



2023 Annual Report

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, 2023
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 001-33092

LEMAITRE VASCULAR, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)
63 Second Avenue, Burlington, Massachusetts
(Address of principal executive offices)
04-2825458
(I.R.S. Employer Identification No.)
01803
(Zip Code)
Registrant's telephone number, including area code 781-221-2266

Securities registered under Section 12(b) of the Act:

Title of each class	Trading symbol	Name of exchange on which registered
Common stock, \$0.01 par value per share	LMAT	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 Section 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, a smaller reporting company, or 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 checkmark 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 Act). Yes: ☐ No: ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was approximately \$1.3 billion computed by reference to the last reported sale price of \$67.28 per share as reported by The Nasdaq Global Market as of the last business day of the registrant's most recently completed second fiscal quarter.

At February 27, 2024, the registrant had 22,337,216 shares of common stock, par value \$0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this annual report.

This page intentionally left blank

LEMAITRE VASCULAR
2023 ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

PART I	1
Item 1. Business	1
Item 1A. Risk Factors	15
Item 1B. Unresolved Staff Comments	28
Item 1C. Cybersecurity	28
Item 2. Properties	29
Item 3. Legal Proceedings	29
Item 4. Mine Safety Disclosures	29
PART II	30
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	30
Item 6. Reserved	32
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.....	32
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	46
Item 8. Financial Statements and Supplementary Data.....	46
Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	46
Item 9A. Controls and Procedures	46
Item 9B. Other Information	49
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	49
PART III	49
Item 10. Directors, Executive Officers and Corporate Governance.....	49
Item 11. Executive Compensation	49
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	50
Item 13. Certain Relationships and Related Transactions, and Director Independence	50
Item 14. Principal Accounting Fees and Services	50
PART IV	51
Item 15. Exhibits and Financial Statements Schedules.....	51
Item 16. Form 10-K Summary	54
SIGNATURES	55

This page intentionally left blank

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the U.S. Private Securities Litigation Reform Act of 1995) that involve substantial risks and uncertainties, particularly risks related to the regulatory environment, our common stock, fluctuations in our quarterly and annual results, our ability to successfully integrate acquisitions into our business, and risks related to our business and industry generally, such as risks inherent in the process of developing and commercializing products and services that are safe and effective for use in the peripheral vascular disease market. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future net sales, gross margin expectations, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, our actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. No forward-looking statement can be guaranteed and actual results may vary materially from those projected in the forward-looking statements. We intend to take advantage of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995 regarding our forward-looking statements, and are including this sentence for the express purpose of enabling us to use the protections of the safe harbor with respect to all forward-looking statements. These risks and uncertainties include, but are not limited to: the status of our global regulatory approvals and compliance with regulatory requirements to market and sell our products both in the U.S. and outside of the U.S.; risks from implementing a new enterprise resource planning system; the risks from competition from other companies; the risk of significant fluctuations in our quarterly and annual results due to numerous factors; the risk that assumptions about the market for the Company’s products and the productivity of the Company’s direct sales force and distributors may not be correct; the risk that we may not be able to maintain our recent levels of profitability; the risk that the Company may not realize the anticipated benefits of its strategic activities; risks related to the integration of acquisition targets; the acceleration or deceleration of product growth rates; risks related to product demand and market acceptance of the Company’s products and pricing; the risk that a recall of our products could result in significant costs or negative publicity; and the risk that the Company is not successful in transitioning to a direct-selling model in new territories.

The following discussion should be read in conjunction with our consolidated financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings.

Unless the context indicates otherwise, references to “LeMaitre Vascular,” “LeMaitre,” “we,” “our,” and “us” in this Annual Report on Form 10-K refer to LeMaitre Vascular, Inc. and its subsidiaries.

LeMaitre, AlboGraft, AnastoClip, AnastoClip GC, Artegraft, Cardial, CardioCel, Eze-Sit, Glow ‘N Tell, LeverEdge, LifeSpan, ProCol, Pruitt, Pruitt F3, RestoreFlow, TufTex, VasculCel, VasculTape, and XenoSure are registered trademarks of LeMaitre Vascular or one of its subsidiaries, and Chevalier, DuraSure, Flexcel, Omniflow, PeriVu and Syntel are trademarks of LeMaitre Vascular. This Annual Report on Form 10-K also includes the registered and unregistered trademarks of other persons, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or TM symbols.

Item 1. Business

Overview

LeMaitre Vascular is a global provider of medical devices and human tissue cryopreservation services largely used in the treatment of peripheral vascular disease, end-stage renal disease, and to a lesser extent cardiovascular disease. We develop, manufacture, and market devices to address the needs of vascular surgeons and, to a lesser degree, other specialties such as cardiac surgeons, general surgeons and neurosurgeons. Our diversified portfolio of devices consists of brand name products that are used in arteries and veins and are well known to vascular surgeons. Our principal product offerings are sold globally, primarily in the United States, Europe, Canada and Asia Pacific. We estimate that the annual worldwide market for peripheral vascular devices exceeds \$5 billion, within which we estimate that the market for our products is approximately \$800 million.

We sell our products and services primarily through a direct sales force. As of December 31, 2023, our sales force comprised 136 sales representatives in North America, Europe and Asia Pacific, including three export managers. Our worldwide headquarters is located in Burlington, Massachusetts, and we also have North American sales offices in Chandler, Arizona and Vaughan, Canada. Our European headquarters is located in Sulzbach, Germany, and we also have European sales offices in Milan, Italy; Madrid, Spain; Hereford, England; and Dublin, Ireland. Our Asia Pacific headquarters is located in Singapore, and we also have Asia Pacific sales offices in Tokyo, Japan; Shanghai, China; Kensington, Australia; Seoul, Korea; and Bangkok, Thailand. During the year ended December 31, 2023, approximately 96% of our net sales were generated in territories in which we employ direct sales representatives. We also sell our products in other countries through distributors.

The Peripheral Vascular Disease Market

Based on industry statistics, we estimate that peripheral vascular disease affects more than 200 million people worldwide and that the annual worldwide market for all peripheral vascular devices exceeds \$5 billion. The disease encompasses a number of conditions in which the arteries or veins that carry blood to or from the legs, arms, or organs other than the heart become narrowed, obstructed, weakened, or otherwise compromised. In many cases peripheral vascular disease goes undetected, sometimes leading to life-threatening events (including stroke, ruptured aneurysm, and pulmonary embolism) or death. Clinical studies have identified several factors that increase the risk of peripheral vascular disease, including smoking, diabetes, obesity, high blood pressure, lack of exercise, coronary artery disease, high cholesterol, and being over the age of 65. Demographic trends suggest an increase in the prevalence of peripheral vascular disease over time, driven primarily by rising levels of obesity and diabetes and an aging population. We believe that our strong brands, established sales force, suite of peripheral vascular device offerings, and broad network of vascular surgeon customers position us to capture an increasing share of this market.

Vascular surgeons treat peripheral vascular disease and perform vascular procedures associated with other diseases, such as end-stage renal disease. We estimate that there are more than 22,000 vascular surgeons worldwide. In contrast to other specialists, such as interventional cardiologists and interventional radiologists, vascular surgeons perform both open vascular surgeries and endovascular procedures. Open vascular surgery involves opening the body, cutting vessels, and suturing. Endovascular procedures typically are minimally invasive, catheter-based, and treat vessels from within using real-time imaging. We estimate that in 2023, over 95% of our net sales were from devices used in open surgical procedures.

Our Business Strategies

We have grown our business by using a three-pronged strategy: 1) pursuing a focused call point, 2) competing for sales of low-rivalry, niche products, and 3) expanding our worldwide direct sales force while acquiring complementary devices. We have used acquisitions as a primary means of further penetrating the peripheral vascular device market, and we expect to continue this strategy in the future. We currently manufacture most of our products in our Burlington, Massachusetts headquarters.

- ***Focused call point.*** We have historically directed our product offering and selling efforts towards the vascular surgeon, and estimate that in 2023 approximately 80% of our sales were from devices and cryopreserved tissue used by vascular surgeons. As vascular surgeons typically perform both open vascular surgeries and endovascular procedures, we sell devices in both the open and endovascular markets to the same end user. More recently we have begun to focus on adjacent market end users, such as cardiac surgeons, who can be served by our devices and tissue processing capabilities.
- ***Low rivalry niche segments.*** We seek to build and maintain leading positions in niche segments, which we define as under \$250 million in annual worldwide revenue. We believe that the relative lack of focus on these segments by larger competitors, as well as the differentiated features and consistent quality of our products, enable higher selling prices and market share gains.
- ***Direct sales force expansion and the addition of complementary products.*** We sell our products primarily through a direct sales force in North America, Europe and Asia Pacific. We ended 2023 with 136 direct sales representatives, including three export managers. We believe that direct-to-hospital sales build closer customer relationships, allow for higher selling prices and gross margins, and are not subject to the risk of customer loss related to distributor turnover. In countries where we do not have a direct sales force, we sell our products through distributors. For the year ended December 31, 2023, approximately 96% of our net sales were generated through our direct-to-hospital sales force, and no single hospital customer accounted for more than 2% of our net sales. We intend to further expand and diversify our product offerings and add new technology platforms, mostly

through acquisitions. We believe our experience acquiring and integrating product lines and businesses is one of our competitive advantages. We continually evaluate the acquisition of additional product lines and businesses that may be complementary to our product offerings, refine our current product lines or develop new applications for our existing technologies. We also obtain regulatory approvals for our devices and services in new segments and geographies in order to further access the broader peripheral vascular device market and select other markets.

Acquisition History

We were founded in 1983 by George D. LeMaitre, M.D., a vascular surgeon who designed and developed the LeMaitre Valvulotome. Through a combination of 24 complementary acquisitions as well as research and development, we have expanded to 16 product lines, which include 13 different product types:

Year	Acquisition	Key Product(s) and Services
1998	VascuTape	Radiopaque tape manufacturing operations
1999	TufTex	Embolectomy catheters
2001	Pruitt F3 Shunt	Carotid shunts, balloon catheters, and laparoscopic cholecystectomy devices
2003	Credent	Polycarbonate grafts
2004	AnastoClip	Vessel closure systems
2005	Endomed	Stent grafts
2007	LeverEdge	Contrast injector
2007	MollRing Cutter	Remote endarterectomy devices
2007	UnBalloon	Stent graft modeling catheters
2007	AlboGraft	Polyester grafts and patches
2010	LifeSpan	ePTFE grafts
2012	XenoSure	Biologic patches
2013	Pruitt F3-S Shunt	Carotid shunts and embolectomy catheters
2013	TRIVEX	Powered phlebectomy system
2014	Omniflow II	Biosynthetic grafts
2014	PeriVu	Angioscopes
2015	Eze-Sit OUS	Valve cutters
2016	ProCol	Biologic grafts
2016	RestoreFlow	Human tissue cryopreservation services
2018	Syntel	Embolectomy catheters
2018	Cardial	Polyester grafts, valve cutters, surgical glue
2019	Eze-Sit US	Valve cutters
2019	CardioCel	Biologic patches
2020	Artegraft	Biologic grafts

We manufacture most of our devices in-house, having fully relocated the manufacturing operations of 21 of our 24 acquisitions to our Burlington, Massachusetts headquarters. The human tissue processing and cryopreservation operations associated with RestoreFlow allografts occurs in our Fox River Grove, Illinois facility. Artegraft biologic graft production takes place in our North Brunswick, New Jersey facility. On a limited basis, we use third-party manufacturers, and we currently purchase our CardioCel and VascuCel patches from Anteris Technologies Ltd (Anteris, formerly Admedus Ltd) in Malaga, Australia. During 2022, we began the process of relocating the production of CardioCel and VascuCel patches to Burlington.

Our Products and Services

Our portfolio of product lines is primarily used to treat vascular disease, of which most are used in open vascular surgery and dialysis access. We also offer human vascular and cardiac tissue cryopreservation services. No single product line accounted for more than 20% of our revenues in 2023, 2022 or 2021.

Our product offerings include a suite of biologic products. These offerings include the XenoSure patch (bovine pericardium), CardioCel and VascuCel patches (bovine pericardium), Artegraft (bovine carotid artery), Omniflow II biosynthetic graft (ovine tissue and synthetic mesh), RestoreFlow allograft cryopreservation services (human cadaveric tissue), and cardiovascular patches (porcine extracellular matrix) that we distribute for Elutia Inc. (Elutia, formerly Aziyo Biologics, Inc.). These biologic offerings represented 51% of our sales in 2023, 49% of our sales in 2022, and 48% of our sales in 2021.

Allografts

Through our RestoreFlow allograft business, we provide human cadaver tissue cryopreservation services, in particular the processing and cryopreservation of veins, arteries and cardiac valved conduits. Our RestoreFlow allografts are cryopreserved human tissue grafts, including saphenous veins, femoral veins and arteries, aorta and iliac arteries, aortic and pulmonary valved conduits and pulmonary patches. These allografts are used in a variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections, as well as in cardiac repair and reconstruction.

Angioscopes

Our PeriVu disposable angioscope is a fiberoptic catheter used for viewing the lumen of a blood vessel. PeriVu also provides direct visualization of valves during in-situ bypass procedures.

Balloon Catheters for Embolectomy and Thrombectomy

Our TufTex and Syntel lines of embolectomy catheters are used to remove blood clots from arteries. We sell single-lumen latex and latex-free embolectomy catheters, as well as dual-lumen latex and latex-free embolectomy catheters. The dual-lumen embolectomy catheters enable clot removal and simultaneous irrigation or guide-wire trackability. Our Syntel thrombectomy catheter features a silicone balloon and is designed for removing thrombi in the venous system.

Balloon Catheters for Occlusion and Perfusion

Our occlusion catheters temporarily occlude blood flow to allow the surgeon time and space to complete a procedure. Perfusion catheters perfuse blood and other fluids into the vasculature. Our Pruitt line of occlusion and perfusion catheters reduces vessel trauma by using internal balloon fixation rather than traditional external clamping.

Bovine Grafts

Our Artegraft biologic graft is a bovine carotid artery used for dialysis access. Its biological fibrous matrix is processed to enhance long-term patency and provide a tightly woven, cross-linked conduit that is flexible and compliant. Artegraft is also indicated for lower extremity bypass.

Vascular and Cardiac Patches

Our XenoSure biologic patches are made from bovine pericardium and are used primarily for closure of vessels after surgical intervention.

Our VascuCel and CardioCel biologic patches are acellular, collagen bioscaffolds with optimized biocompatibility and zero aldehyde toxicity. These bovine pericardium patches are used in vessel repair as well as heart repair and reconstruction, including neonatal repairs.

The cardiovascular patches that we distribute for Elutia are made of an extracellular matrix designed to decrease inflammation and stimulate the formation of healthy tissue. These porcine patches are used in heart repair as well as vessel repair and reconstruction, including neonatal repairs.

Carotid Shunts

Our Pruitt F3 and Flexcel carotid shunts are used to temporarily shunt blood to the brain while the surgeon removes plaque during carotid endarterectomy surgery. Our Pruitt F3 shunt features internal balloon fixation. Our Flexcel shunt is a non-balloon shunt offered for surgeons who prefer external fixation.

Closure Systems

Our AnastoClip AC and AnastoClip GC closure systems attach vessels to one another with titanium clips instead of sutures. These closure systems create an interrupted anastomosis that expands and contracts as the vessel pulses, which some surgeons believe improves the durability of the anastomosis. The AnastoClip AC and AnastoClip GC closure systems also enable dura closure in neuro applications.

Ovine Vascular Grafts

Our Omniflow II biosynthetic vascular graft is a composite of cross-linked ovine collagen with a polyester mesh endoskeleton. It is indicated for lower extremity bypass and dialysis access.

Polyester Vascular Grafts

Our AlboGraft and Cardial vascular grafts are collagen-impregnated polyester woven and knitted grafts used to bypass or replace diseased arteries. These prostheses are available in straight tube and bifurcated versions.

ePTFE Vascular Grafts

Our LifeSpan vascular graft is an expanded polytetrafluoroethylene (ePTFE) graft used to bypass or replace diseased arteries and to create dialysis access sites. LifeSpan is available in both regular and thin wall options with optional full or partial external spiral support. Our stepped and tapered LifeSpan grafts are designed to reduce the risk of steal syndrome and high cardiac output, complications that sometimes arise in dialysis access grafts.

Radiopaque Tape

Our VascuTape radiopaque tape is a flexible, medical-grade tape with centimeter or millimeter markings printed with a proprietary radiopaque ink which is visible to the eye and an x-ray machine or fluoroscope. VascuTape is applied to the skin and provides surgeons and interventionalists with a simple way to cross-reference between the inside and the outside of a patient's body, allowing them to locate tributaries or lesions beneath the skin.

Valvulotomes

Our valvulotomes cut or disrupt valves in the saphenous vein, a vein that runs from the foot to the groin, so the vein can be repurposed as an artery to carry blood past diseased arteries to the lower leg or foot. We believe our valvulotomes reduce costs for hospitals by enabling lower extremity bypass surgery to be performed with several small incisions rather than one continuous ankle-to-groin incision, thereby reducing hospital stays and the likelihood of wound complications.

Sales and Marketing

As of December 31, 2023, we employed 136 sales representatives, including three export managers. We believe the expansion of our sales force has been a key success factor and it remains one of our primary long-term strategies. Approximately 96% of 2023 net sales occurred in territories in which we employ sales representatives. Outside our direct markets, we generally sell our products through country-specific distributors.

Our marketing efforts include direct mail, digital marketing and exhibitions at medical congresses, which we believe are important to our brand development. We believe that marketing allows us to connect with vascular surgeons who are beyond the reach of our direct sales force and also reinforces our brand recognition and product offering to current customers.

We also provide training to our vascular surgeons on specific procedures including in situ bypass, carotid endarterectomy and interrupted anastomosis, as well as a general surgical skills training program targeting less-experienced doctors as a way to introduce them to our product offerings.

Research and Development

Our research and development efforts are comprised of regulatory and clinical work, process engineering, manufacturing transfers and product development. More recently, we have focused our research and development efforts on cardiac allograft and next-generation powered phlebectomy projects, as well as manufacturing transfers and significant process engineering changes aimed at increasing our gross margin. In 2022 we completed the relocation work for the Omniflow II product line and were granted approval to market devices manufactured in Burlington in the European Union (EU). Transfer activities around this product line concluded in 2023. The CardioCel and VascuCel transfer to Burlington is now substantially complete and we have applied for CE marking. Additionally, we will begin marketing the CardioCel and VascuCel devices made in Burlington in the U.S., Canada and portions of Asia Pacific in the first half of 2024.

We often use feedback received from independent physicians to demonstrate product functionality before commencing full-scale marketing of any product. To this end, we will initiate the Limited Market Release (LMR) of the next-generation powered phlebectomy device, PhasTIPP, in the U.S. in the first half of 2024.

Separately, in 2022 we began the review and update of the manufacturing process of the Artegraft product line in an effort to apply for its European Medical Device Regulation (2017/745) (MDR) CE Mark. The “Artegraft MDR Readiness” project was considered a high-priority project in 2023 and the CE Mark was applied for in December 2023. We do not anticipate approval to market in the EU until the second half of 2025. We will pursue approvals for allograft preservation services in other European markets in 2024 and 2025. For example, we made applications in 2023 to the Irish and German health authorities seeking approval to import and sell our allograft preservation services in these geographies.

Our regulatory and clinical efforts have historically been focused on obtaining and maintaining regulatory approvals in various geographies. In the past, we have typically not conducted clinical trials as we have usually acquired product lines with established regulatory approvals. In addition, we preferred to avoid the time, expense and risk associated with initiating clinical trials. However, increasing regulatory requirements in many geographies have resulted in the need for more clinical testing. As such, this component of our research and development spending has increased in recent years. In 2017, we initiated clinical trials in an effort to obtain the approval of our XenoSure patch in China for cardiac and vascular indications. We have completed enrollment of the trials and submitted the cardiac license application in June 2022. We expect to make our vascular submission to the Chinese National Medical Products Administration (NMPA) in 2024. In 2021 we also entered into an agreement with Anteris to assume primary responsibility for the post-market clinical follow-up studies of our CardioCel and VasculCel products.

In 2017 the European Union (EU) adopted MDR, which replaced the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC) (MDD) and became effective as of May 26, 2021. After this date, our MDD certificates then in effect remained valid until their expiration dates, which ranged from August 2023 to May 2024. The full application of the MDR was subsequently extended by the European Commission, allowing our products’ certificates to remain valid until 2027 and 2028, depending on their classifications. Our products will eventually be subject to the MDR, which require all of our products, regardless of classification, to obtain a new CE mark in accordance with the new, more stringent, standards. Going forward, we expect a significant portion of our regulatory and clinical time and expenses to be devoted to this transition. In 2023, we received MDR CE marks for our Pruitt F3 Shunt, Flexcel Shunt, and our XenoSure pericardial patch. See —“Government Regulation” below for more information about the status of our MDD certificates.

Manufacturing and Processing

Our primary manufacturing facilities are located in Burlington, Massachusetts. We also have facilities in North Brunswick, New Jersey where Artegraft is produced, and Fox River Grove, Illinois where RestoreFlow allografts are processed.

Our strategy is to transfer the manufacturing of most acquired product lines into our Burlington operations. In 2019, we expanded our biologic cleanroom, and in 2020, we began the manufacturing transfer of Omniflow II in this new cleanroom. In 2019, we leased a fifth Burlington building and relocated substantially all of our administrative functions into this building so we could expand our manufacturing footprint. In 2020, we completed the transfer of the Syntel embolectomy business into Burlington. In 2021, we completed the construction of an additional biologic cleanroom for the manufacturing of CardioCel and VasculCel. In 2022, we expanded the footprint of our main Burlington cleanroom and raw materials warehouse by approximately 40% in an effort to accommodate increased production and the 2021 and 2022 direct labor hiring surge. In 2023, we substantially completed the transfer of our manufacturing of CardioCel and VasculCel. We believe these cleanroom expansions and product transfers will improve working efficiency for our operations staff.

We manufacture certain proprietary components, assemble most of our devices ourselves, and inspect, test, and package all of our finished products. By manufacturing products from raw materials and assembling and testing as many of our products as practical, we believe we can maintain better quality control, ensure compliance with applicable regulatory standards, limit outside access to our proprietary technology, ensure adequate product supply, and make design modifications quickly. We have custom-designed proprietary manufacturing and processing equipment and have developed proprietary enhancements for existing production machinery. Our products are built to stock.

We process and cryopreserve human tissue provided to us by qualified U.S. tissue procurement organizations. Donated human tissue is procured from deceased donors by these organizations. We have strict specifications relating to the physical condition and characteristics of the tissue and donor, as well as the donors’ medical history.

Our management information systems provide us with the ability to evaluate our performance, collect business intelligence, and make better strategic decisions. These systems include customer relationship management, order entry, invoicing, on-line inventory management, lot traceability, purchasing, shop floor control, shipping and distribution analysis, as well as various accounting-oriented functions. These systems enable us to track our products from order inception to manufacturing and then to delivery to our customers.

We purchase certain components from, and have certain product lines manufactured by, third parties. Most of our components are readily available from several supply sources, but we do rely on single- and limited-source suppliers for several key components or products, most notably the purchase of CardioCel and VasculCel devices from Anteris in Malaga, Australia. While we do have a contractual arrangement with Anteris, we do not have contractual arrangements with many suppliers and manufacturers, and we order supplies and products as-needed. There are relatively few, or in some cases no, alternative, validated sources for some supplies, products or components. At any time, our suppliers could discontinue or become incapable of manufacturing these materials on acceptable terms. Identifying and qualifying additional or replacement suppliers, if required, may not be accomplished quickly or at all and could involve significant costs. To date, we have not experienced any significant supply disruptions.

Quality Assurance

Our Burlington and North Brunswick manufacturing facilities have been certified to ISO 13485 standards, which enables us to provide high-quality products and satisfy regulatory requirements of the EU, Canada, and other foreign jurisdictions. Our Fox River Grove, Illinois facility has been accredited by the American Association of Tissue Banks for the processing, storage and distribution of cardiac and vascular tissue for transplantation. All of our manufacturing and processing facilities are subject to periodic inspections by various regulatory authorities and Notified Bodies to ensure compliance with regulatory requirements. See “Government Regulation” for further information. During 2023, we underwent seven regulatory audits and eighteen internal audits. There were no material findings. During this same period, we had one class II recall in Europe that was related to a manufacturing process and one class 3 recall in the U.S. related to a supply process. Neither recall involved a patient injury.

Competition

The segments in which we compete are characterized by periodic change resulting from technological advances and scientific discoveries. No one company competes against all of our product lines; rather, we compete with a range of companies. Notable larger competitors include Abbott, Baxter International, Inc., Artivion, Becton, Dickinson and Company, Edwards Lifesciences Corporation, Getinge, LifeNet Health, Silk Road Medical, Terumo Medical Corporation, and W. L. Gore & Associates.

Many of our competitors have substantially greater financial, technological, research and development, regulatory, marketing, sales, and personnel resources than we do. Certain competitors are able to manufacture at lower costs and may therefore offer their products at lower prices, especially products such as polyester and ePTFE vascular grafts. Certain competitors may also have greater experience in developing and improving products, obtaining regulatory approvals, and manufacturing and marketing such products. In the case of allografts, certain competitors may have an advantage in sourcing tissue. Additionally, some of our competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization before us, which could adversely affect our business.

The success of our products relies on effective in-person support as well as superior technology, quality, availability, reliability, ease of use, cost-effectiveness, physician familiarity, and brand recognition. While we also compete on the basis of price, our more technologically advanced products are often sold at higher prices. Our continued success may depend on our ability to broaden and optimize our direct sales channel, acquire complementary vascular devices, obtain regulatory and reimbursement approvals, maintain sufficient inventory, and retain skilled personnel.

We also compete on the basis of procedure type. The treatment of peripheral vascular disease has experienced a shift from open vascular surgery towards minimally invasive endovascular procedures, and most of our products are used primarily in open vascular surgery. Thus, our ability to compete effectively relies on keeping pace with product offerings in the vascular device market, as well as in the minimally invasive endovascular market.

Our products are used to treat cardiovascular disease, renal disease, diabetes and other related illnesses. The market for our products and services is competitive and affected by new product introductions and activities of other industry participants, including the introduction of novel products and therapies. Therapies like the recently introduced glucagon-like peptide 1 (GLP-1) drugs, have suggested that this class of drugs may lead to long term weight loss. This could decrease

the size of our addressable market and reduce our sales. Despite the high cost, inconvenient delivery method (injection) and potential side effects, there is no guarantee that GLP-1's will not adversely affect our business.

Intellectual Property

We believe that our success is dependent, to a certain extent, on our development and maintenance of proprietary technologies. We rely on a combination of trade secret laws, patents, trademarks and confidentiality to protect our intellectual property rights.

We maintain a limited portfolio of patents in the U.S., and our issued U.S. patents are set to expire through 2031.

We believe that our brands have also been an important factor in our success. We rely on common law and registered trademarks to protect our brands. Some of our registered trademarks include LeMaitre, Artegraft, XenoSure, Pruitt, VascuTape, Glow 'N Tell and RestoreFlow, each of which is registered in the U.S., the EU, or both, and in certain cases in other foreign countries.

Most of our products are not protected by patents. Patent protection is not available when we acquire a commercialized product that is not patented, such as the Artegraft biologic graft. In the past, other companies have independently developed or otherwise acquired comparable or substantially equivalent proprietary information and techniques, and there can be no assurance that others will not do so in the future. We require employees and consultants to sign confidentiality agreements. These confidentiality agreements require employees to assign to us all rights to any inventions made or conceived during their employment with us. We also generally require our consultants to assign to us any inventions made during their engagement. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies.

The laws of foreign countries often do not protect our proprietary rights to the same extent as do U.S. laws and we may experience more difficulty enforcing our proprietary rights in certain foreign jurisdictions.

See "Item 1A. Risk Factors" for a description of certain risks associated with our intellectual property.

Government Regulation

Medical devices and human tissues are subject to regulation by the U.S. FDA and other federal and state authorities and foreign governments.

U.S. Regulation of Medical Devices

Most of our products are medical devices subject to extensive regulation by the FDA under 21 U.S. Code Chapter 9, the Federal Food, Drug, and Cosmetic Act (the FDCA). FDA regulations govern, among other things, product development, testing, manufacturing, packaging, labeling, storage, clearance or approval, advertising and promotion, sales and distribution, and import and export.

Premarket Pathways

Most medical devices must receive either 510(k) clearance or Premarket Application approval (PMA approval) from the FDA prior to commercial distribution. Devices deemed to pose relatively less risk are placed in either Class I or II, which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Some low-risk devices are exempted from this requirement. Class II devices may be subject to special controls, such as performance standards and FDA guidelines that are not applied to Class I devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices deemed not substantially equivalent to a previously 510(k)-cleared device or to a pre-amendment Class III device (*i.e.*, one in commercial distribution before May 28, 1976) for which PMA applications have not been called, are placed in Class III, which generally requires PMA approval. In all cases, a user fee is required for 510(k) submissions and PMA applications.

510(k) Clearance. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and performance to a "predicate device" (*i.e.*, a previously 510(k)-cleared Class I or Class II device or a pre-amendment Class III device). The FDA's 510(k) clearance pathway usually takes from three to 12 months. In reviewing a 510(k) clearance, the FDA may request additional information, including clinical data. Nearly all of our devices sold in the U.S. have 510(k) clearance, with the exception of our Artegraft biologic vascular graft.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change as specified by FDA guidelines, requires a new 510(k) clearance. The FDA requires each manufacturer to make this determination, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may require a new 510(k) clearance. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance is obtained.

PMA Approval. The PMA approval pathway requires proof of the safety and effectiveness of the proposed device to the FDA's satisfaction, making this pathway more costly, lengthy, and uncertain. A PMA application must provide preclinical and clinical trial data, as well as information about the device and its components regarding device design, manufacturing, and labeling. As part of the PMA review, the FDA will often inspect the manufacturer's facilities for compliance with the Quality System Regulation (QSR).

If the FDA approves a PMA, the approved indications or claims may be more limited than those sought. The PMA can include post-approval conditions to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale, and distribution. The FDA may also impose requirements for post-market studies or registries. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement can be required if the device or its labeling or manufacturing process are modified. Supplements to a PMA can require the submission of the same type of information required for an original PMA, though the supplement is generally limited to that information needed to support the proposed change.

Clinical Trials. A clinical trial is typically required to support a PMA application and is sometimes required to support 510(k) clearance. In some cases, smaller feasibility studies may precede a more comprehensive, pivotal Investigational Device Exemption (IDE) clinical trial. All clinical studies of investigational devices must be conducted in compliance with the FDA's requirements. If an investigational device could pose a significant risk to patients, the FDA must approve an IDE application. A non-significant risk device does not require an IDE submission. Both significant risk and non-significant risk investigational devices require approval from institutional review boards (IRBs) at the study centers. The FDA and the IRB may suspend a clinical trial at any time. During a study, the investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record-keeping requirements.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that FDA may impose with respect to manufacturing.

Historically, our devices have been introduced into the U.S. market using 510(k) clearance. We have not used the PMA process for any products that we currently market or sell in the U.S., other than our Artegraft vascular grafts, which had PMA approval at the time of acquisition.

Postmarket Regulation

After a device is placed on the market, regardless of the classification or premarket pathway, significant regulatory requirements apply, including:

- annual manufacturing establishment registration and device listing with the FDA;
- QSR compliance, which requires finished device manufacturers and contract manufacturers to follow design, testing, control, documentation, and other quality assurance procedures;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label uses and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA any field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. The most recent FDA inspection of our Burlington facility was in May 2023, the results of which yielded one observation that was subsequently addressed. Non-compliance with FDA requirements can result in, among other things, public warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the FDA to grant marketing approvals, withdrawal of marketing approvals, and criminal prosecutions. In the event that one of our suppliers fails to maintain compliance with our quality requirements as described above, we may have to qualify a new supplier and could experience manufacturing delays.

We participate in the Medical Device Single Audit Program (MDSAP), which allows manufacturers to undergo a universal quality system audit that is accepted in the U.S., Japan, Australia, Canada and Brazil in lieu of individual audits by each regulator. Maintenance of this certification is a requirement to maintain sales in certain geographies including Canada. Failure to maintain this certification in good standing could result in suspension of our sales efforts in Canada or the other geographies. Our last MDSAP audit was in July 2023 and the audit results were deemed satisfactory by SGS, our notified body.

International sales of medical devices manufactured in the U.S. that are not approved or cleared by the FDA are subject to FDA export requirements. Before exporting unapproved products to a foreign country, we must comply with the FDA's exporting procedures.

International Regulation of Medical Devices

Sales of medical devices are subject to regulatory requirements in many countries. The regulatory review process may vary from country to country. The EU has adopted numerous directives and standards relating to medical devices regulating their design, manufacture, clinical trials, labeling, and adverse event reporting, including the MDD, and more recently, the MDR. Devices that comply with the requirements of the MDD or MDR are entitled to bear a CE mark and can be distributed in EU countries, as well as the United Kingdom (UK), Iceland, Lichtenstein, Norway, Turkey and Switzerland. Each member state of the EU has established a "Competent Authority" to apply the directive/regulations in its territory.

In April 2017, the EU adopted the new MDR regulations for medical devices, which replace the MDD, and which took effect as of May 26, 2021, with a transition period ending respectively in 2027 and 2028 for most Class II and Class III devices. Our products are subject to the MDR, which requires all of our products, regardless of classification, to obtain a new CE mark in accordance with the new, more stringent, standards under the MDR. As a condition to CE mark approval, clinical evidence from clinical investigations will be required for Class III and implantable devices. As our Notified Bodies continue their transition from MDD to MDR, they have begun to enforce these more rigorous requirements on us in order to maintain the CE marks on certain of our products. If we fail to obtain new CE marks on any of our other products under the MDR in a timely manner, or at all, future sales of our products in the EU could be adversely impacted. In January 2023, we received our first CE marking under the MDR for our Pruitt F3 Shunt, and in November 2023 we received marks for the XenoSure and Flexcel devices. The MDD CE Marks for our CardioCel and VasculCel products were set to expire in August 2023, but have been subsequently extended until May 2028. We currently have a supply agreement with Anteris to continue supplying products through January 2025, at which time we expect to transition to our Burlington facility to supply the product. We have submitted our MDR application in June 2023 for the Burlington manufactured version of these products and expect approval in 18-24 months. If we fail to obtain MDR CE marking or experience significant delays, our European sales of CardioCel and VasculCel could be adversely impacted.

The MDD and MDR define the essential requirements that devices must meet before being placed on the market, establish procedures for approving a device, and create directives for Competent Authorities. Essential requirements include manufacturing, design, performance, labeling, and safety requirements, and may include providing certain clinical data.

A manufacturer of low-risk devices typically may demonstrate conformity based on a self-declaration. The European Standardization Committees have adopted numerous harmonized standards for specific types of medical devices. Compliance with relevant standards establishes a presumption of conformity with the essential requirements. Manufacturers of higher-risk devices generally must use a "Notified Body"—an appointed independent third party—to assess conformity. This third-party assessment may consist of an audit of the manufacturer's quality system and testing of the manufacturer's devices. An assessment by a Notified Body in one country within the EU is generally required in order to commercially distribute the product. Most of our devices are considered higher-risk devices that require Notified Body assessment.

The MDD and MDR also address advertising and promotion of medical devices, clinical investigations, and requirements for handling adverse events. Post-market surveillance of medical devices is generally conducted on a country-by-country basis; however, the MDD and MDR set forth certain requirements for reporting adverse events. The Medical Device Vigilance system is the mechanism by which adverse event reporting is managed and monitored in the EU.

The UK left the EU on January 31, 2020, commonly referred to as “Brexit”. We opened our Hereford, England office in 2019 largely in response to Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020. After December 31, 2020, medical device manufacturers wishing to import their devices into the UK were provided a transition period for registration of their devices until the end of 2021. We have complied with this deadline and all of our CE marks continue to be recognized in the UK. The UK Medicines and Healthcare Products Regulatory Agency (“MHRA”) subsequently announced that CE marking will continue to be recognized in the UK and certificates issued by EU-recognized notified bodies will continue to be valid in the UK market until 2027 and 2028, in alignment with the MDR transition. After this time, all devices marketed in the UK will require UK Conformity Assessed (“UKCA”) Marks certified by a UK Approved Body. If we fail to obtain UKCA conformity our sales in the UK could be negatively affected. In January 2023 we received our first UKCA mark for the Pruitt F3 Shunt, and in November 2023 we received our second and third UKCA marks for XenoSure and Flexcel.

If our products prove to be defective, we can voluntarily recall, or the FDA or international equivalent could require us to recall. If someone is harmed by a malfunction or a product defect, we may experience product liability claims. Any corrective action, voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital. Future recalls or claims could also result in significant costs and adverse publicity.

In some cases, we rely on international distributors or third-party agents to obtain premarket approvals and complete product registrations. In the future, we expect to continue to rely on distributors and agents in this manner where appropriate.

Canada regulates medical devices through Health Canada (HC). HC classifies medical devices into four classifications, with Class I being the lowest risk. Class I and II devices are often cleared for sale after they are CE marked or listed on the company’s ISO certification and filed via fax-back applications. Higher risk devices (Class III and IV) require dossiers that resemble United States 510(k) applications. As a holder of Canadian device licenses, we are subject to inspection by HC at our Vaughan, Canada office, and we must maintain a valid MDSAP certificate. Our Vaughan, Canada office was most recently inspected in August 2017, the results of which were satisfactory. Our Burlington office was most recently audited under the MDSAP in July 2023, the results of which were satisfactory.

In Japan, the Ministry of Health, Labor and Welfare (MHLW) regulates medical devices through the Pharmaceutical Affairs Law. As a holder of Japanese device licenses, we are also subject to inspection by several Japanese authorities including Japan’s Pharmaceutical and Medical Device Agency (PMDA), Tokyo Metropolitan Government (TMG), and third parties such as Japan’s Electrical Safety & Environmental Technologies Laboratories (JET). Our Tokyo office was most recently inspected by JET in March 2023, the results of which were satisfactory.

Australia regulates the import and sale of medical devices through the Therapeutic Goods Administration (TGA). The TGA has built its regulatory framework around requirements similar to Europe. As such, lower risk medical devices may gain marketing clearance using their existing EU-issued CE marking. Higher risk devices must go through a design review which can be costly and take longer. Issued licenses for medical devices do not require renewal, but do require an annual fee to remain active. As a holder of Australian device licenses, we are also subject to inspection by TGA in both Australia and the U.S. Our North Melbourne facility, where we previously manufactured our Omniflow II graft, was inspected by TGA in December 2018, and our Burlington facility was inspected in July 2023 under the MDSAP, the results of both inspections were satisfactory. Australia requires all foreign manufacturers to have an in country ‘sponsor’ who must have a licensed business inside Australia. Our licenses are managed by our sponsor, Emergo Group.

In China, the National Medical Products Administration (NMPA) regulates and approves all medical devices. China has a three-class risk classification system, with Class I being the lowest. Home country approval, such as 510(k) or PMA clearance, is required as a prerequisite. Additionally, the NMPA often tests devices at its own testing laboratory. The approval process is lengthy and usually requires clinical trials. NMPA licenses are valid for five years and require renewal. As a holder of Chinese device licenses, we are subject to inspection by NMPA in both China and the U.S. Our Shanghai offices were inspected by NMPA in August 2018, the results of which were satisfactory. The NMPA requires all companies located outside of China to appoint a legal entity who maintains a registered business inside of China as the license holder. After forming our Chinese subsidiary in 2015, we transferred our licenses from the third-party license holders to our subsidiary.

U.S. Regulation of Human Tissue

FDA

Our allografts are subject to extensive regulation by the FDA under Title 21 of the Code of Federal Regulations, Part 1271 (Human Cells, Tissues, and Cellular and Tissue-Based Products). These regulations were promulgated under Section 361 of the Public Health Service Act, which authorized the FDA to issue regulations to prevent the spread of communicable disease. Under these regulations, the FDA requires registration of establishments that process human cells, tissues, and cellular and tissue-based products. These FDA regulations also establish donor-eligibility criteria, current good tissue practice and other procedures to prevent the introduction, transmission, and spread of communicable diseases by such products, including through donor screening and testing. Our Fox River Grove, Illinois facility and our Chandler, Arizona facility are both registered with the FDA's Center for Biologics Evaluation and Research. The regulations also provide for FDA inspection of tissue establishments. The FDA most recently inspected our Fox River Grove, Illinois facility in April 2023 and the results were satisfactory.

AATB

We voluntarily comply with the standards of the tissue bank industry's accreditation organization, the American Association of Tissue Banks (the AATB). The AATB has established standards for tissue banking and administers an accreditation program. Accreditation must be renewed every three years. Our Fox River Grove, Illinois facility has been accredited by the AATB for the processing, storage and distribution of cardiac and vascular tissue for transplantation through May 13, 2024. The AATB is entitled to inspect members at any time. The AATB most recently inspected our Fox River Grove, Illinois facility in November 2023, and the results were satisfactory.

NOTA

Under the National Organ Transplant Act (NOTA), it is unlawful for any person or entity to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. However, "valuable consideration" excludes reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ. We believe the compensation we receive with respect to our allografts falls within this statutory exception.

State Regulation

Certain states regulate the processing, storage and distribution of human tissue. We are licensed or registered with California, Delaware, Florida, Illinois, Maryland, New York and Oregon. The regulatory agencies of these states may inspect our Fox River Grove, Illinois facility from time to time to monitor compliance with their regulations.

Other U.S. Regulations

Our products and services are subject to a variety of state and local laws in jurisdictions where our products and services are marketed or distributed. There are federal, state, and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous substances. We are subject to various federal and state laws governing our relationships with the physicians and others who purchase or make referrals for our products. For instance, federal law prohibits payments of any form that are intended to induce a referral for any item payable under Medicare, Medicaid, or any other federal healthcare program. Many states have similar laws. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations now or in the future, or that such laws or regulations will not have an adverse effect on our business.

We are subject to federal, state, and local laws, rules, regulations, and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling, and disposal of certain hazardous and potentially hazardous substances used in connection with our operations. Although we believe we have complied with these laws and regulations and have never been required to correct any noncompliance, there can be no assurance that we will not be required to comply with environmental regulations in the future.

International Regulation of Human Tissue

Sales of human tissues services outside the US are subject to international regulatory requirements that vary from country to country. Similar to medical devices, an approval to distribute tissue in the EU is first obtained from a member state that allows entry of the tissue onto the European market. Subsequent distribution to other member states is subject to varying registration requirements based on the state and local authorities in that country. In Canada, our allograft preservation services are regulated by Health Canada's Biologics and Genetic Therapies Directorate, Health Products and Food Branch. We received approval to market our allograft preservation services in Canada in 2017. In the UK, we are regulated by the Human Tissue Authority (HTA) and received approval to provide our allograft preservation services in 2022. Applications to UK and European states might also require an inspection of our facilities as well as our suppliers prior to approval. We made applications in 2023 to the Irish and German health authorities seeking approval to import and sell our allograft preservation services inside the European market. As a result of our applications, the German authority has inspected our Fox River Grove Facility and two of our tissue recovery partners.

Third-Party Reimbursement

United States

Healthcare providers that purchase medical devices generally rely on third-party payors, including the Medicare and Medicaid programs and private payors (such as indemnity insurers, employer group health insurance programs, and managed care plans) to reimburse all or part of the cost of those products. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. For example, Medicare reimbursement policies favor outpatient treatment. Furthermore, payments from Medicare, Medicaid, and other third-party payors are subject to legislative and regulatory changes and are susceptible to budgetary pressures.

In the U.S., third-party payors generally pay healthcare providers directly for the procedures they perform and in certain instances for the products they use. Our sales volumes depend on the extent to which third-party payors cover our products and the procedures in which they are used. In general, a third-party payor only covers a medical product or procedure when the plan administrator is satisfied that the product or procedure is medically necessary because it improves health outcomes, including quality of life or functional ability, in a safe and cost-effective manner. Even if a device has received clearance or approval for marketing by the FDA, there is no assurance that third-party payors will cover the cost of the device and related procedures in which the device is used.

In many instances, third-party payors cover the procedures performed using our products using price fee schedules that do not vary reimbursement to reflect the cost of the products and equipment used in performing those procedures. In other instances, payment or reimbursement is separately available for the products and equipment used, in addition to payment or reimbursement for the procedure itself. Even if coverage is available, third-party payors may place restrictions on the circumstances in which they provide coverage or may offer reimbursement that is not sufficient to cover the cost of our products.

In addition, many third-party payors are moving to managed care systems in which providers contract to provide comprehensive healthcare for a fixed cost per person rather than the traditional fee for service model. Managed care providers often attempt to control the cost of healthcare by authorizing fewer elective surgical procedures. Under current prospective payment systems, such as the diagnosis-related group system and the hospital out-patient prospective payment system, both of which are used by Medicare and in many managed care systems used by private third-party payors, the reimbursement for our products is incorporated into the overall reimbursement of a procedure, and there is no separate reimbursement for our products.

International

Our success in international markets will depend partly upon the availability of reimbursement from the third-party payors through which healthcare providers are paid in those markets. Reimbursement and healthcare payment systems in non-U.S. markets vary by country. The main types of healthcare payment systems are government-sponsored healthcare and private insurance. As in the U.S., reimbursement is subject to legislative and regulatory changes and budgetary pressures. Reimbursement approval must be obtained individually in each country. Outside the U.S., we may pursue reimbursement approval in countries where we sell directly to the hospital. In other markets, we generally rely on our distributors to obtain reimbursement approval.

U.S. Fraud and Abuse Laws

We may directly or indirectly be subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the U.S. federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment, and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General, or OIG, has issued a series of regulations, known as “safe harbors.” Safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy safe harbors may result in increased scrutiny by government enforcement authorities.

U.S. Patient Protection and Affordable Care Act

In March 2010, reforms to the U.S. healthcare system were adopted in the form of the Patient Protection and Affordable Care Act (the PPACA). Under the PPACA we are subject to the Open Payments Act, which requires detailed public disclosure of certain payments and “transfers of value” from us to healthcare professionals, such as the payment of royalties, compensation for services provided and reimbursement for travel and meal expenses. Certain states also require us to disclose similar information or even prohibit some forms of these payments.

Employees and Human Capital Management

We had 630 employees, including 614 full-time employees, at December 31, 2023. Our full-time employees are comprised functionally as follows: 332 manufacturing and operations, 183 sales and marketing, 57 general and administrative and 42 research and development. On a monthly basis we review (1) hiring needs, (2) the number of new hires, and (3) our voluntary turnover. In 2023, we increased our headcount by 23 full-time employees and our world-wide voluntary resignation rate was 7.1%.

Diversity and Inclusion

Our goal is to provide employees with a stimulating and rewarding work environment by emphasizing teamwork and decentralized decision-making. We are committed to providing equal employment and advancement opportunities to all individuals. We do not discriminate on the basis of race, color, religion, sex, national origin, age, disability, sexual orientation, gender identity, breastfeeding or related medical conditions, religious dress, military or veteran status or any other characteristic protected by law. This policy governs all aspects of employment. As of December 31, 2023, our global workforce was made up of approximately 50% female employees and approximately 38% of our Executive Committee is female. Our U.S. workforce was made up of approximately 62% of employees identifying as non-white, comprised of the following ethnic/racial affiliations: Asian (48.4%), Hispanic or Latino (8.2%), Black or African American (4.8%), two or more races (not Hispanic or Latino) (0.6%), Native Hawaiian or Other Pacific Islander (0.2%).

Compensation and Benefits

We believe in providing competitive pay and benefits. We use third-party benchmarks to help determine wages. Our compensation is designed to attract, retain, and motivate employees to achieve results while balancing short- and long-term company performance. We occasionally work with external benefits consultants to evaluate the quality, competitiveness, and cost of our benefit offerings to all employees annually. In 2023, we increased our employer medical benefits contribution for U.S. salaried employees from 60% to 70% following a similar increase for our U.S. hourly employees in 2022.

Customers

Our sales are not dependent on any single customer or distributor, and we continue to expand our distribution channel worldwide through direct sales representatives and independent distributors. No single customer accounted for more than 2% of our net sales in 2023.

Corporate Information

On October 19, 2006, we executed our initial public offering, and our common stock trades on The Nasdaq Global Market under the symbol “LMAT.” In January 2021 we changed our brand name from “LeMaitre Vascular” to “LeMaitre”. Our principal executive offices are located at 63 Second Avenue, Burlington, Massachusetts 01803, and our telephone number is (781) 221-2266. Our website address is www.lemaitre.com.

Where You Can Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through the investor relations portion of our website (www.lemaitre.com) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). The address of the SEC’s website is www.sec.gov. Information on our investor relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference, and you should not consider any information contained in, or that can be accessed through, our website as part of this Annual Report on Form 10-K. The SEC maintains an internet site that contains reports, proxy and information statements and other information. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless required to do so by law. In addition, our Corporate Governance Guidelines, Code of Business Conduct and Ethics and Charters of our Audit, Compensation and Nominating and Corporate Governance Committees are available on our website and are available in print to any stockholder who requests such information.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should consider the following information about the risks described below, together with the other information contained in this Report and in our other public filings in evaluating our business. The following factors, among others, could cause our actual operating results to differ materially from those indicated or suggested by forward-looking statements made in this Report or presented elsewhere by management. Investors should consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are not material may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

Risks Related to Our Business

We face external competition from other companies, technologies such as GLP-1’s, and alternative medical procedures and we may not be able to compete effectively.

Companies that may not be deemed competitors in the peripheral vascular device space may develop technologies, products or services that may impact the use of our products and services. For example, certain therapeutic treatments, such as drugs used to treat diabetes or weight loss such as GLP-1’s, may enhance patient health and lower the occurrence and severity of vascular disease. If we do not introduce new products, services and enhancements in a timely manner, there may be a decrease in the use of certain of our products and services, in which case our operating results could suffer.

The segments in which we primarily operate are also competitive, subject to change, and affected by new product introductions. Although no company competes against us in all of our products, a number of device manufacturers have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, larger research and development or regulatory staffs; have established reputations with our target customers; and have developed larger distribution channels than ours. Our competitors could elect to devote additional resources to the specific segments in which we operate. Also, although we currently have leading positions in the segments for some of our products, this is not true for all of our products.

Certain competitors are able to manufacture and distribute products more efficiently at lower costs and may offer comparable products at lower prices. Certain competitors may also have greater experience in developing and improving products, obtaining regulatory approvals, obtaining favorable reimbursement, and manufacturing and marketing products. For example, vascular surgeons may choose to utilize our competitors’ new or enhanced products for carotid stenting instead of our carotid endarterectomy products. In addition, certain competitors may obtain patent protection or regulatory

approval or clearance, or achieve product commercialization, before us. Further, if the trend towards endovascular procedures versus open vascular procedures continues or accelerates, this could harm our results. The vascular disease market is characterized by extensive research efforts and technological progress. Competitors may develop technologies and products that are safer, more effective, easier to use, or less expensive than ours. In addition, many of our products face competition from alternative procedures. Increased competition could also result in price reductions or loss of market share.

If we do not comply with international regulatory requirements to market our products outside the U.S. or are required to modify our operations or products as a result of such requirements, our business will be harmed.

Sales of medical devices outside the U.S. are subject to international regulatory requirements that vary from country to country. These requirements and timing may differ from our experiences with the U.S. FDA. In some countries, we rely on our international distributors to obtain premarket approvals, complete product registrations, and comply with clinical trial requirements. Failure to satisfy foreign regulations might impact our ability to sell our products in these countries. There can be no assurance that we will be able to obtain or maintain the required international regulatory approvals.

Our devices are currently regulated in the EU and the UK under the MDD and the MDR. In order to market our medical devices in the EU, we are required to obtain CE marks, which denote conformity to the essential requirements of the MDD or MDR, and manufacturers of higher-risk devices generally must use a “Notified Body”—an appointed independent third party to assess conformity. We currently use three Notified Bodies. We have received CE marks under the MDD to sell most of our products and have recently received our first three CE marks under the MDR for our Pruitt F3 Shunt, Flexcel Shunt and XenoSure Biologic Patch.

The EU adopted new regulations for medical devices, the MDR, which replace the MDD and which took effect as of May 26, 2021. The final deadline for compliance with MDR was revised to December 31, 2027 and December 31, 2028. Our products will eventually be fully subject to the MDR, which requires all of our products to obtain a new CE mark in accordance with MDR. Some of our Notified Bodies have already begun to impose these more rigorous requirements on us. Nearly all of our products have been submitted to our Notified Bodies for review under the MDR. If we fail to obtain new CE marks under the MDR, future sales of our products in the EU could be adversely impacted.

As a result of the UK’s exit from the EU, the UK Medicines and Healthcare Products Regulatory Agency (“MHRA”) announced that CE marking will continue to be recognized in the UK and certificates issued by EU-recognized Notified Bodies will continue to be valid in the UK market until July 1, 2024. This deadline was subsequently revised to coincide with the 2027 and 2028 EU extensions. Following such dates, all devices marketed in the UK will require UK Conformity Assessed (“UKCA”) Marks. If we fail to obtain UKCA marks by these deadlines, or at all, our sales in the UK could be negatively affected.

Our facilities are subject to periodic inspection by numerous regulatory authorities, including governmental agencies and Notified Bodies, and we must demonstrate compliance with the applicable medical device regulations. Any failure by us to comply with regulatory requirements may entail our taking corrective action, such as modification of our policies and procedures. In addition, we may be required to cease all or part of our operations for some period of time until we can demonstrate that appropriate steps have been taken. There can be no assurance that we will be found in compliance with such standards in future audits.

We also pursue registrations in other jurisdictions in which we sell our devices directly, such as Japan and China. In 2015, the China Food and Drug Administration (NMPA) significantly increased the application fees for product registrations and imposed additional requirements for obtaining product approval, which includes requirements for conducting clinical trials to support the registration application process on newly introduced products in China. As a result, we may not seek registration for certain products where the cost is not justified. Any delay in product registrations could have a negative impact on our results of operations.

If we are unable to expand our product and service offerings, we may not achieve our growth objectives and our results of operations could suffer.

Treatment of peripheral vascular and cardiovascular disease includes both open vascular surgery and minimally invasive endovascular procedures, and most of our products are used primarily or exclusively in open surgery procedures. We market and sell our products primarily to vascular surgeons. We estimate that in 2023 over 95% of our sales were from devices used in open surgical procedures.

A core component of our growth strategy is the acquisition of complementary product lines, principally in open vascular surgery. The number of appropriately sized targets in open vascular surgery could be limited, and if we are unable to execute our acquisition strategy, growth of our sales may be inhibited.

We may not be able to compete effectively unless we can keep pace with existing or new products, services and technologies in the vascular device market and the minimally invasive endovascular procedure segment, in particular. Our success in developing and commercializing new products and new versions of our existing products and services, or acquiring new products, is affected by our ability to:

- recognize in a timely manner new market trends and customer needs;
- identify products or services that address those trends or needs;
- identify and execute on suitable acquisition targets;
- obtain regulatory clearance or approval;
- develop cost-effective manufacturing processes for such products; and
- introduce such products, services and technologies.

If we are unable to expand our product or service offerings, whether through internal development or by acquisition, we may not grow sales and our operating results and stock price could suffer.

If we are unable to increase our selling prices to customers, or if we are required to make price concessions, our sales growth could be reduced and our operating results could suffer.

In the years ended December 31, 2023, 2022 and 2021, a material portion of our sales growth was driven by higher average selling prices, particularly with respect to valvulotome and carotid shunt sales. In the past, we have been able to rely upon our well-known brands and established reputation to increase prices. Also, we may become unable to implement further price increases:

- if healthcare spending is reduced, particularly in the U.S., in response to government-enacted healthcare reform, general economic conditions, or the influence of accountable care organizations;
- if the reimbursement rates for the medical procedures in which our products are used are reduced or limited;
- if competitors introduce lower-priced products of comparable safety and efficacy; or
- if customers engage in information sharing regarding competitive pricing of medical devices.

Marketplace changes might also place pressure on pricing as hospitals join group purchasing organizations, integrated delivery networks and managed care organizations. Due to pricing pressures, surgeons may even perform alternative procedures. If we become unable to raise prices it could reduce our rate of net sales growth and harm our operating results.

We are implementing a new enterprise resource planning system, and challenges with the implementation of the system may impact our business and operations.

We are implementing a new enterprise resource planning system (ERP). ERP implementations are complex, time-consuming, labor intensive, and involve substantial expenditures. The new ERP is critical to our ability to gather important information, obtain and deliver products, send invoices, fulfill contractual obligations, maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, and otherwise operate our business. ERP implementations also require transformation of internal processes. Any such implementation involves risks, including loss of information and potential disruption in operations. The implementation and maintenance of the new ERP system may be subject to delays and cost overruns.

Any disruptions, delays or deficiencies in the implementation of the new ERP system could affect our ability to process orders, ship products, send invoices, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, including reports required by the SEC such as the evaluation of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, and otherwise operate our business. Additionally, if we do not implement the new ERP as planned, the effectiveness of our internal control over financial reporting could be adversely affected.

We may experience significant fluctuations in our quarterly and annual results.

Fluctuations in our quarterly and annual financial results have resulted and will continue to result from numerous factors, including:

- changes in demand for the products and services we sell;
- increased product and price competition, due to market conditions, the regulatory landscape or other factors;
- our pricing strategy with respect to different product lines and services;
- productivity of our sales force;
- acquisitions of businesses or products or divestitures or discontinuations of products;
- effects of domestic and foreign economic and political conditions and exchange rates;
- the relocation and integration of manufacturing or processing operations;
- regulatory actions that may necessitate recalls of our products or warning letters;
- changes to the regulatory status of our products;
- the payment or cessation of quarterly cash dividends, and/or the amount and frequency at which to increase them;
- costs incurred by us to terminate contractual and other relationships, including those of distributors/agents;
- we have not focused on Group Purchasing Organization (GPO) contracts, which may reduce unit sales;
- our ability to collect accounts receivable in selected countries outside of the U.S.;
- changes in laws in the jurisdictions in which we do business;
- the expiration, elimination or utilization of deferred tax assets such as net operating loss carry-forwards; and
- the loss of any significant customer, especially in regard to any product or service that has a limited customer base.

These factors, some of which are not within our control, may cause the price of our common stock to fluctuate. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop. We believe the quarterly comparisons of our financial results are not always meaningful and should not be relied upon as the sole indicator of our performance.

We may not be able to maintain our historic levels of profit growth.

Our annual operating income for 2023 was 37% higher than 2022. This was due in part to substantial investments we made in growing our sales force and our direct labor pool in 2022 and 2023. There can be no assurance that we will be able to achieve this level of profit growth in 2024 or in future years. If we are unable to effectively manage our operating expenses, we may need to implement cost-cutting measures to maintain profitability. Decreased investment levels could inhibit future growth.

Additionally, our ability to maintain and increase profitability will be influenced by many factors, including:

- the level and timing of future sales, manufacturing costs and operating expenses;
- our ability to restrain or reduce operating expenses;
- the productivity of our direct sales force;
- fluctuations in foreign currency exchange rates;
- market acceptance of our new products and services;
- our ability to successfully build direct sales organizations in new markets;
- our ability to successfully acquire and develop competitive products
- our ability to successfully integrate acquired businesses;
- the impact on our business of competing products, technologies, and procedures;
- our ability to obtain or maintain regulatory approvals for our products;
- reimbursement rates for the medical products and procedures;
- the cost of litigation, if any; and
- changes in tax laws.

Our dependence on sole- and limited-source suppliers could hinder our ability to deliver our products and services to our customers and could harm the results of operations.

We rely on sole- and limited-source suppliers for many of our important components and certain products. For example, we rely on a sole-source supplier for ovine material used in our Omniflow II graft. With respect to our RestoreFlow allografts, we rely on tissue procurement organizations to provide donated tissue to us. While we have relationships with multiple tissue procurement organizations, we cannot be sure that a sufficient supply of suitable human tissue will be available to us, in which case our allograft preservation service revenues could be adversely affected.

When we acquire a product line, we often enter into an agreement with the seller for a defined period for supply of the acquired product until we can transfer manufacturing to our facilities. Those arrangements are always sole source supply arrangements. The supplier may not allocate sufficient resources to the manufacture of our product. Additionally, there is a risk if the supplier does not have the financial means to continue to supply product. For example, in the case of our 2019 acquisition of the CardioCel and VascuCel biologic patches, Anteris has agreed to continue to supply those products until January 2025. If Anteris fails to meet its obligations under the supply agreement, then we may experience interruptions in our supply. If we have insufficient supply of an acquired product, this could lead to loss of sales and our results of operations could be harmed.

There are relatively few, or in some cases no, alternative, validated sources of supply for these materials and products. We do not always have supply agreements in place with suppliers, instead placing orders on an as-needed basis. At any time, these suppliers could discontinue or become incapable of the manufacture or supply of these materials or products. We do not ordinarily carry a significant inventory of these materials and products. Identifying and qualifying additional or replacement suppliers, if required, may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption from our suppliers or failure to obtain replacement suppliers would interrupt our ability to manufacture our products and result in production delays and increased costs. This could lead to loss of sales and customers, and our results of operations could be harmed. In some cases, changes to raw material suppliers or use of alternative raw materials may require significant testing and subsequent regulatory approval.

Significant disruptions of information technology systems or breaches of information security systems could adversely affect our business.

We rely upon a combination of information technology systems and traditional recordkeeping to operate our business. In the ordinary course of business, we collect, store, and transmit confidential information (including, but not limited to, information about our business, financial information, personal data, intellectual property, and, in some very limited instances, patient data). Our information technology and information security systems and records are potentially vulnerable to security breaches, service interruptions, data loss, or malicious attacks resulting from inadvertent or intentional actions by our employees, vendors, or other third parties. In addition, due to our international presence and mobile sales force, we have implemented remote work arrangements for certain employees, and those employees may use outside technology and systems that are vulnerable to security breaches, service interruptions, data loss or malicious attacks, including by third parties.

While we have invested, and continue to invest, in our information technology and information security systems and employee information security training, there can be no assurance that our efforts will prevent all security breaches, phishing/fraud attempts, service interruptions, or data losses. Although we are not aware of having experienced any prior material data breaches, regulatory non-compliance incidents or cyber security incidents, we may in the future be impacted by such an event, exposing our clients and us to a risk of someone obtaining access to our information, to information of our clients or their customers, or to our intellectual property, disabling or degrading service, or sabotaging systems or information. Any such security breach could result in a loss of confidence in the security of our services, damage our reputation, disrupt our business, require us to incur significant costs of investigation, remediation and/or payment of a ransom, lead to legal liability, negatively impact our future sales, and result in a substantial financial loss.

We may experience difficulties in sourcing, acquiring and integrating businesses and products into our business, or we may not realize the anticipated benefits of these acquisitions.

To expand our product offerings, we have completed 24 acquisitions, and a key part of our strategy is to acquire additional businesses, products, or technologies. We have not completed an acquisition since 2020. If we are unable to complete acquisitions on satisfactory terms or at all, our growth objectives and sales could be negatively affected.

Even if we complete acquisitions, we may experience:

- difficulties in integrating any acquired businesses, personnel, and products into our existing business;
- difficulties or delays in integrating manufacturing operations into our existing business or successfully replicating manufacturing processes at new manufacturing facilities on a cost-effective basis;
- degradation in our corporate gross margin due to lower margins associated with our acquired devices;
- the sudden reduction in volume from a key customer, particularly where the acquired company had concentrated sales;
- diversion of management's time from other business concerns;
- higher costs of integration than anticipated;
- unanticipated liabilities included as part of the acquisition;
- disputes or litigation with former owners related to contingent payments, liabilities assumed or other matters;
- challenges in complying with regulatory requirements to which we were not previously subject;
- increased regulatory scrutiny;
- challenges in transferring, maintaining or obtaining regulatory approvals for acquired products;
- difficulties in retaining key employees of the acquired business;
- difficulties if the acquired company is remote to our Burlington, Massachusetts, headquarters;
- difficulties or delays in transitioning clinical studies or unfavorable results from such clinical studies;
- loss of key suppliers or issues with the ongoing supply of the acquired product from its former owners;
- charges related to the acquisition of in-process research and development;
- dilution as a result of equity financing required to fund acquisition costs; or
- debt, because of financing to fund acquisitions, which would be senior to our common stock, would require interest payments to our lenders, and could restrict our ability to pay dividends to our shareholders.

We could also discover deficiencies withheld from us due to fraud or otherwise not uncovered in our due diligence, including deficiencies in internal controls, data adequacy and integrity, product quality, and regulatory compliance, as well as undisclosed contractual or other liabilities and product liabilities, any of which could result in us becoming subject to penalties or other liabilities. Any of these difficulties could negatively impact our ability to realize the intended and anticipated benefits from our acquisitions or future acquisitions.

Our call point focus on the vascular surgeon with a product portfolio largely used in open vascular surgical procedures may be too narrow, which may adversely affect our future sales.

The treatment of peripheral vascular disease continues to shift from open vascular surgery to minimally invasive endovascular procedures. For example, some vascular surgeons have begun using transcatheter arterial revascularization, a new minimally invasive procedure, to treat carotid artery disease in lieu of a procedure in which our carotid shunts and vascular patches are used. We market and sell our products primarily to vascular surgeons, and the majority of our marketing efforts and sales relate to products used in open vascular surgery rather than in endovascular procedures. We estimate that in 2023, over 95% of our net sales were from devices used in open surgical procedures.

Demographic trends and other factors, such as reimbursement rates, are driving vascular surgeons to increasingly specialize in certain kinds of procedures, such as the creation and maintenance of dialysis access sites and endovascular therapies. Vascular surgeon training programs may focus on those therapies to the exclusion of open vascular procedures. If there is a decline in vascular surgeons training in open vascular procedures in favor of training in minimally invasive endovascular procedures, this could limit the number of vascular surgeons using our products due to lack of open vascular skills. If this trend continues, it could lead to the fragmentation of our customer base, which would reduce cross-selling opportunities, which could negatively impact our business.

Some of our devices are sold to a different call point from that of most of our product lines, and we may not be successful in selling to that call point.

Some of our products are sold to a call point that is different from our main call point focus. For example, historically, a significant portion of our CardioCel sales have been to pediatric cardiac surgeons while the majority of our marketing efforts and sales relate to products used by vascular surgeons. As a result, our sales representatives call predominantly on vascular surgeons and to a lesser extent, cardiac and neuro surgeons. Our success in selling products like CardioCel in the cardiac space will depend, in part, on our sales representatives devoting a portion of their time and establishing

relationships with pediatric cardiac surgeons. If they do not undertake these activities or are unsuccessful in doing so, then this could lead to the loss of CardioCel sales. Cross-selling opportunities to pediatric cardiac surgeons are limited. Conversely, if our sales representatives spend less time focused on vascular surgeons, the sales of our vascular products could decrease.

Our tissue processing and preservation services are subject to a variety of risks, including those related to the procurement of human tissue and regulatory requirements.

Our ability to successfully provide RestoreFlow allograft processing, preservation and distribution services may be affected by the following:

- maintenance of quality standards and controls to mitigate the risk that processed tissue cannot be sterilized;
- compliance with regulatory and legal requirements specific to human tissue or changes in those requirements;
- maintenance of our AATB accreditation, FDA establishment registration and state licensures;
- the degree to which our tissue procurement organizations are successful in procuring the gift of tissue donation;
- procurement from tissue procurement organizations of adequate amounts of human tissue of a type and quality that meets our specifications;
- processing human tissue in a cost-effective manner;
- controlling turnover in a workforce skilled in tissue processing and cryopreservation; and
- compliance of our tissue procurement organizations to current good tissue practices.

Our failure in any one or more of these areas could adversely impact our ability to provide processing, preservation and distribution services related to allografts and therefore our business and operations.

Any disruption in our manufacturing facilities could harm our results of operations.

Our principal worldwide executive, distribution, and manufacturing operations are located in five leased facilities in Burlington, Massachusetts. We also have a manufacturing site in North Brunswick, New Jersey as well as a tissue processing, preservation and distribution facility in Fox River Grove, Illinois. These facilities and the equipment we use to manufacture our products and services would be difficult to replace and could require substantial lead-time to repair or replace in the event of a natural or man-made disaster. In such event, we could not shift production or processing to alternate manufacturing facilities, and we would be forced to rely on third-party manufacturers, if available at all. Although we carry insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses, including potential damage to our reputation, and may not continue to be available to us on acceptable terms, or at all. We carry significant amounts of finished goods which could also help mitigate these issues.

Certain of our products contain materials derived from animal sources and may become subject to additional regulation.

Our AlboGraft vascular grafts, Artegraft biologic patch, XenoSure biologic patch, and CardioCel and VascuCel patch products contain bovine tissue or material derived from bovine sources, and our Omniflow II Biosynthetic Vascular Graft contains ovine tissue. Products that contain materials derived from animal sources are increasingly subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans. This public scrutiny has been acute in Japan and Western Europe with respect to products derived from animal sources because of concern that bovine materials infected with the agent that causes bovine spongiform encephalopathy, otherwise known as BSE or mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt-Jakob Disease, an ultimately fatal disease with no known cure. Cases of BSE in cattle discovered in Canada and the U.S. have also increased awareness of the issue in North America. Certain regions or countries have issued regulations that require products to be processed from bovine tissue sourced from countries, like Australia or New Zealand, where no cases of BSE have occurred. Products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries. Significant new regulations, or a ban of our products, could impair our current business.

The risks inherent in operating internationally and the risks of selling and shipping our products and of purchasing our components and products internationally may adversely impact our net sales, results of operations, and financial condition.

We derive a significant portion of our net sales from outside of the U.S. For the year ended December 31, 2023, 39% of our net sales were outside of the U.S. Our international sales operations expose us and our representatives, agents, and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- fluctuations in foreign currency exchange rates;
- the imposition of additional U.S. and foreign governmental controls or regulations, including export licensing requirements, duties and tariffs, and other trade restrictions;
- the risk of non-compliance with the Foreign Corrupt Practices Act or other anti-corruption laws by our personnel, distributors, and other agents;
- changing medical device regulations that may impede our ability to register our products in a jurisdiction;
- the imposition of U.S. and/or international sanctions against a country or party with whom we do business;
- changes in third-party reimbursement policies;
- clawback of funds spent on healthcare in excess of budgeted amounts by foreign governments;
- the imposition of restrictions on the activities of foreign agents, representatives, and distributors;
- scrutiny of foreign tax authorities, which could result in fines, penalties, and additional taxes;
- pricing pressure;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables;
- difficulties in enforcing or defending intellectual property rights;
- exposure to different legal, data privacy and political standards; and
- political, economic, and/or social instability.

We cannot assure you that one or more of these factors will not harm our business. Any material decrease in our international sales would adversely impact the results of operations.

Material adverse developments in global economic conditions, or the occurrence of certain other world events, could affect demand for our products, increase our costs of operation and harm our business.

The global macro environment continues to be challenging. For example, Russia's invasion on Ukraine has triggered significant sanctions from the U.S. and Europe which has negatively impacted our operations. Similar conflicts or tensions exist in Israel and Palestine, China and Taiwan and elsewhere. These sanctions, or non-compliance with sanctions, could result in operational delays, increased costs or fines, or material decreases in our international sales, all of which could have an adverse effect on our business.

The use or misuse of our products and the tissues we distribute may result in injuries that lead to product liability suits, which could be costly to our business.

If our products or the tissue we process are defectively designed, manufactured, processed or labeled, contain defective components, or are misused, or found to have caused or contributed to injuries or death, we may become subject to costly litigation. Although we offer training for physicians, we do not require that physicians be trained in the use of our products, and physicians may use our products incorrectly or in procedures not contemplated by us. We are from time to time involved in product liability claims. Product liability claims could divert management's attention from our core business, damage our reputation, be expensive to defend, and result in sizable damage awards against us.

We cannot assure you that our product liability insurance coverage will be sufficient to satisfy claims made against us. Further, we may not be able to maintain the same level of coverage, and we may not be able to obtain adequate coverage at a reasonable cost and on reasonable terms, if at all. Additionally, if any such product liability claim or series of claims is brought against us for uninsured liabilities or is in excess of our insurance coverage, our business could be harmed.

From time to time, we are involved in litigation where the outcome is uncertain and which could entail significant expense.

We are subject, from time to time, to legal proceedings and litigation, including, but not limited to, actions relating to product liability, employment matters, intellectual property, contract disputes and other commercial matters. Because the outcome of litigation is inherently difficult to predict, it is possible that the outcome of litigation, or even simply the defense of litigation, could entail significant cost for us, divert management's attention, and adversely affect our reputation. The fact that we operate in international markets also increases the risk that we may face legal exposure as we seek to comply with a large number of varying legal and regulatory requirements. If any such proceedings were to result in an unfavorable outcome, it could adversely affect our results of operations.

Risks Related to the Regulatory Environment

Oversight of the medical device industry might affect the manner in which we may sell medical devices and compete in the marketplace.

There are laws and regulations that govern how healthcare companies may market their products and services to healthcare professionals, including for example, the federal Anti-Kickback Statute, the federal False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996, state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions and debarment from state or federal healthcare programs. Although we strive to comply with those laws and regulations, we cannot assure you that government officials will not assert that we are in violation of those laws or regulations. Federal and state laws are also sometimes open to interpretation, and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

Our business is subject to complex, costly, and burdensome regulations. We could be subject to significant penalties if we fail to comply.

The production and marketing of our products and services and our ongoing research and development are subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. U.S. and foreign regulations applicable to medical devices and human tissues are wide-ranging and govern, among other things, the testing, marketing, and premarket clearance or approval of new medical devices and services related to human tissue, as applicable, in addition to regulating manufacturing and processing practices, reporting, promotion and advertising, importing and exporting, labeling, and record-keeping procedures.

Within recent years, there has been an increase in the scope and enforcement of data privacy laws in the jurisdictions in which we do business. The European Parliament adopted the General Data Protection Regulation (GDPR), effective May 2018. The California Consumer Privacy Act (CCPA), effective January 2020, requires covered companies to provide, among other things, new disclosure to consumers about such companies' data collection, as well as new use and sharing practices. Following the passage of the CCPA, several other U.S. states passed similar data privacy laws, most of which went into effect in 2023 or go into effect in 2024. In 2023, Europe finalized the first-ever comprehensive legal framework for governance of the use of artificial intelligence, the EU Artificial Intelligence Act, with an anticipated effective date in 2026. Compliance with these varying regimes has caused and will cause us to incur additional costs, including as may result from any non-compliance or asserted non-compliance.

Our failure to comply with applicable regulatory requirements could result in governmental agencies or a court taking action, including any of the following:

- issuing public warning letters to us;
- imposing fines and penalties on us;
- issuing an injunction preventing us from selling or distributing our products;
- bringing civil or criminal charges against us;
- ordering a recall of, or detaining or seizing, our products or cryopreserved human tissue; or
- withdrawing or denying approvals or clearances for our products.

If any or all of the foregoing were to occur, our business, results of operations, and brand could be materially adversely affected.

If we are not successful in obtaining additional and maintaining current clearances and approvals from governmental agencies for our medical devices, we might not be able to sell our products, and our future growth might be hampered.

Each medical device that we wish to market in the U.S. generally must receive either 510(k) clearance or approval of a premarket application (PMA). Either process can be lengthy and expensive. The FDA's 510(k) clearance procedure usually takes three to twelve months. Although 510(k) clearances have been obtained for nearly all of our current products that require such clearances, the FDA may condition, limit or prohibit our sales of these products if safety or effectiveness problems develop with the devices. Our new products or significantly modified existing products could be denied 510(k) clearance.

The PMA approval process is more costly, lengthy, and uncertain. It generally takes from six months to three years. Achieving premarket approval typically requires extensive clinical trials and may require the filing of numerous amendments. We do not have significant experience in obtaining PMA approval or conducting these studies for our products.

The FDA has previously proposed changes for which FDA clearance to market would possibly require clinical data, more extensive manufacturing information and post market data. As part of the 510(k) reform, the FDA proposes to issue regulations defining grounds and procedures for rescission of 510(k) applications that have previously been cleared to market. The FDA may also require the more extensive PMA process for certain products. Our ability to market our products outside the United States is also subject to regulatory approval, including our ability to demonstrate the safety and effectiveness of our products in the clinical setting. Even if regulatory approval or clearance of a product is granted, the approval or clearance could limit the uses or the claims for which the product may be labeled and promoted, which may limit the market for our products. If we do not obtain and maintain foreign regulatory or FDA approval with respect to our products, as applicable, we will not be able to sell our products, and our future growth could be affected.

If we or some of our suppliers fail to comply with the FDA's Quality System Regulation and other applicable requirements, our manufacturing or processing operations could be disrupted, and we may become subject to a variety of FDA enforcement actions.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with all regulatory requirements. If the FDA finds that we have failed to comply with any regulatory requirements, it can institute a wide variety of enforcement actions, including, but not limited to, warning letters, fines and penalties, injunctions, civil or criminal charges, mandatory recalls, and withdrawal of clearances to sell products.

We and some of our suppliers must comply with the FDA's Quality System Regulation, which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage, and shipping of medical devices. Our Fox River Grove operations must comply with the FDA's current Good Tissue Practices. The FDA enforces its regulations through pre-announced and unannounced inspections. We are subject to such inspections by the FDA and other regulatory bodies. The timing of future audits is unknown, and it is possible that audits may result in one or more unsatisfactory results. If we or one of our suppliers fails an inspection, or if a corrective action plan adopted by us or one of our suppliers is not sufficient, the FDA may bring an enforcement action against us.

We participate in the MDSAP, which allows manufacturers to undergo a universal quality system audit that is accepted in the U.S., Japan, Australia, Canada and Brazil in lieu of individual routine audits by each regulator. Maintenance of this certification is a requirement to maintain sales in certain geographies including Canada. Failure to maintain this certification in good standing could result in suspension of our sales efforts in Canada or other geographies.

We are also subject to the FDA's general prohibition against promoting our products for unapproved or off-label uses and to the medical device reporting regulations that require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. We must also file reports with the FDA of some device corrections and removals, and we must adhere to the FDA's rules on labeling and promotion. If we fail to comply with these or other FDA requirements or fail to take adequate corrective action in response to any significant compliance issue raised by the FDA, the FDA can take significant enforcement actions, which could harm our business, results of operations, and our reputation.

In addition, most other countries, such as Japan, require us to comply with manufacturing and quality assurance standards for medical devices that are similar to those in the U.S. before marketing and selling our products in those countries.

Even after our products have received marketing approval or clearance, our products and the tissue we process may be subject to recall. Licenses, registrations, approvals and clearances could be withdrawn or suspended due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval.

Our products, services, marketing, sales and development activities, and manufacturing processes are subject to extensive and rigorous regulation by the FDA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. If those regulatory bodies feel that we have failed to comply with regulatory standards, there can be no assurance that any approval, licensure or registration will not be subsequently withdrawn, suspended or conditioned upon extensive post-market study requirements, even after having received marketing approval or clearance or licenses and registrations. Further, due to the interconnectedness of the various regulatory agencies, particularly within the EU, there is also no assurance that withdrawal or suspension of any of our approvals, licenses or registrations by any single regulatory agency will not precipitate one or more additional regulatory agencies from also withdrawing or suspending their approval, license or registration.

In the event that any of our products prove to be defective, we can voluntarily recall, or the FDA or foreign equivalent could require us to implement a recall, any of our products. In the EU and UK, adverse event reporting requirements mandate that we report incidents which led or could have led to death or serious deterioration in health. Recalls, whether voluntary or required, could result in significant costs to us and significant adverse publicity. In severe instances, the FDA may also issue a warning letter and/or destruction of defective product and/or order the suspension or cessation of manufacturing of defective product. Additionally, if someone is harmed by a malfunction or a product defect, we may experience product liability claims for such defects. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital and may harm our financial results. Future recalls or claims could also result in significant costs to us and significant adverse publicity, which could harm our ability to market our products in the future.

Domestic and foreign legislative or administrative reforms resulting in restrictive reimbursement practices of third-party payors and cost containment measures could decrease the demand or prices for our products.

Our products and our allograft preservation services are purchased principally by hospitals or physicians which typically bill various third-party payors, such as governmental programs (e.g., Medicare, Medicaid and comparable foreign programs), private insurance plans and managed care plans. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payors contributes to the success of our products and services because. Reimbursement varies by country and can impact the acceptance of new technology. Implementation of healthcare reforms in the U.S. and in major overseas markets such as Germany, Japan and France may limit, reduce or eliminate reimbursement for our products and services.

Major third-party payors for hospital services in the U.S. and abroad continue to work to contain healthcare costs. For example, in an effort to decrease costs, certain hospitals and other customers may reprocess our products intended for a single use or purchase reprocessed products from third-party reproducers.

Further legislative or administrative reforms to the reimbursement systems in the U.S. and abroad, or adverse decisions relating to our products by administrators of these systems in coverage or reimbursement, could reduce reimbursement for procedures using our medical devices or result in the denial of coverage for those procedures. Examples of these reforms or adverse decisions include price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. Any of such reforms or adverse decisions could have an adverse impact on the prices our customers are willing to pay for our products.

Risks Related to Intellectual Property

If we fail to adequately protect our intellectual property rights, or prevent use of our intellectual property by third parties, we could lose a significant competitive advantage and our business may suffer.

Our success depends in part on maintaining and enforcing our intellectual property rights. We take precautionary steps to protect our technological advantages and intellectual property. We rely upon patent, trade secret, copyright, know-how, and trademark laws, as well as license agreements and contractual provisions, to establish our intellectual property rights and protect our products. These measures may only provide limited protection.

We have few patents on our technology. Even where we do have patents, the issuance of a patent is not always conclusive as to its validity or enforceability. Our patents could be circumvented or designed around by third parties. Furthermore, patents expire after a certain duration, depending on the jurisdiction in which they are issued. To the extent any manufacturers are successful in challenging our patents or they enter the market following the expiration of our patents, this could have an adverse impact on our business.

We may not be able to effectively protect our rights in unpatented technology, trade secrets, and confidential information. We have a policy of requiring key employees and consultants and corporate partners with access to trade secrets or other confidential information to execute confidentiality agreements. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment. We also generally require consultants to assign to us any inventions made during their engagement with us. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer, or disclosure of confidential information or inventions.

In addition, the laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the U.S. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products, or services and our competitors could commercialize similar technologies, which could result in a decrease in our sales and market share.

If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs, and we may have to redesign or discontinue selling the affected product.

Companies operating in our industry often seek patent protection for their novel product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. We face the risk of claims that we have infringed on third parties' intellectual property rights, and we cannot assure you that our products or methods do not infringe the patents or other intellectual property rights of third parties. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages;
- harm our reputation;
- cause us to cease making or selling products;
- require us to redesign, reengineer, or rebrand our products, which may not be possible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management and key personnel from other tasks important to the success of our business; or
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

It is also possible that a third party could claim that our manufacturing process violates an existing patent or other intellectual property rights. If we were unsuccessful in defending such a claim, we may be forced to stop production at one or more of our manufacturing facilities. In addition, new patents obtained by our competitors could threaten a product's continued life in the market even after it has already been introduced. If our business is successful, the possibility may increase that others will assert infringement claims against us.

If we believe our product is or may be the subject of a patent or other intellectual property rights of a third party, we may attempt to reach a license agreement with them to manufacture, market, and sell these products. If we fail to reach an agreement, we could be required to pay significant damages to third parties for past use of the asserted intellectual property and may be forced to cease making or selling products that incorporate the challenged intellectual property.

In addition, we may become subject to interference proceedings conducted in the United States Patent Office or opposition proceedings conducted in foreign patent offices challenging the priority of invention or the validity of our patents.

Risks Related to Our Common Stock

Our stock price may be volatile, and an investment in our common stock could suffer a decline in value.

There can be significant volatility in the market price and trading volume of equity securities that is unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our common stock. Some factors that may have a significant effect on our common stock market price include:

- actual or anticipated fluctuations in our operating results or future prospects;
- changes in our growth rates;
- our announcements or our competitors' announcements of new products;
- the public's reaction to our press releases, our other public announcements, and our filings with the SEC;
- our determination whether or not to continue the payment of quarterly cash dividends;
- our determination whether or not to undertake or continue a share repurchase program;
- strategic actions by us or our competitors, such as acquisitions, divestitures or restructurings;
- dilutive issuances of additional securities;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- the discontinuation of a product line or other revenue generating activity;
- adverse regulatory actions which may necessitate recalls of our products or services or warning letters that negatively affect the markets for our products or services;
- sales of common stock by us or our directors, officers, or principal stockholders;
- control by our affiliates and insiders of a significant percentage of our common stock;
- reduced or lower volume of trading in our common stock; and
- our inclusion in or removal from stock market indices, such as the S&P 600 or Russell 2000.

The stock market has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. The market price of our common shares may also fluctuate significantly due to a variety of factors unrelated to our financial results, including political instability, natural disasters, pandemics, war and/or events of terrorism; comments by securities analysts; and general market conditions in our industry or in the economy as a whole. Broad market and industry factors may affect the market price of companies' stock, including ours, regardless of actual operating performance. In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Our chief executive officer has significant voting power and may take actions that may not align with the interests of our other stockholders.

Our chief executive officer controls approximately 11% of our outstanding common stock as of December 31, 2023. As a result, he could have significant influence on matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock, and may not be fully aligned with the interests of other stockholders.

We have not established a minimum dividend payment level for our common stockholders and there are no assurances of our ability to pay dividends to common stockholders in the future.

In February 2011, our Board of Directors adopted a quarterly dividend program for the purpose of returning capital to our stockholders. However, we have not established a minimum dividend payment level for our common stockholders and our ability to pay dividends may be harmed by the risks and uncertainties described in this Annual Report on Form 10-K and in the other documents we file from time to time with the SEC. Future dividends, if any, will be authorized by our Board of Directors. In addition, financial covenants in our credit facility may restrict our ability to pay future quarterly dividends. We can provide no assurance of our ability to pay dividends in the future.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

LeMaitre Vascular recognizes the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data.

Managing Material Risks & Integrated Overall Risk Management

We have strategically integrated cybersecurity risk management into our broader risk management framework to promote a company-wide culture of cybersecurity risk management, with the goal of ensuring that cybersecurity considerations are an integral part of our decision-making processes. Our IT department continuously evaluates and addresses cybersecurity risks during our risk assessment process, in alignment with our business objectives and operational needs.

Engage Third-Parties on Risk Management

Recognizing the complexity and evolving nature of cybersecurity threats, we engage with external experts, including cybersecurity assessors and consultants, to evaluate and test our risk management systems. Our collaboration with third-parties includes periodic audits, threat assessments, and consultation on security enhancements.

Oversight of Third-party Risk

Using a risk-based approach, we review third-party service providers as part of our IT general controls, particularly focusing on financial risk and the third-party applications and controls around that risk.

Risks from Cybersecurity Threats

Although we are not aware of having experienced any prior material data breaches, regulatory non-compliance incidents or cyber security incidents, we may in the future be impacted by such an event, exposing our clients and us to a risk of someone obtaining access to our information, to information of our clients or their customers, or to our intellectual property, disabling or degrading service, or sabotaging systems or information. Any such security breach could result in a loss of confidence in the security of our services, damage our reputation, disrupt our business, require us to incur significant costs of investigation, remediation and/or payment of a ransom, lead to legal liability, negatively impact our future sales, and result in a substantial financial loss.

Governance

The Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats. The Board has established robust oversight mechanisms to ensure effective governance in managing risks associated with cybersecurity threats because we recognize the significance of these threats to our operational integrity and stakeholder confidence.

Board of Directors Oversight

The Audit Committee is central to the Board's oversight of cybersecurity risks and bears the primary responsibility for this domain. On a periodic basis, our Audit Committee reviews the adequacy of our computer systems controls, cybersecurity risk management and related governance and incident disclosures.

Management's Role Managing Risk

Our VP, Information Technology and our Chief Financial Officer (CFO) play a pivotal role in informing the Audit Committee on cybersecurity risks. They provide comprehensive briefings to the Audit Committee on a regular basis, with a minimum frequency of once per year. These briefings encompass a broad range of topics, including:

- Current cybersecurity landscape and emerging threats;
- Status of ongoing cybersecurity initiatives and strategies;
- Incident reports and learnings from any cybersecurity events; and
- Compliance with regulatory requirements and industry standards.

In addition to our scheduled meetings, the Audit Committee, our VP, Information Technology and our CFO maintain an ongoing dialogue regarding emerging or potential cybersecurity risks.

Risk Management Personnel

Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with our VP, Information Technology, who has over 25 years of experience in the field. As each relates to cybersecurity, our VP, Information Technology leads testing of our compliance with standards, remediation of known risks, and our employee training program.

Monitor Cybersecurity Incidents

Our VP, Information Technology leads our implementation and oversight of processes for the regular monitoring of our information systems. We have developed a cybersecurity incident response plan that is overseen by our VP, Information Technology and that includes immediate actions to mitigate the impact and longer-term strategies for remediation and prevention of future incidents.

Reporting to Board of Directors

Our VP, Information Technology, in his capacity, regularly informs the CFO about matters related to cybersecurity risks and incidents. Together, our VP, Information Technology and CFO then update our Audit Committee and Board on significant cybersecurity matters, and strategic risk management.

Item 2. Properties

Our principal worldwide executive, distribution, and manufacturing operations are located at five leased facilities with square footage totaling 109,354 in Burlington, Massachusetts. Four of the five Burlington leases expire in December 2034 and the fifth lease expires December 2030. The Company has no option to extend or renew the four leases beyond December 2034. In connection with our acquisition of the Artegraft biologic graft business, we assumed a 16,732 square foot lease in North Brunswick, New Jersey, which expires in October 2029. In addition, our European operations are headquartered at a 21,410 square foot leased facility located in Sulzbach, Germany, with a lease expiring in June 2031. We also lease additional manufacturing, processing, distribution and sales offices in other U.S., Europe, UK and Asia Pacific locations. Based on our current operating plans, we believe our current facilities are adequate for our needs.

Item 3. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation consisting of intellectual property, contractual, commercial, employment, and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of December 31, 2023, that, in the opinion of management, would be reasonably expected to have a material adverse effect on our financial position, results of operations or cash flows.

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

Our common stock is publicly traded on The Nasdaq Global Market under the symbol "LMAT". Prior to our initial public offering on October 19, 2006, there was no public trading market for our common stock.

Holders of Record

On February 20, 2024, the closing price per share of our common stock was \$62.49 as reported on The Nasdaq Global Market, and we had approximately 144 stockholders of record. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

Dividends

In February 2011, our Board of Directors approved a policy for the payment of quarterly cash dividends on our common stock. In 2023, we paid a quarterly cash dividend of \$0.140 per share and, in 2022, we paid a quarterly cash dividend of \$0.125 per share. On February 21, 2024, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.160 per share payable on March 28, 2024, to stockholders of record at the close of business on March 14, 2024, which will total approximately \$3.6 million. Future declarations of quarterly dividends and the establishment of future record and payment dates are subject to approval by our Board of Directors on a quarterly basis.

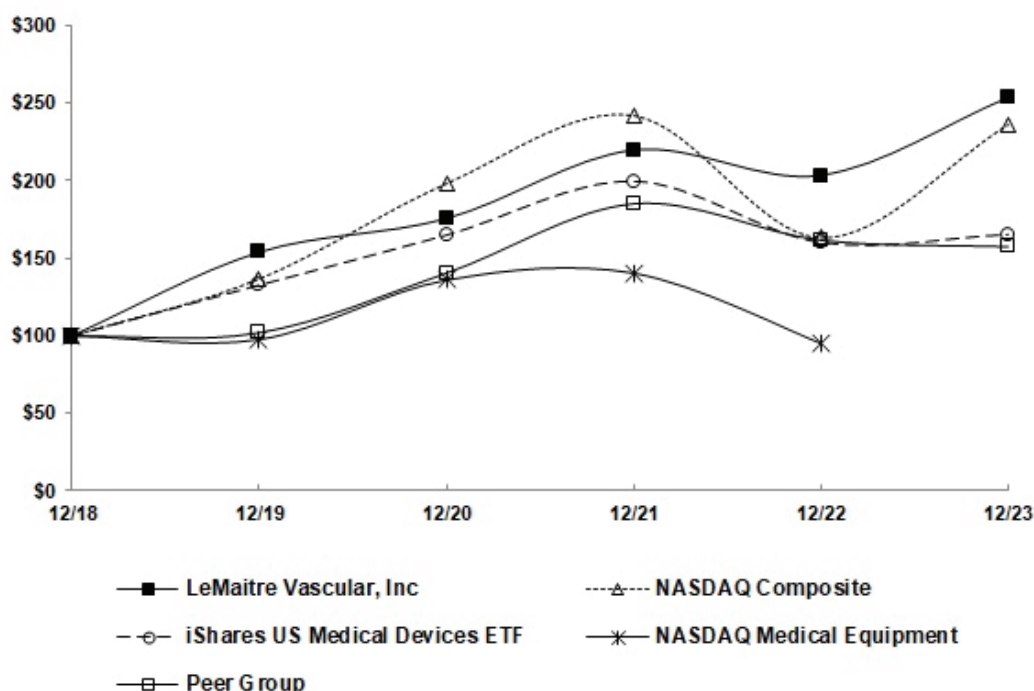
Stock Price Performance Graph

Set forth below is a graph comparing the cumulative total stockholder return on LeMaitre's common stock with the Nasdaq Composite Index, the iShares US Medical Devices ETF Index and a peer group for the period covering from December 31, 2018, through the end of LeMaitre's fiscal year ended December 31, 2023. We have adopted iShares US Medical Devices ETF Index as a comparator this year, replacing the Nasdaq Medical Equipment Index, because the Nasdaq Medical Equipment Index ceased to exist as a published index during 2023. Accordingly, while we have included reference to the Nasdaq Medical Equipment Index in the below graph through December 31, 2022, we are unable to present this index with respect to the year ended December 31, 2023, and do not intend to include it in future years. The graph assumes an investment of \$100.00 made on December 31, 2018, in (i) LeMaitre's common stock, (ii) the stocks comprising the Nasdaq Composite Index, (iii) the stocks comprising the iShares US Medical ETF Index, (iv) the stocks comprising our peer group, and (v) the stocks comprising the Nasdaq Medical Equipment Index. The following shall not be deemed incorporated by reference into any of our other filings under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, except to the extent we specifically incorporate it by reference into such filings.

The comparisons in the graph below are based upon historical data and are not indicative of, nor intended to forecast, future performance of our common stock.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among LeMaitre Vascular, Inc, the NASDAQ Composite Index,
the iShares US Medical Devices ETF Index,
the NASDAQ Medical Equipment, and a Peer Group



*\$100 invested on 12/31/18 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	12/18	12/19	12/20	12/21	12/22	12/23
LeMaitre Vascular, Inc	100.00	153.77	175.43	219.49	203.27	253.28
NASDAQ Composite.....	100.00	136.69	198.10	242.03	163.28	236.17
iShares US Medical Devices ETF.....	100.00	132.72	164.81	199.47	160.14	165.28
NASDAQ Medical Equipment	100.00	97.52	136.07	140.62	94.93	-
Peer Group	100.00	102.10	140.38	184.86	161.55	157.36

LeMaitre's fiscal year ends on the last day of December each year; data in the above table reflects market values for our stock and Nasdaq and peer group indices as of the close of trading on the last trading day of the year presented. The peer group includes the following companies: AngioDynamics, Inc., Artivion, Inc., Atricure, Inc., Inari Medical, Inc., Merit Medical Systems, Inc., Penumbra, Inc., Shockwave Medical, Inc., and Silk Road Medical, Inc.

Recent Sales of Unregistered Securities

Not Applicable.

Issuer Purchases of Equity Securities

Period	Issuer Purchases of Equity Securities			
	Total Number of Shares (or Units) Purchased (1)	Average Price Paid Per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Program	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that may yet be Purchased under the Plans or Program
October 1, 2023 through October 31, 2023	-	\$ -	N/A	N/A
November 1, 2023 through November 30, 2023 ..	-	\$ -	N/A	N/A
December 1, 2023 through December 31, 2023 ...	12,077	\$ 55.28	N/A	N/A
Total	12,077	\$ 55.28	N/A	N/A

- (1) For the three months ended December 31, 2023, we repurchased 12,077 shares of our common stock to satisfy employees' obligations with respect to minimum statutory withholding taxes in connection with the vesting of restricted stock units.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our consolidated financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings. The following discussion may contain predictions, estimates, and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks could cause our actual results to differ materially from any future performance suggested below.

The principal objectives of this Management's Discussion and Analysis of Financial Condition and Results of Operations are to enhance our overall financial disclosures by providing explanation and analysis of the Company's financial results and condition, as viewed by our management.

Overview

We are a global provider of medical devices and human tissue cryopreservation services largely used in the treatment of peripheral vascular disease, end-stage renal disease, and to a lesser extent cardiovascular disease. We develop, manufacture, and market vascular devices to address the needs of vascular surgeons and, to a lesser degree, other specialties such as cardiac surgeons, general surgeons and neurosurgeons. Our diversified portfolio of devices consists of brand name products that are used in arteries and veins and are well known to vascular surgeons. Our principal product offerings are sold globally, primarily in the United States, Europe, Canada and Asia Pacific. We estimate that the annual worldwide market for peripheral vascular devices exceeds \$5 billion, within which we estimate that the market for our products is approximately \$800 million. We have grown our business using a simple three-pronged strategy: 1) pursuing a focused call point, 2) competing for sales of low-rivalry, niche products, and 3) expanding our worldwide direct sales force while acquiring complementary devices. We have used acquisitions as a primary means of further penetrating the peripheral vascular device market, and we expect to continue this strategy in the future. We currently manufacture most of our products in our Burlington, Massachusetts headquarters.

Our products and services are used primarily by vascular surgeons who treat peripheral vascular disease through both open surgical methods and endovascular techniques. In contrast to interventional cardiologists and interventional radiologists, vascular surgeons can perform both open surgical and minimally invasive endovascular procedures, and therefore can provide a wider range of treatment options to their patients. More recently, however, we have begun to explore adjacent market customers, or non-vascular surgeon customers, who can be served by our vascular device technologies, such as cardiac surgeons and neurosurgeons.

Our principal product lines include the following: anastomotic clips, biologic vascular and dialysis grafts, biologic vascular and cardiac patches, carotid shunts, embolectomy catheters, occlusion catheters, radiopaque marking tape, synthetic vascular and dialysis grafts, and valvulotomes. Through our RestoreFlow allografts business, we also provide services related to the processing and cryopreservation of human vascular and cardiac tissue.

Our principal biologic offerings include vascular and cardiac patches as well as vascular and dialysis grafts. In 2023, biologics represented 51% of our worldwide sales. We view our biologic device offerings favorably, as we believe they represent differentiated and, in some cases, growing product segments.

To assist us in evaluating our business strategies, we monitor long-term technology trends in the peripheral vascular device market. Additionally, we consider the information obtained from discussions with the medical community in connection with the demand for our products, including potential new product launches. We also use this information to help determine our competitive position in the peripheral vascular device market and our manufacturing capacity requirements.

Our business opportunities include the following:

- growing our direct sales force in North America, Europe, the UK, and Asia Pacific, including replacing distributors with our direct sales personnel;
- increasing the average selling prices of our devices;
- acquiring complementary products;
- introducing our products into new territories upon receipt of regulatory approvals or registrations;
- consolidating product manufacturing at our Burlington, Massachusetts facilities, and
- updating existing products and introducing new products through research and development.

We sell our products and services primarily through a direct sales force. As of December 31, 2023, our sales force was comprised of 136 sales representatives in North America, Europe, the UK, and Asia Pacific, including three export managers. Our worldwide headquarters is located in Burlington, Massachusetts, and we also have North American sales offices in Chandler, Arizona and Vaughan, Canada. Our European headquarters is located in Sulzbach, Germany, and we also have European sales offices in Milan, Italy; Madrid, Spain; Hereford, England; and Dublin, Ireland. Our Asia Pacific headquarters is located in Singapore, and we also have Asia Pacific sales offices in Tokyo, Japan; Shanghai, China; Kensington, Australia; Seoul, Korea; and Bangkok, Thailand. During the year ended December 31, 2023, approximately 96% of our net sales were generated in territories in which we employ direct sales representatives. We also sell our products in other countries through distributors.

Historically we have experienced success in lower-rivalry niche segments. In the valvulotome market, for example, our highly differentiated devices have historically allowed us to increase our selling prices while maintaining unit share. In contrast, we have experienced less success in highly competitive markets such as the polyester vascular graft market, where we face competition from larger companies with greater resources and lower per unit costs.

We have also experienced success in international markets, such as Europe, where we have a significant sales force, and sometimes offer comparatively lower average selling prices than in North America. If we continue to seek growth opportunities outside of North America, we may experience downward pressure on our gross margin.

Our strategy for growing our business includes the acquisition of complementary product lines and companies, which can be difficult to identify, negotiate and purchase, and there can be no assurance that we will be able to do so in the future.

- In June 2020, we entered into an agreement with Artegraft to purchase the assets of their bovine graft business for \$72.5 million plus additional payments of up to \$17.5 million, contingent upon 2021 – 2023 unit sales.

Occasionally we discontinue or divest products that are no longer complementary to our business or not commercially viable.

- During 2021, we made decisions to wind down or discontinue our TRIVEX powered phlebectomy systems, remote endarterectomy devices and surgical glue. These product lines totaled approximately \$2.2 million in 2021 revenues.
- During 2022, we made the decision to wind down the ProCol graft, AlboSure polyester patch, LeverEdge and Latis graft cleaning catheter product lines. These products totaled approximately \$0.7 million in 2022 revenues.
- During 2023, we made the decision to discontinue the sales of AlboGraft and LifeSpan synthetic graft product lines in the U.S. These products totaled approximately \$0.3 million and less than \$0.1 million, respectively, in 2023 revenues.

From time to time we may undertake SKU reductions and transition sales to other SKUs or products with similar features. For example, in 2022, we initiated the transition of sales of our Syntel spring tip catheter to our Syntel regular tip catheter. Any of these actions may result in inventory write-offs and temporary or permanent negative impacts to our sales, gross margin and customer relationships.

Because we believe that direct-to-hospital sales engender closer customer relationships, and allow for higher selling prices and gross margins, we periodically enter into transactions with our distributors to transition their sales of our medical devices into our direct sales organization:

- In May 2022, we entered into a distribution transition agreement with our Korean distributor in order to sell products directly in Korea and dissolve the existing distribution arrangement. We have been selling direct-to-hospital in Korea since December 2022. The distribution termination fees totaled approximately \$0.5 million.
- In March 2023, we entered into a distribution transition agreement with our Thailand distributor in order to sell products directly in Thailand and dissolve the existing distribution arrangement. We have been selling direct-to-hospital in Thailand since August 2023. The distribution termination fees totaled approximately \$0.7 million.

We also benefit, to a lesser extent, from internal product development efforts to bring differentiated technologies and next-generation products to market:

- In 2020, we launched RestoreFlow cardiac allografts for use in cardiac repair and restoration.
- In March 2022, we received U.S. FDA clearance to market PhasTIPP, a portable powered phlebectomy device used to remove varicose veins in the leg. We expect to launch this product in 2024 or 2025.

In addition to our sales growth strategies, we have also executed several operational initiatives designed to consolidate manufacturing into our Burlington facilities. We expect these plant consolidations and manufacturing transfers will result in improved control over production quality as well as reduced costs. Our most recent manufacturing transfers included:

- In October 2018, we acquired the Cardial business from Becton Dickinson. Cardial manufactured polyester vascular grafts, valvulotomes and surgical glue at its St. Etienne, France facility. In June 2022, we closed the St. Etienne factory in order to streamline manufacturing operations and to reduce expenses. We are transitioning Cardial graft sales to our Burlington-manufactured polyester graft product (AlboGraft) for additional cost savings and improved margins.
- In October 2019, we acquired the CardioCel and VascuCel biologic patch businesses from Anteris. In July 2020, we initiated a project to transfer production to our Burlington facilities. The transfer to Burlington was substantially completed in 2023. In June 2023, the MDR CE mark application to market these Burlington produced devices was submitted, and we anticipate this application process to take 18-30 months.

Finally, from time to time we may enter into distribution agreements of complementary product lines with the option to acquire the product line in the future:

- In April 2023, we entered into an agreement with Elutia to become the exclusive U.S. distributor of their cardiovascular porcine patches. Under the agreement, we can distribute the products for three years with an option to acquire Elutia's worldwide cardiovascular patch business during the second and third year of the agreement. Sales through LeMaitre Vascular for the nine months ended December 31, 2023 were \$4.1 million.

Our execution of these initiatives may affect the comparability of our financial results and may cause fluctuations from period to period as we incur related expenses such as process engineering and other charges.

In February 2024, we began implementing a new ERP system to replace our software reporting and planning system. We expect that the new ERP system will be beneficial in a number of areas, including inventory management, pricing programs, financial operations and real time reporting. While we have been preparing for this transition since 2022 and have hired an experienced consulting team to assist in this transition, there can be no assurances that the implementation will be successful or executed in a timely manner. As of December 31, 2023, we have capitalized approximately \$3.6 million of costs associated with this ERP system.

Fluctuations in the exchange rates between the U.S. dollar and foreign currencies, primarily the Euro, affect our financial results. For the year ended December 31, 2023, approximately 39% of our sales took place outside of the U.S., largely in currencies other than the U.S. dollar. We expect foreign currencies will represent a significant percentage of future sales. Selling, marketing, and administrative costs related to these sales are also denominated in foreign currencies, thereby partially mitigating our bottom-line exposure to exchange rate fluctuations. However, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases we will record less revenue in U.S. dollars than we did before the exchange rate changed. For 2023, we estimate that the effects of changes in foreign exchange rates increased our reported sales by approximately \$0.2 million, as compared to rates in effect for 2022.

Net Sales and Expense Components

The following is a description of the primary components of our net sales and expenses:

Net sales. We derive our net sales from the sale of our products and services, less discounts and returns. Net sales include the shipping and handling fees paid for by our customers. Most of our sales are generated by our direct sales force and are shipped and billed to hospitals or clinics throughout the world. In countries where we do not have a direct sales force, sales are primarily to distributors, who in turn sell to hospitals and clinics. In certain cases our products are held on consignment at a hospital or clinic prior to purchase; in those instances we recognize revenue at the time the product is used in surgery rather than at shipment.

Cost of sales. We manufacture the majority of the products that we sell. Our cost of sales consists primarily of manufacturing personnel, raw materials and components, depreciation of property and equipment, and other allocated manufacturing overhead, as well as the freight expense we pay to ship products to customers.

Sales and marketing. Our sales and marketing expense consists primarily of salaries, commissions, stock-based compensation, travel and entertainment, sales meetings, attendance at vascular and cardiac congresses, training programs, advertising and product promotions, direct mail and other marketing costs.

General and administrative. General and administrative expense consists primarily of executive, finance and human resource salaries, stock based compensation, legal and accounting fees, information technology expense, intangible asset amortization expense and insurance expense.

Research and development. Research and development expense primarily includes costs associated with obtaining and maintaining regulatory approval of our products, salaries, laboratory testing and supply costs. It also includes costs associated with the design and execution of clinical studies, costs to register, maintain, and defend our intellectual property, and costs to transfer the manufacturing of acquired product lines to our Burlington facility. Also included are costs associated with the design, development, testing and enhancement of new or existing products.

Other income (expense). Other income (expense) primarily includes interest income and expense, foreign currency gains (losses), and other miscellaneous gains (losses).

Income tax expense. We are subject to federal and state income taxes for earnings generated in the U.S., which include operating losses or profits in certain foreign jurisdictions for certain years depending on tax elections made, and foreign taxes on earnings of our wholly-owned foreign subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) in the U.S. and foreign subsidiaries, permanent items, discrete items, unrecognized tax benefits, and amortization of goodwill for U.S. tax reporting purposes.

Results of Operations

Comparison of the year ended December 31, 2023 to the year ended December 31, 2022

The following table sets forth, for the periods indicated, our net sales by geography, and the change between the specified periods expressed as a percentage increase or decrease:

	2023	2022	\$ Change	Percent change
	(\$ in thousands)			
Net sales	\$ 193,484	\$ 161,651	\$ 31,833	20%
Net sales by geography:				
Americas	\$ 130,308	\$ 109,439	\$ 20,869	19%
Europe, Middle East and Africa.....	51,099	41,854	9,245	22%
Asia Pacific	12,077	10,358	1,719	17%
Total	\$ 193,484	\$ 161,651	\$ 31,833	20%

Net sales. Net sales increased by \$31.8 million, or 20%, to \$193.5 million for the year ended December 31, 2023, compared to \$161.7 million for the year ended December 31, 2022. The increase was driven primarily by higher average selling prices, elevated hospital procedure volumes, additional sales representatives, and \$4.1 million in sales related to our new porcine patch product line. Valvulotome sales increased \$6.3 million, bovine vascular patch sales increased \$4.6 million, bovine graft sales increased \$4.2 million, allograft preservation services increased \$3.7 million, and carotid shunt sales increased \$3.1 million. We estimate that the weaker U.S. dollar increased net sales by \$0.2 million during the year ended December 31, 2023 as compared to the year ended December 31, 2022.

Direct-to-hospital net sales were 96% and 95% of our total net sales for the years ended December 31, 2023 and 2022, respectively.

Net sales by geography. Net sales in the Americas increased \$20.9 million, or 19%, for the year ended December 31, 2023 as compared to the year ended December 31, 2022. The increase was driven primarily by increased sales of valvulotomes of \$5.2 million, bovine grafts of \$4.2 million, porcine patches of \$4.1 million, allograft preservation services of \$2.8 million, and bovine vascular patches of \$2.0 million.

EMEA net sales increased \$9.2 million, or 22%, for the year ended December 31, 2023 as compared to the year ended December 31, 2022. The increase was driven primarily by increased sales of bovine vascular patches of \$2.1 million, carotid shunts of \$1.9 million, bovine cardiac patches of \$1.2 million, valvulotomes of \$1.1 million, and ovine grafts of \$1.0 million.

Asia Pacific net sales increased \$1.7 million, or 17%, for the year ended December 31, 2023 as compared to the year ended December 31, 2022. The increase was driven primarily by increased sales of occlusion catheters of \$0.7 million, bovine vascular patches of \$0.5 million, and ePTFE vascular grafts and carotid shunts of \$0.2 million, respectively.

Gross Profit. The following table sets forth the change in our gross profit and gross margin for the periods indicated:

	2023	2022	Change	Percent change
	(\$ in thousands)			
Gross profit.....	\$ 127,049	\$ 104,896	\$ 22,153	21%
Gross margin	65.7%	64.9%	0.8%	*

* Not applicable

Gross profit increased \$22.2 million, or 21%, to \$127.0 million for the year ended December 31, 2023, and gross margin increased by 80 basis points to 65.7% in the period. The increase in gross profit was driven primarily by increased sales, particularly from valvulotomes, bovine vascular patches, bovine grafts and porcine patches. The increase in gross margin was driven primarily by favorable product mix, including sales of comparatively higher margin valvulotomes, and manufacturing efficiencies, which were partially offset by increased scrap and excess and obsolescence charges.

Operating Expenses. The following table sets forth the change in our operating expenses for the periods indicated and the change between the specified periods expressed as a percentage increase or decrease:

	2023	2022	\$ change	Percent change	2023 as a % of Net Sales	2022 as a % of Net Sales
	(\$ in thousands)					
Sales and marketing	\$ 41,054	\$ 32,921	\$ 8,133	25%	21%	20%
General and administrative.....	31,832	28,745	3,087	11%	16%	18%
Research and development.....	16,966	13,294	3,672	28%	9%	8%
Restructuring	485	3,107	(2,622)	(84%)	0%	2%
	<u>\$ 90,337</u>	<u>\$ 78,067</u>	<u>\$ 12,270</u>	<u>16%</u>	<u>47%</u>	<u>48%</u>

Sales and marketing. For the year ended December 31, 2023, sales and marketing expenses increased 25% to \$41.1 million. The increase was driven primarily by higher sales and associated commissions, contest and bonus expenses, increased sales rep and marketing headcounts, and an increase in salaries and wages. Compensation and related expenses increased by \$6.1 million, travel and training expenses increased by \$0.8 million, and sales meetings and trade show expenses increased by \$0.7 million. Sales rep headcount was 136 as of December 31, 2023, a 4% increase from December 31, 2022. As a percentage of net sales, sales and marketing expenses increased to 21% for the year ended December 31, 2023, up from 20% in the prior period.

General and administrative. For the year ended December 31, 2023, general and administrative expenses increased 11% to \$31.8 million. The increase was driven primarily by higher compensation and related expenses of \$1.7 million due to an increase in personnel. Additionally, professional fees and outside services expenses increased \$1.4 million. As a percentage of sales, general and administrative expenses decreased to 16% for the year ended December 31, 2023, down from 18% in the prior period.

Research and development. For the year ended December 31, 2023, research and development expenses increased 28% to \$17.1 million. The increase was driven primarily by higher outside services and testing expenses of \$2.0 million, due to higher consulting and third-party costs largely associated with European regulatory approvals. Our products are currently regulated in the EU and the UK under the European MDD and MDR. Additionally, compensation and related expenses increased \$1.4 million due to an increase in personnel. As a percentage of sales, total research and development expenses increased to 9% for the year ended December 31, 2023, up from 8% in the prior period.

Restructuring. For the year ended December 31, 2023, restructuring expenses were \$0.5 million. On June 30, 2022, we ceased operations at our St. Etienne, France factory. The closure resulted in a restructuring charge of \$3.1 million for the year ended December 31, 2022. These charges consisted primarily of employment termination costs, impairment of fixed assets and inventory, and third-party costs. For the year ended December 31, 2023 we recorded additional restructuring charges in conjunction with the St. Etienne, France factory closure of \$0.5 million. The additional charges consisted primarily of employment termination, settlement, legal and other third-party costs. As a percentage of sales, restructuring expenses was less than 1% for the year ended December 31, 2023.

Income tax expense. We recorded a tax provision of \$9.4 million on pre-tax income of \$39.5 million for the twelve months ended December 31, 2023, compared to \$6.9 million on pre-tax income of \$27.5 million for the twelve months ended December 31, 2022.

Our effective income tax rate was 25.3% and 23.7% for the three- and twelve-month periods ended December 31, 2023. Our tax expense for 2023 is based on an estimated annual effective tax rate of 26.1%, adjusted in the applicable quarterly periods for discrete stock option exercises and other discrete items. Our income tax expense for 2023 varies from the statutory rate mainly due to federal and state tax credits, permanent items, different statutory rates from our foreign entities, and a discrete item for stock option exercises.

Our effective income tax rate was 27.8% and 24.9% for the three- and twelve-month periods ended December 31, 2022. Our 2022 provision was based on an estimated annual effective tax rate of 26.0%, adjusted in the applicable quarterly period for discrete stock option exercises and other discrete items. Our income tax expense for 2022 varied from the statutory rate mainly due to permanent items, different statutory rates from our foreign entities, and a discrete item for stock option exercises.

We monitor the mix of profitability by tax jurisdiction and adjust our annual expected rate on a quarterly basis as needed. While it is often difficult to predict the final outcome or timing of the resolution for any particular tax matter, we believe our tax reserves reflect the probable outcome of known contingencies.

We assess the likelihood that our deferred tax assets will be realized through future taxable income and record a valuation allowance to reduce gross deferred tax assets to an amount we believe is more likely than not to be realized. As of December 31, 2023, we have provided a valuation allowance of \$1.7 million for deferred tax assets primarily related to Australian net operating loss and capital loss carry forwards and Massachusetts tax credit carry forwards that are not expected to be realized.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to amortize such expenditures over five years for tax purposes. This provision resulted in a cash tax liability for the 2023 tax year of approximately \$0.7 million. Our net deferred tax assets increased in 2023 by approximately \$0.8 million as a result as well. This provision is also expected to increase our 2024 cash tax liability. The actual impact on 2024 cash tax liability will depend on the amount of research and development expenses paid or incurred in 2024 among other factors. While the largest impacts of this provision will be to 2022 and 2023 cash tax liability, the impact will continue over the five-year amortization period, but will decrease ratably over the period.

The Inflation Reduction Act (IRA) was enacted into law on August 16, 2022. Included in the IRA was a provision to implement a 15% corporate alternative minimum tax on “adjusted financial statement income” for applicable corporations and a 1% excise tax on repurchases of stock. These provisions are effective for tax years beginning after December 31, 2022. We have evaluated the provisions of the IRA, and we do not currently believe the IRA will have a material impact on our reported results, cash flows or financial position.

Comparison of the year ended December 31, 2022 to the year ended December 31, 2021

The following table sets forth, for the periods indicated, our net sales by geography, and the change between the specified periods expressed as a percentage increase or decrease:

	2022	2021	\$ Change	Percent change
	(\$ in thousands)			
Net sales	\$ 161,651	\$ 154,424	\$ 7,227	5%
Net sales by geography:				
Americas	\$ 109,439	\$ 102,265	\$ 7,174	7%
Europe, Middle East and Africa..	41,854	42,132	(278)	(1%)
Asia Pacific	10,358	10,027	331	3%
Total	<u>\$ 161,651</u>	<u>\$ 154,424</u>	<u>\$ 7,227</u>	<u>5%</u>

Net sales. Net sales increased by \$7.2 million, or 5%, to \$161.7 million for the year ended December 31, 2022, compared to \$154.4 million for the year ended December 31, 2021. The increase was driven primarily by increased bovine graft sales of \$2.9 million, carotid patch sales of \$2.4 million, shunt sales of \$2.4 million, and allograft preservation services of \$1.7 million. The increased sales were partially offset by decreased ovine graft sales of \$1.5 million (largely due to regulatory and production related back-orders which totaled approximately \$1.0 million at year end) and surgical glue sales of \$0.7 million. We estimate that the stronger U.S. dollar decreased net sales by \$6.1 million during the year ended December 31, 2022 as compared to the year ended December 31, 2021.

Direct-to-hospital net sales were 95% and 94% of our total net sales for the years ended December 31, 2022 and 2021, respectively.

Net sales by geography. Net sales in the Americas increased \$7.2 million, or 7%, for the year ended December 31, 2022 as compared to the year ended December 31, 2021. The increase was driven primarily by increased bovine graft sales of \$2.9 million, allograft preservation services of \$1.3 million, shunt sales of \$1.1 million, valvulotomes sales of \$0.9 million, and carotid patch sales of \$0.6 million.

EMEA net sales decreased \$0.3 million, or 1%, for the year ended December 31, 2022 as compared to the year ended December 31, 2021. The decrease was driven primarily by a comparatively stronger dollar in 2022, as well as decreased ovine graft sales of \$1.5 million (largely due to regulatory and production related back-orders which totaled approximately \$1.0 million at year end), and surgical glue sales of \$0.7 million. The decreased sales were partially offset by increased shunt sales of \$1.4 million and carotid patch sales of \$1.1 million.

Asia Pacific net sales increased \$0.3 million, or 3%, for the year ended December 31, 2022 as compared to the year ended December 31, 2021. The increase was driven primarily by increased carotid patch sales of \$0.7 million and embolectomy catheters sales of \$0.3 million. The increased sales were partially offset by a comparatively stronger dollar in 2022, as well as decreased occlusion catheters, valvulotome, shunt, and clip sales of \$0.1 million each.

Gross Profit. The following table sets forth the change in our gross profit and gross margin for the periods indicated:

	2022	2021	Change	Percent change
			(\$ in thousands)	
Gross profit.....	\$ 104,896	\$ 101,382	\$ 3,514	3%
Gross margin	64.9%	65.7%	(0.8%)	*

* Not applicable

Gross profit increased \$3.5 million, or 3%, to \$104.9 million for the year ended December 31, 2022, and gross margin decreased by 80 basis points to 64.9% in the period. The increase in gross profit was driven primarily by increased sales from bovine grafts, carotid patches, and shunts. The decrease in the gross margin was driven primarily by unfavorable changes in foreign currency exchange rates, manufacturing inefficiencies largely related to increased direct labor and quality costs, and unfavorable product mix including higher sales of comparatively lower margin embolectomy catheters and polyester grafts and lower sales of comparatively higher margin valvulotomes.

Operating Expenses. The following table sets forth the change in our operating expenses for the periods indicated and the change between the specified periods expressed as a percentage increase or decrease:

	2022	2021	\$ change	Percent change	2022 as a % of Net Sales	2021 as a % of Net Sales
			(\$ in thousands)			
Sales and marketing	\$ 32,921	\$ 27,655	\$ 5,266	19%	20%	18%
General and administrative.....	28,745	25,501	3,244	13%	18%	17%
Research and development.....	13,294	11,801	1,493	13%	8%	8%
Restructuring	3,107	-	3,107	*	2%	0%
	<u>\$ 78,067</u>	<u>\$ 64,957</u>	<u>\$ 13,110</u>	<u>20%</u>	<u>48%</u>	<u>42%</u>

* Not a meaningful percentage.

Sales and marketing. For the year ended December 31, 2022, sales and marketing expenses increased 19% to \$32.9 million. The increase was driven primarily by higher salaries and related expenses of \$4.1 million, including higher sales commissions of \$1.4 million. From December 31, 2021 to December 31, 2022, we increased our sales representative headcount from 103 to 131. We also added two additional regional sales managers in the period. Travel and related expenses were also higher by \$0.8 million. Expense reduction programs implemented in 2020 through 2021 in response to COVID-19, including a reduction in sales force, lowered expenses for the year ended December 31, 2021. We have since rehired in many areas, including our sales force. As a percentage of net sales, sales and marketing expenses increased to 20% for the year ended December 31, 2022, up from 18% in the prior period.

General and administrative. For the year ended December 31, 2022, general and administrative expenses increased 13% to \$28.7 million. The increase was driven primarily by higher salaries and related expenses of \$2.7 million due to an increase in personnel. Additionally, in 2021 we recognized a gain of \$0.5 million related to the amendment of a contingent purchase obligation associated with our 2019 Anteris biologic patch acquisition which lowered general and administrative expenses. As a percentage of sales, general and administrative expenses increased to 18% for the year ended December 31, 2022, up from 17% in the prior period.

Research and development. For the year ended December 31, 2022, research and development expenses increased 13% to \$13.3 million. The increase was driven primarily by higher salaries and related expenses of \$1.1 million due to an increase in personnel. Outside services and testing also increased by \$0.5 million primarily due to higher third-party costs associated with European regulatory approvals. Our products are currently regulated in the EU and the UK under the MDD and MDR. As a percentage of sales, total research and development expenses was 8% for both 2022 and 2021.

Restructuring. For the year ended December 31, 2022, restructuring expenses was \$3.1 million. On June 30, 2022 we ceased operations at our St. Etienne, France factory. The closure resulted in a restructuring charge of \$3.1 million for the year ended December 31, 2022. Charges primarily consisted of employment termination costs, impairment of fixed assets and inventory, and third-party costs.

Income tax expense. We recorded a tax provision of \$6.9 million on pre-tax income of \$27.5 million for the twelve months ended December 31, 2022, compared to \$7.4 million on pre-tax income of \$34.3 million for the twelve months ended December 31, 2021.

Our effective income tax rate was 27.8% and 24.9% for the three- and twelve-month periods ended December 31, 2022. Our tax expense for 2022 is based on an estimated annual effective tax rate of 26.0%, adjusted in the applicable quarterly periods for discrete stock option exercises and other discrete items. Our income tax expense for 2022 varies from the statutory rate mainly due to permanent items, different statutory rates from our foreign entities, and a discrete item for stock option exercises.

Our effective income tax rate was 21.9% and 21.5% for the three- and twelve-month periods ended December 31, 2021. Our 2021 provision was based on an estimated annual effective tax rate of 24.7%, adjusted in the applicable quarterly period for discrete stock option exercises and other discrete items. Our income tax expense for 2021 varied from the statutory rate mainly due to federal and state tax credits, permanent items, different statutory rates from our foreign entities, and a discrete item for stock option exercises.

As of December 31, 2022, we had provided a valuation allowance of \$1.6 million for deferred tax assets primarily related to Australian net operating loss and capital loss carry forwards and Massachusetts tax credit carry forwards that are not expected to be realized.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to amortize such expenditures over five years for tax purposes. This provision resulted in a cash tax liability for the 2022 tax year of approximately \$0.7 million. Our net deferred tax assets increased in 2022 by approximately \$0.7 million as a result as well.

Liquidity and Capital Resources

On February 21, 2024, our Board of Directors authorized the repurchase of up to \$50.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 21, 2025. The repurchase program may be suspended or discontinued at any time. To date we have not made any repurchases under this program.

As of December 31, 2023, our cash and cash equivalents were \$24.3 million as compared to \$19.1 million as of December 31, 2022. We had \$80.8 million in short-term marketable securities as of December 31, 2023 and \$63.6 million as of December 31, 2022. Our cash and cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase, and consist primarily of operating bank accounts. Our short-term marketable securities consist of a managed income mutual fund investing mainly in short-term investment grade, U.S.-dollar denominated fixed and floating-rate debt, and a short-duration bond fund. As of December 31, 2023 our short-term marketable securities reflected an unrealized loss of \$1.2 million as a result of increasing market interest rates.

On July 16, 2021, we closed an offering of 1,000,000 shares of our common stock, \$0.01 par value per share, at a price to the public of \$54.50 per share less underwriting discounts. The net proceeds, after deducting the underwriting discounts and other offering expenses, were approximately \$51.0 million. We used a portion of the proceeds from the offering to repay our outstanding debt. On August 4, 2021, the underwriters purchased an additional 150,000 shares pursuant to an option granted to them in connection with the offering described above. The net proceeds to the Company, after deducting underwriting discounts and other offering expenses, were approximately \$7.6 million.

In June 2020, in connection with the Artegraft acquisition, we incurred debt of \$65 million including a five-year revolving line of credit of \$25 million and a five-year term loan of \$40 million. The loans bore interest at either the Base Rate as defined in the agreement plus an applicable margin of 1.25% to 1.75% depending on our consolidated leverage ratio, or the Eurodollar Rate plus an applicable margin of 2.25% to 2.75% depending on our consolidated leverage ratio. In July 2021, we repaid the balance under the term loan, plus accrued interest, in full. In November 2021, we terminated the credit agreement, including the revolving line of credit, as allowed for in the original agreement.

Operating and Capital Expenditure Requirements

We require cash to pay our operating expenses, make capital expenditures, and pay our long-term liabilities. Since our inception, we have funded our operations through public offerings and private placements of equity securities, short-term and long-term borrowings, and funds generated from our operations.

We recognized operating income of \$36.7 million for the year ended December 31, 2023, \$26.8 million for the year ended December 31, 2022, and \$36.4 million for the year ended December 31, 2021. We expect to fund any increased costs and expenditures from our existing cash and cash equivalents, though our future capital requirements depend on numerous factors. These factors include, but are not limited to, the following:

- revenues generated by sales of our products and services;
- payments associated with potential future quarterly cash dividends to our common stockholders;
- future acquisition-related payments;
- payments associated with income and other taxes;
- costs associated with expanding our manufacturing, marketing, sales, and distribution efforts;
- costs associated with our initiatives to sell direct-to-hospital in new countries;
- costs of obtaining and maintaining U.S. FDA and other regulatory clearances;
- costs associated with obtaining European MDR clearances;
- the number, timing, and nature of acquisitions, divestitures and other strategic transactions, and
- potential future share repurchases.

Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, pay dividends, repurchase shares of our common stock and make deferred payments related to prior acquisitions. We believe that our cash, cash equivalents, investments and the interest we earn on these balances will be sufficient to meet our anticipated cash requirements for at least the next twelve months and to meet our known long-term cash requirements. If these sources of cash are insufficient to satisfy our liquidity requirements beyond the next twelve months, we may seek to sell additional equity or debt securities or take out a loan. The sale of additional equity and debt securities may result in dilution to our stockholders, as was the case with our July 2021 equity offering. If we raise additional funds through the issuance of debt securities, such securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations and possibly our ability to pay dividends. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all.

Cash Flows

	Year ended December 31,		
	2023	2022	2021
		(\$ in thousands)	
Cash and cash equivalents.....	\$ 24,269	\$ 19,134	\$ 13,855
Cash flows provided by (used in):			
Operating activities.....	\$ 36,751	\$ 25,378	\$ 35,102
Investing activities.....	(24,715)	(10,371)	(61,076)
Financing activities.....	(7,131)	(9,234)	13,702

Net cash provided by operating activities. Net cash provided by operating activities was \$36.8 million for the year ended December 31, 2023, and consisted of \$30.1 million net income, adjusted for non-cash items of \$17.9 million (including primarily depreciation and amortization of \$9.5 million, stock-based compensation of \$5.3 million, provisions for inventory write-offs and credit losses of \$2.6 million, provision for deferred income taxes of \$0.8 million, and loss on divestitures of \$0.5 million, offset by foreign currency transaction effect on income of \$0.7 million and fair value adjustments to contingent consideration obligations for acquisitions of \$0.1 million), as well as cash used for working capital of \$11.3 million. The net cash used for working capital was driven by increases in inventory and other deferred costs of \$9.8 million, increases in accounts receivable of \$3.1 million, and increases in prepaid expenses and other assets of \$2.9 million, offset by increases in accounts payable and other liabilities of \$4.6 million.

Net cash provided by operating activities was \$25.4 million for the year ended December 31, 2022, and consisted of \$20.6 million net income, adjusted for non-cash items of \$18.1 million (including primarily depreciation and amortization of \$9.4 million, stock-based compensation of \$4.2 million, provisions for inventory write-offs and credit losses of \$3.2 million, loss on divestitures of \$2.0 million, and loss on disposal of fixed assets of \$0.1 million, offset by foreign currency transaction effect on income of \$0.3 million, benefit for deferred income taxes of \$0.2 million, gain on sale of building of \$0.1 million, and fair value adjustments to contingent consideration obligations for acquisitions of \$0.1 million), as well as cash used for working capital of \$13.4 million. The net cash used for working capital was driven by increases in inventory and other deferred costs of \$7.4 million, increases in accounts receivable of \$3.5 million, and increases in prepaid expenses and other assets of \$3.1 million, offset by increases in accounts payable and other liabilities of \$0.6 million.

Net cash provided by operating activities was \$35.1 million for the year ended December 31, 2021, and consisted of \$26.9 million net income, adjusted for non-cash items of \$18.2 million (including primarily depreciation and amortization of \$11.1 million, stock-based compensation of \$3.5 million, provisions for inventory write-offs and credit losses of \$4.0 million, foreign currency transaction effect on income of \$0.2 million, and provision for deferred income taxes of \$0.1 million, offset by fair value adjustments to contingent consideration obligations for acquisitions of \$0.7 million), as well as cash used for working capital of \$10.0 million. The net cash used for working capital was driven by increases in inventory and other deferred costs of \$5.5 million, increases in prepaid expenses and other assets of \$1.9 million, decreases in accounts payable and other liabilities of \$1.7 million and increases in accounts receivable of \$0.8 million.

Net cash used in investing activities. Net cash used in investing activities was \$24.7 million for the year ended December 31, 2023, including purchases of marketable securities of \$16.6 million, purchases of property and equipment of \$7.3 million, and acquisition related payments of \$0.9 million.

Net cash used in investing activities was \$10.4 million for the year ended December 31, 2022, including purchases of marketable securities of \$8.0 million and purchases of property and equipment of \$3.2 million, offset by proceeds from the sale of the St. Etienne, France building of \$0.9 million.

Net cash used in investing activities was \$61.1 million for the year ended December 31, 2021, including net purchases of marketable securities of \$56.2 million and purchases of property and equipment of \$4.9 million.

Net cash provided by (used in) financing activities. Net cash used in financing activities was \$7.1 million for the year ended December 31, 2023. Use of cash included dividend payments of \$12.4 million. This use of cash was offset by proceeds from stock option exercises of \$5.3 million, net of shares repurchased to cover employee payroll taxes.

Net cash used in financing activities was \$9.2 million for the year ended December 31, 2022. Use of cash included dividend payments of \$11.0 million and deferred payments for acquisitions of \$1.1 million. These uses of cash were offset by proceeds from stock option exercises of \$2.8 million, net of shares repurchased to cover employee payroll taxes.

Net cash provided by financing activities was \$13.7 million for the year ended December 31, 2021. Sources of cash included primarily net proceeds from an equity offering of \$58.7 million and proceeds from stock option exercises of \$3.7 million, net of shares repurchased to cover employee payroll taxes. These sources of cash were offset by payments made on our long-term debt of \$39.0 million, dividend payments of \$9.3 million and deferred payments for acquisitions of \$0.4 million.

Dividends

In February 2011, our Board of Directors approved a policy for the payment of quarterly cash dividends on our common stock. Future declarations of quarterly dividends and the establishment of future record and payment dates are subject to approval by our Board of Directors on a quarterly basis. The dividend activity for the periods presented is as follows:

<u>Record Date</u>	<u>Payment Date</u>	<u>Per Share Amount</u>	<u>Dividend Payment</u>
			(in thousands)
Fiscal Year 2023			
March 9, 2023	March 23, 2023	\$ 0.140	\$ 3,099
May 17, 2023	June 1, 2023	\$ 0.140	\$ 3,116
August 17, 2023	August 31, 2023	\$ 0.140	\$ 3,117
November 16, 2023	November 30, 2023	\$ 0.140	\$ 3,117
Fiscal Year 2022			
March 8, 2022	March 24, 2022	\$ 0.125	\$ 2,743
May 17, 2022	June 2, 2022	\$ 0.125	\$ 2,745
August 25, 2022	September 8, 2022	\$ 0.125	\$ 2,750
November 17, 2022	December 1, 2022	\$ 0.125	\$ 2,750

On February 21, 2024, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.160 per share payable on March 28, 2024, to stockholders of record at the close of business on March 14, 2024, which will total approximately \$3.6 million.

Critical Accounting Policies and Estimates

We have adopted various accounting policies to prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP). Our most significant accounting policies are described in Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The preparation of our consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to revenue recognition, inventory valuation, valuation of intangible assets and goodwill, contingent consideration and income taxes are reviewed on an ongoing basis and updated as appropriate. Actual results could differ from those estimates.

Certain of our more critical accounting policies require the application of judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, and observance of trends in the industry, as appropriate. Different, reasonable estimates could have been used in the current period. Additionally, changes in accounting estimates are reasonably likely to occur from period to period. Both of these factors could have a material impact on the presentation of our financial condition, changes in financial condition, or results of operations.

We believe that the following financial estimates and related accounting policies are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recorded in our consolidated financial statements for all periods presented. Management has discussed the development, selection and disclosure of our most critical financial estimates with the audit committee of our board of directors and our independent registered public accounting firm. The judgments about those financial estimates are based on information available as of the date of our consolidated financial statements. Those financial estimates and related policies include:

Revenue Recognition

Our revenue is derived primarily from the sale of disposable or implantable devices used during vascular surgery. We sell primarily directly to hospitals and to a lesser extent to distributors, as described below, and, during the periods presented in our consolidated financial statements, entered into consigned inventory arrangements with either hospitals or distributors on a limited basis. We also derive revenues from the processing and cryopreservation of human tissue for implantation in patients. These revenues are recognized when services have been provided and the tissue has been shipped to the customer, provided all other revenue recognition criteria discussed in the succeeding paragraph have been met.

We record revenue under the provisions of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of Topic 606 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard explains that to achieve the core principle, an entity should take the following actions:

Step 1: Identify the contract with a customer

Step 2: Identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price

Step 5: Recognize revenue when or as the entity satisfies a performance obligation

Revenue is recognized when or as a company satisfies a performance obligation by transferring a promised good or service to a customer (which is when the customer obtains control of that good or service). In instances in which shipping and handling activities are performed after a customer takes control of the goods (such as when title passes upon shipment from our dock), we have made the policy election allowed under Topic 606 to account for these activities as fulfillment costs and not as performance obligations.

We generally reference customer purchase orders to determine the existence of a contract. Orders that are not accompanied by a purchase order are confirmed with the customer either in writing or verbally. The purchase orders or similar correspondence, once accepted, identify the performance obligations as well as the transaction price, and otherwise outline the rights and obligations of each party. We allocate the transaction price of each contract among the performance obligations in accordance with the pricing of each item specified on the purchase order, which is in turn based on standalone selling prices per our published price lists. In cases where we discount products or provide certain items free of charge, we allocate the discount proportionately to all performance obligations, unless it can be demonstrated that the discount should be allocated entirely to one or more, but not all, of the performance obligations.

We record revenue, net of allowances for returns and discounts, fees paid to group purchasing organizations, and any sales and value added taxes required to be invoiced, which we have elected to exclude from the measurement of the transaction price as allowed by the standard, at the time of shipment (taking into consideration contractual shipping terms), or in the case of consigned inventory, when it is consumed. Shipment is the point at which control of the product and title passes to our customers, and at which LeMaitre has a present right to receive payment for the goods.

We do not carry any contract assets or contract liabilities, as there are generally no unbilled amounts due from customers under contracts for which we have partially satisfied performance obligations, or amounts received from customers for which we have not satisfied performance obligations. We satisfy our performance obligations under revenue contracts within a short time period from receipt of the orders, and payments from customers are typically received within 30 to 60 days of fulfillment of the orders, except in certain geographies such as Italy, Spain and France where the payment cycle is customarily longer. Accordingly, there is no significant financing component to our revenue contracts. Additionally, we have elected as a policy that incremental costs (such as commissions) incurred to obtain contracts are expensed as incurred, due to the short-term nature of the contracts.

Customers returning products may be entitled to full or partial credit based on the condition and timing of the return. To be accepted, a returned product must be unopened (if sterile), unadulterated, and undamaged, must have at least 18 months remaining prior to its expiration date, or twelve months for our hospital customers in Europe, and generally be returned within 30 days of shipment. These return policies apply to sales to both hospitals and distributors. The amount of products returned to us, either for exchange or credit, has not been material. Nevertheless, we provide for an allowance for future sales returns based on historical return experience, which requires judgment. Our cost of replacing defective products has not been material and is accounted for at the time of replacement.

Inventory and Other Deferred Costs

Inventory and Other Deferred Costs consists of finished products, work-in-process, raw materials and costs deferred in connection with human tissue cryopreservation services of our RestoreFlow allograft business. We value inventory and other deferred costs at the lower of cost or market value. Cost includes materials, labor and manufacturing overhead and is determined using the first-in, first-out (FIFO) method. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based primarily on product expiration dating and our estimated sales forecast, which is based on sales history and anticipated future demand. Our estimates of future product demand may not be accurate, and we may understate or overstate the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations.

Valuation of Intangible Assets and Goodwill

Intangible assets consist primarily of purchased developed technology, patents, customer relationships and trademarks, and are amortized over their estimated useful lives, ranging from 2 to 16 years. Goodwill represents the amount of consideration paid in connection with business acquisitions in excess of the fair value of assets acquired and liabilities assumed. We generally calculate the fair value of our intangible assets as the present value of estimated future cash flows we expect to generate from the asset using a risk-adjusted discount rate. In determining our estimated future cash flows associated with our intangible assets, we use estimates and assumptions about future revenue contributions, cost structures, and remaining useful lives of the asset. These estimates and assumptions require significant judgment and actual results may differ from assumed or estimated amounts. Other intangible assets, net of accumulated amortization, were \$41.7 million as of December 31, 2023 and \$46.5 million as of December 31, 2022. Goodwill was \$65.9 million as of both December 31, 2023 and December 31, 2022.

Contingencies

In the normal course of business, we are subject to proceedings, lawsuits, and other claims and assessments for matters related to, among other things, business acquisitions, employment, commercial matters, intellectual property matters, product liability and product recalls. We assess the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of reserves required, if any, for these contingencies is made after careful analysis of each individual issue. The required reserves may change in the future due to new developments in each matter or changes in approach such as a change in settlement strategy in dealing with these matters. We record charges for the costs we anticipate incurring in connection with litigation and claims against us when we determine a loss is probable and we can reasonably estimate these costs. During the years ended December 31, 2023, 2022, and 2021, we were not subject to any material litigation, claims or assessments.

In connection with certain of our acquisitions, we may enter into agreements to pay additional future consideration upon the satisfaction of certain agreed-upon criteria. We record liabilities for these arrangements at estimated fair value reflecting management's assumptions of the likelihood of achieving the specified criteria at the time of the closing, which may require significant judgment. These amounts are remeasured each reporting period, with any adjustments recorded in income from operations.

Income Taxes

We account for income taxes under the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred taxes are determined based on the difference between the financial reporting and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. The provision for income taxes includes taxes currently payable and deferred taxes resulting from the tax effects of temporary differences between the financial statement and tax bases of assets and liabilities. We maintain valuation allowances where it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in the valuation allowances are included in our tax provision in the period of change. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings, carry-back and carry-forward periods and tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset.

We recognize, measure, present and disclose in our financial statements, uncertain tax positions that we have taken or expect to take on a tax return. We recognize in our financial statements the impact of tax positions that meet a "more likely than not" threshold, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense.

Recent Accounting Pronouncements

See Note 1 “Significant Accounting Policies and Related Matters” of the Notes to Consolidated Financial Statements in Item 8 “Financial Statements and Supplementary Data” for additional information regarding recent accounting pronouncements, including the respective expected dates of adoption and estimated effects, if any, on our Consolidated Financial Statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

In the ordinary course of conducting business, we are exposed to certain risks associated with potential changes in market conditions. These market risks include changes in currency exchange rates and interest rates which could affect operating results, financial position and cash flows.

Foreign Currency Risk

During both fiscal 2023 and 2022, 39% of our total revenue was from customers outside of the U.S. In addition, a significant portion of our operating costs incurred outside the U.S. are denominated in currencies other than the U.S. dollar. We conduct business on a worldwide basis and as a result, a portion of our revenue, earnings, net assets, and net investments in foreign affiliates is exposed to changes in foreign currency exchange rates. We measure our net exposure for cash balance positions and for cash inflows and outflows in order to evaluate the need to mitigate our foreign exchange risk. We may enter into foreign currency forward contracts to minimize the impact related to unfavorable exchange rate movements, although we did not do so during 2023 or 2022. Our largest exposures to foreign currency exchange rates exist primarily with the Euro, British pound, Canadian dollar, Australian dollar and Japanese yen.

During the years ended December 31, 2023 and 2022, we recorded \$0.3 million and \$0.4 million of net foreign currency exchange losses, respectively, related to the settlement and remeasurement of transactions denominated in currencies other than the functional currency of our operating subsidiaries. Our analysis of operating results transacted in various foreign currencies indicated that a hypothetical 10% change in the foreign currency exchange rates could have increased or decreased the consolidated results of operations by approximately \$1.6 million for 2023.

Interest Rate Risk

As of December 31, 2023, we held \$24.3 million in cash and cash equivalents and \$80.8 million in a short-term managed income mutual fund investment. We believe that a hypothetical 10% increase or decrease in interest rates could have a material impact on our cash balances and financial position, results of operations or cash flows. As of December 31, 2023, our short-term marketable securities reflected an unrealized loss of \$1.2 million as a result of increasing market interest rates.

Item 8. Financial Statements and Supplementary Data

See the consolidated financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below, which are incorporated by reference herein.

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

Not Applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for our disclosure controls and procedures pursuant to Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified under SEC rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is

accumulated and communicated to our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. We design our disclosure controls and procedures to ensure, at reasonable assurance levels, that such information is timely recorded, processed, summarized and reported, and then accumulated and communicated appropriately.

Based on an evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at reasonable assurance levels.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Management assessed the effectiveness of our internal controls over financial reporting as of December 31, 2023. Management based its assessment on criteria established in the *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment under the criteria set forth in the *Internal Control — Integrated Framework*, management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

Our internal control over financial reporting as of December 31, 2023 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their respective report which is included herein.

Changes in Internal Control over Financial Reporting

As previously disclosed, we are in the process of completing an implementation of a new ERP system. The ERP implementation required the integration of the new ERP system with multiple new and existing information systems and business processes. The new ERP is designed to accurately maintain our books and records and provide information to our management teams which is important to the operations of the business. As the phased implementation of the new ERP system progresses, we expect to continue to change certain processes and procedures which, in turn, are expected to result in changes to our internal control over financial reporting. As such changes occur, we will evaluate quarterly whether such changes materially affect our internal control over financial reporting. As of December 31, 2023, the new ERP system was not in service and therefore did not impact our internal control over financial reporting.

There were no other changes to our internal control over financial reporting that occurred during the fiscal year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Notwithstanding the foregoing, our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. 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, within the company 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 control. The design of any system of controls also is 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, control may become inadequate because of changes in conditions, or the degree of compliance with the 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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
LeMaitre Vascular, Inc.

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of LeMaitre Vascular, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2023, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated financial statements of the Company as of and for the year ended December 31, 2023, and our report dated February 29, 2024 expressed an unqualified opinion on those financial statements.

Basis for opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and limitations of internal control over financial reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ GRANT THORNTON LLP

Boston, Massachusetts
February 29, 2024

Item 9B. Other Information

During the fiscal quarter ended December 31, 2023, none of our directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement, as those terms are defined in Regulation S-K, Item 408.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III**Item 10. Directors, Executive Officers and Corporate Governance**

The information responsive to this item is incorporated by reference herein from the information to be contained in the sections entitled “Directors, Executive Officers and Key Employees,” “Corporate Governance,” and “Meetings and Committees of the Board of Directors” in our 2024 definitive proxy statement (2024 Definitive Proxy Statement) for the 2024 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2023.

The information required by this item concerning compliance with Section 16(a) of the Exchange Act is incorporated herein by reference from the information contained in the section entitled “Delinquent Section 16(a) Reports” in our 2024 Definitive Proxy Statement, to the extent required to be included.

Code of Ethics

Certain documents relating to our corporate governance, including our Code of Business Conduct and Ethics, which is applicable to our directors, officers, and employees, and the charters of the Audit Committee, Compensation Committee, and Corporate Governance and Nominating Committee of our Board of Directors, are available on our website at <http://www.lemaitre.com>. We intend to disclose substantive amendments to or waivers (including implicit waivers) of any provision of the Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions, by posting such information on our website available at <http://www.lemaitre.com>.

Item 11. Executive Compensation

The information responsive to this item is incorporated herein by reference from the information to be contained in the section entitled “Compensation of Executive Officers and Directors” in our 2024 Definitive Proxy Statement.

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

The information responsive to this item is incorporated herein by reference from the information to be contained in the section entitled “Security Ownership of Certain Beneficial Owners and Management” in our 2024 Definitive Proxy Statement.

Equity Compensation Plan Information

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2023. Each of our equity compensation plans is an “employee benefit plan” as defined by Rule 405 of Regulation C of the Securities Act of 1933, as amended.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans, excluding securities reflected in column (a)
	(a)	(b)	(c)
<i>Equity compensation plans approved by security holders</i>	961,282	\$ 43.95	273,588
<i>Equity compensation plans not approved by security holders</i>	-	-	-
Total	<u>961,282</u>	<u>\$ 43.95</u>	<u>273,588</u>

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

The information required responsive to this item is incorporated herein by reference from the information to be contained in the sections entitled “Certain Relationships and Related Transactions” and “Corporate Governance” in our 2024 Definitive Proxy Statement.

Item 14. Principal Accountant Fees and Services

The information responsive to this item is incorporated herein by reference from the information to be contained in the sections entitled “Ratification of Independent Registered Public Accounting Firm” and “Additional Information Regarding Our Independent Registered Public Accounting Firm” in our 2024 Definitive Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

a) Documents filed as part of this Report.

(1) The following consolidated financial statements are filed herewith in Item 8 of Part II above.

- (i) Report of Independent Registered Public Accounting Firm
- (ii) Consolidated Balance Sheets
- (iii) Consolidated Statements of Operations
- (iv) Consolidated Statements of Changes in Stockholders' Equity
- (v) Consolidated Statements of Comprehensive Income
- (vi) Consolidated Statements of Cash Flows
- (vii) Notes to Consolidated Financial Statements

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

(3) Exhibits

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
2.1	Asset Purchase Agreement dated October 11, 2019 between the Registrant and Admedus Ltd and certain of its subsidiaries	10-K	3/12/20	001-33092	
2.2	Amendment No. 1 to Asset Purchase Agreement dated October 11, 2019 between the Registrant and Admedus Ltd (now known as Anteris Technologies Ltd) and certain of its subsidiaries.	8-K	9/1/21	001-33092	
2.3^	Asset Purchase Agreement, dated June 22, 2020, by and between the Company and Artegraft, Inc.	8-K	6/24/20	001-33092	
3.1	Amended and Restated By-laws of the Registrant	S-1/A	5/26/06	001-33092	
3.2	Second Amended and Restated Certificate of Incorporation of the Registrant	10-K	3/29/10	001-33092	
3.3	Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant	8-K	6/15/12	001-33092	
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	6/22/06	333-133532	

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
4.2	Description of Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended	10-K	3/12/20	001-33092	
10.1	Director Compensation Policy	10-Q	8/5/21	001-33092	
10.2†	Executive Retention and Severance Agreement dated October 10, 2005, by and between the Registrant and George W. LeMaitre	S-1/A	5/26/06	333-133532	
10.3†	First Amendment to Executive Retention and Severance Agreement dated December 23, 2008, by and between the Registrant and George W. LeMaitre	10-K	3/31/09	001-33092	
10.4†	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts	S-1/A	6/22/06	333-133532	
10.5†	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and David Roberts	10-K	3/31/09	001-33092	
10.6†	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino	S-1/A	6/22/06	333-133532	
10.7†	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and Joseph P. Pellegrino	10-K	3/31/09	001-33092	
10.8†	Form of Indemnification Agreement between the Registrant and its directors and executive officers	S-1/A	5/26/06	333-133532	
10.9	Northwest Park Lease dated March 31, 2003, by and between the Registrant and Roger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, as amended	S-1	4/25/06	333-133532	
10.10	Second Amendment of Lease dated May 21, 2007, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	8-K	6/15/07	001-33092	
10.11	Third Amendment of Lease dated February 26, 2008, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	8-K	4/10/08	001-33092	
10.12	Fourth Amendment of Lease dated October 31, 2008, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	10-K	3/31/09	001-33092	
10.13	Fifth Amendment of Lease dated March 23, 2010, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	10-K	3/29/10	001-33092	
10.14	Sixth Amendment of Lease dated December 20, 2013, by and between NWP Building 5 LLC, as successor-in-interest to the Trustees of Northwest Associates, and Registrant	8-K	12/23/13	001-33092	
10.15	Seventh Amendment of Lease dated October 29, 2019 between NWP BUILDING 5 LLC and the Registrant	8-K	11/1/19	001-33092	
10.16	Eighth Amendment of Lease dated October 18, 2023 between NWP Building 5 LLC and the Registrant	10-Q	11/7/23	001-33092	

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
10.17	Northwest Park Lease dated March 23, 2010, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	10-K	3/29/10	001-33092	
10.18	First Amendment to Northwest Park Lease dated September 14, 2010, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	10-K	3/27/12	001-33092	
10.19	Second Amendment to Northwest Park Lease dated October 31, 2011, by and between NWP Building 4 LLC, as successor-in-interest to Trustees of Northwest Associates, and Registrant	10-K	3/27/12	001-33092	
10.20	Third Amendment of Northwest Park Lease dated August 31, 2012, by and between NWP Building 4 LLC, as successor-in-interest to Trustees of Northwest Associates, and Registrant	10-K	3/27/13	001-33092	
10.21	Fourth Amendment of Lease dated December 20, 2013, by and between NWP Building 4 LLC, as successor-in-interest to the Trustees of Northwest Associates, and Registrant	8-K	12/23/13	001-33092	
10.22	Fifth Amendment of Lease dated October 29, 2019 between NWP BUILDING 4 LLC and the Registrant	8-K	11/1/19	001-33092	
10.23	Sixth Amendment of Lease dated October 18, 2023 between NWP Building 4 LLC and Registrant	10-Q	11/7/23	001-33092	
10.24	Lease dated December 20, 2013, by and between N.W. Building 3 Trust and Registrant	8-K	12/23/13	001-33092	
10.25	First Amendment of Lease dated October 29, 2019 between NWP BUILDING 3 LLC and the Registrant	8-K	11/1/19	001-33092	
10.26	Second Amendment of Lease dated October 18, 2023 between NWP Building 3 LLC and the Registrant	10-Q	11/7/23	001-33092	
10.27	Lease dated November 26, 2019 between NWP Retail 18 LLC and the Registrant.	8-K	12/3/19	001-33092	
10.28	First Amendment of Lease dated October 18, 2023 between NWP Retail 18 LLC and the Registrant	10-Q	11/7/23	001-33092	
10.29†	Amended and Restated Management Incentive Compensation Plan	8-K	2/25/14	001-33092	
10.30†	Third Amended and Restated 2006 Stock Option and Incentive Plan	8-K	6/8/15	001-33092	
10.31†	Form of Restricted Stock Unit Award Agreement under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	8-K	3/9/18	001-33092	
10.32†	Form of Incentive Stock Option Agreement under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	10-K	3/9/18	001-33092	
10.33†	Form of Non-Qualified Stock Option Agreement (Employees) under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	10-K	3/9/18	001-33092	
10.34	Form of Non-Qualified Stock Option Agreement (Non-Employee Directors) under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	10-K	3/9/18	001-33092	
10.35^	License Agreement dated October 11, 2019 between the Registrant and Admedus Ltd and certain of its subsidiaries	10-K	3/12/20	001-33092	

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
10.36†	Eighth Amended and Restated Equity Award Grant Policy	8-K	7/9/21	001-33092	
10.37†	Form of Restricted Stock Unit Award Agreement – Performance Based Award under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	10-K	2/28/22	001-33092	
21.1	List of Subsidiaries				X
23.1	Consent of Grant Thornton LLP				X
24.1	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K)				X
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
97.1	LeMaitre Vascular, Inc. Compensation Recovery Program				X
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).				
†	Indicates a management contract or any compensatory plan, contract, or arrangement.				
*	The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of LeMaitre Vascular, Inc. 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.				
^	Portions of the exhibit (indicated by “[***]”) have been omitted because they are not material and is the type that LeMaitre Vascular, Inc. treats as private and confidential.				

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on February 29, 2024.

LEMAITRE VASCULAR, INC.

By: /S/ GEORGE W. LEMAITRE

George W. LeMaitre,
Chief Executive Officer and Chairman of
the Board

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints George W. LeMaitre and Joseph P. Pellegrino, Jr., and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all 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 in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, 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
<u>/s/ GEORGE W. LEMAITRE</u> George W. LeMaitre	Chief Executive Officer and <i>(Principal Chairman of the Board Executive Officer)</i>	February 29, 2024
<u>/s/ JOSEPH P. PELLEGRINO, JR.</u> Joseph P. Pellegrino, Jr.	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i> and Director	February 29, 2024
<u>/s/ LAWRENCE J. JASINSKI</u> Lawrence J. Jasinski	Director	February 29, 2024
<u>/s/ JOHN J. O'CONNOR</u> John J. O'Connor	Director	February 29, 2024
<u>/s/ DAVID B. ROBERTS</u> David B. Roberts	President and Director	February 29, 2024
<u>/s/ JOHN A. ROUSH</u> John A. Roush	Director	February 29, 2024
<u>/s/ BRIDGET A. ROSS</u> Bridget A. Ross	Director	February 29, 2024
<u>/s/ MARTHA M. SHADAN</u> Martha M. Shadan	Director	February 29, 2024

INDEX TO FINANCIAL STATEMENTS

LeMaitre Vascular, Inc.	Page
 <i>Consolidated Financial Statements</i>	
Report of Independent Registered Public Accounting Firm (PCAOB ID Number 248).....	57
Consolidated Balance Sheets as of December 31, 2023 and 2022	58
Consolidated Statements of Operations for the Years Ended December 31, 2023, 2022 and 2021	59
Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2023, 2022 and 2021	60
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2023, 2022 and 2021	61
Consolidated Statements of Cash Flows for the Years Ended December 31, 2023, 2022 and 2021	62
Notes to Consolidated Financial Statements	63

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
LeMaitre Vascular, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of LeMaitre Vascular, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive income, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2023 and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2023, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”), and our report dated February 29, 2024 expressed an unqualified opinion.

Basis for opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the 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 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ GRANT THORNTON LLP

We have served as the Company’s auditor since 2015.

Boston, Massachusetts
February 29, 2024

LeMaitre Vascular, Inc.
Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,269	\$ 19,134
Short-term marketable securities	80,805	63,557
Accounts receivable, net of allowances of \$941 at December 31, 2023 and \$835 at December 31, 2022	25,064	22,040
Inventory and other deferred costs.....	58,080	50,271
Prepaid expenses and other current assets	6,380	6,731
Total current assets.....	194,598	161,733
Property and equipment, net.....	21,754	17,901
Right-of-use leased assets	18,027	15,634
Goodwill.....	65,945	65,945
Other intangibles, net	41,711	46,527
Deferred tax assets	1,003	1,745
Other assets	3,740	991
Total assets	<u>\$ 346,778</u>	<u>\$ 310,476</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable.....	\$ 3,734	\$ 2,903
Accrued expenses	23,650	19,967
Acquisition-related obligations.....	24	573
Lease liabilities - short-term	2,471	1,886
Total current liabilities	29,879	25,329
Lease liabilities - long-term.....	16,624	14,710
Deferred tax liabilities.....	107	69
Other long-term liabilities	2,268	2,167
Total liabilities.....	48,878	42,275
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 3,000,000 shares; none outstanding ...	-	-
Common stock, \$0.01 par value; authorized 37,000,000 shares; issued 23,911,760 shares at December 31, 2023, and 23,655,716 shares at December 31, 2022	239	237
Additional paid-in capital	200,755	189,268
Retained earnings.....	115,430	97,773
Accumulated other comprehensive loss.....	(4,625)	(6,031)
Treasury stock, at cost; 1,584,512 shares at December 31, 2023 and 1,568,595 shares at December 31, 2022.....	(13,899)	(13,046)
Total stockholders' equity	297,900	268,201
Total liabilities and stockholders' equity.....	<u>\$ 346,778</u>	<u>\$ 310,476</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Operations

	Year ended December 31,		
	2023	2022	2021
	(in thousands, except per share data)		
Net sales	\$ 193,484	\$ 161,651	\$ 154,424
Cost of sales	<u>66,435</u>	<u>56,755</u>	<u>53,042</u>
Gross profit.....	127,049	104,896	101,382
Sales and marketing	41,054	32,921	27,655
General and administrative.....	31,832	28,745	25,501
Research and development.....	16,966	13,294	11,801
Restructuring	485	3,107	-
Total operating expenses	<u>90,337</u>	<u>78,067</u>	<u>64,957</u>
Income from operations.....	36,712	26,829	36,425
Other income (expense):			
Interest income.....	3,077	986	197
Interest expense	-	-	(2,219)
Other income (loss), net.....	<u>(314)</u>	<u>(325)</u>	<u>(116)</u>
Income before income taxes.....	39,475	27,490	34,287
Provision for income taxes.....	<u>9,370</u>	<u>6,854</u>	<u>7,380</u>
Net income	<u>\$ 30,105</u>	<u>\$ 20,636</u>	<u>\$ 26,907</u>
Earnings per share of common stock:			
Basic	<u>\$ 1.36</u>	<u>\$ 0.94</u>	<u>\$ 1.27</u>
Diluted	<u>\$ 1.34</u>	<u>\$ 0.93</u>	<u>\$ 1.25</u>
Weighted-average shares outstanding:			
Basic	<u>22,217</u>	<u>21,975</u>	<u>21,157</u>
Diluted	<u>22,423</u>	<u>22,171</u>	<u>21,475</u>
Cash dividends declared per common share.....	<u>\$ 0.56</u>	<u>\$ 0.50</u>	<u>\$ 0.44</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Comprehensive Income

	Year ended December 31,		
	2023	2022	2021
Net income	\$ 30,105	\$ 20,636	\$ 26,907
Other comprehensive income (loss):			
Foreign currency translation adjustment, net.....	734	(1,071)	(1,604)
Unrealized gain (loss) on short-term marketable securities	672	(1,525)	(306)
Total other comprehensive income (loss).....	<u>1,406</u>	<u>(2,596)</u>	<u>(1,910)</u>
Comprehensive income	<u>\$ 31,511</u>	<u>\$ 18,040</u>	<u>\$ 24,997</u>

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional	Retained	Accumulated	Treasury Stock		Total
	Shares	Amount	Paid-in	Earnings	Other	Shares	Amount	Stockholders'
			Capital		Income (Loss)			Equity
Balance at December 31, 2020	22,061,554	221	114,924	70,554	(1,525)	1,538,572	(11,602)	172,572
Net income				26,907				26,907
Other comprehensive income (loss) ..					(1,910)			(1,910)
Issuance of common stock, net of issuance costs	1,150,000	12	58,683					58,695
Issuance of common stock for stock options exercised.....	217,121	2	4,544					4,546
Vested restricted stock units	49,109	-	-					-
Stock-based compensation expense...			3,479					3,479
Repurchase of common stock for net settlement of equity awards						16,333	(802)	(802)
Common stock cash dividend paid				(9,336)				(9,336)
Balance at December 31, 2021	23,477,784	235	181,630	88,125	(3,435)	1,554,905	(12,404)	254,151
Net income				20,636				20,636
Other comprehensive income (loss) ..					(2,596)			(2,596)
Issuance of common stock for stock options exercised.....	133,963	1	3,465					3,466
Vested restricted stock units	43,969	1	-					1
Stock-based compensation expense...			4,173					4,173
Repurchase of common stock for net settlement of equity awards						13,690	(642)	(642)
Common stock cash dividend paid				(10,988)				(10,988)
Balance at December 31, 2022	23,655,716	\$ 237	\$ 189,268	\$ 97,773	\$ (6,031)	1,568,595	\$ (13,046)	\$ 268,201
Net income				30,105				30,105
Other comprehensive income (loss) ..					1,406			1,406
Issuance of common stock for stock options exercised.....	207,643	2	6,168					6,170
Vested restricted stock units	48,401	-	-					-
Stock-based compensation expense...			5,319					5,319
Repurchase of common stock for net settlement of equity awards						15,917	(853)	(853)
Common stock cash dividend paid				(12,448)				(12,448)
Balance at December 31, 2023	23,911,760	\$ 239	\$ 200,755	\$ 115,430	\$ (4,625)	1,584,512	\$ (13,899)	\$ 297,900

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
Operating activities			
Net income	\$ 30,105	\$ 20,636	\$ 26,907
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization.....	9,515	9,433	11,070
Stock-based compensation.....	5,319	4,173	3,479
Provision for inventory write-downs	2,237	2,572	3,779
Provision (benefit) for deferred income taxes	783	(182)	79
Loss on divestitures	485	1,954	-
Provision for credit losses.....	344	637	263
Fair value adjustments to contingent consideration obligations	(78)	(108)	(674)
Gain on sale of building.....	-	(115)	-
Loss on disposal of PP&E	-	95	-
Foreign currency transaction effect on income.....	(705)	(315)	163
Changes in operating assets and liabilities:			
Accounts receivable.....	(3,135)	(3,533)	(818)
Inventory and other deferred costs	(9,794)	(7,418)	(5,485)
Prepaid expenses and other assets	(2,924)	(3,096)	(1,927)
Accounts payable and other liabilities.....	4,599	645	(1,734)
Net cash provided by operating activities.....	36,751	25,378	35,102
Investing activities			
Purchases of short-term marketable securities	(16,551)	(8,000)	(59,194)
Purchases of property and equipment.....	(7,265)	(3,229)	(4,882)
Payments related to acquisitions	(899)	-	-
Proceeds from sale of building	-	858	-
Proceeds from sales of marketable securities	-	-	3,000
Net cash used in investing activities.....	(24,715)	(10,371)	(61,076)
Financing activities			
Common stock cash dividend paid.....	(12,448)	(10,988)	(9,336)
Proceeds from issuance of common stock.....	6,170	3,466	63,241
Purchase of treasury stock for net settlement of equity awards.....	(853)	(642)	(802)
Payment of deferred acquisition consideration	-	(1,070)	(401)
Payments of long-term debt	-	-	(39,000)
Net cash provided by (used in) financing activities.....	(7,131)	(9,234)	13,702
Effect of exchange rate changes on cash and cash equivalents	230	(494)	(637)
Net increase (decrease) in cash and cash equivalents.....	5,135	5,279	(12,909)
Cash and cash equivalents at beginning of year	19,134	13,855	26,764
Cash and cash equivalents at end of year	<u>\$ 24,269</u>	<u>\$ 19,134</u>	<u>\$ 13,855</u>

Supplemental disclosures of cash flow information (see Notes 6 and 9).

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Notes to Consolidated Financial Statements
December 31, 2023

1. Significant Accounting Policies and Related Matters

Description of Business

Unless the context requires otherwise, references to LeMaitre, LeMaitre Vascular, we, our, and us refer to LeMaitre Vascular, Inc. and our subsidiaries. We develop, manufacture, and market medical devices and implants used primarily in the field of vascular surgery. We also derive revenues from the processing and cryopreservation of human tissues for implantation in patients. We operate in a single segment in which our principal product lines include the following: anastomotic clips, biologic vascular and dialysis grafts, biologic vascular and cardiac patches, carotid shunts, embolectomy catheters, occlusion catheters, radiopaque marking tape, synthetic vascular grafts, and valvulotomes. Our offices and production facilities are located in Burlington, Massachusetts; Fox River Grove, Illinois; North Brunswick, New Jersey; Chandler, Arizona; Vaughan, Canada; Sulzbach, Germany; Milan, Italy; Madrid, Spain; Hereford, England; Dublin, Ireland; Kensington, Australia; Tokyo, Japan; Shanghai, China; Singapore; Seoul, Korea; and Bangkok, Thailand.

Consolidation and Basis of Presentation

Our consolidated financial statements include the accounts of LeMaitre Vascular and the accounts of our wholly-owned subsidiaries, LeMaitre Vascular GmbH, LeMaitre Vascular GK, Vascutech Acquisition LLC, LeMaitre Acquisition LLC, LeMaitre Vascular SAS, LeMaitre Vascular S.r.l., LeMaitre Vascular Spain S.L, LeMaitre Vascular Switzerland GmbH, LeMaitre Vascular ULC, LeMaitre Vascular AS, LeMaitre Vascular Pty Ltd, Bio Nova International Pty Ltd, Bio Nova Holdings Pty Ltd, LeMaitre Vascular, Ltd., LeMaitre Medical Technology (Shanghai) Co. Ltd, LeMaitre Cardial SAS, LeMaitre Pte Ltd, LeMaitre Ltd, and LeMaitre Co., Ltd. All significant intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency Translation

Balance sheet accounts of foreign subsidiaries are translated into U.S. dollars at year-end exchange rates. Operating accounts are translated at average exchange rates for each year. Net translation gains or losses are adjusted directly to a separate component of other comprehensive income (loss) within stockholders' equity. Foreign exchange transaction gains (losses), substantially all of which relate to intercompany activity between us and our foreign subsidiaries, are included in other income (expense) in the accompanying consolidated statements of operations.

Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. The Company is not aware of any specific event or circumstance that would require an update to its accounting estimates or adjustments to the carrying value of its assets and liabilities. Our estimates and assumptions, including those related to bad debts, inventories, intangible assets, sales returns and discounts, share-based compensation, and income taxes, are reviewed on an ongoing basis and updated as appropriate. Actual results could differ from those estimates.

Revenue Recognition

Our revenue is derived primarily from the sale of disposable or implantable devices used during vascular surgery. We sell primarily directly to hospitals and to a lesser extent to international distributors, as described below, and, during the periods presented in our consolidated financial statements, entered into consigned inventory arrangements with either hospitals or distributors on a limited basis. We also derive revenues from the processing and cryopreservation of human tissues for implantation in patients. These revenues are recognized when services have been provided and the tissue has been shipped to the customer, provided all other revenue recognition criteria discussed in the succeeding paragraph have been met.

We record revenue under the provisions of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The core principle of Topic 606 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard explains that to achieve the core principle, an entity should take the following actions:

Step 1: Identify the contract with a customer

Step 2: Identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price to the performance obligations

Step 5: Recognize revenue when or as the entity satisfies a performance obligation

Revenue is recognized when or as a company satisfies a performance obligation by transferring a promised good or service to a customer (which is when the customer obtains control of that good or service). In instances in which shipping and handling activities are performed after a customer takes control of the goods (such as when title passes upon shipment from our dock), we have made the policy election allowed under Topic 606 to account for these activities as fulfillment costs and not as performance obligations.

We generally reference customer purchase orders to determine the existence of a contract. Orders that are not accompanied by a purchase order are confirmed with the customer either in writing or verbally. The purchase orders or similar correspondence, once accepted, identify the performance obligations as well as the transaction price, and otherwise outline the rights and obligations of each party. We allocate the transaction price of each contract among the performance obligations in accordance with the pricing of each item specified on the purchase order, which is in turn based on standalone selling prices per our published price lists. In cases where we discount products or provide certain items free of charge, we allocate the discount proportionately to all performance obligations, unless it can be demonstrated that the discount should be allocated entirely to one or more, but not all, of the performance obligations.

We record revenue, net of allowances for returns and discounts, fees paid to group purchasing organizations, and any sales and value added taxes required to be invoiced, which we have elected to exclude from the measurement of the transaction price as allowed by the standard, at the time of shipment (taking into consideration contractual shipping terms), or in the case of consigned inventory, when it is consumed. Shipment is the point at which control of the product and title passes to our customers, and at which LeMaitre has a present right to receive payment for the goods.

Below is a disaggregation of our revenue by major geographic area, which is among the primary categorizations used by management in evaluating financial performance, for the periods indicated (in thousands):

	Year ended December 31,		
	2023	2022	2021
Americas.....	\$ 130,308	\$ 109,439	\$ 102,265
Europe, Middle East and Africa	51,099	41,854	42,132
Asia Pacific.....	12,077	10,358	10,027
Total	<u>\$ 193,484</u>	<u>\$ 161,651</u>	<u>\$ 154,424</u>

We do not carry any contract assets or contract liabilities, as there are generally no unbilled amounts due from customers under contracts for which we have partially satisfied performance obligations, or amounts received from customers for which we have not satisfied performance obligations. We satisfy our performance obligations under revenue contracts within a very short time period from receipt of the orders, and payments from customers are typically received within 30 to 60 days of fulfillment of the orders, except in certain geographies such as Italy, Spain and France where the payment cycle is customarily longer. Accordingly, there is no significant financing component to our revenue contracts. Additionally, we have elected as a policy that incremental costs (such as commissions) incurred to obtain contracts are expensed as incurred, due to the short-term nature of the contracts.

Customers returning products may be entitled to full or partial credit based on the condition and timing of the return. To be accepted, a returned product must be unopened (if sterile), unadulterated, and undamaged, must have at least 18 months remaining prior to its expiration date, or twelve months for our hospital customers in Europe, and generally be returned within 30 days of shipment. These return policies apply to sales to both hospitals and distributors. The amount of

products returned to us, either for exchange or credit, has not been material. Nevertheless, we provide for an allowance for future sales returns based on historical returns experience, which requires judgment. Our cost of replacing defective products has not been material and is accounted for at the time of replacement.

Research and Development Expense

Research and development costs, principally salaries, laboratory testing, and supplies, are expensed as incurred and also include royalty payments associated with licensed and acquired intellectual property.

Shipping and Handling Costs

Shipping and handling fees paid by customers are recorded within net sales, with the related expense recorded in cost of sales.

Advertising Costs

Advertising costs are expensed as incurred and are included as a component of sales and marketing expense in the accompanying consolidated statements of operations. Advertising costs are as follows:

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
Advertising expense	<u>\$ 240</u>	<u>\$ 195</u>	<u>\$ 236</u>

Cash and Cash Equivalents

We consider all highly liquid instruments purchased with maturity dates of 90 days or less to be cash equivalents. Cash and cash equivalents are primarily invested in money market funds. These amounts are stated at cost, which approximates fair value.

Short-term Marketable Securities

Our short-term marketable securities are available-for-sale securities carried at fair value, with unrealized gains and losses recorded in other comprehensive income. They include a managed income mutual fund investing mainly in short-term investment-grade, U.S. dollar denominated fixed and floating rate debt, and a short-duration bond fund.

Concentrations of Credit Risk

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Cash equivalents represent highly liquid investments with maturities of 90 days or less at the date of purchase. Credit risk related to cash and cash equivalents are limited based on the creditworthiness of the financial institutions at which these funds are held. We maintain cash balances in several banks. Accounts located in the U.S. are insured by the Federal Deposit Insurance Corporation (FDIC) up to \$250,000. Certain of our account balances exceed the FDIC limit. Cash balances held outside the U.S. totaled approximately \$10.0 million as of December 31, 2023.

Our accounts receivable are with customers based in the U.S. and internationally. Accounts receivable generally are due within 30 to 60 days of invoice and are stated at amounts due from customers, net of an allowance for credit losses and sales returns, other than in certain European markets where the payment cycle is customarily longer. We perform ongoing credit evaluations of the financial condition of our customers and adjust credit limits based upon payment history and the current creditworthiness of the customers, as determined by a review of their current credit information. We continuously monitor aging reports, collections, and payments from customers, and maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues we identify.

We closely monitor outstanding receivables for potential collection risks, including those that may arise from economic conditions, in both the U.S. and international economies. Our European sales to government-owned or supported customers such as hospitals, distributors and agents, particularly in Italy, Spain and France, may be subject to significant payment delays due to government austerity measures impacting funding and payment practices. As of December 31, 2023 our receivables in Italy, Spain and France totaled \$1.1 million, \$1.0 million and \$1.2 million, respectively. Receivables

balances with certain government-owned hospitals and government-supported customers in these countries can accumulate over a period of time and then subsequently be settled as lump sum payments. While we believe our allowance for credit losses in these countries is adequate as of December 31, 2023, if significant changes were to occur in the payment practices of these European governments or if government funding becomes unavailable, we may not be able to collect on receivables due to us from these customers and our write offs of uncollectible amounts may increase.

We write off accounts receivable when they become uncollectible. Such credit losses have historically been within our expectations and allowances. The allowance for credit losses is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for credit losses on a monthly basis and all past due balances are reviewed individually for collectability. The provision for the allowance for credit losses is recorded in general and administrative expenses. The following is a summary of our allowance for credit losses and sales returns:

	Balance at Beginning of Period	Additions (recoveries) charged to Income	Deductions from Reserves	Balance at End of Period
	(in thousands)			
Allowance for credit losses and sales returns:				
Year ended December 31, 2023	\$ 835	\$ 344	\$ 238	\$ 941
Year ended December 31, 2022	679	637	481	835
Year ended December 31, 2021	623	263	207	679

Fair Value of Financial Instruments

Our financial instruments include cash and cash equivalents, short-term marketable securities, accounts receivable and trade payables. The fair value of these instruments approximates their carrying value based upon their short-term nature or variable rates of interest. Unrealized gains and losses on our short-term marketable securities are recorded in other comprehensive income. As of December 31, 2023 and 2022, our short-term marketable securities reflected an unrealized loss of \$1.2 million and \$1.8 million, respectively, as a result of increasing market interest rates.

Inventory and Other Deferred Costs

Inventory and Other Deferred Costs consists of finished products, work-in-process, raw materials and costs deferred in connection with human tissue cryopreservation services of our RestoreFlow allograft business. We value inventory and other deferred costs at the lower of cost or market value. Cost includes materials, labor and manufacturing overhead and is determined using the first-in, first-out (FIFO) method. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based primarily on product expiration dating and our estimated sales forecast, which is based on sales history and anticipated future demand. Our estimates of future product demand may not be accurate, and we may understate or overstate the provision required for excess and obsolete inventory. Accordingly, any significant unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations.

Cloud Computing Arrangements

The Company capitalizes qualifying set-up and implementation costs related to the Company's cloud computing arrangements. The deferred costs are amortized over the term of the associated cloud computing arrangement on a straight-line basis which is representative of the pattern in which the Company expects to benefit from access to the cloud computing arrangement.

Capitalized cloud computing implementation costs are presented in prepaid expenses and other current assets and other assets on the consolidated balance sheet. As of December 31, 2023, the Company had net capitalized cloud computing implementation costs of \$3.6 million.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided over the estimated useful lives of the related assets using straight-line method as follows:

Description	Useful Life (in years)
Computer hardware	3 – 5
Machinery and equipment	3 – 10
Building and leasehold improvements	The shorter of its useful life or lease term

Expenditures for maintenance and repairs are charged to operations when incurred, while additions and betterments are capitalized. When assets are retired or disposed, the asset's original cost and related accumulated depreciation are eliminated from the accounts and any gain or loss is reflected in the statement of operations.

Valuation of Business Combinations

We assign the value of the consideration transferred to acquire a business to the tangible assets and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. We assess the fair value of assets, including intangible assets, using a variety of methods and are usually performed by an independent appraiser who measures fair value from the perspective of a market participant.

Acquisitions have been accounted for using the acquisition method, and the acquired companies' results have been included in the accompanying consolidated financial statements from their respective dates of acquisition. Acquisition transaction costs have been recorded in general and administrative expenses, and are expensed as incurred. Allocation of the purchase price for acquisitions is based on estimates of the fair value of the net assets acquired and is subject to adjustment upon finalization of the purchase price allocation.

Our acquisitions have historically been made at prices above the fair value of the acquired assets, resulting in goodwill, due to expectations of synergies of combining the businesses. These synergies include use of our existing commercial infrastructure to expand sales of the acquired businesses' products, use of the commercial infrastructure of the acquired businesses to cost-effectively expand sales of our products, and the elimination of redundant facilities, functions and staffing.

Contingent Consideration

Contingent consideration for acquisitions is recognized at the date of acquisition, based on the fair value at that date, and then re-measured periodically through adjustments to net income.

Impairment of Long-lived Assets

We review our long-lived assets (primarily property and equipment and intangible assets) subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Conditions that may indicate impairment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset, a product recall, or an adverse action or assessment by a regulator. If an impairment indicator exists, we test the intangible asset for recoverability. We record impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. Impairment is measured based on the fair market value of the affected asset using discounted cash flows.

Goodwill

Goodwill represents the amount of consideration paid in connection with business acquisitions in excess of the fair value of assets acquired and liabilities assumed. Goodwill is evaluated for impairment annually, or more frequently if indicators of impairment are present or changes in circumstances suggest that an impairment may exist. We evaluate the December 31 balance of the carrying value of goodwill based on a single reporting unit annually. We perform an assessment of qualitative factors to determine if it is "more likely than not" that the fair value of our reporting unit is less than its carrying value as a basis for determining whether it is necessary to perform the quantitative goodwill impairment test. The "more likely than not" threshold is defined as having a likelihood of more than 50 percent. The quantitative

goodwill impairment test compares the fair value of a reporting unit with its carrying amount, including goodwill. If the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not impaired. If the carrying amount of a reporting unit exceeds its fair value, an impairment loss is recognized in an amount equal to that excess, limited to the total amount of goodwill allocated to that reporting unit. We have determined that no goodwill impairment charges were required for the years ended December 31, 2023, 2022 or 2021.

Other Intangible Assets

Other intangible assets consist primarily of patents, trademarks, technology licenses, and customer relationships acquired in connection with business acquisitions and asset acquisitions and are amortized over their estimated useful lives, ranging from 2 to 16 years.

Stock-based Compensation

We recognize, as expense, the estimated fair value of stock options to employees determined using the Black-Scholes option pricing model. Share-based compensation charges are recorded across the consolidated statement of operations based upon the grantee's primary function. We have elected to recognize the compensation cost of all share-based awards on a straight-line basis over the vesting period of the award. In periods that we grant stock options, fair value assumptions are based on volatility, interest, dividend yield, and expected term over which the stock options will be outstanding. The computation of expected volatility is based on the historical volatility of the company's stock. The interest rate for periods within the contractual life of the award is based on the U.S. Treasury risk-free interest rate in effect at the time of grant. Historical data on exercise patterns is the basis for estimating the expected life of an option. The expected annual dividend rate was calculated by dividing our annual dividend, based on the most recent quarterly dividend rate, by the closing stock price on the grant date.

We also issue restricted stock units (RSUs) and performance-based restricted stock units (PSUs) as additional forms of equity compensation to our employees, officers, and directors, pursuant to our stockholder-approved 2006 Plan. RSUs entitle the grantee to an issuance of stock at no cost and generally vest over a period of time determined by our Board of Directors at the time of grant. PSUs granted in December 2022 vested based on achievement of operating income for 2023 against budgeted operating income as approved by our Board of Directors. The fair market value of the award is determined based on the number of RSUs and PSUs granted and the market value of our common stock on the grant date and is amortized to expense over the period of vesting. Unvested RSUs and PSUs are forfeited and canceled as of the date that employment or service to the company terminates. RSUs and PSUs are settled in shares of our common stock upon vesting. We typically repurchase common stock upon our employees' vesting in RSUs and PSUs in order to cover any minimum tax withholding liability as a result of the awards having vested. PSUs granted in December 2022 based on achievement of operating income for 2023 against budgeted operating income as approved by our Board of Directors were achieved and therefore awarded to the recipients.

Commitments and Contingencies

In the normal course of business, we are subject to proceedings, lawsuits, and other claims and assessments for matters related to, among other things, patent infringement, business acquisitions, employment, commercial matters and product recalls. We assess the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of reserves required, if any, for these contingencies is made after careful analysis of each individual issue. The required reserves may change in the future due to new developments or changes in approach, such as a change in settlement strategy in dealing with each matter. We record charges for anticipated losses in connection with litigation and claims against us when we conclude a loss is probable and we can reasonably estimate the loss. Legal costs associated with loss contingencies are expensed as incurred. During the years ended December 31, 2023, 2022 and 2021, we were not subject to any material litigation or claims and assessments.

Sales of medical devices outside the U.S. are subject to international regulatory requirements that vary from country to country. These requirements and the amount of time required for approval may differ from our experiences with the U.S. FDA. In the EU we are required to obtain CE marks for our products, which denote conformity to essential requirements for manufacturers of higher-risk devices. Failure to obtain, retain or maintain these CE marks would impact our ability to sell our products in certain European countries and could cause our business to suffer.

Income Taxes

We account for income taxes under the asset and liability method of accounting for income taxes. Under the asset and liability method, deferred taxes are determined based on the difference between the financial reporting and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. The provision for income taxes includes taxes currently payable and deferred taxes resulting from the tax effects of temporary differences between the financial statement and tax bases of assets and liabilities. We maintain valuation allowances where it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in the valuation allowances are included in our tax provision in the period of change. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings, carry-back and carry-forward periods and tax strategies that could potentially enhance the likelihood of the realization of a deferred tax asset.

We recognize, measure, present and disclose in our financial statements, uncertain tax positions that we have taken or expect to take on a tax return. We recognize in our financial statements the impact of tax positions that meet a “more likely than not” threshold, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate settlement.

Our policy is to classify interest and penalties related to unrecognized tax benefits as income tax expense.

Comprehensive Income

Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Other than reported net income, comprehensive income includes foreign currency translation adjustments and unrealized gains and losses on our marketable securities, which are disclosed in the accompanying consolidated statements of comprehensive income. There were no reclassifications out of comprehensive income for the years ended December 31, 2023, 2022 or 2021.

Accumulated other comprehensive loss consisted of foreign currency translation adjustment losses of \$3.4 million and \$4.2 million as of December 31, 2023 and 2022, respectively, and unrealized losses on short-term marketable securities of \$1.2 million and \$1.8 million as of December 31, 2023 and 2022, respectively.

Restructuring

We record restructuring charges incurred in connection with consolidation or relocation of operations, exited business lines, reductions in force, or distributor terminations. These restructuring charges, which reflect our commitment to a termination or exit plan, are based on estimates of the expected costs associated with site closure, legal matters, contract terminations, severance payments, or other costs directly related to the restructuring. If the actual cost incurred exceeds the estimated cost, an additional charge to earnings will result. If the actual cost is less than the estimated cost, a credit to earnings will be recognized.

Earnings per Share

We compute basic earnings per share by dividing net income available for common stockholders by the weighted average number of shares outstanding during the year. Except where the result would be anti-dilutive to net income per share, diluted earnings per share has been computed using the treasury stock method and reflects the potential vesting of restricted common stock and the potential exercise of stock options, as well as their related income tax effects.

The computation of basic and diluted net income per share is as follows:

	Year ended December 31,		
	2023	2022	2021
	(in thousands, except per share data)		
Basic:			
Net income available for common stockholders.....	\$ 30,105	\$ 20,636	\$ 26,907
Weighted average shares outstanding	22,217	21,975	21,157
Basic earnings per share	\$ 1.36	\$ 0.94	\$ 1.27
Diluted:			
Net income available for common stockholders.....	\$ 30,105	\$ 20,636	\$ 26,907
Weighted-average shares outstanding.....	22,217	21,975	21,157
Common stock equivalents, if dilutive	206	196	318
Shares used in computing diluted earnings per common share	22,423	22,171	21,475
Diluted earnings per share	\$ 1.34	\$ 0.93	\$ 1.25
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	295	293	10

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies and are generally adopted by the Company as of the specified effective date.

Not Yet Effective

In December 2023 the FASB issued ASU 2023-09, Income Taxes Topic 740 - Improvements to Income Tax Disclosures. This amendment is expected to enhance the transparency and decision usefulness of income tax disclosures by requiring public business entities, on an annual basis, to disclose specific categories in the rate reconciliation, additional information for reconciling items that meet a quantitative threshold and certain information about income taxes paid. This revised guidance is effective for financial statements issued for fiscal years beginning after December 15, 2024. We are currently evaluating the impacts of the new standard.

In November 2023 the FASB issued ASU 2023-07, Segment Reporting Topic 280- Improvements to Reportable Segment Disclosures. This amendment requires disclosure of incremental segment information on an annual and interim basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. We are currently evaluating the impacts of the new standard.

2. Divestitures

On April 26, 2022, we committed to a plan to close our St. Etienne, France factory, which supported our LeMaitre Cardial SAS (Cardial) business, in order to streamline manufacturing operations and reduce expenses. The Cardial business consisted of the manufacture of polyester vascular grafts, valvulotomes, surgical glue and selected OEM devices. We acquired the Cardial business in 2018.

On June 30, 2022, we ceased operations at the St. Etienne, France factory. The closure resulted in a restructuring charge of \$3.1 million for the year ended December 31, 2022. Charges primarily consisted of employment termination costs, impairment of fixed assets and inventory, and third-party costs.

On October 10, 2022 we sold the St. Etienne, France building, building improvements, and land for \$0.9 million less closing costs of \$0.1 million, resulting in a gain of approximately \$0.1 million recorded for the year ended December 31, 2022.

For the year ended December 31, 2023, we recorded additional restructuring charges of \$0.5 million in conjunction with the St. Etienne, France factory closure. The additional charges consisted primarily of employment termination, settlement, legal and other third-party costs.

3. Inventory and Other Deferred Costs

Inventory and other deferred costs consists of the following:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	(in thousands)	
Raw materials.....	\$ 18,333	\$ 14,929
Work-in-process	2,869	3,662
Finished products	31,131	26,688
Other deferred costs.....	5,747	4,992
Total inventory and other deferred costs	<u>\$ 58,080</u>	<u>\$ 50,271</u>

We had inventory on consignment at customer sites of \$2.0 million and \$1.5 million at December 31, 2023 and 2022, respectively.

In connection with our RestoreFlow allograft business, other deferred costs include costs incurred for the preservation of human tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By federal law, human tissues cannot be bought or sold. Therefore, the tissues we preserve are not held as inventory, and the costs we incur to procure and process vascular tissues are instead accumulated and deferred. These costs include fixed and variable overhead costs associated with the cryopreservation process, including primarily direct labor costs, tissue recovery fees, inbound freight charges, indirect materials and facilities costs. General and administrative expenses and selling expenses associated with the provision of these services are expensed as incurred.

4. Property and Equipment

Property and equipment consists of the following:

	<u>As of December 31,</u>	
	<u>2023</u>	<u>2022</u>
	(in thousands)	
Computer hardware	\$ 5,319	\$ 5,689
Machinery and equipment	16,942	22,104
Building and leasehold improvements.....	20,981	15,232
Gross property and equipment.....	43,242	43,025
Less accumulated depreciation.....	(21,488)	(25,124)
Property and equipment, net.....	<u>\$ 21,754</u>	<u>\$ 17,901</u>

During the years ended December 31, 2023, 2022 and 2021 we wrote off fully depreciated assets with gross values of \$7.1 million, \$0.5 million and \$0.1 million, respectively.

Depreciation expense is as follows:

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
Depreciation expense.....	\$ 3,423	\$ 3,250	\$ 3,280

5. Goodwill and Other Intangibles

Goodwill consists of the following:

	As of December 31,	
	2023	2022
Balance at beginning of year	\$ 65,945	\$ 65,945
Additions for acquisitions	-	-
Purchase accounting adjustments.....	-	-
Effects of currency exchange	-	-
Balance at end of year	\$ 65,945	\$ 65,945

Other intangibles consist of the following:

	December 31, 2023			December 31, 2022		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
	(in thousands)					
Product technology and intellectual property.....	\$ 29,549	\$ 16,048	\$ 13,501	\$ 29,549	\$ 13,319	\$ 16,230
Trademarks, tradenames and licenses	3,767	1,909	1,858	3,647	1,533	2,114
Customer relationships.....	37,171	11,064	26,107	36,197	8,359	27,838
Other intangible assets.....	1,643	1,398	245	1,461	1,116	345
Total identifiable intangible assets	\$ 72,130	\$ 30,419	\$ 41,711	\$ 70,854	\$ 24,327	\$ 46,527

These assets are being amortized over useful lives ranging from 2 to 16 years. The weighted-average amortization period for these intangibles as of December 31, 2023, is 9.3 years. Amortization expense is included in general and administrative expense and is as follows:

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
Amortization expense.....	\$ 6,092	\$ 6,183	\$ 6,195

Estimated amortization expense for each of the next five fiscal years, based upon the intangible assets at December 31, 2023, is as follows:

	Year ended December 31,				
	2024	2025	2026	2027	2028
	(in thousands)				
Amortization expense.....	\$ 5,904	\$ 5,554	\$ 5,119	\$ 4,842	\$ 4,456

6. Revolving Line of Credit and Long-term Debt

In connection with the acquisition of the Artegraft biologic graft business, we incurred debt in the amount of \$65 million under a senior secured credit facility with a group of banks. This credit arrangement included a \$25 million revolving credit line that was fully drawn at inception, as well as a \$40 million five-year term loan. During the year ended December 31, 2020, we made scheduled principal payments on the term loan of \$1.0 million and repaid the revolving line of credit in full. During the year ended December 31, 2021, we made scheduled principal payments on the term loan of \$1.0 million, repaid the loan in full, and terminated the credit agreement in accordance with its terms.

Under the terms of the agreement, the loans bore interest at a rate per annum of, at our option, either (i) the Base Rate plus an applicable margin of from 1.25% to 1.75% depending on our consolidated leverage ratio, or (ii) the Eurodollar Rate plus an applicable margin of from 2.25% to 2.75% depending on our consolidated leverage ratio. Base Rate was defined in the credit agreement as a fluctuating rate per annum of the Federal Funds rate plus 0.5% or the prime rate of interest established from time to time by KeyBank National Association. Cash paid for interest during both of the years ended December 31, 2021 and 2020 was \$0.9 million.

We incurred debt issuance costs in connection with this credit arrangement of approximately \$1.8 million. These costs were allocated between the revolving line of credit and the term loans, with the portion related to the revolving line of credit of \$0.7 million recorded in other assets on our balance sheet, and the portion allocated to the term loan recorded as a deduction from the amount of the debt. All of these transaction costs were being amortized into interest expense on a straight-line basis as the result would not be materially different from using the interest method, over the five-year term of the arrangement. This resulted in an effective interest rate of approximately 4.2%.

In November 2021, we terminated the credit agreement, including the revolving line of credit, as permitted under the original agreement.

7. Accrued Expenses and Other Long-term Liabilities

Accrued expenses consist of the following:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	(in thousands)	
Compensation and related taxes	\$ 13,353	\$ 10,770
Accrued purchases	5,152	3,748
Accrued expenses	4,251	4,640
Income and other taxes	390	449
Professional fees	104	108
Other	400	252
Total	<u>\$ 23,650</u>	<u>\$ 19,967</u>

Other long-term liabilities consist of the following:

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	(in thousands)	
Acquisition-related liabilities	\$ 1,406	\$ 1,354
Income taxes	637	636
Other	225	177
Total	<u>\$ 2,268</u>	<u>\$ 2,167</u>

8. Commitments and Contingencies

Leases

The Company determines if an arrangement is a lease at inception of the contract. The Company has operating leases for buildings, primarily for office space, manufacturing and distribution, as well as automobiles and printing equipment. As of December 31, 2023, the Company had the following building and facility leases capitalized on the balance sheet:

Location (leases)	Purpose	Approx. Sq. Ft.	Expiration
Americas			
Burlington, MA (4)	Corporate headquarters and manufacturing	96,476	December 2034
North Brunswick, NJ (1)	Artegraft biologic business	16,732	October 2029
Burlington, MA (1)	US distribution	12,878	December 2030
Fox River Grove, IL (3)	RestoreFlow allografts business	11,765	November 2025
Vaughn, Canada	Canada sales office and distribution	3,192	February 2026
Chandler, Arizona	US sales office	2,058	August 2025
Europe, Middle East and Africa			
Sulzbach, Germany	European headquarters and distribution	21,410	June 2031
Milan, Italy	Italy sales office and distribution	5,705	July 2027
Hereford, England	United Kingdom sales office and distribution	3,575	October 2029
Madrid, Spain	Spain sales office	2,260	June 2029
Asia Pacific			
Singapore	Asia Pacific headquarters and distribution	1,270	June 2024
Tokyo, Japan	Japan sales office and distribution	4,236	July 2025
Bangkok, Thailand	Thailand sales office and distribution	2,810	August 2026
Seoul, Korea	Korea sales office and distribution	2,300	April 2027
Shanghai, China	China sales office and distribution	1,152	August 2024
Ballarat, Australia	Supply facility	Up to 350 acres	December 2030

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future lease minimum payments over the lease term at commencement date. Many of the lease agreements contain renewal or termination clauses that are factored into the determination of the lease term if it is reasonably certain that these options would be exercised. The Company recognizes lease expense for these leases on a straight-line basis over the lease term.

None of our noncancelable lease payments include non-lease components such as maintenance contracts; we generally reimburse the landlord for direct operating costs associated with the leased space. We have no subleases, and there are no residual value guarantees associated with, or restrictive covenants imposed by, any of our leases. There were no assets held under capital leases as of December 31, 2023. We elected the package of practical expedients that allow us to omit leases with initial terms of 12 months or less from our balance sheet, which are expensed on a straight-line basis over the life of the lease.

The interest rate implicit in lease agreements is typically not readily determinable, and as such the Company used the incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The incremental borrowing rate is defined as the interest the Company would pay to borrow on a collateralized basis.

Additional information with respect to our leases is as follows:

	Year ended December 31, 2023 (in thousands)	Year ended December 31, 2022 (in thousands)
Lease cost		
Operating lease cost.....	\$ 2,420	\$ 2,203
Short-term lease cost	378	632
Total lease cost	<u>\$ 2,798</u>	<u>\$ 2,835</u>
Other information		
Cash paid for amounts included in the measurement of operating lease liabilities.....	<u>\$ 3,139</u>	<u>\$ 2,878</u>
Right-of-use assets obtained in exchange for new operating lease liabilities.....	<u>\$ 4,813</u>	<u>\$ 2,766</u>
Weighted average remaining lease term - operating leases (in years)	7.3	7.1
Weighted average discount rate - operating leases	6.57%	4.93%

As of December 31, 2023, the minimum noncancelable operating lease rental commitments with initial or remaining terms of more than one year are as follows:

Year ending December 31,	
2024	\$ 3,622
2025	3,364
2026	2,699
2027	2,503
2028	2,469
Thereafter.....	10,906
Adjustment to net present value as of December 31, 2023	(6,468)
Minimum noncancelable lease liability.....	<u>\$ 19,095</u>

Purchase Commitments

As part of our normal course of business, we have commitments to purchase approximately \$5.1 million of inventory through 2024. These purchases are to be used in the normal course of business and do not represent excess commitments or loss contracts.

9. Income Taxes

Income (loss) before income taxes is as follows:

	Year ended December 31,		
	2023	2022	2021
		(in thousands)	
United States	\$ 37,356	\$ 26,274	\$ 34,153
Foreign	2,119	1,216	134
Total	<u>\$ 39,475</u>	<u>\$ 27,490</u>	<u>\$ 34,287</u>

Certain of our foreign subsidiaries are included in the U.S. tax return as branches but are included as foreign for purposes of the table above.

The provision (benefit) for income taxes is as follows:

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
Current:			
Federal.....	\$ 6,203	\$ 5,063	\$ 5,024
State.....	1,300	938	990
Foreign	1,084	1,035	1,287
	8,587	7,036	7,301
Deferred:			
Federal.....	616	(144)	63
State.....	122	(83)	(9)
Foreign	45	45	25
	783	(182)	79
Provision for income taxes.....	<u>\$ 9,370</u>	<u>\$ 6,854</u>	<u>\$ 7,380</u>

We have reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. As of December 31, 2023, the gross amount of unrecognized tax benefits exclusive of interest and penalties was \$0.6 million, which may increase within the twelve months ending December 31, 2024. We remain subject to examination until the statute of limitations expires for each remaining respective tax jurisdiction. The statute of limitations will be open with respect to these tax positions through 2030. A reconciliation of the beginning and ending amount of our unrecognized tax benefits is as follows:

	2023	2022	2021
	(in thousands)		
Unrecognized tax benefits at the beginning of year	\$ 612	\$ 768	\$ 820
Additions/adjustments for tax positions of current year.....	-	-	-
Additions/adjustments for tax positions of prior years.....	(25)	(57)	(52)
Reductions for settlements with taxing authorities.....	-	-	-
Reductions for lapses of the applicable statutes of limitations.....	-	(99)	-
Unrecognized tax benefits at the end of the year.....	<u>\$ 587</u>	<u>\$ 612</u>	<u>\$ 768</u>

Deferred taxes are attributable to the following temporary differences:

	As of December 31,	
	2023	2022
	(in thousands)	
Deferred tax assets:		
Inventory	\$ 2,280	\$ 2,002
Net operating loss carryforwards	942	1,027
Tax credit carryforwards	1,092	996
Capital loss carryforwards	462	462
Reserves and accruals	823	1,090
Operating lease liabilities	3,721	3,295
Intangible assets	4,503	4,468
Stock options	696	446
Other	1,741	573
Total deferred tax assets	16,260	14,359
Deferred tax liabilities:		
Property and equipment	(2,996)	(1,473)
Goodwill	(6,311)	(5,610)
Operating lease right-of-use assets	(3,472)	(3,066)
Foreign branch deferred offset	(700)	(742)
Other	(183)	(164)
Total deferred tax liabilities	(13,662)	(11,055)
Net deferred tax assets before valuation allowance	2,598	3,304
Valuation allowance	(1,702)	(1,628)
Net deferred tax liability	\$ 896	\$ 1,676
Deferred tax classification		
Long-term deferred tax asset	\$ 1,003	\$ 1,745
Long-term deferred tax liability	(107)	(69)
Net long-term deferred tax asset	\$ 896	\$ 1,676

In 2022, we decreased our valuation allowance by \$0.1 million mainly attributable to Australian net operating loss carry forwards and Massachusetts credit carryforwards. In 2023, we increased our valuation allowance by \$0.1 million mainly attributable to Australian net operating loss carry forwards and Massachusetts credit carryforwards.

As of December 31, 2023, we have provided a valuation allowance of \$1.7 million for deferred tax assets primarily related to Australian net operating loss and capital loss carry forwards and Massachusetts tax credit carry forwards that are not expected to be realized. The valuation allowance against our deferred tax assets may require adjustment in the future based on changes in the mix of temporary differences, changes in tax laws, and operating performance.

Realization of our deferred tax assets is dependent on our generating sufficient taxable income in future periods. Although we believe it is more likely than not that future taxable income will be sufficient to allow us to recover substantially all of the value of our deferred tax assets remaining after we apply the valuation allowances, realization is not assured and future events could cause us to change our judgment. In the event that actual results differ from our estimates, or we adjust these estimates in the future periods, further adjustments to our valuation allowance may be recorded, which could materially impact our financial position and net income (loss) in the period of the adjustment.

As of December 31, 2023, we have net operating loss carryforwards in Australia of \$1.2 million that do not expire, in France of \$1.7 million that do not expire, in Spain of \$0.5 million that do not expire, in Norway of \$0.1 million that do not expire, and in China of \$0.4 million that expire in four years. We have a capital loss carryforward in Australia of \$1.5 million that does not expire. We also have state tax credit carryforwards of approximately \$1.7 million that are available to reduce future tax liabilities, which begin to expire in 2030, or can be carried forward indefinitely.

In December 2018, we reevaluated our international operations and as a result, are no longer indefinitely reinvested with respect to undistributed earnings from our German and Australian subsidiaries. There was no material deferred tax expense recorded for foreign and state tax costs associated with the future remittance of these undistributed earnings. We remain permanently reinvested with respect to undistributed earnings from our other foreign subsidiaries. It is not practicable to estimate the amount of deferred tax liability, if any, with respect to these permanently reinvested undistributed earnings.

A reconciliation of the U.S. federal statutory rate to our effective tax rate is as follows:

	<u>2023</u>	<u>2022</u>	<u>2021</u>
Federal statutory rate	21.0%	21.0%	21.0%
State tax, net of federal benefit	2.8%	2.7%	2.7%
Effect of foreign taxes	1.7%	4.0%	3.7%
Federal tax on foreign income	0.3%	0.0%	0.2%
Valuation allowance	0.2%	(0.2%)	(0.1%)
Foreign deferred tax liability offset	(0.1%)	(0.2%)	(0.1%)
Research & development tax credits	(0.6%)	0.0%	(0.4%)
Stock options	(1.8%)	0.0%	(3.1%)
Uncertain tax positions	0.1%	(0.3%)	0.2%
Other permanent differences	0.4%	(1.8%)	(2.4%)
Other	(0.3%)	(0.3%)	(0.2%)
Effective tax rate	<u>23.7%</u>	<u>24.9%</u>	<u>21.5%</u>

We are not currently under income tax audit in any tax jurisdictions.

As of December 31, 2023, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions are:

United States	2020 and forward
Foreign	2016 and forward

Supplemental disclosures of cash flow information are as follows:

	<u>Year ended December 31,</u>		
	<u>2023</u>	<u>2022</u>	<u>2021</u>
		(in thousands)	
Cash paid for income taxes, net	\$ 7,549	\$ 8,343	\$ 10,147

10. Stockholders' Equity

Authorized Shares

Our certificate of incorporation, as amended and restated from time to time, authorizes the issuance of up to 37,000,000 shares of common stock and up to 3,000,000 shares of undesignated preferred stock.

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of the preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. Currently, we have no shares of preferred stock outstanding.

Equity Offering

On July 16, 2021, we closed an offering of 1,000,000 shares of our common stock, \$0.01 par value per share, at a price to the public of \$54.50 per share, less underwriting discounts. The net proceeds, after deducting the underwriting discounts and other offering expenses, were approximately \$51.0 million. We used a portion of the proceeds from the offering to repay our outstanding debt. At the time of the offering we intended to use the remaining proceeds for general corporate purposes, including working capital needs and capital expenditures, dividend payments, deferred payments related to prior acquisitions, and the funding of future acquisitions.

On August 4, 2021, the underwriters purchased an additional 150,000 shares pursuant to an option granted to them in connection with the offering described above. The net proceeds to the Company, after deducting underwriting discounts and other offering expenses, were approximately \$7.6 million. At the time of the offering, we intended to use the proceeds for general corporate purposes.

Stock Award Plans

In May 2006 we approved a 2006 Stock Option and Incentive Plan (as subsequently amended, the 2006 Plan), which became effective upon our initial public offering. The 2006 Plan allows for the granting of an aggregate 5,500,000 shares of incentive stock options, non-qualified stock options, stock appreciation rights, RSUs, PSUs, unrestricted stock awards, and deferred stock awards to our officers, employees, directors, and consultants. Incentive stock options are required to be issued at not less than fair market value at the date of the grant and generally vest over four or five years. The term of the options is determined by our Board of Directors but in no event will exceed ten years from date of grant. In connection with the adoption of the 2006 Plan, no further option grants were permitted under any previous stock option plans and any expirations, cancellations, or terminations under the previous plans are available for issuance under the 2006 Plan. We may satisfy awards upon exercise of stock options, RSUs or PSUs with either newly issued shares or treasury shares. The total number of shares currently authorized for the 2006 Plan is 7,118,003 shares, of which 273,588 remain available for grant as of December 31, 2023.

We have computed the fair value of employee stock options granted each year using the following weighted average assumptions:

	2023	2022	2021
Dividend yield	1.02%	1.06%	0.91%
Volatility	43.0%	44.6%	46.0%
Risk-free interest rate	4.3%	3.9%	1.1%
Weighted average expected option term (in years)	4.5	4.5	4.6
Weighted average fair value per share of options granted..... \$	20.75 \$	18.10 \$	17.64

A summary of option activity as of December 31, 2023 and for the three years then ended is presented below:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u> (in years)	<u>Aggregate Intrinsic Value</u> (in thousands)
Balance outstanding at December 31, 2020	931,840	\$ 28.22	4.49	\$ 11,442
Granted	151,161	\$ 48.60		
Exercised	(217,121)	\$ 20.95		\$ 6,975
Canceled / Expired	(19,126)	\$ 23.18		
Balance outstanding at December 31, 2021	<u>846,754</u>	\$ 33.83	4.50	\$ 13,888
Granted	159,275	\$ 47.21		
Exercised	(133,963)	\$ 25.80		\$ 3,021
Canceled / Expired	(12,091)	\$ 35.53		
Balance outstanding at December 31, 2022	<u>859,975</u>	\$ 37.53	4.35	\$ 7,878
Granted	148,115	\$ 54.71		
Exercised	(207,643)	\$ 29.72		\$ 5,914
Canceled / Expired	(19,323)	\$ 41.55		
Balance outstanding at December 31, 2023	<u>781,124</u>	\$ 42.78	4.42	\$ 10,924
Exercisable at:				
December 31, 2021	301,692	\$ 27.40	3.30	\$ 6,886
December 31, 2022	369,593	\$ 32.16	3.17	\$ 5,223
December 31, 2023	356,519	\$ 36.83	3.21	\$ 7,107
Expected to vest at:				
December 31, 2021	545,062	\$ 37.38	5.16	
December 31, 2022	490,382	\$ 41.59	5.23	
December 31, 2023	424,605	\$ 47.78	5.43	

Cash received from stock options exercised during the years ended December 31, 2023, 2022 and 2021 was \$6.2 million, \$3.5 million and \$4.5 million, respectively.

Restricted Stock Units and Performance-based Restricted Stock Units

The fair value of restricted stock unit awards with time-based vesting is based on the intrinsic value of the awards at the date of grant.

We also issue restricted stock unit awards with vesting based on performance conditions. Performance-based restricted stock units awarded vest based on our achievement of operating income relative to our target operating income. For restricted stock unit awards that include vesting based on performance conditions, the fair values are based on the intrinsic values of the awards at the date of grant.

A summary of our restricted stock unit activity as of December 31, 2023 and for the three years then ended is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance outstanding at December 31, 2020	147,015	\$ 30.24
Granted	48,298	\$ 48.65
Vested.....	(51,414)	\$ 26.32
Canceled	(10,068)	\$ 30.70
Balance outstanding at December 31, 2021	<u>133,831</u>	<u>\$ 38.26</u>
Granted	51,031	\$ 47.11
Vested.....	(45,489)	\$ 35.75
Canceled	(6,229)	\$ 40.79
Balance outstanding at December 31, 2022	<u>133,144</u>	<u>\$ 42.38</u>
Granted	48,225	\$ 54.68
Vested.....	(49,400)	\$ 39.31
Canceled	(5,975)	\$ 42.89
Balance outstanding at December 31, 2023	<u>125,994</u>	<u>\$ 48.20</u>

The number of RSUs vested includes the shares that we withheld on behalf of employees to satisfy minimum statutory tax withholding requirements. The fair values of the RSUs that vested during 2023, 2022 and 2021 were \$2.7 million, \$2.1 million, and \$2.5 million, respectively.

We repurchase shares of our common stock in order to cover any minimum tax withholding liability associated with RSU vestings. A summary of our repurchases is as follows:

	2023	2022	2021
Shares of common stock repurchased for net settlement of equity awards.....	15,917	13,690	16,333
Average per share repurchase price..... \$	53.59	\$ 46.90	\$ 49.10
Aggregate purchase price (in thousands)..... \$	853	\$ 642	\$ 802

A summary of our performance-based restricted stock unit activity as of December 31, 2023 and for the three years then ended is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance outstanding at December 31, 2020	-	\$ -
Granted.....	31,181	\$ 48.60
Vested	-	\$ -
Canceled.....	-	\$ -
Balance outstanding at December 31, 2021	<u>31,181</u>	<u>\$ 48.60</u>
Granted.....	28,830	\$ 47.13
Vested	-	\$ -
Canceled.....	<u>(31,538)</u>	<u>\$ 48.53</u>
Balance outstanding at December 31, 2022	<u>28,473</u>	<u>\$ 47.19</u>
Granted.....	26,883	\$ 54.65
Vested	-	\$ -
Canceled.....	<u>(1,192)</u>	<u>\$ 47.19</u>
Balance outstanding at December 31, 2023	<u>54,164</u>	<u>\$ 50.85</u>

Stock-based Compensation

The components of stock-based compensation expense included in the consolidated statements of operations are as follows:

	2023	2022	2021
		(in thousands)	
Stock option awards	\$ 2,705	\$ 2,487	\$ 2,199
Restricted stock units	1,951	1,654	1,247
Performance-based restricted stock units	<u>663</u>	<u>32</u>	<u>33</u>
Total stock-based compensation.....	<u>\$ 5,319</u>	<u>\$ 4,173</u>	<u>\$ 3,479</u>

Stock-based compensation is included in our statements of operations as follows:

	2023	2022	2021
		(in thousands)	
Cost of sales	\$ 686	\$ 494	\$ 407
Sales and marketing	966	771	527
General and administrative.....	3,143	2,500	2,185
Research and development.....	<u>524</u>	<u>408</u>	<u>360</u>
Total stock-based compensation.....	<u>\$ 5,319</u>	<u>\$ 4,173</u>	<u>\$ 3,479</u>

We expect to record the unamortized portion of share-based compensation expense of \$15.1 million for existing stock options, RSUs and PSUs outstanding as of December 31, 2023, over a weighted-average period of 2.0 years.

Stock Repurchase Plans

On February 21, 2024, our Board of Directors authorized the repurchase of up to \$50.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 21, 2025. The repurchase program may be suspended or discontinued at any time. To date we have not made any repurchases under this program.

Dividends

In February 2011, our Board of Directors approved a policy for the payment of quarterly cash dividends on our common stock. Future declarations of quarterly dividends and the establishment of future record and payment dates are subject to approval by our Board of Directors on a quarterly basis. The dividend activity for the periods presented is as follows:

<u>Record Date</u>	<u>Payment Date</u>	<u>Per Share Amount</u>	<u>Dividend Payment</u> (in thousands)
Fiscal Year 2023			
March 9, 2023	March 23, 2023	\$ 0.140	\$ 3,099
May 17, 2023	June 1, 2023	\$ 0.140	\$ 3,116
August 17, 2023	August 31, 2023	\$ 0.140	\$ 3,117
November 16, 2023	November 30, 2023	\$ 0.140	\$ 3,117
Fiscal Year 2022			
March 8, 2022	March 24, 2022	\$ 0.125	\$ 2,743
May 17, 2022	June 2, 2022	\$ 0.125	\$ 2,745
August 25, 2022	September 8, 2022	\$ 0.125	\$ 2,750
November 17, 2022	December 1, 2022	\$ 0.125	\$ 2,750

On February 21, 2024, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.160 per share payable on March 28, 2024, to stockholders of record at the close of business on March 14, 2024, which will total approximately \$3.6 million.

11. Profit-Sharing Plan

We offer a 401(k) profit-sharing plan (the Plan) covering eligible U.S. employees to make tax-deferred contributions, a portion of which are matched by us. We may also make discretionary profit sharing contributions to the Plan in an amount determined by our Board of Directors. Our contributions vest ratably over six years of employment and amounted to approximately \$0.8 million, \$0.6 million and \$0.5 million for 2023, 2022 and 2021, respectively. A similar plan is offered to our Canadian employees.

12. Segment and Enterprise-wide Disclosures

The FASB establishes standards for reporting information regarding operating segments in financial statements. Operating segments are identified as components of an enterprise that engage in business activities for which separate, discrete financial information is available and is regularly reviewed by the chief operating decision-maker in making decisions on how to allocate resources and assess performance. We view our operations and manage our business as one operating segment. No discrete operating information is prepared by us except for sales by product line and operations by legal entity for local purposes.

Most of our revenues are generated in the United States, Germany, the UK and other European countries and Canada. Substantially all of our assets are located in the United States and Germany. Net sales to unaffiliated customers by country were as follows:

	Year ended December 31,		
	2023	2022	2021
	(in thousands)		
United States	\$ 117,811	\$ 99,463	\$ 93,866
Germany	13,420	11,223	12,968
Canada	10,786	8,336	7,054
United Kingdom	8,561	5,841	5,046
Other countries	42,906	36,788	35,490
Net sales	<u>\$ 193,484</u>	<u>\$ 161,651</u>	<u>\$ 154,424</u>

Long-term assets by country, including property and equipment, net and right-of-use leased assets were as follows:

	As of December 31,	
	2023	2022
	(in thousands)	
United States	\$ 34,729	\$ 29,042
Germany	2,350	2,462
Other countries	2,702	2,031
Total long-term assets	<u>\$ 39,781</u>	<u>\$ 33,535</u>

13. Fair Value Measurements

The fair value accounting guidance requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

Level 1 assets being measured at fair value on a recurring basis as of December 31, 2023 included our short-term investment and short-duration bond mutual fund accounts.

We had no Level 2 assets being measured at fair value on a recurring basis as of December 31, 2023.

Several of our acquisition-related assets and liabilities have been measured using Level 3 techniques. During 2020 we recorded a contingent liability associated with our acquisition of the bovine carotid graft business from Artegraft. The agreement required us to make potential additional payments to Artegraft of up to \$17.5 million, depending on the achievement of certain unit sales milestones during the first three calendar years following the acquisition through December 31, 2023. We recorded this liability at a fair value of \$0.4 million in 2020 to reflect management's estimate of the likelihood of achieving these targets at the time of the Closing, as well as the time value of money until payment. This amount was being remeasured each quarter during the earn-out period, with any adjustments recorded in income from operations. As of December 31, 2023, there were no unit sales milestones achieved during the earn-out period and therefore we reduced the remaining liability to zero. As a result, during the quarter ended December 31, 2023, we recorded a reduction to the remaining liability of \$0.1 million with the offset recorded in income from operations.

During 2019, we recorded contingent liabilities associated with our acquisition of the Anteris biologic patch business. The agreement includes the potential for us to pay up to \$7.8 million of additional consideration beyond payments made to date, with \$0.3 million contingent upon the delivery of audited financial statements of the acquired business to us; \$2.0 million (CE Mark Contingency) contingent on LeMaitre's success in obtaining CE marks under MDR regulations on the acquired products, \$0.5 million contingent upon Anteris' success in extending the shelf life of the acquired products as specified in the agreement; and another \$5.0 million contingent on the achievement of specified levels of revenues in the first 12 and 24 months following the acquisition date. This additional contingent consideration was initially valued in total at \$2.3 million and is being remeasured each quarter until the payment requirement ends, with any adjustments reported in income from operations. The contingent payment related to the delivery of audited financial statements of the business was paid in November 2019 upon satisfaction of the deliverable. The contingent payments related to Anteris' extending the shelf life of the acquired products and achieving the revenue targets during the first 12 and 24 month periods following the acquisition were not met, and the portion of the liabilities related to these items was adjusted through income from operations. The agreement was amended in August 2021 such that the CE Mark Contingency amount may be reduced for certain costs incurred by LeMaitre in achieving the CE marks. During the quarter ended September 30, 2021 we recorded a reduction to the liability of \$0.5 million, with the offset recorded in income from operations, to reflect our estimate of costs to be deducted from the contingent payment in connection with this amendment. Additionally, during the quarter ended December 31, 2022 we recorded a reduction to the liability of approximately \$0.1 million, with the offset recorded in income from operations.

In September 2023, the agreement was further amended in order to (i) place a cap on the total amount of costs incurred by LeMaitre in achieving the CE marks under MDR regulations that could be used as a deduction toward the \$2.0 million holdback, and (ii) require a prorata payment to Anteris of the CE Mark Contingency, less costs described above, by January 2025 if the CE marks are not obtained by that date. During the quarter ended September 30, 2023 we recorded a reduction to the liability of \$0.1 million, with the offset recorded in income from operations.

The following table provides a roll-forward of the fair value of these liabilities, as determined by Level 3 unobservable inputs including management's forecast of future revenues for the acquired businesses, as well as, management's estimates of the likelihood of achieving the other specified criteria:

	Year ended December 31,		
	2023	2022	2021
		(in thousands)	
Beginning balance	\$ 1,339	\$ 1,492	\$ 2,240
Additions	-	-	-
Payments	-	-	-
Change in fair value included in earnings	(115)	(153)	(748)
Ending balance	<u>\$ 1,224</u>	<u>\$ 1,339</u>	<u>\$ 1,492</u>

14. Accumulated Other Comprehensive Income (Loss)

	Year ended December 31,		
	2023	2022	2021
		(in thousands)	
Beginning balance	\$ (6,031)	\$ (3,435)	\$ (1,525)
Other comprehensive income (loss) before reclassifications	1,406	(2,596)	(1,910)
Amounts reclassified from accumulated other comprehensive loss...	-	-	-
Ending Balance	<u>\$ (4,625)</u>	<u>\$ (6,031)</u>	<u>\$ (3,435)</u>

Changes to our accumulated other comprehensive loss consisted primarily of foreign currency translation and unrealized losses on short-term marketable securities for the years ended December 31, 2023, 2022 and 2021.

15. Quarterly Financial Data (unaudited)

2023	Three months ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Total net sales.....	\$ 47,075	\$ 50,115	\$ 47,411	\$ 48,883
Gross profit.....	30,883	32,086	30,815	33,265
Income from operations.....	7,874	9,452	9,180	10,206
Net income	6,040	8,098	7,502	8,465
Earnings per share				
Basic	\$ 0.27	\$ 0.36	\$ 0.34	\$ 0.38
Diluted	\$ 0.27	\$ 0.36	\$ 0.33	\$ 0.38

2022	Three months ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Total net sales.....	\$ 39,561	\$ 42,108	\$ 39,028	\$ 40,954
Gross profit.....	25,962	27,810	25,070	26,054
Income from operations.....	7,928	5,784	6,150	6,967
Net income	6,038	3,515	5,456	5,627
Earnings per share				
Basic	\$ 0.28	\$ 0.16	\$ 0.25	\$ 0.26
Diluted	\$ 0.27	\$ 0.16	\$ 0.25	\$ 0.25

This page intentionally left blank

This page intentionally left blank

BOARD OF DIRECTORS

LAWRENCE J. JASINSKI^{1, 2, 3}

Chief Executive Officer
Lifeward, Inc.
Director since 2003

GEORGE W. LEMAITRE

Chairman & Chief Executive Officer
LeMaitre Vascular, Inc.
Director since 1992

JOHN J. O'CONNOR¹

Retired Vice Chairman of Services
PricewaterhouseCoopers LLP
Director since 2008

JOSEPH P. PELLEGRINO, JR.

Chief Financial Officer & Secretary
LeMaitre Vascular, Inc.
Director since 2016

DAVID B. ROBERTS

President
LeMaitre Vascular, Inc.
Director since 2001

BRIDGET A. ROSS³

Chief Executive Officer
ChroniSense Medical, Ltd.
Director since 2020

JOHN A. ROUSH^{1, 2}

Operating Executive Advisor
ACON Investments, LLC
Director since 2014

MARTHA SHADAN²

Retired President & Chief Executive Officer
Miach Orthopaedics
Director since 2022

¹ Member of the Audit Committee

² Member of the Compensation Committee

³ Member of the Nominating and Corporate Governance Committee

STOCKHOLDER INFORMATION

PRICE RANGE OF COMMON STOCK

Our common stock trades on the Nasdaq Global Market under the symbol "LMAT". The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

PRICE RANGE

	2022	HIGH	LOW
First Quarter	\$51.50	\$40.48	
Second Quarter	\$47.85	\$39.05	
Third Quarter	\$55.99	\$45.29	
Fourth Quarter	\$52.25	\$41.94	
	2023	HIGH	LOW
First Quarter	\$51.92	\$44.73	
Second Quarter	\$68.21	\$50.38	
Third Quarter	\$67.23	\$53.45	
Fourth Quarter	\$58.41	\$45.37	

TRANSFER AGENT

Inquiries concerning the transfer or exchange of shares, lost stock certificates, duplicate mailings or changes of address should be directed to our transfer agent at:

Computershare Investor Services

150 Royall Street
Canton, MA 02021

INDEPENDENT AUDITORS

Grant Thornton LLP

Boston, MA
Auditors since 2015

ANNUAL MEETING

The annual meeting of stockholders will take place on Monday, June 3, 2024, beginning at 10:00 a.m. at our offices at 32 Third Avenue, Burlington, Massachusetts.

INVESTOR INFORMATION REQUESTS

Investors, stockholders and security analysts seeking information about us should refer to our investor relations website at ir.lemaitre.com or call Investor Relations at 781-221-2266.

OTHER INFORMATION

Reports on Form 10-K and Form 10-Q, Current Reports on Form 8-K and amendments to those reports are available free of charge through the investor relations section of our website at ir.lemaitre.com. Copies of these reports are also available by writing us at:

INVESTOR RELATIONS

LeMaitre Vascular, Inc.

63 Second Avenue
Burlington, MA 01803 USA

EXECUTIVE COMMITTEE

GEORGE W. LEMAITRE

Chairman & Chief Executive Officer

DAVID B. ROBERTS

President

JOSEPH P. PELLEGRINO, JR.

Chief Financial Officer

TRENT G. KAMKE

Senior Vice President, Operations

KIMBERLY L. CIESLAK

Vice President, Marketing

RYAN H. CONNELLY

SVP, Advanced Manufacturing Engineering

GIOVANNELLA DEIURE

Vice President, Sales - Southern Europe

HELEN GOULDING

Director, Sales - Northern Europe

DAVID HISSONG

Vice President, General Counsel

ANDREW HODGKINSON

SVP, Clinical, Regulatory & Quality Affairs

CHANCE KRIESEL

Vice President, Sales, The Americas

ROLI KUMAR-CHOUDHURY

Vice President, Quality Affairs

INA LEININGER

Director, Sales - Central Europe

STÉPHANE MAIER

Senior Vice President, EMEA Operations

CHRISTOPHER D. MINNETT

Country Manager, Canada

DANIEL J. MUMFORD

Director, Human Resources

JONATHAN W. NGAU

Vice President, Information Technology

JACOB PETERSEN

Vice President, Asia-Pacific

JAMES RUSSELL

Vice President, Production & Supply Chain

KATHRYN TEBBE

Senior Director, Financial Reporting

XIANG ZHANG

Vice President, Regulatory Affairs

*Corporate
Headquarters*

LeMaitre Vascular, Inc.

63 Second Avenue
Burlington, MA 01803
USA

T +1 781 221 2266

F +1 781 425 5049

*European
Headquarters*

LeMaitre Vascular GmbH

Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany

T +49 (0)6196 659230

F +49 (0)6196 527072

*Asia Pacific
Headquarters*

LeMaitre Vascular Singapore, Pte. Ltd.

138 Robinson Road
#12-02 Oxley Tower
068906

Singapore

T +65 6813 0281