liabilities	834	699
Non-cash issue of shares/options to consultants for services provided	430	2,624

The accompanying notes are an integral part of these consolidated financial statements.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

1. DESCRIPTION OF BUSINESS

Anteris Technologies Global Corp. ("ATGC," "Anteris," "Company," "we," "us," or "our") was incorporated in Delaware on January 29, 2024. ATGC was formed 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 would be a Delaware corporation (the "reverse recapitalization").

On December 16, 2024, the Company received 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 cancelled all existing options it had outstanding in exchange for the ATGC issuing replacement options to acquire shares of ATGC's common stock, par value $0.0001 per share ("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.

Prior to completion of the reverse recapitalization, ATGC had no business or operations and following completion of the reverse recapitalization, the business and operations of ATGC consist solely of the business and operations of ATL and its subsidiaries. As a result of the reverse recapitalization, ATGC became the parent company of ATL, and for financial reporting purposes the historical financial statements of ATL became the historical financial statements of ATGC as a continuation of the predecessor.

On December 16, 2024, the Company completed the reverse recapitalization. On December 16, 2024, following the reverse recapitalization, the Company completed an initial public offering ("IPO") of 14,800,000 shares of Common Stock.

ATGC's principal activities consist of:

- Continued research and development ("R&D") of development of DurAVR® THV consisting of a single-piece biomimetic valve made with our primary ADAPT® tissue-enhancing technology and deployed with our ComASUR® balloon-expandable 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 blood flow. This new class of technology can be used to treat new aortic stenosis patients and to treat aortic stenosis patients where their current bioprosthetic aortic valve is failing ("valve-in-valve");
- Generating and compiling data to gain United States Food and Drug Administration ("FDA") approval to commence the randomized global pivotal study (the "Pivotal Trial"), a key milestone on the path to commercialization; and
- The co-development with v2vmedtech, inc. ("v2v"), 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. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of presentation

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.

Unless noted otherwise, all dollar amounts are in thousands of United States dollars ("US dollars" or "$"). Some amounts may not reconcile due to rounding.

For the year ended December 31, 2024, the consolidated financial statements reflect the consolidated results of operations, comprehensive loss, cash flows, and changes in equity of ATL and its wholly-owned subsidiaries for the period of January 1, 2024 up to December 16, 2024, the closing date of the reverse recapitalization (the "Closing Date"), and the consolidated results of operations, comprehensive income/(loss), cash flows, and changes in stockholders' equity of ATGC and its consolidated subsidiaries, including ATL, for the period of December 16, 2024 through December 31, 2024. The Consolidated Balance Sheet at December 31, 2024 presents the financial condition of the Company and its consolidated subsidiaries, including ATL, and reflects the initial recording of ATGC's assets and liabilities at their historical cost.

In accordance with ASC 805, *Business Combinations,* ATL's historical equity has been retrospectively restated for all periods up to the Closing Date to reflect the number of shares of Common Stock issued to Legacy ATL Holders in connection with the reverse recapitalization. Additionally, the par value of Common Stock has been restated to align with the post-transaction capital structure.

The Company is an emerging growth company ("EGC"), as defined in Section 2(a) of the *Securities Act of 1933*, as modified by the *Jumpstart Our Business Startups Act of 2012* (the "JOBS Act"), which permits the Company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(b) Principles of consolidation

The consolidated financial statements include the accounts of ATGC, its wholly-owned subsidiaries, entities for which the Company has a controlling financial interest, as well as any variable interest entities ("VIEs") for which ATGC has been determined to be the primary beneficiary. ATGC 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 ATGC 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.

(c) 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 Committee and the Board of Directors (the "Board"). 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.

- Timing of recognition of the research and development tax incentive income: 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 a Black-Scholes option pricing model ("Black-Scholes model") and a Monte Carlo model which require various inputs including the exercise price and share price at grant date, plus other judgmental assumptions, such as share price volatility, risk-free interest rate, and the expected option term.

(d) Foreign currency translation

The financial statements are presented in United States dollars, which is ATGC'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 Stockholders' 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. ATGC and Anteris Technologies Corporation have the U.S. dollar (USD or $) as their functional currency, ATL and the Australian subsidiaries' use the Australian dollar (AUD $) as their functional currency, and another subsidiary has the Swiss franc (CHF) as its functional currency.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(e) Net sales

Net sales from the sale of goods, which is primarily ADAPT® tissue, are recognized at a point in time when the performance obligation is satisfied, typically being upon delivery to the customer's premises when 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."

(f) Other income

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.

(g) 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. The Company's restricted cash primarily represent funds placed in escrow related to operating leases and as collateral for a credit line. As of December 31, 2024, the restricted cash balance was $0.4 million.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(h) 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.

(i) 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.

(j) 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 licenses that will contribute to future period financial benefits through revenue generation and/or cost reduction are capitalized to software and systems. Costs capitalized 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.

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.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(k) 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 8 *Leases* 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.

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.

ROU 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 ROU 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.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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).

(l) 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.

(m) 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. Hybrid instruments measured at fair value are not evaluated for embedded derivatives.

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.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(n) 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.

Convertible notes

The Company elected to measure its convertible note financial liabilities at fair value through profit or loss. Related upfront costs and fees are recognized in earnings as incurred and not deferred.

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.

(o) 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 deferred taxes in the period in which such determination is made. The Group has not recorded any unrecognized tax benefits at December 31, 2024.

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.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(p) 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 of the date of modification.

Employee service-based stock-based compensation

Anteris offers employees service-based stock options and restricted stock units ("RSUs") 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 stockholders.

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 and upon completion of the RSU vesting conditions, the Company issues shares of Common Stock.

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. 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.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(q) Earnings/Loss per share

Basic earnings (or loss) per share is computed by dividing net profit/loss by the weighted-average Common Stock outstanding during the period. Diluted earnings/loss per share is computed based on the weighted-average Common Stock outstanding plus the effect of dilutive potential Common Stock outstanding during the period calculated using the treasury stock method. Dilutive potential Common Stock includes employee equity stock options, non-vested shares, and similar equity instruments granted by the Company. Potential Common Stock equivalents have been excluded where their inclusion would be anti-dilutive.

(r) 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, maximizing the use of relevant observable inputs and minimizing 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; or
- Level 3: Unobservable inputs for the asset or liability.

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.

(s) 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 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.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(t) 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 12.0% of the participant's annual eligible compensation (post July 1, 2024) subject to certain contribution caps. The rate has increased by 0.5% annually for the past three years. The net expense related to these plans was $0.7 million and $0.6 million in fiscal years 2024 and 2023, respectively.

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.

(u) 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.

(v) 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 segment 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 acquire 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.

(w) Variable Interest Entities

Under 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 Variable Interest Entity ("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 stockholder loans to the entity and the execution of any future significant agreements between the entity and its stockholders and/or other third parties.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(x) 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 Vice Chairman and Chief Executive Officer ("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® anti-calcification tissue. This is focused on the DurAVR® THV system.

(y) Reverse recapitalization

In accordance with ASC 805, *Business Combinations*, when ATGC (or "the legal parent") acquired ATL ("the legal subsidiary"), the transaction was accounted for as a reverse recapitalization. The substance of the transaction was that the pre-transaction shareholders of ATL (the accounting acquirer) had effectively obtained control of ATGC.

Under reverse recapitalization accounting, the consolidated financial statements are issued under the name of the legal parent (being ATGC) but, with the exception of stockholder's equity, the financial statements will represent a continuation of ATL's (the legal subsidiary's) financial information. ATL's assets and liabilities will be recognized at historical cost with no goodwill or other intangible assets recorded in the financial statements.

At the date of acquisition, the assets and liabilities of the Group were recognized and measured in the consolidated financial statements at their pre-combination carrying amounts and added to the assets and liabilities of ATGC.

The Consolidated Statement of Stockholders' Equity for comparative periods has been restated to reflect the equity structure of ATGC, while maintaining the historical retained earnings of ATL.

(z) 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 was 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 11 *Debt Obligations.*

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 was effective January 1, 2024. The adoption of ASU 2023-07 on January 1, 2024 resulted in additional disclosures as shown in note 21 *Segment reporting*.

(aa) New Accounting Standards Not Yet Adopted

New accounting pronouncements are issued by the 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 November 2024, the FASB issued ASU 2024-03*, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* This ASU is effective January 1, 2027. ASU 2024-03 will require the Company to disclose the amounts of purchases of inventory, employee compensation, depreciation and intangible asset amortization, as applicable, included in certain expense captions in the Consolidated Statements of Operations, as well as qualitatively describe remaining amounts included in those captions. ASU 2024-03 will also require the Company to disclose both the amount and the Company's definition of selling expenses.

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 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 our existing equity securities. Nevertheless, the Company will apply the guidance and incorporate the new required disclosures in future filings as needed.

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3. GOING CONCERN

The 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 $76.2 million and had net cash outflows from operating activities of $61.2 million for the financial year ended December 31, 2024. As of that date, the Group had a cash balance of $70.5 million.

The Group has been investing in research and development activities associated with the continuing development and proposed commercialization of DurAVR® THV system, as well as continuing to invest in research and development. In the year ended December 31, 2024, amounts invested in research and development activities and general operations exceeded cash inflows associated with sales of CardioCel™ and VascuCel™ products tissue products plus research and development tax incentives from the Australian government. The Company generated proceeds of $127.2 million from the issue of equity securities (before underwriting discounts, commissions and other 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 system 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 system, that generate significant revenue. For medtech devices, including DurAVR® THV system, 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 shares of Common Stock, debt instruments, or other securities that can be converted into Common Stock. 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 IPO of 14,800,000 shares of Common Stock for gross proceeds of $88.8 million before underwriting discounts, commissions and other transaction costs in Q4 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.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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4. NET SALES

(in thousands)	2024 $	2023 $
Net sales from contracts with customers, at a point in time		
ADAPT® tissue products	2,703	2,735
Total net sales	2,703	2,735

5. OTHER NON-OPERATING INCOME, NET

(in thousands)	2024 $	2023 $
Government grants (1)	1,043	717
LeMaitre holdback income (2)	922	434
Early Feasibility Study ("EFS") income (3)	-	300
Interest income	430	428
Sundry income	47	56
Total other non-operating income, net	2,442	1,935

(1) In 2024, Government grants consists of $0.8 million research and development tax incentive income accrued relating to the year ended December 31, 2024 plus $0.3 million research and development tax incentive income recognized relating to the year ended December 31, 2023. In 2023, Government grants primarily consisted of $0.7 million research and development tax incentive income accrued relating to the year ended December 31, 2023.

(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 the European Union Medical Device Regulation ("EUMDR").

In 2023, the agreement with LeMaitre was amended to require LeMaitre to be responsible for obtaining regulatory approvals under the EUMDR. Anteris is entitled to receive a holdback amount of $2.0 million less the associated regulatory approval costs incurred by LeMaitre (capped at €0.6 million) payable in the following instalments:

- Anteris is entitled to 33% of the holdback amount by January 26, 2025 if LeMaitre does not obtain the regulatory approvals for either the CardioCel™ and VascuCel™ by January 11, 2025. The payment will be reduced by 33% of eligible deductions. The first instalment was recognized as other non-operating income in 2023 and is recognized in other current assets as of December 31, 2024.

- The remaining 67% of the holdback amount is due on the following basis with the eligible deductions applied on a proportional basis 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 was recognized as income as of December 31, 2024 as it was considered probable that LeMaitre will receive the regulatory approval and a significant reversal of the income will not occur. Subsequent to year-end, LeMaitre confirmed that they had received the regulatory approvals from the EUMDR.

(3) EFS income generated while assessing the feasibility and viability of the DurAVR® THV system is measured at the fair value of the consideration received or receivable.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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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:

(in thousands)	2024 $	2023 $
United States	60,063	35,851
Australia	17,060	11,078
Other international	(1,156)	(165)
Loss/(income) before income taxes from continuing operations	75,967	46,764

(b) Deferred Tax Assets and Liabilities

Deferred tax assets and liabilities are attributable to the following:

(in thousands)	2024 $	2023 $
Deferred tax assets		
Accrued and other liabilities	2,153	1,178
Share issue costs	301	338
Intangible assets	272	109
Other capitalized costs	144	101
Stock-based payments	3,350	1,583
Operating lease liabilities	346	319
Capitalized R&D	10,364	4,362
Tax credit carryforwards	1,232	1,356
Operating loss carryforwards	39,841	28,209
Other	-	35
Total deferred tax assets	58,003	37,590
Deferred tax liabilities		
Plant and equipment	(14)	(12)
Operating lease ROU assets	(226)	(310)
Accounts receivable from customers, net of allowances	(48)	(24)
Prepaid expenses	(52)	(92)
FX on revaluation of intercompany loans to denomination currency	(2,939)	-
Other	(182)	(21)
Total deferred tax liabilities	(3,461)	(459)
Total net deferred tax assets (prior to valuation allowance)	54,542	37,131
Valuation allowance	(54,542)	(37,131)
Net deferred tax assets	-	-

The valuation allowance of $54.5 million as of December 31, 2024 and $37.1 million as of December 31, 2023 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 research and development 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 $2.1 million in 2024 and 2023.

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FOR THE YEAR ENDED DECEMBER 31, 2024

6. INCOME TAX (continued)

(c) Operating loss carryforwards

Information about net operating and capital loss carryforwards at December 31, 2024 is summarized as follows:

(in thousands)	Balance at December 31, 2024 $
Australian net operating and capital loss carryforwards	58,407
United States federal net operating loss carryforwards	94,164
United States state net operating loss carryforwards	63,247
Other net operating loss carryforwards	4,638
Total	220,456

Included within the Australian carryforwards disclosed above, the Australian tax consolidated group has $4.1 million of transferred losses at December 31, 2024, 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, 2024.

At December 31, 2024, the Company had $220.5 million of operating loss carryforwards in the United States, Australia and other international jurisdictions, of up to $145.5 million carryforward indefinitely, with the remaining $75.0 million due to expire during fiscal years 2026 through to 2045 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 wholly-owned subsidiaries have been filed for the period ended December 31, 2023. With limited exceptions, all years prior to 2020 in Australia and 2021 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: (in thousands)	Net operating loss carry forward $
2026	508
2027	1,101
2028	1,428
2029	17
2030	13
2031	88
2032	70
2033	102
2034	1,244
2035	3,964
2036	6,840
2037 and later	59,575
Indefinite	145,506
Total	220,456

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6. INCOME TAX (continued)

(d) Tax credit carryforwards

Tax credit carryforwards for the period are summarized as follows:

(in thousands)	Balance at December 31, 2024 $
Australian research expenditure tax credits	1,232
Total	1,232

Tax credit carryforwards will carry forward indefinitely and are not subject to expiration.

(e) Effective income tax rate varied from the parent's 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 statutory income tax rate of the parent entity, the income tax rate of the parent entity's country of domicile, as follows (in thousands of dollars):

	2024	2023
Statutory income tax rate of the parent entity	21%	25%
Domicile of parent	USA	Australia
Income tax (benefit) at the statutory income tax rate	(15,953)	(11,691)
Increase / (decrease) in income tax expense resulting from:		
Non-deductible other expenses	1,045	289
Non-deductible stock-based payments	244	222
Non-assessable income	(273)	(292)
Non-deductible R&D expenditure	573	427
Loss on acquisition of subsidiary	-	101
Foreign statutory income tax rate differential	(682)	1,421
US State Taxes	(7,632)	-
Under/Over	744	-
Change in valuation allowance	21,934	9,523
Reported income tax expense	-	-

The 25% tax rate used is the Australian corporate tax rate. The basis for using this rate is that as of December 31, 2023, the registered office of ATL, the parent entity at that time, was based in Australia.

Current tax expense includes an income tax benefit of $0.2 million and $0.1 million in 2024 and 2023, respectively, for the realization of operating loss carryforwards for which a valuation allowance has been previously applied against the related deferred tax asset.

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7. PLANT AND EQUIPMENT, NET

(in thousands)	Estimated Useful Lives	2024 $	2023 $
Plant and equipment	3 – 10 years	9,135	7,082
Capital work in progress		207	492
Information technology equipment, under finance lease	2 – 5 years	10	43
		9,352	7,617
Less accumulated depreciation		(4,578)	(3,582)
		4,774	4,035

Depreciation expense of $1.3 million and $1.0 million was recognized in fiscal years 2024 and 2023, respectively.

8. LEASES

The Group's lease agreements include leases accounted for as operating leases and those accounted for as finance leases. 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 or adjusted to reflect pre-agreed charges or 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. Finance lease ROU 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 ROU assets, lease liabilities, lease costs, cash flows, and lease maturities associated with the Group's finance leases were not material to the consolidated financial statements for fiscal years 2024 and 2023.

The below table discloses the balance sheet information relating to the Group's operating leases:

(in thousands)	Balance sheet Classification	2024 $	2023 $
ROU assets	Operating lease ROU assets	1,085	1,444
Current liability	Current Operating lease liabilities	747	660
Non-current liability	Non-current Operating lease liabilities	645	923

Operating lease costs of $806,475 and $689,721 were recognized in fiscal years 2024 and 2023, respectively. 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 2024 and 2023 were not material.

As of December 31, 2024, the weighted-average remaining lease terms of the Group's operating leases was 2.6 years, compared to 2.2 years as of December 31, 2023. The weighted-average discount rate applied to the Group's operating leases was 14.8% for both 2024 and 2023.

The following table summarizes the ROU assets obtained in exchange for lease liabilities and as a result of lease modifications:

(in thousands)	2024 $	2023 $
ROU assets obtained in exchange for new operating lease liabilities	25	109
Non-cash changes related to lease modifications, net of lease incentive	270	932

8. LEASES (continued)

The following table summarizes the maturities of the Company's operating leases at December 31, 2024. 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 (in thousands)	Operating Leases $
2025	896
2026	351
2027	163
2028	167
2029	114
Thereafter	-
Total expected lease payments	1,691
Less imputed interest	(299)
Total lease liabilities	1,392

9. OTHER ASSETS

(in thousands)	2024 $	2023 $
Current		
Holdback receivable (refer to note 5)	1,376	-
Research and development tax incentive	792	714
Lease incentive receivable	175	114
Other receivables	489	610
	2,832	1,438
Non-current		
Holdback receivable	-	417
	-	417

10. ACCRUED AND OTHER LIABILITIES

(in thousands)	2024 $	2023 $
Current		
Accrued liabilities	4,490	1,899
Employee compensation and withholdings	3,989	2,705
Estimated legal contingency liability	1,440	-
Cash-settled stock-based payment provision	2	122
	9,921	4,726
Non-current		
Employee compensation and retirement benefits	84	48
Lease asset retirement obligation	452	471
Cash-settled stock-based payment provision	222	633
Other variable liabilities	54	94
	812	1,246

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10. ACCRUED AND OTHER LIABILITIES (continued)

Estimated legal contingency liability

The Company has received a legal claim in connection with an equity raise undertaken in 2024 and the subsequent United States IPO. Anteris denies the claims and no court proceedings have been filed at this stage. A provision of $1.4 million has been recognized in relation to this claim. Any further developments that could impact this estimate will be assessed in future reporting periods.

Cash-settled stock-based payment provision

Refer to note 16 *Stock-based Compensation*.

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 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.

11. DEBT OBLIGATIONS

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 Scheme, and implementation of the IPO. The Convertible Note Facility was assumed by the Company upon completion of the Scheme. In connection with the Convertible Note Facility, Obsidian was granted a senior-ranking security interest over all of ATL's assets.

ATL or ATGC (following the implementation of the Scheme) was able to draw up to AUD $25.0 million (the "Facility Limit", equivalent to $15.5 million as of December 31, 2024) from the Convertible Note Facility, with an initial AUD $7.5 million drawdown (the "First Drawdown") and subsequent drawdowns (subject to mutual agreement) in increments of AUD $5.0 million or the balance of the Facility Limit, whichever was lesser. On each drawdown, we were required to (i) issue notes convertible into Common Stock ("Convertible Notes") and (ii) pay a fee of 3% of the drawdown amount. The aggregate face value of the Convertible Notes issued pursuant to a drawdown were equal to 115% of the principal amount of the relevant drawdown. Each Convertible Note had a face value of $1.15.

In addition, at each drawdown, ATL would issue options to Obsidian, each exercisable into one ordinary share of ATL or share of Common Stock (following the implementation of the Scheme) ("Obsidian Options"), with each Obsidian Option to have a strike price of $15.92 (AUD $25.00) and a term of three years from the date of issuance. The number of Obsidian Options issued were to be such that the aggregate strike price would be equal to 25% of the amount drawn under the relevant drawdown. For the First Drawdown, this equated to 75,000 Obsidian Options.

On November 7, 2024, 4,956,750 Convertible Notes were issued as a result of the First Drawdown of $5.0 million (AUD $7.5 million). As a result of the First Drawdown, ATL had an obligation to grant the Obsidian Options (subject to ATL obtaining shareholder approval), or if shareholder approval was not obtained, ATL or the Company (following the implementation of the Scheme) was obliged to pay AUD $0.3 million to Obsidian.

On December 16, 2024, following the closing of the IPO and the Scheme, the Company received a notice of redemption from Obsidian, requiring the Company to redeem all outstanding convertible notes for cash. On December 19, 2024, the Company paid Obsidian $5.7 million for the Convertible Notes and additional $0.2 million in lieu of the Obsidian options required to be issued in connection with the first drawdown (representing AUD $0.3 million converted to U.S. dollars using the opening spot rate reported by the Reserve Bank of Australia of $0.6367 to AUD $1.00 on December 16, 2024). The loss on debt extinguishment has been disclosed in the Consolidated Statements of Operations. No Convertible Notes were outstanding under the Convertible Note Facility.

On February 18, 2025, the Convertible Note Facility was terminated, and the security interest was released.

Warrant liabilities

In conjunction with receiving a loan facility from Partners For Growth ("PFG') in October 2017, ATL issued PFG a 7-year warrant for the issue of 49,388 ordinary shares in ATL at an exercise price of $17.31 (AUD $ 25.32) per share. The holder of the warrant also had the option to put the warrant to the Company for $1.0 million (AUD $1.5 million) on the expiration or on the occurrence of certain events. Prior to expiration of the warrant on October 26, 2024, PFG exercised the put option. On October 31, 2024, ATL settled the warrant liability by making a $1.0 million payment to PFG. At December 31, 2023, the outstanding balance was $0.9 million.

11. DEBT OBLIGATIONS (continued)

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 December 31, 2024 or December 31, 2023.

The roll forward of Anteris' outstanding payment obligations to the insurance supplier under this arrangement, are as follows:

(in thousands)	2024 $	2023 $
Confirmed obligations outstanding at the beginning of the year	-	-
Invoices confirmed during the year	504	771
Confirmed invoices paid during the year	(504)	(771)
Confirmed obligations outstanding at the end of the year	-	-

Contractual obligations

The Company had no significant financing arrangements outstanding as of December 31, 2024, or December 31, 2023.

12. DERIVATIVES

The following table summarizes the balance sheet classification and fair value of derivative instruments included in the Consolidated Balance Sheets as of December 31, 2023. No balances were outstanding as of December 31, 2024. 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	
(in thousands)	Balance sheet classification	Fair value $
December 31, 2023		
Derivatives not designated as hedging instruments		
Warrant liabilities	Current debt obligations	923
Total derivatives at December 31, 2023		923

No significant gains or losses have been recognized in relation to derivative liabilities not designated as hedging instruments.

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13. 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.

(in thousands)	Note	Level 1 $	Level 2 $	Level 3 $	Total $
December 31, 2024					
Liabilities					
Other variable liabilities		-	-	54	54
Total liabilities		-	-	54	54
December 31, 2023					
Liabilities					
Warrant liabilities	11	-	-	923	923
Other variable liabilities		-	-	94	94
Total liabilities		-	-	1,017	1,017

Changes in the fair value of the level 3 liabilities were as follows:

(in thousands)	Warrant liabilities $	Other variable liabilities $
Balance as of January 1, 2023	937	-
Issuance	-	81
Mark to market adjustment	(14)	13
Balance as of December 31, 2023	923	94
Mark to market adjustment	63	(40)
Repayment of debt	(986)	-
Balance as of December 31, 2024	-	54

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13. FAIR VALUE MEASUREMENT (continued)

Fair value of warrant liabilities – Level 3

As of December 31, 2023, the fair value of outstanding warrants were valued using a Black-Scholes model that incorporated a share price hurdle and a discounted cashflow methodology. During the year ended December 31, 2024, the warrant liability was fully settled for $1.0 million. The inputs used in the measurement of the fair values of the warrant liabilities (translated using prior year-end exchange rates) are detailed below.

		2023
Fair value per warrant	$	18.68
Assumptions used:		
Share price	$	13.75
Exercise price (AUD25.31)	$	17.31
Share price hurdle (AUD55.68)	$	38.08
Expected volatility		55%
Time to maturity		0.82 years
Risk-free interest rate		3.69%
Exercise price of the put option (AUD30.37)	$	20.77
Put option discount rate		14.75%

As the fair value of the other variable liabilities was insignificant as of December 31, 2024 and December 31, 2023, no additional disclosure has been included.

14. EQUITY

(a) Share Capital

The Company's authorized share capital consists 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 ("preferred stock").

Prior to the reverse recapitalization, ATL's issued ordinary shares had no par value, as permitted under the Corporations Act, which also does not require companies to have authorized capital.

Stockholders of the Company hold either Common Stock or a CHESS Depositary Interest ("CDI"). CDIs confer the beneficial ownership of the Company's 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 Company has never declared or paid any cash dividends on its capital stock and does not anticipate paying any cash dividends in the foreseeable future.

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14. EQUITY (continued)

(b) Movements in Common Stock

During the year ended December 31, 2024 and prior to the reverse recapitalization, ATL issued the following ordinary shares:

- In January 2024, 667 unlisted options issued under the Anteris Employee Incentive Plan ("2020 EIP") were exercised. These options had an exercise price of $5.67 equivalent per share (AUD $8.60).
- At various dates throughout the year, external investors exercised 403,000 unlisted options for $6.58 equivalent per share (AUD $10.00) raising $2.7 million.
- In April 2024, 1,000,000 new shares were issued to various sophisticated and professional investors at $14.74 equivalent per share (AUD $23.00) for total consideration of $14.7 million.
- In July 2024, 1,875,000 new shares were issued to various sophisticated and professional investors at $10.49 equivalent per share (AUD $16.00) for total consideration of $19.7 million.
- In July 2024, 41,000 new shares were issued to a consultant for services provided. The equivalent price per share was $10.49 (AUD $16.00).

In connection with the IPO and completion of the reverse recapitalization in December 2024, ATGC issued 14,800,000 shares of Common Stock at the IPO price of $6.00 per share for gross $88.8 million prior to underwriting discounts, commissions and other estimated offering expenses.

For the comparable year ended December 31, 2023, ATL issued the following ordinary shares:

- In February 2023, 1,454,167 new shares and 1,454,167 free-attaching options were issued to various sophisticated and professional investors for $16.65 equivalent per share (AUD $24.00) for total consideration of $24.2 million. The consideration received for both the shares and free-attaching options was reflected as an increase in share capital.
- In March 2023, 168 unlisted options issued under the 2020 EIP were exercised. These options had a weighted average exercise price of $5.48 equivalent per share (AUD $8.19).
- 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.
- At various dates throughout the year, 160,250 unlisted options were exercised for $6.56 equivalent per share (AUD $10.00) raising $1.1 million.
- At various dates throughout the year, 134,364 unlisted options were exercised for $7.75 equivalent per share (AUD $11.50) raising $1.1 million.
- In May 2023, 4,167 new shares and 4,167 free-attaching options were issued to Wayne Paterson, ATL's CEO and Managing Director, for $16.65 equivalent per share (AUD$24.00), for consideration of $0.06 million, which is on the same terms as other investors who participated in the February 2023 capital raise. Shareholder approval was obtained at ATL'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 for $12.86 equivalent per share (AUD $20.00) to various sophisticated and professional investors for total consideration of $21.4 million.
- In December 2023, 500,000 unlisted options were exercised for $10.12 equivalent per share (AUD $15.00) raising $5.1 million.

(c) Stock options held by investors

As of December 31, 2024 and December 31, 2023, the Company had 6,047,807 and 6,026,608 options outstanding, respectively, with varying exercise prices and expiration dates. For those options issued as stock-based compensation, information is detailed in note 16 *Stock-based Compensation*. The remaining options held by investors total 1,958,933 and 2,361,933, respectively, to purchase shares of Common Stock, with exercise prices ranging from $6.37 to $18.46 and expiration dates between February 2025 and September 2025. As of December 31, 2024, these options had no intrinsic value, as the exercise price exceeded the market price of the underlying shares. As of December 31, 2023, these options had intrinsic value of $5.7 million. The weighted average exercise price of these options was $15.37 and $13.83 as of December 31, 2024 and December 31, 2023, respectively.

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15. LOSS PER SHARE

The below table presents the computation of basic and diluted loss per share:

			2024	2023
Loss for the year, attributable to the owners of the Company	$	'000	76,291	46,022
Weighted average number of shares outstanding: used in the denominator in calculating basic and diluted loss per share		Number	20,252,919	15,605,878
Basic and diluted loss per share	$		3.68	2.95

As of December 31, 2024 and 2023, there were outstanding stock options, RSUs and warrants for the purchase of 6,797,806 and 6,075,996 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 14 *Equity* and 16 *Stock-based Compensation*.

Details of the issues of Common Stock that occurred since reporting date are included in note 25 *Subsequent Events*.

16. STOCK-BASED COMPENSATION

On December 16, 2024, contemporaneously with implementation of the Scheme (refer note 1 *Description of Business*), ATL amended all existing options it had on issue to be options to acquire Common Stock pursuant to a scheme of arrangement between ATL and its option holders (the "Option Scheme"). Upon amendment of the options, the exercise prices, base prices and share price hurdles of all stock-based compensation instruments outstanding (primarily those held by non-Australian employees and directors) were converted to U.S. dollars using the spot rate of $0.6367 to AUD $1.00. The amendment was structured as an exchange of equivalent awards, so that holders remained in the same economic position with unchanged vesting conditions and terms following the recapitalization. Since the amendment did not change the fair value, vesting conditions, or other terms of the awards, it was not treated as a modification under ASC 718 *Compensation—Stock Compensation,* and no incremental compensation expense was recognized.

In connection with the reverse recapitalization, the Company has adopted the ATGC 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. Stock awards, including restricted stock, RSUs, cash incentive awards, performance shares, PSUs, and other equity-based awards may be granted under the Equity Plan. No further grants will be made under the incentive plans previously established by ATL.

Number of Authorized Shares

Initially, 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, provided, however, that the Board may act prior to the first day of a given fiscal year to provide that the increase for such fiscal year will be a lesser number of shares of Common Stock. 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 as of the IPO, 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 nonemployee director during the fiscal year, may not exceed $0.75 million 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 million for (i) the non-executive chair of our Board and (ii) a new non-employee director during his or her first year of service on our Board.

In the event of certain changes in the capitalization of the Company, the administrator of the Equity Plan 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 in specific circumstances, shares subject to an award under the Equity Plan that are cancelled, forfeited, expire, or become un-exercisable 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.

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16. STOCK-BASED COMPENSATION (continued)

(a) Stock-based compensation expense

The following table presents the components and classification of stock-based compensation expense recognized for stock options, cash-settled stock-based payments rights, restricted stock units and shares issued to employees, directors and consultants:

(in thousands)	2024 $	2023 $
Equity-settled stock-based payments (including stock options and RSUs)	6,304	4,846
Modification of equity-settled stock-based payments	-	900
Cash-settled stock-based payments (SPP rights)	(530)	745
Shares issued as compensation to consultants	215	14
Total stock-based compensation expense	5,989	6,505
Classification of stock-based compensation expense		
Cost of products sold	5	5
Research and development expense*	788	2,690
Selling, general and administrative expense	5,196	3,810
Total stock-based compensation expense	5,989	6,505
Stock-based compensation capitalized to equity (transaction cost)	215	2,624
Income tax benefit	-	-
Total stock-based compensation	6,204	9,129

* The reduction in the research and development related stock-based compensation expense is due to the decline in the share price impacting the fair value of the SPP rights.

(b) Stock options

Stock options issued by the Company to employees, directors and consultants have been described below. Each option, when exercised, entitles the holder to subscribe for and be allotted one share in the capital of the Company.

Employee service-based stock options

The key terms of the 2020 EIP currently outstanding include:
- Options held by Australian employees have an AUD base currency and convert into CDIs. All other options held by non-Australian employees have a USD base currency and convert into shares of Common Stock;
- Options are issued to selected eligible employees for nil cost;
- The exercise price of the options have been determined by the Board in its absolute discretion. Generally, the exercise price has been determined with reference to the 5-day or 20-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 or 10 years after the grant date under 2020 EIP;
- All options expire on the earlier of their expiration 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 may, determine in its absolute discretion the treatment of the participant's unvested awards and the timing of such treatment.

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16. STOCK-BASED COMPENSATION (continued)

Director stock options

On June 19, 2024, following approval by ATL stockholders at the Annual General Meeting on May 29, 2024, the Company issued 475,000 options with an exercise price of $15.29 equivalent (AUD $23.00) per share to the following Directors:

- John Seaberg (Chair) – 75,000 options
- Wayne Paterson (Vice Chairman and CEO) – 300,000 options
- Stephen Denaro (Non-executive director and ATL 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 2020 EIP.

On September 15, 2023 following approval by ATL stockholders 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 (AUD $24.00) per share to the following directors relating to the 2023 financial year:

- John Seaberg (Chair) – 157,500 options
- Wayne Paterson (Vice Chairman and CEO) – 700,000 options
- Stephen Denaro (Non-executive director and ATL Company Secretary) – 80,500 options
- Wenyi Gu (Non-executive director) – 80,500 options

The above director stock options expire after 5 years and 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 2020 EIP. There were no performance conditions attached to the director options issued. These options were valued using the Black-Scholes model.

Modification of director options

On February 17, 2023, in relation to options issued in the 2020 year, the Board 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 $0.9 million. The value was expensed at the date of the modification.

Consultant options

No options were issued to consultants during the year ended December 31, 2024. On February 15, 2023, ATL 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.

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 (in thousands) $
Outstanding at January 1, 2024	2,159,675	$ 12.36		
Granted during the year	642,950	$ 14.61		
Forfeited during the year	(2,584)	$ 13.05		
Exercised during the year	(667)	$ 5.67		
Outstanding at December 31, 2024	2,799,374	$ 12.08	3.3	92
Expected to vest at December 31, 2024	1,378,985	$ 14.24	3.9	-
Exercisable at December 31, 2024	1,346,243	$ 9.85	2.7	92

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16. STOCK-BASED COMPENSATION (continued)

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 as of December 31, 2024.

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, 2023	1,506,200	$	13.92
Granted	642,950	$	14.61
Vested	(693,603)	$	4.09
Forfeited	(2,416)	$	12.91
Non-vested at December 31, 2024	1,453,131	$	14.14

As of December 31, 2024, there was $5.0 million of total unrecognized compensation cost related to non-vested stock option arrangements granted. That cost is expected to be recognized over a weighted-average period of 1.3 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 (in thousands) $
Outstanding at January 1, 2024	435,000	$	7.66		
Forfeited during the year	(145,500)	$	7.31		
Outstanding at December 31, 2024	289,500	$	7.13	0.2	-
Exercisable at December 31, 2024	289,500	$	7.13	0.2	-

The 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 expiration date and the associated options were canceled on March 20, 2024.

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 (in thousands) $
Outstanding at January 1, 2024	1,070,000	$	12.91		
Expired during the year	(70,000)	$	6.24		
Outstanding and exercisable at December 31, 2024	1,000,000	$	12.12	0.4	-

16. STOCK-BASED COMPENSATION (continued)

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:

(in thousands)	2024 $	2023 $
Cash proceeds from options exercised	4	2,137
Intrinsic value of options exercised	3	805
Income tax benefit related to options exercised	-	-

(c) Shares issued as compensation

On July 30, 2024, 41,000 shares were issued to a consultant as compensation for services received. On April 17, 2023, ATL issued 1,000 shares as compensation for expert advisory services received. No amounts were payable for the issue of the shares.

(d) Share Price Performance Rights (Cash-settled)

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. 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 (as amended per below) 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 (as amended per below) to the exercise date.

The base prices and share price hurdles were converted to U.S. dollars in connection with the Scheme to ensure that holders retained the value of their outstanding SPP Units both immediately before and after the reverse recapitalization. All other vesting terms and conditions remained unchanged.

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 (in thousands) $
SPP with service conditions					
Non-vested at January 1, 2024	850,000	$	16.42		
Forfeited during the year	(283,332)	$	16.13		
Non-vested at December 31, 2024	566,668	$	15.28	1.2	31
SPP with service and performance conditions					
Non-vested at January 1, 2024	700,000	$	16.42		
Non-vested at December 31, 2024	700,000	$	15.28	3.7	193

As of December 31, 2024, there was $0.3 million of total unrecognized compensation cost related to non-vested SPP rights outstanding. That cost is expected to be recognized over a weighted-average period of 1.5 years.

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16. STOCK-BASED COMPENSATION (continued)

(e) RSU

The fair value of the RSUs is based on the market value of the Company's Common Stock on the date of grant. RSUs vest over 3 years with the compensation cost, adjusted for estimated forfeitures, being recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in-substance, multiple awards. RSUs are not considered issued or outstanding Common Stock of the Company. Dividend equivalent units are accumulated on RSUs during the vesting period and are subject to the same restrictions on transferability as the underlying RSUs.

The following table summarizes the RSU activity during the year:

	Number of RSUs	Weighted-average grant price	Grant Date Fair Value (in thousands) $
Non-vested at January 1, 2024	-	-	-
Granted during the year	749,999	$ 6.00	4,500
Non-vested at December 31, 2024	749,999	$ 6.00	4,500

As of December 31, 2024, there was $4.4 million of total unrecognized compensation cost related to non-vested RSU arrangements granted. That cost is expected to be recognized over a weighted-average period of 2.0 years.

On December 16, 2024, in connection with the IPO, the Board, approved the grant of RSUs with the following target fair values as of the date of the pricing of the IPO, each of which are subject to approval by stockholders in accordance with the rules of the ASX. Each grant of RSUs will vest annually over a three-year period:

- Chief Executive Officer: $6 million
- Non-executive Chair: $0.5 million
- Non-employee directors: $0.25 million

As of December 31, 2024, the Company has not recognized any stock-based compensation expense for the director's RSUs, as the grant date has not been established under ASC 718.

(f) Fair Value Disclosures

The Company uses the Black-Scholes model to determine the fair value of stock options and SPP rights 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 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.

	2024	2023	2023 Modification
Quantity issued/modified during the year	475,000	1,018,500	145,500
Weighted average fair value per option at grant date (incremental value for modification)	$ 4.87	$ 6.84	$ 6.18
Weighted average assumptions used:			
Share price at grant date or modification date	$ 12.62	$ 13.32	$ 15.19
Exercise price	$ 15.29	$ 15.37	$ 7.66
Expected volatility	56.2%	75.0%	65.0%
Expected life	3.5 years	3.5 years	2.1 years
Expected dividends	Nil	Nil	Nil
Risk-free interest rate range	4.07% - 4.08%	3.80% - 3.82%	3.52%

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16. STOCK-BASED COMPENSATION (continued)

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.

	EIP 2024	EIP 2023
Quantity issued during the year	167,950	13,800
Weighted average fair value per option at grant date	$ 7.50	$ 7.53
Assumptions used:		
Share price at grant date range	$ 10.86 - $14.80	$ 12.16 - $16.63
Exercise price range	$ 10.87 - $13.02	$ 12.56 - $14.40
Expected volatility range	52.5% - 65.0%	60.5% - 75.1%
Expected life range	3 - 4 years	3 - 4 years
Expected dividends	Nil	Nil
Risk-free interest rate range	3.63% - 4.06%	3.21% - 4.29%

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. No options were granted to consultants during the year ended December 31, 2024.

	Consultant 2024	Consultant 2023
Quantity issued during the year	-	500,000
Weighted average fair value per option at grant date	-	$ 5.26
Assumptions used:		
Share price at grant date	-	$ 16.72
Exercise price	-	$ 20.17
Expected volatility	-	64.8%
Expected life	-	2.0 years
Expected dividends	-	Nil
Risk-free interest rate	-	3.34%

16. STOCK-BASED COMPENSATION (continued)

SPP rights

The inputs used in the measurement of the fair values of the SPP rights at each reporting date were as follows:

Service based SPP	December 31, 2024	December 31, 2023
Weighted average fair value per right	$ 0.12	$ 3.00
Share price at measurement date	$ 5.58	$ 13.10
Base price	$ 15.28	$ 16.42
Expected volatility (weighted average)	51.3%	57.5%
Expected life (weighted average)	1.2 years	1.7 years
Risk-free interest rate (based on government bonds)	4.21%	3.66%

Service and performance based SPP	December 31, 2024	December 31, 2023
Weighted average fair value per right	$ 0.71	$ 5.40
Share price at measurement date	$ 5.58	$ 13.10
Base price	$ 15.28	$ 16.42
Expected volatility (weighted average)	57.5%	60.0%
Expected life (weighted average)	2.7 years	3.7 years
Risk-free interest rate (based on government bonds)	4.27%	3.8%

17. VARIABLE INTEREST ENTITY

At each reporting period, the Company reassesses whether it remains the primary beneficiary for VIEs consolidated under the VIE model.

On April 18, 2023, the Group entered into a series of agreements with 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 $0.2 million, 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 identifiable 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 and certain benefits through equity ownership. Therefore, the Company consolidated v2v from the acquisition date of its equity interest.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

17. VARIABLE INTEREST ENTITY (continued)

The following table presents the assets and liabilities for VIE:

	AS OF	
(in thousands)	DECEMBER 31, 2024 $	DECEMBER 31, 2023 $
Assets		
Other current assets	28	25
Total assets	28	25
Liabilities		
Other current liabilities	86	25
Non-current liabilities	54	94
Total liabilities	140	119
Net (liabilities)/assets	(112)	(94)

Included in other current liabilities is a loan from v2v's parent entity amounting to $0.02 million as of December 31, 2024, and $0.02 million 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 Group. The Group contributed $2.4 million to v2v to finance its operations during the year ended December 31, 2024.

Non-controlling Interests

Non-controlling 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 non-controlling interests. Under HLBV, the non-controlling interests are calculated as the amount that would be paid to non-controlling interest holders upon a hypothetical liquidation of the entity at book value as of the reporting date.

The Company recognizes non-controlling interests related to v2v and provides a roll forward of the non-controlling interests balance, as follows (in thousands):

Balance as of December 31, 2023	$	(403)
Net gain attributable to non-controlling interests		324
Balance as of December 31, 2024	$	(79)

18. ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table presents the components of Accumulated Other Comprehensive Loss:

(in thousands)	Foreign currency translation adjustments $	Total Accumulated Other Comprehensive Loss $
December 31, 2022	9,937	9,937
Other comprehensive loss – equity adjustment from foreign currency translation	(382)	(382)
December 31, 2023	9,555	9,555
Other comprehensive income – equity adjustment from foreign currency translation	1,336	1,336
December 31, 2024	10,891	10,891

No income taxes have been allocated to the translation adjustments.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

19. RELATED PARTY TRANSACTIONS

(a) Accounting parent entity

The accounting parent entity within the Group is ATL.

(b) Legal parent entity

The legal parent entity within the Group is ATGC.

(c) Subsidiaries

The Company may provide letters of support to its subsidiary companies when required.

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 17 *Variable Interest Entity*). There have been no other changes in the Company's ownership interests in subsidiaries during the year ended December 31, 2024.

20. COMMITMENTS AND CONTINGENCIES

As of December 31, 2024 the Group had commitments to purchase $0.3 million of plant and equipment, as compared to no commitments at December 31, 2023.

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.

Contingent liabilities

The Group 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 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.

21. 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 CODM which is the Vice Chairman and 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® anti-calcification tissue. This is focused on the DurAVR® THV system.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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21. SEGMENT REPORTING (continued)

(b) Segment information

The revenue and cost information relating to all of the ADAPT® products including both the DurAVR® THV system and regenerative tissue products are regularly reviewed by the CODM on an aggregate basis.

The CODM assesses performance and allocates resources based on the Company's Consolidated Statements of Operations and key components and processes of the Company's operations are managed centrally. Segment asset information is not used by the CODM to allocate resources. As a single reportable segment entity, the Company's segment performance measure is net income / (loss).

(in thousands)	2024 $	2023 $
Net sales from external customers	2,703	2,735
Depreciation & amortization	(1,507)	(1,158)
Interest income	430	428
Interest expense	(47)	(67)
Other segment items	(77,546)	(48,702)
Segment net loss	(75,967)	(46,764)

No detailed asset information by reportable segment has been reported given that the single segment's information is already presented in the Consolidated Balance Sheets. Refer to the Consolidated Statements of Cash Flows for significant non-cash items and total expenditure for additions of long-lived assets.

(c) Geographic information

Segment revenues (net sales) 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.

	Net sales		Long-lived assets, net	
(in thousands)	2024 $	2023 $	2024 $	2023 $
United States	1,782	2,256	4,895	4,043
Germany	900	471	-	-
Australia	21	8	829	1,174
Switzerland	-	-	107	183
Sweden	-	-	28	79
	2,703	2,735	5,859	5,479

(d) Major customers

The following table summarizes revenues from major customers that individually accounted for 10% or more of the Company's total revenues during the years ended December 31, 2024 and 2023:

(in thousands)	2024 $	2023 $
Customer A	1,312	1,449
Customer B	1,370	1,277

Amounts outstanding from these customers at reporting date was $0.2 million and $0.1 million, as of December 31, 2024 and 2023, respectively.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

22. VALUATION AND QUALIFYING ACCOUNTS

Description (in thousands)	Balance at beginning of period $	Additions: Charged to Costs and Expenses $	Additions: Charged to Other Accounts $	Deductions: Charged to Costs and expenses $	Deductions: Charged to Other Accounts $	Balance at End of Period $	Net change $
Allowance for doubtful accounts							
Year ended December 31, 2024	-	-	-	-	-	-	-
Year ended December 31, 2023	-	-	-	-	-	-	-
Inventory reserve							
Year ended December 31, 2024	-	-	-	-	-	-	-
Year ended December 31, 2023	-	-	-	-	-	-	-
Deferred tax asset valuation allowance							
Year ended December 31, 2024	37,132	22,423	-	(489)	(4,524)	54,542	17,410
Year ended December 31, 2023	26,699	9,741	909	(217)	-	37,132	10,433

Allowance for doubtful accounts

The allowances for doubtful accounts deductions represent accounts receivable which have been written off.

The Group's revenues are primarily derived from two external customers, both of which have no recent history of default. As of December 31, 2024 and 2023, 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, 2024 and 2023, 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 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.

23. DEED OF CROSS GUARANTEE

ATGC and ATL (ACN 088 221 078) are party to a deed of cross guarantee dated December 20, 2024 ("Deed"). ATGC and ATL were the only parties to the Deed at December 31, 2024, and comprise the "closed group" for the purposes of the Deed and, as there are no other parties to the Deed that are controlled by ATGC, ATGC and ATL also represent the "extended closed group." By entering into the Deed, ATGC and ATL have guaranteed the debts of each other. There have been no changes in ownership of any members of the closed group or in the parties to the deed of cross guarantee since December 31, 2024.

ANTERIS TECHNOLOGIES GLOBAL CORP.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

23. DEED OF CROSS GUARANTEE (continued)

A consolidated Statement of Operations and Other Comprehensive Income and consolidated Balance Sheet, comprising the Company and controlled entities which are a party to the Deed, after eliminating all transactions between parties to the Deed of Cross Guarantee, for the year ended December 31, 2024 is set out as follows:

(in thousands)	$
Statement of Operations and Other Comprehensive Income	
Net sales	-
Costs and expenses:	
Research and development expense	(195)
Selling, general and administrative expense	(17,160)
Operating loss	(17,355)
Other non-operating income, net	1,518
Impairment expenses (1)	(56,769)
Interest and amortization of debt discount and expense	(35)
Net foreign exchange losses	(319)
Debt issuance costs	(465)
Loss on debt extinguishment	(904)
Fair value movement of derivatives	(101)
Loss before income taxes from continuing operations	(74,430)
Income tax expense	-
Loss after income tax attributable to owners of the Company	(74,430)
Items that may be reclassified to profit or loss:	
Foreign currency translation adjustments	354
Other comprehensive income for the year, net of tax	354
Total comprehensive loss for the period, net of tax	(74,076)
Movements in Retained earnings/(Accumulated Deficit)	
Accumulated Deficit, opening balance	(140,868)
Loss after income tax	(74,430)
Accumulated Deficit, closing balance	(215,298)

(1) Impairment expenses are in relation to loans and trade receivables from subsidiaries.

No dividends were declared or paid during the year.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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23. DEED OF CROSS GUARANTEE (continued)

(in thousands)	$
Transfers to/(from) reserves*	
Stock-based compensation	6,304
Foreign currency translation adjustments	354
Balance Sheet	
ASSETS	
Current Assets	
Cash and cash equivalents	69,088
Prepaid expenses	168
Other current assets	1,220
Total Current Assets	70,476
Non-Current Assets	
Plant and equipment, net	46
Operating lease right-of-use assets, net	56
Intangible assets, net	36
Total Non-Current Assets	138
TOTAL ASSETS	70,614
LIABILITIES	
Current Liabilities	
Accounts payable	92
Accrued and other liabilities	4,383
Current portion of operating lease liabilities	44
Total Current Liabilities	4,519
Non-Current Liabilities	
Operating lease liabilities	25
Other liabilities	96
Total Non-Current Liabilities	121
TOTAL LIABILITIES	4,640
COMMITMENTS AND CONTINGENCIES	
STOCKHOLDERS' EQUITY	
Common stock	4
Additional paid in capital	289,421
Accumulated other comprehensive loss	(8,153)
Accumulated deficit	(215,298)
TOTAL STOCKHOLDERS' EQUITY	65,974
TOTAL LIABILITIES AND EQUITY	70,614

* Reserves includes the foreign currency translation reserve and the stock-based compensation reserve.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED DECEMBER 31, 2024

24. ASIC RELIEF FOR ATL

Australian Securities Investments Commission ("ASIC") has granted ATL relief from the requirement to prepare a financial report and directors' report for the financial year ended December 31, 2024 by issuing ASIC Instrument 25-0066 (the "Relief Instrument"). ATL obtained the financial reporting relief under the Relief Instrument because, during the financial year ended December 31, 2024, ATL was a "disclosing entity" and therefore would otherwise not be eligible for relief under the *ASIC Corporations (Wholly-owned Companies) Instrument 2016/785)*. The effect of the Relief Instrument is that subject to various conditions, including compliance with the conditions of the *ASIC Corporations (Wholly-owned Companies) Instrument 2016/785)* (other than the requirement in relation to "disclosing entities"), and certain other additional conditions as set out in the Relief Instrument, ATL is relieved from the requirement to prepare a financial report and directors' report for the financial year ended December 31, 2024.

As detailed in note 2(y) Reverse recapitalization, when ATGC acquired ATL, the transaction was accounted for as a reverse recapitalization. The substance of the transaction was that the pre-transaction shareholders of ATL (the accounting acquirer) had effectively obtained control of ATGC. The effect of this is that the consolidated financial statements of ATL are equivalent to the consolidated financial statements of ATGC.

A consolidated Statement of Comprehensive Income and movements in retained earnings and reserves, comprising ATL and its controlled entities for the year ended December 31, 2024 is set out as follows:

(in thousands)	$
Net sales	2,703
Costs and expenses:	
Cost of products sold	(1,437)
Research and development expense	(51,451)
Selling, general and administrative expense	(28,187)
Acquired in-process research and development	-
Operating loss	(78,372)
Other non-operating income, net	2,442
Interest and amortization of debt discount and expense	(47)
Net foreign exchange gains	1,440
Debt issuance costs	(465)
Loss on debt extinguishment	(904)
Fair value movement of derivatives	(61)
Loss on asset acquisition of a variable interest entity	-
Loss before income taxes from continuing operations	(75,967)
Income tax (expense)/benefit	-
Loss after income tax	(75,967)
Net income attributable to non-controlling interests	324
Loss attributable to ATL	(76,291)
Loss after income tax	(75,967)
Items that may be reclassified to profit or loss:	
Foreign currency translation adjustments	(1,336)
Other comprehensive loss for the year, net of tax	(1,336)
Total comprehensive loss for the period, net of tax	(77,303)
Movements in Retained earnings/(Accumulated Deficit)	
Accumulated Deficit, opening balance	(200,097)
Loss after income tax	(76,291)
Accumulated Deficit, closing balance	(276,388)
Transfers to/(from) reserves*	
Stock-based compensation	6,304
Foreign currency translation adjustments	(1,336)

* Reserves includes the foreign currency translation reserve and the stock-based compensation reserve.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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25. SUBSEQUENT EVENTS

Management has evaluated the impact of subsequent events through to March 3, 2025.

On January 15, 2025, TD Cowen, Barclays and Cantor, as representatives of the underwriters in the IPO, partially exercised the option to purchase additional shares granted by the Company in connection with the IPO in respect of 78,481 shares of Common Stock of the Company at the IPO price of $6.00 per share, generating $0.5 million in gross proceeds, before underwriting discounts and commissions of $0.42 per share.

Since December 31, 2024, 1,955,416 options have been cancelled due to expiration or forfeiture. The weighted average exercise price of these options was $18.46.

On February 18, 2025, the Convertible Note Facility was terminated, and the security interest was released.

On March 6, 2025 the Board appointed Mr. St Denis as the Company's President and a Class II director of the Board, effective immediately. As a non-independent director, Mr. St Denis will not serve on any committees of the Board.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2024, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, solely as a result of the material weaknesses in our internal control over financial reporting described below, as of December 31, 2024, our disclosure controls and procedures were not effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There are no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control financial reporting.

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, which remained unremediated as of December 31, 2024. 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.

While we believe that these efforts will improve our internal control over financial reporting, the design and implementation of our remediation is ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

Management's Report on Internal Control over Financial Reporting

This Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

Attestation Report of Registered Public Accounting Firm

This Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Inherent Limitation on the Effectiveness of Internal Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

Insider Trading Arrangements and Policies

During the fiscal quarter ended December 31, 2024, none of our directors or officers (as defined in Section 16 of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Code of Business Conduct and Ethics

We have adopted a written Code of Business Conduct and Ethics, which applies to all our directors, officers and employees, and is available on our website.

The Audit and Risk Committee is responsible for overseeing the Code of Business Conduct and Ethics 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.

The other information required to be included by Item 10 of Form 10-K will be included in the definitive proxy statement (the "Proxy Statement") for our 2025 Annual Meeting of Stockholders and such information is incorporated by reference herein. The Proxy Statement will be filed electronically with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K pursuant to Regulation 14A of the Exchange Act.

Item 11. Executive Compensation.

The information required by this item of Form 10-K will be included under the caption "Executive and Director Compensation" in the Proxy Statement and is incorporated by reference herein.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item of Form 10-K will be included under the captions "*Security Ownership of Certain Beneficial Owners and Management"* and "*Securities Authorized for Issuance Under Equity Compensation Plans*" in the Proxy Statement and is incorporated by reference herein.

In addition to the Company's primary listing on the Nasdaq, our shares of Common Stock are also quoted in the form of CDIs on the ASX and trade under the ticker symbol "AVR". As part of our ASX listing, we are required to comply with the various disclosure requirements as set out under the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules (where that information has not been provided elsewhere in this Form 10-K).

Australian Disclosure Requirements

Issued capital

As of January 31, 2025, the Company's issued equity instruments consisted of:

- 18,615,386 shares of Common Stock quoted held by 28 stockholders of record on Nasdaq;
- 17,402,911 shares of Common Stock, held by CHESS Depositary Nominees Pty Limited as Depository Nominee on behalf of 3,666 CDI holders, representing 17,402,911 CDIs quoted on the ASX;
- 6,046,558 unquoted unlisted options which entitle the holders of those securities, upon vesting of their conversion rights, to be issued shares of Common Stock (including in certain cases in the form of CDIs) held by 237 holders; and
- 749,999 unquoted Restricted Stock Units ("RSUs") which entitle the holders of those securities, upon completion of the service period, to be issued shares of Common Stock (including in certain cases in the form of CDIs) of the Company held by three holders.

As of January 31, 2025, the Company did not have any restricted securities (within the meaning of the ASX Listing Rules) that are on issue or any securities subject to voluntary escrow that are on issue.

Principal Stockholders and Management

The following table provides certain information regarding the ownership of our Common Stock (including our CDIs), as of January 31, 2025 by each person or group of affiliated persons known to us to be the beneficial owner of more than 5% of our Common Stock (including our CDIs); each of our named executive officers ("NEOs"); each of our directors; and all of our named executive officers and directors as a group. The table also sets out the names of all persons (to the best of our knowledge) who have disclosed pursuant to the Corporations Act 2001 (Cth) or in filings made with the SEC that they are "substantial shareholders" of our company and carry 5% or more of the voting rights attached to our issued securities.

Unless otherwise indicated in the table or the related notes thereto, the address for each person named in the table is c/o Anteris Technologies Global Corp. 860 Blue Gentian Road, Suite 340, Eagan, Minnesota 55121.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership – Common Stock (1)		Percentage (2)
Directors and NEOs			
J. Seaberg	188,358	(3)	*
W. Paterson	837,082	(4)	2.3%
S. Denaro	90,555	(5)	*
W. Gu	66,833	(6)	*
D. St Denis	198,764	(7)	*
M. McDonnell	95,335	(8)	*
All directors and executive officers as a group (six persons)	1,476,927		3.9%
5% + Stockholders (Substantial stockholders)			
L1 Capital Pty Ltd	6,741,401	(9)	18.7%
Sio Capital Management, LLC	3,465,005	(10)	9.6%
Perceptive Advisors, LLC	2,440,000	(11)	6.8%

* Represents beneficial ownership of less than 1% of the outstanding Common Stock.

(1) Except as otherwise indicated, we believe that the beneficial owners of the Common Stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

(2) Percentage of ownership is based on 36,018,297 shares of our Common Stock issued and outstanding as of January 31, 2025 (including shares of Common Stock represented by CDIs). Shares of Common Stock underlying options or RSUs exercisable within 60 days of January 31, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or RSUs but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(3) Reflects 15,858 shares of Common Stock and 172,500 stock options to acquire 172,500 shares of our Common Stock exercisable within 60 days of January 31, 2025.

(4) Reflects 20,334 shares of Common Stock and 816,748 stock options to acquire 816,748 shares of our Common Stock exercisable within 60 days of January 31, 2025.

(5) Reflects 7,222 shares of Common Stock held by Citicorp Nominees Pty Limited and 83,333 stock options to acquire 83,333 shares of our Common Stock exercisable within 60 days of January 31, 2025 which are held by Sloane Pty Ltd as Trustee for the Denaro Family Trust. Mr. Denaro serves as the director and sole shareholder of Sloane Pty Ltd, which Mr. Denaro is deemed to beneficially own.

(6) Reflects 66,833 stock options to acquire 66,833 shares of our Common Stock exercisable within 60 days of January 31, 2025.

(7) Reflects 198,764 stock options to acquire 198,764 shares of our Common Stock exercisable within 60 days of January 31, 2025.

(8) Reflects 95,335 stock options to acquire 95,335 shares of our Common Stock exercisable within 60 days of January 31, 2025 which are held by Quadroo Pty Ltd, as Trustee for the McDonnell Family Trust. Mr. McDonnell and his spouse serve as directors of Quadroo Pty Ltd and share voting and investment power over such shares.

(9) Represents shares of Common Stock beneficially owned by L1 Capital Pty Ltd, as of December 16, 2024, as reported on the Schedule 13G filed by L1 Capital Pty Ltd with the SEC on January 23, 2025. The address for L1 Capital Pty Ltd is Level 45, 101 Collins Street, Melbourne, VIC 3000 Australia.

(10) Represents shares of Common Stock beneficially owned by Sio Capital Management, LLC ("Sio"), as of December 31, 2024, as reported on the Schedule 13G filed by Sio with the SEC on February 10, 2025. Sio is a registered investment adviser to certain affiliated funds that directly hold the shares of Common Stock for the benefit of their respective investors, and in such capacity, Sio has voting and dispositive power over such shares. The address for Sio is 600 Third Avenue, 2nd Floor, New York, NY 10016.

(11) Represents shares of Common Stock beneficially owned by Perceptive Life Sciences Master Fund, Ltd (the "Master Fund"), as of December 31, 2024, as reported on the Schedule 13G filed by Perceptive Advisors LLC with the SEC on February 14, 2025. Perceptive Advisors LLC serves as the investment manager to the Master Fund and may be deemed to beneficially own such shares. Mr. Joseph Edelman is the managing member of Perceptive Advisors LLC and may be deemed to beneficially own such shares. The address for the Master Fund, Perceptive Advisors LLC and Mr. Edelman is 51 Astor Place, 10th Floor, New York, NY 10003.

Jurisdiction of Incorporation and Restrictions on the Acquisition of Securities

The Company is incorporated in the State of Delaware in the United States of America. As a foreign company registered in Australia, the Company is not subject to Chapters 6, 6A, 6B and 6C of the Corporations Act 2001 (Cth) dealing with the acquisition of its shares (including substantial holdings and takeovers).

Under the Delaware General Corporation Law (the "DGCL"), our Common Stock are generally freely transferable, subject to restrictions that may be imposed by United States federal or state securities laws, by our Second Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") or Amended and Restated Bylaws (the "Bylaws") or by an agreement binding on our stockholders. The Certificate of Incorporation and Bylaws do not impose any specific restrictions on the transfer of our Common Stock. Transfers of the Common Stock will be made only on the transfer books or by a transfer agent designated to transfer the Common Stock. Provisions of the DGCL, the Certificate of Incorporation and the Bylaws could make it more difficult to acquire us by means of a tender offer (takeover), a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions could discourage certain types of coercive takeover practices and takeover bids that our Board may consider inadequate and encourage persons seeking to acquire control of our Company to first negotiate with the Board.

Australian Corporate Governance Statement

The Board and our management are committed to achieving and demonstrating the highest standards of corporate governance. We have reviewed our corporate governance practices against the "Corporate Governance Principles and Recommendations" (4th edition) published by the ASX Corporate Governance Council. Our Corporate Governance Statement sets out the ASX Governance Recommendations and the Company's response as to how and whether we follow those recommendations.

The Corporate Governance Statement reflects our corporate governance practices in place throughout the financial year. A description of the Group's current corporate governance practices is set out in our Corporate Governance Statement, which can be viewed at *https://anteristech.com/investors/corporate-governance.html*.

Our most recent Corporate Governance Statement, dated March 12, 2025 and approved by the Board remains accurate as of the date of this Form 10-K. The Corporate Governance Statement is not incorporated by reference herein.

Voting Rights

Except as otherwise required by law, as provided in our Certificate of Incorporation or as provided in resolutions, if any, adopted by the Board with respect to any series of the preferred stock, the holders of our Common Stock (including CDIs) 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.

Holders of CDIs are entitled to receive notice of, and to attend as guests (but not vote at) meetings of stockholders. The Depositary Nominee (or its custodian) is the legal holder of the shares of Common Stock underlying the CDIs. However, as the beneficial owners of the shares of Common Stock underlying the CDIs, holders of CDIs may:

- direct the Depositary Nominee (or its custodian) how to vote the shares of Common Stock represented by their CDIs by completing the CDI Voting Instruction Form that accompanies the relevant notice of meeting or proxy statement; or
- appoint themselves (or another person) to be the Depositary Nominee's proxy with respect to the shares of Common Stock represented by their CDIs for the purposes of attending and voting at the stockholders meeting by completing the CDI Voting Instruction Form that accompanies the relevant notice of meeting or proxy statement.

Alternatively, holders of CDIs may elect to convert their CDIs into Common Stock and vote those shares of Common Stock at a stockholders meeting. Such conversion must be completed prior to the record date fixed by us for determining the entitlement of stockholders to attend and vote at the stockholders meeting.

Unquoted options convert into a fixed number of shares of Common Stock or CDIs on a variety of dates. Each option has a set exercise price and expiry date. Holders of unquoted options are not entitled to vote at our annual or special meetings of stockholders.

RSUs convert into a fixed number of shares of Common Stock or CDIs upon completion of vesting conditions. RSUs are cancelled if vesting conditions are not satisfied. Holders of RSUs are not entitled to vote at our annual or special meetings of stockholders.

Twenty Largest Holders as of January 31, 2025

Below is a statement of the 20 largest holders of shares of Common Stock and CDI holders, the number and percentage of shares of Common Stock held by those holders, and the percentage of shares of Common Stock (including that are held as both Common Stock or CDIs), based on the Company's registers at January 31, 2025.

Common Stock

Rank	Name	Shares of Common Stock	Percentage of Common Stock and CDIs Outstanding (1)
1	CEDE & CO	35,401,791	98.3%
2	AMEDAN PTY LTD	224,280	0.6%
3	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED <A/C SEG>	90,000	0.2%
4	MLAD HOLDINGS PTY LTD <A/C MLAD SUPER FUND>	73,416	0.2%
5	DANIEL WEE KANG CHIEW	37,801	0.1%
6	AGSC CAPITAL PTY LTD <A/C AGSC CAPITAL INVESTMENT>	30,594	0.1%
7	AMELIA WEE LYNN CHIEW	20,650	0.1%
8	WAYNE GEOFFREY PATERSON	20,334	0.1%
9	BLACK DOG FUND PTY LTD <A/C BLACK DOG SUPER FUND>	20,173	0.1%
10	JOHN SEABERG	15,858	0.0%
11	LUCY IK CHIW LAU	15,446	0.0%
12	CHEE HIEN CHIEW	12,890	0.0%
13	NIGEL DOUGLAS WILLIAMS	10,100	0.0%
14	RICKY STEVEN NEUMANN	10,000	0.0%
15	BRENT CHRISTOPHER MARRS	9,000	0.0%

(1) Percentage of ownership is based on 36,018,297 shares of Common Stock issued and outstanding as of January 31, 2025 (including shares of Common Stock represented by CDIs).

CDIs

Rank	Name	Number of CDIs	Percentage of Total Common Stock Outstanding (1)
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	4,161,001	11.6%
2	CITICORP NOMINEES PTY LIMITED	1,376,453	3.8%
3	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	790,166	2.2%
4	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED <GSCO CUSTOMERS A/C>	734,664	2.0%
5	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	421,964	1.2%
6	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	403,250	1.1%
7	MR. PATRICK CHEW	390,797	1.1%
8	MR. RICKY STEVEN NEUMANN	362,698	1.0%
9	EVOLUTION CAPITAL ADVISORS PTY LTD	329,767	0.9%
10	LTL CAPITAL PTY LTD	312,556	0.9%
11	BNP PARIBAS NOMS PTY LTD <GLOBAL MARKETS>	255,890	0.7%
12	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	254,756	0.7%
13	MUTUAL TRUST PTY LTD	230,892	0.6%
14	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT>	227,768	0.6%
15	THROUGH2 INVESTMENTS PTY LTD <THROUGH2 SUPER FUND A/C>	120,000	0.3%
16	MDM LEBY HWANG	117,700	0.3%
17	SUPERIOR COATINGS (AUST) PTY LTD	113,000	0.3%
18	MR. DAVID LAMM	107,100	0.3%
19	MR. DANIEL BERNARD CLOUGH	101,000	0.3%
20	BNP PARIBAS NOMS PTY LTD	93,568	0.3%
	Total	**10,904,990**	
	Remaining CDI Holders	6,497,921	
	Total Common Stock held with CDI shares	**17,402,911**	

(1) Percentage of ownership is based on 36,018,297 shares of Common Stock issued and outstanding as of January 31, 2025 (including shares of Common Stock represented by CDIs).

Unlisted Options

As of January 31, 2025, no holder owned 20% or more of the unlisted options, other than holders which acquired the unlisted options under an employee incentive scheme.

Restricted Stock Units ("RSUs")

As of January 31, 2025, no holder owned 20% or more of the RSUs, other than holders which acquired the RSUs under an employee incentive scheme.

Distribution of Common Stock and CDI Holders at January 31, 2025

Below is a distribution schedule of the number of holders of Common Stock and CDIs, categorized by the size of their holdings, based on the Company's registers as of January 31, 2025.

Common Stock

Range	Number of Holders of Record	Shares of Common Stock	Percentage of Common Stock Outstanding (1)
1 – 1,000	6	2,448	0.0%
1,001 – 5,000	6	15,447	0.0%
5,001 - 10,000	3	27,069	0.1%
10,001 - 100,000	11	347,262	1.0%
100,001 and over	2	35,626,071	98.9%
Total	28	36,018,297	

(1) Percentage of ownership is based on 36,018,297 shares of Common Stock issued and outstanding as of January 31, 2025 (including shares of Common Stock represented by CDIs).

CDIs

Range	Number of Holders of Record	Share of Common Stock	Percentage of total Common Stock outstanding (1)
1 – 1,000	2,721	768,538	2.1%
1,001 – 5,000	656	1,489,449	4.1%
5,001 - 10,000	134	985,918	2.7%
10,001 - 100,000	136	3,347,584	9.3%
100,001 and over	19	10,811,422	30.0%
Total	3,666	17,402,911	

(1) Percentage of ownership is based on 36,018,297 shares of Common Stock issued and outstanding as of January 31, 2025 (including shares of Common Stock represented by CDIs).

The Number of Holders Holding Less than a Marketable Parcel of Securities

There were 364 stockholders and/or CDI holders holding less than a marketable parcel of shares of Common Stock and/or CDIs (where a "marketable parcel" means a parcel of securities worth at least AUD $500, pursuant to the ASX Operating Rules) as of January 31, 2025 at $9.29 per share.

Buy-Back of Securities

There is no active on-market buyback of our securities at this time.

Distribution of Unlisted Options Holders at January 31, 2025

Below is a distribution schedule of the number of holders of unlisted options, categorized by the size of their holdings, based on our records as of January 31, 2025.

Range	Number of Holders of Record	Units	Percentage of unquoted options
1 – 1,000	117	51,212	0.9%
1,001 – 5,000	54	137,305	2.3%
5,001 - 10,000	20	147,621	2.4%
10,001 - 100,000	32	838,933	13.9%
100,001 and over	14	4,871,487	80.6%
Round	-	-	-0.1%
Total	237	6,046,558	100.0%

Distribution of RSU Holders at January 31, 2025

Below is a distribution schedule of the number of holders of RSUs, categorized by the size of their holdings, based on our records as of January 31, 2025.

Range	Number of Holders of Record	Units	Percentage of RSUs
10,001 - 100,000	1	83,333	11.1%
100,001 and over	2	666,666	88.9%
Total	3	749,999	100.0%

General Information

Mr. Wayne Paterson is our Secretary.

The address of our registered and principal administrative office in Australia is Toowong Tower, Level 3, Suite 302, 9 Sherwood Road, Toowong QLD 4066, Australia and our telephone number there is +61 1300 550 310.

Registers of securities are held as follows:

- for CDIs in Australia, at Computershare Investor Services Pty Ltd, Level 1, 200 Mary Street, Brisbane, QLD 4000 Australia, Investor Enquiries 1300 850 505 (within Australia) +61 3 9415 4000 (outside Australia); and

- for shares of Common Stock in the United States, at Computershare Investor Services, 150 Royall Street, Canton, MA 02021 USA, Tel: +1 (781) 575 3100.

We advise that we have used the cash and assets in a form readily convertible to cash that we had at the time of our admission to the Official List of ASX in a way that is consistent with our business objectives.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item of Form 10-K will be included under the captions “Certain Relationships and Related Party Transactions” and “Board of Directors and Corporate Governance-Director Independence” in the Proxy Statement and is incorporated by reference herein.

Item 14. Principal Accountant Fees and Services.

The information required to be included by Item 14 will be included in the Proxy Statement and such information is incorporated by reference herein.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this report:

1. Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Form 10-K.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

The following is a list of exhibits filed or furnished as part of this Form 10-K.

Exhibit Index

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
2.1 †	Scheme Implementation Deed, dated August 13, 2024, by and between Anteris Technologies Global Corp. and Anteris Technologies Ltd	S-1	11/22/2024	2.1	
3.1	Second Amended and Restated Certificate of Incorporation of Anteris Technologies Global Corp.	8-K	12/16/2024	3.1	
3.2	Amended and Restated Bylaws of Anteris Technologies Global Corp.	8-K	12/16/2024	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2				X
4.2 †^	Convertible Securities Agreement, dated October 31, 2024, between Anteris Technologies Ltd and Obsidian Global GP, LLC	S-1	11/22/2024	4.2	
4.3	Description of Registrant's Securities				X
10.1 +	Anteris Technologies Global Corp. Equity Incentive Plan	S-1	11/22/2024	10.1	
10.2 +	Admedus Ltd Employee Long Term Incentive Plan	S-8	12/16/2024	99.2	
10.3 +	Anteris Technologies Ltd Employee Incentive Plan	S-8	12/16/2024	99.3	
10.4+	Form of Indemnification Agreement for Directors and Officers	S-1	11/22/2024	10.2	
10.5 #†^	Development Agreement, dated April 18, 2023, by and between v2vmedtech, inc. and Anteris Technologies Corporation	S-1	11/22/2024	10.3	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.6 #^	License Agreement, dated October 11, 2019, among Admedus Ltd, Admedus Regen Pty Ltd, Admedus Biomanufacturing Pty Ltd and LeMaitre Vascular, Inc.	S-1	11/22/2024	10.4	
10.7 #†^	Transition Services Agreement, dated October 11, 2019, among Admedus Ltd, Admedus Regen Pty Ltd, Admedus Biomanufacturing Pty Ltd and LeMaitre Vascular, Inc.	S-1/A	12/9/2024	10.5	
10.8 #	Amendment No. 1 to Transition Services Agreement, dated August 28, 2021, among Anteris Technologies Ltd, Admedus Regen Pty Ltd, Admedus Biomanufacturing Pty Ltd and LeMaitre Vascular, Inc.	S-1	11/22/2024	10.6	
10.9 #	Amendment No. 2 to Transition Services Agreement, dated December 19, 2022, among Anteris Technologies Ltd, Admedus Regen Pty Ltd, Admedus Biomanufacturing Pty Ltd and LeMaitre Vascular, Inc.	S-1	11/22/2024	10.7	
10.10 #^	Amendment No. 3 to Transition Services Agreement, dated September 18, 2023, among Anteris Technologies Ltd, Anteris Aus Operations Pty Ltd and LeMaitre Vascular, Inc.	S-1	11/22/2024	10.8	
10.11 #†^	Supply and Quality Agreement, dated May 15, 2024, by and between Anteris Aus Operations Pty Ltd and Harvey Industries Group Pty Ltd	S-1	11/22/2024	10.9	
10.12 †^	Second Amended and Restated Supply and License Agreement, dated June 1, 2018, between 4C Medical Technologies, Inc. and Admedus Corporation	S-1	11/22/2024	10.10	
10.13 †^	Amendment No. 1 to Second Amended and Restated Supply and License Agreement, dated March 5, 2024, between 4C Medical Technologies, Inc. and Anteris Technologies Corporation	S-1	11/22/2024	10.11	
10.14 #†^	Supply and Quality Agreement, dated November 16, 2021 between Anteris Technologies Corporation and Aran Biomedical Teoranta	S-1	11/22/2024	10.12	
10.15 ^	Supplier Quality Agreement, dated February 15, 2024, between Taurus Engineering and Manufacturing, Inc. and Anteris Technologies Corporation	S-1	11/22/2024	10.13	
10.16 #†^	First Amended and Restated Services Agreement, dated February 21, 2021, by and between NPX Medical, LLC and Anteris Technologies Corporation	S-1	11/22/2024	10.14	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.17	Amendment No. 1 to First Amended and Restated Services Agreement, dated March 24, 2024, by and between NPX Medical, LLC and Anteris Technologies Corporation	S-1	11/22/2024	10.15	
10.18 #†^	Master Services Agreement, dated June 1, 2021, by and between Anteris Technologies Corporation and Switchback Medical LLC	S-1	11/22/2024	10.16	
10.19 #†^	Sublease Agreement, dated March 1, 2022, by and between Switchback Medical LLC and Anteris Technologies Corporation	S-1	11/22/2024	10.17(a)	
10.20 #^	Sublease Amending Agreement, dated February 24, 2023, by and between Switchback Medical LLC and Anteris Technologies Corporation	S-1	11/22/2024	10.17(b)	
10.21 #^	Sublease Amending Agreement, dated August 18, 2023, by and between Switchback Medical LLC and Anteris Technologies Corporation	S-1	11/22/2024	10.17(c)	
10.22 #^	Sublease Amending Agreement, dated May 28, 2024, by and between Switchback Medical LLC and Anteris Technologies Corporation	S-1	11/22/2024	10.17(d)	
10.23 †^	Combined Bioinformatics Master Services Agreement, dated September 1, 2021, by and between Anteris Technologies Corporation and Cardiovascular Research Foundation	S-1	11/22/2024	10.18	
10.24 #†^	Lease of Part 26 Harris Road, Malaga, dated February 1, 2009, by and between Giacomel Pty Ltd, Verigen Australia Pty Ltd and Genzyme Corporation	S-1	11/22/2024	10.19(a)	
10.25 #†	Deed of Variation of Lease, dated June 23, 2014, among Giacomel Pty Ltd, Admedus Biomanufacturing Pty Ltd, Genzyme Corporation and Admedus Ltd	S-1	11/22/2024	10.19(b)	
10.26 #	Deed of Extension and Variation, dated February 19, 2019, by and between Giacomel Pty Ltd, Admedus Biomanufactuing Pty Ltd and Admedus Ltd	S-1	11/22/2024	10.19(c)	
10.27	Deed of Assignment of Lease, dated March 28, 2023 by and between Giacomel Pty Ltd, Admedus Biomanufacturing Pty Ltd, Admedus Regen Pty Ltd and Anteris Technologies Ltd	S-1	11/22/2024	10.19(d)	
10.28 #	Deed of Variation of Lease, dated June 12, 2023, by and between Giamocel Pty Ltd, Anteris Aus Operations Pty Ltd and Anteris Technologies Ltd	S-1	11/22/2024	10.19(e)	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.29 #	Deed of Extension and Variation of Lease, dated February 13, 2024, among Giacomel Pty Ltd, Anteris Aus Operations Pty Ltd and Anteris Technologies Ltd	S-1	11/22/2024	10.19(f)	
10.30 #†^+	Professional Services Agreement, dated September 3, 2021, between Anteris Technologies Corporation and Christopher Meduri, M.D.	S-1	11/22/2024	10.20(a)	
10.31 #†+	Amendment No. 1 to Professional Services Agreement, dated May 1, 2023, between Anteris Technologies Corporation and Christopher Meduri, M.D.	S-1	11/22/2024	10.20(b)	
10.32 +	Executive Service Agreement, dated December 1, 2019, between Admedus Corporation and Wayne Paterson	S-1	11/22/2024	10.21	
10.33 #†+	Employee Agreement, dated December 1, 2019, between Admedus Limited ACN 088 221 078 and Matthew McDonnell	S-1	11/22/2024	10.22	
10.34 †+	Executive Service Agreement, dated May 10, 2017, between Admedus Corporation and David St Denis	S-1	11/22/2024	10.23	
10.35 +^	Amended and Restated Employment Agreement, dated November 18, 2024, by and between Anteris Technologies Global Corp. and Wayne Paterson	S-1	11/22/2024	10.24	
10.36 +†^	Contract of Employment, dated November 19, 2024, by and between Anteris Technologies Ltd and Matthew McDonnell	S-1	11/22/2024	10.25	
10.37 +^	Amended and Restated Employment Agreement, dated November 19, 2024, by and between Anteris Technologies Global Corp. and David St Denis	S-1	11/22/2024	10.26	
10.38 #	Anteris Technologies Global Corp. Non-Employee Director Compensation Policy	S-1	11/22/2024	10.27	
10.39 #†	Contribution and Stock Purchase Agreement, dated April 18, 2023, by and among Anteris Technologies Corporation, v2vmedtech, inc., Dr. Vinayak Bapat, Urmi Bapat, Shalaka Bapat, Susheel Kodali, Michael McDonald and Christopher Meduri	S-1/A	12/9/2024	10.28	
14.1	Code of Business Conduct and Ethics				X
19.1	Insider Trading and Securities Dealing Policy				X
21.1	Subsidiaries of the Registrant	S-1	11/22/2024	21.1	

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
23.1(a)	Consent of Independent Registered Public Accounting Firm for Anteris Technologies Global Corp.				X
23.2	Consent for Future Market Insights, Inc.				X
24.1	Power of Attorney (included in the signature page hereto)				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
97.1	Compensation Clawback Policy				X

* This certification attached as Exhibit 32.1 that accompanies this Form 10-K, is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

\# Certain identified information has been excluded from this exhibit pursuant to Rule 601(b)(10) of Regulation S-K because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential.

† Certain information in this exhibit has been redacted pursuant to Item 601(a)(6) of Regulation S-K.

^ Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. Anteris Technologies Global Corp. agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

\+ Management contract or compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Eagan, State of Minnesota, on the 12th day of March, 2025.

Anteris Technologies Global Corp

By: /s/ Wayne Paterson

Name: Wayne Paterson
Title: Vice Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Wayne Paterson and Matthew McDonnell, and each of them, severally, as his or her true and lawful attorneys-in-fact and agents with the power to act, with or without the other, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in his or her capacity as a director or officer or both, as the case may be, of the Company, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Wayne Paterson Wayne Paterson	Vice Chairman and Chief Executive Officer (Principal Executive Officer)	March 12, 2025
/s/ Matthew McDonnell Matthew McDonnell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2025
/s/ John Seaberg John Seaberg	Chairman of the Board of Directors	March 12, 2025
/s/ David St Denis David St Denis	President and Director	March 12, 2025
/s/ Stephen Denaro Stephen Denaro	Director	March 12, 2025
/s/ Wenyi Gu Wenyi Gu	Director	March 12, 2025