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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, 2020

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	**04-2825458**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
63 Second Avenue, Burlington, Massachusetts	**01803**
(Address of principal executive offices)	**(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 Rule12b-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 form that prepared or issued its audit report. ☑

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 $289,244,419 computed by reference to the last reported sale price of $26.40 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. For purposes of this calculation, shares held by stockholders whose ownership exceeded 5% of the registrant's common stock outstanding were deemed to be held by affiliates. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

At March 2, 2021, the registrant had 20,527,451 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.

LEMAITRE VASCULAR

2020 ANNUAL REPORT ON FORM 10-K
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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 foreign regulatory requirements to market and sell our products outside the United States; the duration of the lapse in CE mark approval for certain of our devices; the closure of an audit by one of our notified bodies in support of the issuance and/or maintenance of CE marks covering certain of our products or the failure of such audit to be successfully closed; 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; the risk that the Company is not successful in transitioning to a direct-selling model in new geographies.

The following discussion should be read in conjunction with our 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 requires 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, Dialine, Eze-Sit, Glow ‘N Tell, InvisiGrip, LeverEdge, LifeSpan, MollRing Cutter, Omniflow, ProcCol, Pruitt, Pruitt F3, Pruitt-Inahara, Python, RestoreFlow, Syntel, VascuCel, VascuTape, TRIVEX, Wovex, XenoSure, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular or one of its subsidiaries, and AlboSure, Chevalier, DuraSure, EndoRE, Flexcel, MultiTASC, Periscope, and PeriVu are unregistered 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 vascular devices to address the needs of vascular surgeons and, to a lesser extent, 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 outside of the heart and are well known to vascular surgeons, and includes the LeMaitre valvulotome, the XenoSure biologic patch, the Artegraft collagen vascular graft, the Pruitt F3 carotid shunt, VascuTape radiopaque tape, and Syntel embolectomy catheters. Our principal product offerings are sold throughout the world, primarily in the United States, Europe, the United Kingdom, Canada and Asia/Pacific Rim. We estimate that the annual worldwide market for our core product lines is approximately $900 million.

We sell our products and services primarily through a direct sales force. As of December 31, 2020 our sales force was comprised of 80 sales representatives in North America, Europe and Asia/Pacific Rim, including two 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, with additional European sales offices in Milan, Italy; Madrid, Spain; and Hereford, England. Our Asia/Pacific Rim headquarters is located in Singapore, with additional Asia/Pacific Rim sales offices in Tokyo, Japan; Shanghai, China; and Kensington, Australia. During the years ended December 31, 2020 and 2019, approximately 95% and 94%, respectively, of our net sales were generated in territories in which we employ direct sales representatives. We sell our products in other countries through distributors.

Since March 2020, the COVID-19 pandemic has significantly impacted the markets into which we sell devices, our sales and our operations. In response to COVID-19, many hospitals have limited elective procedures, and many of our devices are used in elective procedures. Additionally, our sales representatives' access to hospitals and surgeons has been restricted by hospitals or local governments. In areas where the COVID-19 pandemic has materially abated, we have begun to see restrictions eased. During 2020, these dynamics resulted in, and we expect will continue to result in, variable sales. In response to the COVID-19 pandemic, we have modified our manufacturing operations in order to adhere to social distancing requirements dictated by local law. In Q2 2020 we also undertook measures to reduce our operating costs, including temporary base salary cuts and a reduction in force of approximately 13% of our full-time employees. However, as sales have normalized, we have been rehiring personnel in many areas. We ended our temporary base salary cuts on August 31, 2020.

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, and also includes other conditions, such as diabetes, which is caused by kidney failure. In many cases peripheral vascular disease goes undetected, sometimes leading to life-threatening events including stroke, ruptured aneurysm, pulmonary embolism or death. We believe that the peripheral vascular disease market will grow due to the increase in the incidence and diagnosis rates of peripheral vascular disease, a shift by doctors to using higher-priced endovascular devices, and the adoption of western healthcare standards in the developing world. 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 large and growing market.

Vascular surgeons treat peripheral vascular disease and also perform vascular procedures associated with other diseases, such as end-stage renal disease. We estimate that there are more than 17,000 vascular surgeons worldwide, including 2,800 board-certified vascular surgeons and several thousand general surgeons who perform vascular procedures in the United States, as well as more than 3,000 vascular surgeons in Europe and Asia/Pacific Rim. 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 procedures involving repairing vessels from within using real-time imaging. We estimate that in 2020, over 90% of our net sales were from devices used in open vascular procedures.

Our Business Strategies

We have grown our business by using a three-pronged strategy: focusing on the vascular surgeon call point, competing for sales in low rivalry niche markets, and expanding our growth platform through our worldwide direct sales force as well as acquiring and developing complementary vascular devices.

- ***Focused call point.*** We have historically directed our product offering and selling efforts towards the vascular surgeon, and estimate that in 2020 approximately 80% of our sales were to hospitals for use by vascular surgeons. As vascular surgeons are typically positioned to 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 explore adjacent market customers, or non-vascular surgeon customers, who can be served by our vascular device technologies, such as cardiac surgeons and neurosurgeons.

- ***Low rivalry niche segments.*** We seek to build and maintain leading positions in niche product and services segments, which we define as under $200 million in annual worldwide revenue. We believe that the relative lack of competitive 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. We have, however, also sought to sell complementary offerings into larger, more competitive market segments, particularly when we believe that our offerings in those segments are highly differentiated, such as the Artegraft collagen vascular graft, Omniflow II biosynthetic graft, or the RestoreFlow human tissue cryopreservation services.

- ***Direct sales force expansion, and the addition of complementary products through acquisitions and to a lesser extent research and development.*** We sell our products primarily through a direct sales force in North America, Europe and Asia/Pacific Rim. Since 1998, we have built our sales force from zero to 80 direct sales representatives, including two export managers. Prior to Covid-19, we hit a high water mark of 112 direct sales representatives in 2019. 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, 2020, approximately 95% 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 evaluate the acquisition of additional product lines and businesses that may be complementary to our product offerings, refine our current product lines, develop new applications for our existing technologies, and obtain regulatory approvals for our devices 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 complementary acquisitions and research and development efforts, we have expanded to 16 product lines. We have completed 24 acquisitions since 1998:

Year	Acquisition	Key Product(s) and Services
1998	Whittaker Screen Printing	Radiopaque tape manufacturing operations
1999	Vermed	Embolectomy catheters
2001	Ideas for Medicine	Carotid shunts, balloon catheters, and laparoscopic cholecystectomy devices
2003	Credent	Polycarbonate grafts
2004	VCS Clip	Vessel closure systems
2005	Endomed	Stent grafts
2007	Vascular Innovations	Contrast injector
2007	Vascular Architects	Remote endarterectomy devices
2007	UnBalloon	Stent graft modeling catheters
2007	Biomateriali	Polyester grafts and patches
2010	LifeSpan	ePTFE grafts
2012	XenoSure	Biologic patches
2013	Clinical Instruments	Carotid shunts and embolectomy catheters
2013	TRIVEX	Powered phlebectomy system
2014	Xenotis Pty Ltd	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 relocated the manufacturing operations of 19 of our 24 acquisitions to our Burlington, Massachusetts headquarters, and we continue to look at ways to make our operations more efficient. The human tissue processing and cryopreservation operations associated with RestoreFlow allografts take place in our Fox River Grove, Illinois facility. The manufacture of our Cardial devices takes place in our Saint-Etienne, France facility. The manufacture of our recently acquired Artegraft biologic grafts takes place in North Brunswick, New Jersey. On a limited basis, we use third party manufacturers: Specifically, we purchase remote endarterectomy devices and TRIVEX systems from third parties. We also purchase our CardioCel and VascuCel patches from Anteris Technologies Ltd (formerly Admedus Ltd) in Malaga, Australia.

Our Products and Services

We have a portfolio of 16 product offerings, most of which treat vascular disease, and most of which are used in open vascular surgery and dialysis access, and one of which is a service related to the processing and cryopreservation of human vascular tissue.

Our 16 product offerings include seven that are biologic implants, and one that is a service of processing and cryopreserving human tissue for implantation. These offerings include the XenoSure patch (bovine pericardium), CardioCel and VascuCel patches (bovine pericardium), ProCol graft (bovine mesenteric vein), Artegraft (bovine carotid artery), Omniflow II biosynthetic graft (ovine tissue and synthetic mesh), surgical glue (porcine gelatin) and the RestoreFlow Allograft cryopreserved graft (human cadaver tissue). These biologic product lines represented 43% of our sales in 2020, 35% in 2019, and 36% in 2018. No single product line accounted for more than 20% of our revenues in 2020, 2019 or 2018.

Allografts

Through our RestoreFlow allograft business, we provide human cadaver tissue cryopreservation services, in particular the processing and cryopreservation of veins and arteries. Our RestoreFlow allografts are cryopreserved human tissue grafts, including saphenous veins, femoral veins and arteries, aortic 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. Currently we offer these cryopreservation services in the United States and Canada.

Angioscopes

The 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 or veins. 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

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 clamp fixation.

Bovine Grafts

Our ProCol biologic graft is a bovine mesenteric vein used for dialysis access in patients with a previously-failed synthetic graft. Our Artegraft biologic graft is a bovine carotid artery used for dialysis access in patients with or without a previously-failed synthetic graft. 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. Currently we distribute these two bovine grafts only in the United States.

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 AlboSure Vascular Patch is a polyester patch used primarily for vessel closure after surgical intervention.

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

Carotid Shunts

Our Pruitt F3, Pruitt F3-S and Flexcel carotid shunts are used to temporarily shunt blood to the brain while the surgeon removes plaque in a carotid endarterectomy surgery. Our Pruitt F3 and Pruitt F3-S shunts feature internal balloon fixation rather than traditional external clamp fixation, reducing vessel trauma. Our Flexcel shunt is a non-balloon shunt offered for surgeons who prefer external clamp 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 facilitate compliant 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. This device is not available in the United States.

Polyester Vascular Grafts

Our AlboGraft, Wovex and Dialine II vascular grafts are collagen-impregnated polyester grafts used to bypass or replace diseased arteries. These prostheses are available in straight tube and bifurcated versions.

ePTFE Vascular Grafts

Our LifeSpan ePTFE 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 and with an optional full or partial external spiral support. Our stepped and tapered LifeSpan models are designed to reduce the risk of steal syndrome and high cardiac output, complications that sometimes arise in dialysis access grafts.

Powered Phlebectomy

Our TRIVEX powered phlebectomy system is comprised of capital equipment and disposables that enable removal of varicose veins. In this procedure, an illuminator is inserted through a small incision in the leg, enabling visualization of varicose veins. A second instrument, a resector, removes the veins. Compared to conventional hook phlebectomy, this surgical procedure is faster and results in more complete vein removal through fewer incisions.

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. VascuTape is applied to the skin and provides 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.

Remote Endarterectomy Devices

Our EndoRE line of remote endarterectomy devices are used to remove plaque from arteries in the leg in a minimally invasive procedure requiring a single incision. Our EndoRE devices are used to dissect the plaque from the vessel, cut the far end of the plaque to free it for removal, and then withdraw it from the vessel.

Surgical Glue

Our Cardial surgical glue is a biologic-based glue that is typically used for joining dissected vessel layers and reinforcing sutures in cardiac and vascular procedures.

Valvulotomes

Our valvulotomes (or valve cutters) 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 the 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 the length of hospital stays and the likelihood of wound complications.

Sales and Marketing

As of December 31, 2020, we employed 80 field sales representatives, including two export managers. We believe the expansion of our sales force since 1998 has been a key success factor, and it remains one of our primary long-term strategies. Approximately 95% of net sales occurred in territories in which we employ field sales representatives. Outside our direct markets, we generally sell our products through country-specific distributors.

Our marketing efforts include direct mail and exhibitions at medical congresses, which we believe are important to our brand development. We believe that marketing allows us to reach vascular surgeons who are beyond the reach of our direct sales force.

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

Research and Development

Our research and development activities have historically focused on product development, including developing enhancements and extensions to our existing product lines; process engineering, including designing and optimizing our manufacturing lines; and regulatory and clinical, including obtaining and maintaining regulatory approvals in various geographies.

In 2018, our product development and process engineering efforts were primarily focused on expanding and enhancing our biologic product lines including XenoSure and Omniflow II, and the integration of our ProCol manufacturing into our Burlington facility. We also introduced quality-based improvements to the design of the LeMaitre Valvulotome as well as TRIVEX. In 2019, our focus remained on biologic products, launching a biologic dural patch for use in neuro-surgery procedures, and the transfer of Omniflow II and Syntel manufacturing into our Burlington facility. In addition, we undertook a project to begin distribution of cardiac allografts for use in cardiac replacement and repair. We also continued development on a next-generation powered phlebectomy system. In 2020 we continued our efforts with respect to the cardiac allograft and next-generation powered phlebectomy projects as well as the manufacturing transfers, and also provided support to our growing regulatory and clinical efforts. All of our products are subject to our design control procedures throughout the various stages of product development. These procedures may include bench testing, animal testing, human cadaveric studies and human clinical trials conducted by independent physicians, and post-market surveillance of product performance. We may use feedback received from independent physicians to demonstrate product functionality before commencing full-scale marketing of any product.

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 regulatory approvals already established. 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 a clinical trial in an effort to obtain the approval of our XenoSure patch in China for cardiac and vascular indications. We have completed enrollment of this trial, and we expect to make our cardiac submission to the Chinese National Medical Products Administration (NMPA) in 2021 and for the vascular indication in 2022.

In 2017 the EU adopted new regulations for medical devices (MDR), which replace the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC) (MDD) and which apply after a transition period ending on May 26, 2021. After this date, our MDD certificates then in effect will remain valid until their expiration dates, which range from December 2021 to May 2024. Our products will then 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. 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 Saint-Etienne, France where our Wovex and Dialine vascular grafts, Chevalier Valvulotome and surgical glue are produced, North Brunswick, New Jersey where Artegraft is produced and Fox River Grove, Illinois where RestoreFlow allografts are processed, cryopreserved, stored and distributed.

We eventually integrate manufacturing of most acquired lines into our Burlington operations. However, our EndoRE, CardioCel and VascuCel products are currently manufactured by third parties. We renovated our biologic cleanroom in Burlington in 2017, and in 2018 moved our ProCol biologic grafts into this space. In 2019 we expanded our biologic clean room, and in 2020 transferred the manufacturing of Omniflow II into it. In 2018, we initiated a project to transfer the manufacturing of the Syntel embolectomy business we acquired from Applied Medical, which we completed in 2020. In 2019 we leased a fifth Burlington building, which will allow continued expansion of our manufacturing footprint. We are currently constructing another biologic clean room where we expect to manufacture CardioCel and VascuCel.

We manufacture certain proprietary components, assemble most of our devices ourselves, and inspect, test, and package all of our finished products. By designing and manufacturing many of our products from raw materials, and assembling and testing as many of our subassemblies and products as practical, we believe we can maintain better quality control, ensure compliance with applicable regulatory standards and internal specifications, limit outside access to our proprietary technology, ensure adequate product supply for our customers, and make design modifications in a timely manner. 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 the donor, the medical history of the donor and certain test results of the donated tissue. We also use various supplies in connection with the processing and cryopreservation of human tissue, including certain proprietary solutions and antibiotics.

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 through manufacturing and then through 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 of our key product components and our third-party-manufactured products, most notably the purchase of CardioCel and VascuCel devices from Anteris in Malaga, Australia. While we do have a contractual arrangement with Anteris, we do not have contractual arrangements with many of our suppliers and manufacturers, and we order our supplies and products on an as-needed basis. There are relatively few, or in some cases no, alternative, validated sources for these supplies, products and components. At any time, our suppliers could discontinue or become incapable of the manufacture or supply of these materials on acceptable terms or otherwise. We do not ordinarily carry a significant inventory of these supplies, products and components. Identifying and qualifying additional or replacement suppliers, if required, may not be accomplished quickly or at all and could involve significant additional costs. To date, we have not experienced any significant supply disruptions from existing sources of supplies, products and components, but there is no guarantee that we will not experience such disruptions in the future.

Our Burlington and Saint-Etienne manufacturing facilities have been certified to ISO 13485 quality management system standards, which enables us to satisfy certain 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 and licensed by certain state agencies**.** Our manufacturing and processing facilities are subject to periodic inspections by various regulatory authorities and Notified Bodies (described below) to ensure compliance with domestic and international regulatory requirements. See “Government Regulation” for further information.

Competition

The segments in which our product lines compete are characterized by rapid 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 Baxter International, Inc., Boston Scientific Corporation, Cardiovascular Systems, Inc., Medtronic, Becton, Dickinson and Company, CryoLife, Edwards Lifesciences Corporation, Getinge, LifeNet Health, Terumo Medical Corporation, Silk Road Medical and W. L. Gore & Associates.

The success of our products relies on effective service support as well as superior product technology, quality, product and service availability, reliability, ease of use, cost-effectiveness, physician familiarity, and brand recognition. While we also compete on the basis of price, sometimes our more technologically advanced products are sold at higher prices. We believe our continued success may depend on our ability to broaden and optimize our direct sales channel, acquire or develop 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. 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.

Many of our competitors have substantially greater financial, technological, research and development, regulatory, marketing, sales, and personnel resources than we do. Certain of these competitors are able to manufacture at lower costs and may therefore offer comparable products at lower prices, especially commodity products such as polyester and ePTFE vascular grafts. Certain of these 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 due to higher volume purchases and longer term relationships with tissue procurement organizations. Additionally, some of our competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization before us, any of which could adversely affect our business.

Intellectual Property

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

We maintain a limited portfolio of patents in the United States relating to various aspects of our products. The majority of our issued U.S. patents are set to expire at various times from 2021 to 2031.

We manufacture, market, and sell our Periscope Dissector product pursuant to a license agreement with a third-party. This arrangement requires us to pay a royalty, determined as a percentage of our net sales of this product. If we fail to make the required payments or otherwise fail to observe the terms of this license agreement, we may lose our ability to sell these products. We previously had similar license arrangements for our LifeSpan and TRIVEX product lines but these arrangements ended in 2019. We believe that our brands have been an important factor in our success. We rely on common law and registered trademarks to protect our brands. Some of our registered trademarks are LeMaitre, 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.

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. 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 embolectomy catheters we acquired from Applied Medical in September 2018 and the product lines we acquired from Becton, Dickinson in October 2018. 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 or otherwise gain access to our proprietary technology or disclose such technology, or that we can meaningfully protect our trade secrets. We have a policy of requiring employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship. Our confidentiality agreements also require our 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 the course of their engagement. 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.

The laws of foreign countries generally 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, in some instances, other federal and state authorities and foreign governments.

United States 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, which in the case of PMA applications can be very costly.

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 for which the FDA has not yet called for PMA applications). The FDA's 510(k) clearance pathway usually takes from three to 12 months, but it can take longer. In reviewing a premarket notification, the FDA may request additional information, including clinical data. Nearly all of our devices currently sold in the U.S. are marketed pursuant to 510(k) clearance, with the exception of our ProCol 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 in the first instance, 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 retroactively require the manufacturer to seek 510(k) clearance. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, the manufacturer may be subject to significant regulatory fines or penalties.

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 much more costly, lengthy, and uncertain. A PMA application must provide extensive preclinical and clinical trial data, as well as detailed information about the device and its components regarding, among other things, device design, manufacturing, and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation (QSR) which imposes elaborate testing, control, documentation, and other quality assurance procedures on the manufacturing process.

If the FDA approves a PMA, the approved indications or claims may be more limited than those originally sought. The PMA can include post-approval conditions that the FDA believes to be necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale, and distribution. 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 is required if the device or its labeling or manufacturing process are modified. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

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, one or more smaller feasibility Investigational Device Exemption (IDE) studies may precede a pivotal IDE clinical trial intended to comprehensively demonstrate the safety and effectiveness of the investigational device. All clinical studies of investigational devices must be conducted in compliance with the FDA's extensive requirements. If an investigational device could pose a significant risk to patients (as defined in the regulations), the FDA, prior to initiation of clinical use, must approve an IDE application showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A non-significant risk device does not require submission to the FDA of an IDE application. Both significant risk and non-significant risk investigational devices require approval from institutional review boards (IRBs) at the study centers where the device will be used. The FDA and the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. During a study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, record keeping, and prohibitions on the promotion of investigational devices. 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. Required records and reports are subject to inspection by the FDA. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE 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 products have been introduced into the U.S. market using 510(k) clearance, and we have not used the PMA process for any products that we currently market or sell in the U.S., other than our ProCol vascular graft, which had PMA approval at the time we acquired the device. If we were to seek U.S. approval for our Omniflow II biosynthetic vascular graft, for example, we would be required to follow the PMA process.

Postmarket Regulation

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

- annual manufacturing establishment registration and device listing with the FDA;
- the QSR, which requires finished device manufacturers, including third-party or contract manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures in all aspects of manufacturing;
- 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 or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; 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 or to remedy a violation of the FDCA that may present a risk to health.

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 August 2020, the results of which were satisfactory. Non-compliance with applicable 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, a recommendation by the FDA to disallow us to enter into government contracts, and criminal prosecutions. The FDA also has the authority to request repair, replacement, or refund of the cost of any device manufactured or distributed by us. In the event that one of our suppliers fails to maintain compliance with our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result.

International sales of medical devices manufactured in the U.S. that are not approved or cleared by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Before exporting such products to a foreign country, we must first comply with the FDA's regulatory procedures for exporting unapproved devices.

United States 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 Burlington, Massachusetts facility are both registered with the FDA's Center for Biologics Evaluation and Research. The regulations also provide for the inspection of tissue establishments by the FDA. The FDA most recently inspected our Fox River Grove, Illinois facility in February 2018 and the results of that inspection were satisfactory. In the event of non-compliance with these regulations, the FDA may issue a warning letter, order the recall and/or destruction of tissues and/or order the suspension or cessation of processing and preservation of new tissues.

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. Compliance with the AATB's standards are a predicate to accreditation, which 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. Our Burlington, Massachusetts facility is also accredited for the storage and distribution of tissue. The AATB is entitled to inspect accredited members at any time. The AATB most recently inspected our Fox River Grove, Illinois facility in October 2020, and the results were satisfactory.

NOTA

Under the National Organ Transplant Act, 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, as applicable, 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 applicable state regulations.

Other U.S. Regulations

We, and our products and services, are also subject to a variety of state and local laws in those jurisdictions where our products and services are or will be marketed or distributed, and federal, state, and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially 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 that we have complied with these laws and regulations in all material respects, and have never been required to correct any noncompliance, there can be no assurance that we will not be required to incur significant costs to comply with environmental regulations in the future.

International Regulation of Medical Devices

Sales of medical devices are subject to regulatory requirements in many countries. The regulatory review process may vary greatly 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 Medical Devices Directive (93/42/EEC) (the MDD), which is applicable to our products. Devices that comply with the requirements of the MDD are entitled to bear a CE mark, indicating that the device conforms with the essential requirements of the applicable directive and can be commercially distributed in countries that are members of the EU, as well as the United Kingdom, Iceland, Lichtenstein, Norway, Turkey and Switzerland. Each member state of the EU has implemented the directives into its respective national law and has each established a "Competent Authority" to apply the directive in its territory.

The MDD classification system places devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. The MDD also defines the essential requirements that devices must meet before being placed on the market, establishes assessment procedures for approving a device, and creates mechanisms for Competent Authorities to manage implementation or to intervene when public health requires. Essential requirements include manufacturing, design, performance, labeling, and safety requirements, and may include providing certain clinical data. These requirements vary based on the device classification and other related factors.

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 specific testing of the manufacturer's devices. An assessment by a Notified Body in one country within the EU is generally required in order for a manufacturer to commercially distribute the product throughout the EU. Most of our devices are considered higher-risk devices that require Notified Body assessment.

EU medical device laws 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 sets forth certain specific 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.

Our products are regulated in the EU under the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC) (MDD). In order to market our medical devices in the EU, we are required to obtain CE mark certifications, which denote conformity, and manufacturers of higher-risk devices generally must use a "Notified Body"—an appointed independent third party to assess conformity. We have received CE mark certifications to sell nearly all of our products, though currently there is a lapse in our CE mark certifications for some of our products due to one of our Notified Bodies abandoning all MDD services. On June 13, 2019, the Notified Body that issued the majority of our CE marks, Lloyd's Register Quality Assurance or LRQA, notified its clients that it would cease providing all services relating to the MDD to all clients, including us, as of September 12, 2019, subsequently extended to September 30, 2019. As a result, all LRQA-issued CE marks, unless earlier transferred to a new Notified Body, would lapse as of that date. Prior to receipt of such notice, we had begun transitioning most of our CE mark certifications to a new Notified Body, TUV SUD. However, TUV SUD was unable to complete all work necessary to reissue our CE mark certifications by September 30, 2019. Under the MDD, only product placed on the EU market prior to September 30, 2019 was eligible for sale. As a result, prior to September 30, 2019, we manufactured and shipped inventory in amounts that for most products we believed would be sufficient to supply our EU customers while we awaited reissuance of the CE marks by TUV SUD. TUV SUD issued CE mark certifications in February 2020 for many of our products, representing 37% of our 2020 EMEA sales, and in February 2021, we received a CE mark for our LifeSpan ePTFE product from SGS, another one of our Notified Bodies. For some products for which CE marks have not yet been reissued, we have continued selling product from our inventory reserves previously placed on the market in the EU. We had believed those inventory reserves would be adequate to meet demand, but in some cases they have not been sufficient due to the delay in the expected receipt of our CE mark certifications. We currently do not have valid CE marks for the following products:

Product	**Status**	**Notified Body**
XenoSure	Expired/Partially Derogated	TUV SUD
AlboGraft	Expired/Partially Derogated	TUV SUD
AnastoClips	Expired	SGS
Flexcel & Pruitt carotid shunts	Expired	SGS
AlboSure	Expired	SGS

We have been engaged in a process with TUV SUD to obtain CE marks for XenoSure and AlboGraft since February 2019. We have answered a substantial number of questions related to those products, and we believe their review with respect to those products will conclude by May 2021. TUV SUD, in Q4 2020 as part of the XenoSure/AlboGraft CE marking process, also audited our Burlington facility, and that audit remains open. Approximately 60% of the findings in that audit have been accepted by TUV SUD, and the Company is currently engaged in a dialog with TUV SUD to try to resolve the outstanding findings. However, issuance of CE marks for XenoSure and AlboGraft depends in part on a successful audit closure as well as approvals of the product-specific reviews. Together, XenoSure and AlboGraft accounted for 27% of EMEA sales in 2020. Additionally, retention of our other CE marks representing 37% of our 2020 EMEA sales previously issued by TUV SUD could also depend on a successful audit closure. There can be no assurance that TUV SUD will issue CE marks for these products.

We currently expect that CE marks will be issued by SGS for the products AnastoClips, Flexcel shunts and Pruitt shunts by May 2021. However, there can be no assurance that SGS will issue CE marks for these products. We believe it is unlikely that SGS will issue a CE mark for AlboSure.

As a result of the CE mark lapses, we have begun experiencing backorders related to some of these products and our revenues are being impacted. The backorders for these products approximated $0.2 million as of December 31, 2020. To mitigate, in part, the impact of these backorders, we have sought exemptions, or derogations, in certain European countries from the requirement to apply CE marking to XenoSure and AlboGraft on a temporary basis while we continue to seek reissuance of CE marks by TUV SUD. We have received temporary authorization to sell XenoSure without a CE mark in 12 countries in Europe and AlboGraft in 13 countries in Europe, in each case subject to certain conditions and for limited time periods, expiring as soon as April 22, 2021. If we are unsuccessful in obtaining or maintaining extensions for these temporary authorizations or the reissuance of our CE marks for XenoSure or AlboGraft is materially delayed or withheld, our revenues could be further impacted and our business could be harmed.

Additionally, the CE mark for our Omniflow II graft is currently being transferred to our Burlington headquarters due to our discontinuation of operations in Melbourne, Australia in June 2020. If the transfer is not successful, the Omniflow II will be subject to an MDR application process (see below). While the MDD CE mark would still remain valid for Australian-built product, any new Burlington-produced units would not be allowed onto the European market until issuance of the MDR CE mark. We expect that the inventory of the majority of such products held by our European subsidiary will only be sufficient to supply our customers until Q2 2022, based on historical sales, and as a result, we may go into backorder for Omniflow II until the MDR CE mark is issued. If the CE mark certification for Omniflow II is materially delayed or withheld, our European revenues could be impacted and our business could be harmed.

In April 2017, the EU adopted new regulations for medical devices (MDR), which replace the MDD and will apply beginning May 26, 2021. Our products will be 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 start to transition from MDD to MDR, they have begun to impose more rigorous requirements on us in order to obtain approval to renew the CE marks on certain of our products. For example, we have been informed by BSI, our Notified Body for the product lines manufactured in our Saint-Etienne, France facility, that they require more clinical data for three of the four product lines for the continuance of the CE mark certifications and the upcoming MDR certifications for such devices. Additionally, if CE marks are not issued for any or all of our products with lapsed marks before May 26, 2021, then we will need to reinitiate the application process in its entirety under the MDR for any such lapsed product, a process that could take up to two years for each product. If we fail to obtain new CE marks on these products or 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. We believe it is unlikely BSI will re-issue a CE mark for our biologic glue product.

The United Kingdom left the EU on January 31, 2020, which is commonly referred to as “Brexit”. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020. After December 31, 2020, medical device manufacturers wishing to import their devices into the U.K. were provided a transition period for registration of their devices until the end of 2021. The U.K. will continue to recognize CE marking through June 2023 and thereafter, a separate marking will be required for devices. If our efforts to obtain new regulatory approval in the U.K. is materially delayed or denied, we may be required to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU and our future sales may be impacted. We opened our Hereford, England office in 2019 largely in response to Brexit.

In the event that any of our products proves to be defective, we can voluntarily recall, or the FDA or international equivalent could require us to implement a recall of, any of our products and, 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 reputation and 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.

In some cases, we rely on international distributors or third party agents to obtain premarket approvals, complete product registrations, comply with clinical trial requirements, and complete those steps that are customarily taken in the applicable jurisdictions to comply with governmental and quasi-governmental regulation. In the future, we expect to continue to rely on distributors and agents in this manner where appropriate.

Canada regulates the import and sale of medical devices through Health Canada (HC). HC classifies medical devices into four classifications, with Class I being the lowest risk and Class IV being the highest. 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 classification risk devices (Class III and IV) require filing dossiers that resemble US 510(k) applications. These applications can range in cost and typically take longer for approval. As a holder of Canadian device licenses, we are subject to inspection by HC at our Canadian office, and we must maintain a valid Medical Device Single Audit Program (MDSAP) certificate. Our Canadian office was most recently inspected in August 2017, the results of which were satisfactory. Our Burlington office was audited under the MDSAP in November 2020, and the auditing organization conducting the audit, TUV SUD, notified us of their refusal to issue an MDSAP certificate on January 28, 2021. Our facility was subsequently reaudited by a different auditing organization, SGS, in February 2021 under the MDSAP, the results of which were satisfactory. An MDSAP certificate has not yet been issued to us by SGS; however we expect issuance of the MDSAP certificate in March 2021. If we fail to receive the certificate in a timely manner, or at all, Health Canada may suspend or cancel our device licenses until issuance of the certificate.

In Japan, the Ministry of Health, Labor and Welfare (MHLW) regulates medical devices through the Pharmaceutical Affairs Law, which was reformed effective April 1, 2005. The revisions to Japan's regulations have resulted in longer lead times for product registration. 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 Japanese office was most recently inspected by JET in April 2020, 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 those issued in Europe. As such, many medical devices (those with a lower risk profile) may gain relatively fast marketing clearance using their existing EU-issued CE marking. Higher risk devices (those in EU/Aus Class III) must go through a full design review which can be costly and take longer to complete. Issued licenses for medical devices do not require renewal, but do require an annual fee to remain active in the TGA registry. As a holder of Australian device licenses, we are also subject to inspection by TGA in both Australia and the United States. Our North Melbourne facility, where we previously manufactured our Omniflow II graft until we transferred production to Burlington, was most recently inspected by TGA in December 2018, and our Burlington facility was inspected in February 2021 under the MDSAP, the results of which were satisfactory. An MDSAP certificate has not yet been issued to us by SGS; however we expect issuance of the MDSAP certificate in March 2021. If we fail to receive the certificate in a timely manner, or at all, we would be subject to regular surveillance audits by all MDSAP jurisdictions, including Australia. Australia requires all foreign manufacturers to have an in country 'sponsor' who must have a licensed business inside of Australia. Our licenses are managed on our behalf by our sponsor, Emergo Group.

In China, the National Medical Products Administration (NMPA) regulates and must approve all medical devices to be marketed and sold in China. China has a three-class risk classification system, with Class I being the lowest and Class III being the highest risk. Home country approval, such as 510(k) or PMA clearance, is required as a prerequisite to any application. Additionally, the NMPA often tests devices at its own testing laboratory to confirm each device's specifications. The approval process is typically lengthy and usually requires clinical trials. NMPA licenses are valid for five years from date of issuance and require renewal prior to expiration. As a holder of Chinese device licenses, we are subject to inspection by NMPA in both China and the United States. Our Shanghai offices were most recently 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 the formation of our Chinese subsidiary in 2015, we transferred our licenses from our third-party license holders to our subsidiary.

There can be no assurance that new laws or regulations or new interpretations of laws and regulations regarding the release or sale of medical devices will not delay or prevent sale of our current or future products.

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. Many of the products that compete with ours are less expensive. Therefore, although coverage may be available for our products and the related procedures, the levels of approved coverage may not be sufficient to justify using our products instead of those of competitors.

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 will be incorporated into the overall reimbursement of a procedure, and there will be no separate reimbursement for our products. As a result, we cannot be certain that hospital administrators and physicians will purchase our products.

If hospitals and physicians cannot obtain adequate reimbursement for our products or the procedures in which they are used, our business, financial condition, and results of operations could suffer a material adverse impact.

International

Our success in international markets will depend largely 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 significantly 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 is susceptible to budgetary pressures. Reimbursement approval must be obtained individually in each country in which our products are marketed. Outside the United States, we may pursue reimbursement approval in those countries in which we sell directly to the hospital. In other markets, we generally rely on the distributors who sell our products to obtain reimbursement approval. There can be no assurance that reimbursement approval will be received.

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, such as the OIG.

U.S. Patient Protection and Affordable Care Act

In March 2010, significant 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 Physician Payments Sunshine Act, which was enacted as part of the PPACA and 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 such as training, consulting, 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 403 employees, including 386 full-time employees, at December 31, 2020. Our full-time employees are comprised functionally as follows: 216 manufacturing and operations, 114 sales and marketing, 38 general and administrative and 18 research and development.

We strive to create a demanding and rewarding work environment by emphasizing teamwork and decentralized decision-making. We are committed to providing equal employment and advancement opportunities to all individuals, and all employment decisions are based on merit, qualifications, and abilities. LeMaitre Vascular does not discriminate in employment opportunities or practices 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, including selection, job assignment, compensation, discipline, termination, and access to benefits and training.

We believe in providing competitive pay and benefits to all our employees. We utilize third party benchmark compensation data to determine market wages. Our compensation is designed to attract, retain, and motivate employees to achieve results while balancing short- and long-term company performance. We work with external benefits consultants to evaluate the quality, competitiveness, and cost of our benefit offerings to our employees. In 2020, for example, we improved the company match under our U.S. 401(K) plan.

We review the number of new hires every month to understand our ability to attract talent. We also review our voluntary turnover to understand our ability to retain talent. In 2020, we hired 38 new employees and our world-wide voluntary resignation rate was 8.4%.

COVID safety was a significant concern and focus for us in 2020. We have taken extensive measures to keep our employees safe. We are following all COVID safety best practices including but not limited to requiring masks be worn at all times, socially distanced workstations, hand sanitizer and soap available throughout our buildings, closed conference, break and lunch rooms, and a voluntary work from home policy. We have also invested in Kinexon proximity sensors that help our employees stay socially distanced at all times and allow us to contact trace effectively in the case of a positive diagnosis. Our proximity sensors have been assigned to all employees who work in all our offices globally.

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 2020.

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 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 we are 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 carefully 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 important 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 from time to time. Investors should carefully 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 significantly 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

If we do not comply with international regulatory requirements to market our products outside the U.S., 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 the amount of time required for approval may differ from our experiences with the U.S. FDA. In some cases, we rely on our international distributors to obtain premarket approvals, complete product registrations, comply with clinical trial requirements, and complete those steps that are customarily taken in the applicable jurisdictions to comply with governmental and quasi-governmental regulation. In the future, we expect to continue to rely on distributors in this manner in those countries where we continue to market and sell our products through them. Failure to satisfy these foreign regulations would impact our ability to sell our products in these countries and could cause our business to suffer. There can be no assurance that we will be able to obtain or maintain the required regulatory approvals in these countries.

Our products are regulated in the European Union (EU) and the U.K. under the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC) (MDD). 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, and manufacturers of higher-risk devices generally must use a “Notified Body”—an appointed independent third party to assess conformity. We have received CE marks to sell nearly all of our products, though currently there is a lapse in our CE marks for some of our products due to one of our Notified Bodies abandoning all services related to the MDD. On June 13, 2019, the Notified Body that issued the majority of our CE mark certifications, Lloyd's Register Quality Assurance or LRQA, notified its clients that it would cease providing all Notified Body services relating to the MDD to all clients, including us, as of September 12, 2019, which date was subsequently extended to September 30, 2019. As a result, all LRQA-issued CE marks, unless earlier transferred to a new Notified Body, would lapse as of such date. Prior to receipt of such notice, we had begun transitioning our CE marks to a new Notified Body, TUV SUD. However, TUV SUD was unable to complete all work necessary to reissue our CE marks by September 30, 2019. Under the MDD, only product placed on the European market prior to September 30, 2019 was eligible for sale to EU countries. As a result, prior to September 30, 2019, we manufactured and shipped inventory in amounts that for most products we believed would be sufficient to supply our EU customers while we awaited reissuance of the CE marks by TUV SUD. In February 2020, TUV SUD issued CE marks for many of our products, representing 37% of our 2020 EMEA sales, and we most recently received a CE mark for our LifeSpan ePTFE product in February 2021 from another one of our Notified Bodies, SGS. For some products for which CE marks have not yet been reissued, we have continued selling product from our inventory reserves already placed on the market in the EU prior to September 30, 2019. We previously believed those inventory reserves would be adequate to meet demand, but in some cases they have not been sufficient due to the delay in the expected receipt of our CE marks. We currently do not have valid CE marks for the following products:

Product	Status	Notified Body
XenoSure	Expired/Partially Derogated	TUV SUD
AlboGraft	Expired/Partially Derogated	TUV SUD
AnastoClips	Expired	SGS
Flexcel & Pruitt carotid shunts	Expired	SGS
AlboSure	Expired	SGS

We have been engaged in a process with TUV SUD to obtain CE marks for XenoSure and AlboGraft since February 2019. We have answered a substantial number of questions related to those products, and we believe their review with respect to those products will conclude by May 2021. TUV SUD, in Q4 2020 as part of the XenoSure/AlboGraft CE marking process, also audited our Burlington facility, and that audit remains open. Approximately two-thirds of the findings in that audit have been accepted by TUV SUD, and the Company is currently engaged in a dialog with TUV SUD to try to resolve the outstanding findings. Issuance of CE marks for XenoSure and AlboGraft depends on a successful audit closure as well as product-specific approvals. Together, XenoSure and AlboGraft accounted for 27% of EMEA sales in 2020. Additionally, retention of our other CE marks previously issued by TUV SUD could also depend on a successful audit closure, representing 37% of our 2020 EMEA sales. There can be no assurance that TUV SUD will issue CE marks for these products on a timely basis or at all.

We expect that CE marks will be issued by SGS for the products ascribed to them in the chart above by May 2021, except with respect to AlboSure, which may not achieve CE marking by this deadline. There can be no assurance that SGS will issue CE marks for these products on a timely basis or at all.

As a result of the CE mark lapses, we have begun experiencing backorders related to some of these products and our revenues are being impacted. The backorders for these products approximated $0.2 million as of December 31, 2020. To mitigate, in part, the impact of these backorders, we have sought temporary exemptions, or derogations, in certain European countries from the requirement to apply CE marks to XenoSure and AlboGraft while we continue to seek reissuance of CE marks. We have received temporary authorization to sell XenoSure without a CE mark in 13 countries in Europe, and AlboGraft in 14 countries, in each case subject to certain conditions and for limited periods expiring as soon as April 22, 2021. Where customers are not satisfied with this authorization status, they have in some cases decided to stop using our product and/or use a competing product and may continue to do so in the future, which could further impact our revenues. If we are unsuccessful in obtaining extensions of these derogations, or the reissuance of our CE marks for any of these products is materially delayed or withheld, our revenues could be further impacted and our business could be harmed.

Additionally, the CE mark for our Omniflow II graft is currently being transferred to our Burlington headquarters due to our discontinuation of operations in North Melbourne, Australia in June 2020. If the transfer is not successful, the Omniflow II will be subject to an MDR application process (see below). While the MDD CE mark would still remain valid for Australian-built product, Burlington-produced units would not be allowed onto the European market until issuance of the MDR CE mark. We expect that the inventory of the majority of such products held by our European subsidiary will only be sufficient to supply customers until Q2 2022, based on historical sales, and as a result, we may go into backorder for Omniflow II until the MDR CE mark is issued. If the CE mark certification for Omniflow II is materially delayed or withheld, our European revenues could be impacted and our business could be harmed.

In April 2017, the EU adopted new regulations for medical devices (MDR), which replace the MDD and will apply beginning May 26, 2021. Our products will be 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 will be required for Class III and implantable devices. As our Notified Bodies start to transition from MDD to MDR, they have begun to impose more rigorous requirements on us in order to obtain approval to renew the CE marks on certain of our products. For example, we have been informed by BSI, our Notified Body for the product lines manufactured in our Saint-Etienne, France facility, that three of the four product lines require more clinical data for the continuance of current CE mark certifications as well as the upcoming MDR certifications. If we fail to obtain sufficient clinical data for these products, our current CE marks may be suspended or not issued in a timely manner or at all. Additionally, if CE marks are not issued for any or all of our products with lapsed marks before May 26, 2021, then we will need to reinitiate the application process in its entirety under the MDR for any such lapsed product, a process that could take up to two years for each product. Our preparation of filings under the MDR has been delayed due to our work on the other CE mark matters described above. If we fail to obtain new CE marks on these products or 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.

There can be no assurance that we will be able to obtain or maintain CE marks for our existing products, especially those for which TUV SUD functions as our Notified Body, and obtaining CE marks may involve a significant amount of time and expense, stringent clinical and preclinical testing, or modification of our products and could result in limitations being placed on the use of our products in order to obtain approval. If we fail to obtain new CE marks on our products in a timely manner, or at all, future sales of our products could be adversely impacted.

Failure to receive or maintain approval would prohibit us from selling these products in the EU or the U.K., and would require significant delays in obtaining individual country approvals. If we do not receive or maintain these approvals, our business could be harmed. Maintaining a CE mark is contingent upon our continued compliance with applicable European medical device requirements, including limitations on advertising and promotion of medical devices and requirements governing the handling of adverse events. As highlighted above, there can be no assurance that we will be successful in obtaining, retaining or maintaining the CE mark for any of our current products. In particular, adverse event reporting requirements in the EU and the U.K. mandate that we report incidents which led or could have led to death or serious deterioration in health. Under certain circumstances, we could be required to or could voluntarily initiate a recall or removal of our product from the market in order to address product deficiencies or malfunctions. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

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 devices regulations. Our most recent inspections were as follows:

Facility	Agency	Jurisdiction	Date	Result
Fox River Grove	AATB	Worldwide	January 2018	Passed
Fox River Grove	U.S. FDA	United States	January 2018	Passed
Burlington	Notified Body (LRQA)	Europe	January 2018	Passed
North Melbourne	Notified Body (TUV Rheinland)	Europe	January 2018	Passed
Shanghai	China FDA (NMPA)	China	August 2018	Passed
Burlington	Notified Body (LRQA)	Medical Device Single Audit Program (MDSAP)	October 2018	Passed
Burlington	Notified Body (LRQA)	Europe	November 2018	Passed
North Melbourne	Notified Body (TUV Rheinland)	Europe	November 2018	Passed
North Melbourne	Therapeutic Goods Administration (TGA)	Australia	December 2018	Passed
Burlington	Notified Body (LRQA)	Europe	December 2018	Passed
Burlington	Korean FDA	Korea	January 2019	Passed
Saint-Etienne	Notified Body (BSI)	Europe	January 2019	Passed
Tokyo	Notified Body (JET)	Japan	February 2019	Passed
Burlington	Therapeutic Goods Administration (TGA)	Australia	March 2019	Passed
Saint-Etienne	Notified Body (BSI)	Europe	March 2019	Passed
Burlington	Notified Body (LRQA)	MDSAP	March 2019	Passed
North Melbourne	Notified Body (TUV Rheinland)	Europe	June 2019	Passed
Saint-Etienne	Notified Body (BSI)	Europe	October 2019	Passed
Saint-Etienne	Notified Body (BSI)	Europe	January 2020	Passed
Burlington	US FDA	United States	August 2020	Passed
Burlington	Notified Body (BSI)	Europe	October 2020	Passed
Saint-Etienne	Notified Body (BSI)	Europe	October 2020	Passed
Burlington	Notified Body (SGS)	Europe	October 2020	Passed
Fox River Grove	AATB	Worldwide	October 2020	Passed
Burlington	Notified Body (TUV SUD)	MDSAP	October/November 2020	Refused to Certify
Burlington	Notified Body (TUV SUD)	Europe	October/November 2020	Open
Burlington	Notified Body (BSI)	Europe	January 2021	Passed
Burlington	Notified Body (SGS)	MDSAP	February 2021	Passed*

*Certificate issuance pending

As noted above, TUV SUD audited the Company as part of the Medical Device Single Audit Program (MDSAP) in November 2020. In January, TUV SUD determined not to issue an MDSAP certificate. LeMaitre promptly engaged SGS to undertake a new MDSAP audit. The in-person part of the new audit ended on February 25, 2021, with a recommendation for approval, and we expect successful issuance of an MDSAP certificate in March 2021. If we fail to receive the certificate in a timely manner, or at all, Health Canada may act to suspend or cancel our device licenses until issuance of the certificate. Additionally, the other jurisdictions participating in the MDSAP may determine to independently audit us (regardless of receipt of a new certificate). The Company currently does not expect any sales impact in any geography from its MDSAP inactive status.

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.

The COVID-19 global pandemic outbreak has caused disruptions in our business that are expected to continue for an indefinite period of time.

Like many companies, we have experienced negative effects on our revenues and operations as a result of the COVID-19 global pandemic. The wide geographic spread of the pandemic has adversely affected the global economy and has resulted in fluctuating and unpredictable demand for our products, many of which are used in elective surgical procedures. We began to experience the negative impacts of the pandemic in March 2020. The negative impact to sales continued in the quarter ended June 30, 2020, with sales decreasing by approximately 16% as compared to the quarter ended June 30, 2019. During the quarters ended September 30, 2020 and December 31, 2020 our revenues increased as compared to the prior year quarters; however, this was primarily due to our recently acquired Artegraft product line and foreign currency exchange rates.

We currently expect COVID-19's impact on our revenues to continue into 2021, but it is difficult to estimate by how much due to the uncertainty of the duration and severity of the pandemic. In addition, a recession resulting from the spread of COVID-19 could materially affect our revenues, our business and the value of our common stock.

In addition to impacts to our sales, we have experienced other adverse impacts on our business from COVID-19, including, but not limited to, restrictions on employee travel and limitations on our sales representatives' access to customers. While we expect the impacts of COVID-19 to have an adverse effect on our business, financial condition and results of operations, we are unable to predict the extent or nature of these impacts at this time.

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;
- the acceleration or deceleration of growth rates of our products, particularly in the case of biologic vascular patches whose growth rate has declined over recent periods;
- increased product and price competition, due to market conditions, the regulatory landscape or other factors;
- changes in the mix of products and services we sell;
- our pricing strategy with respect to different product lines and services;
- strategic actions by us, such as acquisitions of businesses or products or divestitures or discontinuations of products;
- effects of domestic and foreign economic and political conditions and exchange rates on our industry and/or customers;
- the relocation and integration of manufacturing or processing operations and other strategic restructuring;
- regulatory actions that may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- changes to the regulatory status of our products, including the lapse, suspension or cancellation of licenses or CE marking;
- 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;
- our ability to collect outstanding accounts receivable in selected countries outside of the United States;
- 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;
- market reception of our new or improved product and service offerings; 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 suddenly and significantly. 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 future performance.

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 2020 over 90% of our sales were from devices used in open surgery.

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 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;
- obtain regulatory clearance or approval of new products and technologies;
- successfully develop cost-effective manufacturing processes for such products;
- commercially introduce such products, services and technologies; and
- achieve market acceptance.

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

We may not maintain our recent levels of profitability.

There can be no assurance we will continue to achieve net sales growth and/or profit growth in the future. In 2020 we undertook substantial cost reductions in response to the COIVD-19 pandemic, and we have reversed many of those reductions. If, for example, we are unable to effectively manage our operating expenses due to, for example, additional CE mark expenses, or increased headcount, we may need to implement cost-cutting again in order to maintain or improve our profitability. Decreased investment levels may inhibit future growth in net sales and earnings.

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 through cost-cutting measures;
- market acceptance of our new products and services;
- the productivity of our direct sales force and distributors;
- fluctuations in foreign currency exchange rates;
- 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, products, services or technologies;
- the impact on our business of competing products, technologies, and procedures;
- our ability to obtain or maintain regulatory approvals for our products in new and existing markets;
- the reimbursement rates for the medical procedures in which our products are used;
- the cost of litigation, if any; and
- changes in tax laws.

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

In order 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 in the future. Our growth strategy depends, in part, upon our ability to identify, negotiate, complete, and integrate suitable acquisitions. 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 or loss of orders from a key customer, particularly where the acquired company had concentrated sales;
- diversion of management’s time and attention from other business concerns;
- higher costs of integration than anticipated;
- unknown or unanticipated liabilities included as part of the acquisition;
- disputes or litigation with former owners related to contingent payments, liabilities assumed or not assumed or other matters;
- challenges in complying with new regulatory requirements to which we were not previously subject;
- increased regulatory scrutiny;
- challenges in maintaining or obtaining regulatory approvals for acquired products;
- difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions;
- difficulties if the acquired company is remote or inconvenient to our Burlington, Massachusetts, headquarters, such as the operations we acquired in 2018 in Saint-Etienne, France;
- 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, as a result of financing to fund acquisitions, which we incurred to acquire Artegraft and is senior to our common stock, requires 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 prior to an acquisition, including but not limited to 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 that we currently expect from our acquisitions or from future acquisitions, and could harm our financial condition and results of operations.

For any of these reasons or as a result of other factors, we may not realize the anticipated benefits of our acquisitions and our operating results may be harmed.

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 transcarotid 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 2020, over 90% of our net sales were from devices used in open vascular 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. Further, even those physicians trained in open procedures may discontinue performing them if there is a lack of demand. If this trend continues, it could lead to the fragmentation of our customer base, which would reduce cross-selling opportunities and the efficiency of each sales call by our sales representatives, which in turn could negatively impact our business.

CardioCel is 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.

Historically, the majority of sales of CardioCel have been to pediatric cardiac surgeons, a call point that is different from our main call point focus. 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. As a result, our sales representatives call predominantly on vascular surgeons and to a lesser extent, cardiac and neuro surgeons. Our success in selling CardioCel will depend, in part, on our sales representatives devoting a portion of their time to making sales calls to, 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 and customers, and our financial condition or results of operations could be harmed. Most of our product lines are used in vascular procedures and as a result, our sales representatives are able to cross-sell most of our product portfolio to vascular surgeons. Cross-selling opportunities to pediatric cardiac surgeons are limited. Additionally, if our sales representatives spend less time focused on vascular surgeons, the sales of our vascular products could decrease, and our financial condition or results of operations could be harmed.

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, with which we were previously unfamiliar before our 2016 acquisition of the RestoreFlow operations, 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, particularly as we may compete for these tissues with organizations who may have greater resources than us and as procurement of cadavers has been challenging during the COVID-19 pandemic;
- processing human tissue in a cost effective manner;
- controlling turnover in a workforce skilled in tissue processing and cryopreservation and any subsequent delay necessary for the adequate training of new personnel; and
- compliance of our tissue procurement organizations to current good tissue practices and our own procurement procedures.

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.

Our dependence on sole- and limited-source suppliers could hinder our ability to deliver our products and services to our customers on a timely basis or at all and could harm our results of operations.

We rely on sole- and limited-source suppliers for some of our important components and certain products. For example, components of our EndoRE product line are manufactured for us by third-party suppliers. Also, 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 for processing and cryopreservation. While we have relationships with multiple tissue procurement organizations, we cannot be sure that the supply of suitable human tissue will be available to us at the levels we need, in which case our allograft service revenues could be adversely affected.

When we acquire a product line, we often enter into an agreement with the seller of the product line for a period of one to three years for the supply of the acquired product until we can transition manufacturing to our facilities. Those arrangements are always sole source supply arrangements with a supplier that has determined to divest the product it is manufacturing. As a result, the supplier may not allocate sufficient resources to the manufacture of our product in favor of dedicating resources to its remaining business. Additionally, there is significant 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 Technologies Ltd (formerly known as Admedus Ltd) and its affiliates have agreed to continue to supply those products to us for up to three years. For the year ended December 31, 2020, Anteris reported revenue from continuing operations of A$7.1 million and a loss before income tax from continuing operations of A$15.3 million. If Anteris fails to meet its obligations under the supply agreement on a timely basis, or at all, then we may experience interruptions in our supply of the acquired products or we may not receive a future supply of the acquired products until we establish our own manufacturing. If we do not have sufficient supply of an acquired product, this could lead to loss of sales, customer dissatisfaction and damage to our reputation, and our financial condition or 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 on acceptable terms or otherwise. 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, and may limit our ability to deliver products to our customers. This could lead to loss of sales and customers, and our financial condition or results of operations could be harmed.

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 manufacturing sites in North Brunswick, New Jersey and Saint-Etienne, France 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 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 depend on our senior management team and other key sales and technical personnel, and if we are unable to retain them or recruit additional qualified personnel we may not be able to manage our operations and meet our strategic objectives.

We depend on the continued services of our senior management team and other key sales and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. Each of our key employees may terminate his or her employment with us at any time, and the loss of any of our senior management team or key employees could harm our business. Because we compete for such personnel with other companies, academic institutions, government entities, and other organizations, we may not be able to meet our future hiring needs or retain existing personnel on acceptable terms. Any loss or interruption of the services of our key personnel could also significantly reduce our ability to effectively manage our operations and meet our commercial or strategic objectives, because we cannot be sure that we would be able to find an appropriate replacement on a timely basis.

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

Our AlboGraft vascular graft, AlboSure vascular patch, Artegraft biologic patch, Dialine II vascular graft, Wovex vascular graft, XenoSure biologic patch, ProCol vascular graft and CardioCel and VascuCel patch products contain bovine tissue or material derived from bovine sources, our Omniflow II Biosynthetic Vascular Graft contains ovine tissue, and our surgical glue contains porcine gelatin. 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 via those materials. This public scrutiny has been particularly 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, because of concern over the potential for the transmission of infectious agents. Significant new regulation, or a ban of our products, could impair our current business or our ability to expand our business, and in the case of a ban or suspension, could materially and adversely affect our results of operations.

We face intense competition from other companies, technologies, and alternative medical procedures and we may not be able to compete effectively.

The segments in which we compete are highly competitive, subject to change, and significantly affected by new product introductions and other activities of industry participants. Although no one company competes against us in all of our product lines or services, a number of manufacturers of peripheral vascular devices have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs, and larger facilities than ours; have established reputations with our target customers; and have developed worldwide distribution channels that are more effective than ours. Our competitors could elect to devote additional resources to the segments in which we currently enjoy less competition. Also, although we currently have leading positions in the segments for some of our products, this is not true for all of our products. From time to time, we have experienced difficulties competing against large companies.

Our competitors may be companies who are larger than us and who 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 offer comparable products at lower prices. Certain competitors may also have greater experience in developing and improving products, obtaining regulatory approvals, and manufacturing and marketing products. Certain competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization, before us, any of which could materially adversely affect us. Further, if the trend towards endovascular procedures versus open vascular procedures continues or accelerates, our competitors may be better poised to take advantage of that trend, since our main product lines are used primarily in open vascular procedures. New product developments that could compete with us more effectively are likely because 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, less expensive, or more readily accepted than ours. Their products could make our technology and products obsolete or noncompetitive. Our competitors may also be able to achieve more efficient manufacturing and distribution operations than we can. In addition, many of our products face competition from alternative procedures that utilize different kinds of medical devices than we currently sell. Increased competition could also result in price reductions and loss of market share, any of which could result in lower revenues and reduced gross profits.

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

In the years ended December 31, 2020, 2019 and 2018, a material portion of our increases in net sales was driven by higher average selling prices to our hospital customers across several of our product lines, particularly with respect to valvulotome sales. In the past, we have been able to rely upon our well-known brands and our established reputation to implement price increases.

Additionally, we may become unable to implement further increases in the selling prices of our products:

- 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; or
- if competitors introduce lower-priced products of comparable safety and efficacy.

We also expect marketplace changes to increasingly place pressure on medical device pricing as hospitals join group purchasing organizations, integrated delivery networks, managed care organizations and other groups that seek to aggregate purchasing power and as hospitals are given financial incentives to improve quality and reduce costs. Due to pricing pressures, surgeons may even perform alternative procedures making our products unnecessary.

If we become unable to raise selling prices, or if we are required to make price concessions, it could reduce our rate of net sales growth and harm our operating results.

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, 2020, 42% of our net sales were derived from 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, whether due to, or in reaction to, changes in U.S. trade policy;
- the risk of non-compliance with the Foreign Corrupt Practices Act by our sales representatives or our distributors;
- 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 that would restrict or prohibit continued business with the sanctioned country or party;
- a shortage of high-quality sales personnel and distributors;
- loss of any key personnel who are important to our success in certain international markets;
- changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;
- the imposition of restrictions on the activities of foreign agents, representatives, and distributors;
- scrutiny of foreign tax authorities, which could result in significant fines, penalties and additional taxes on us;
- pricing pressure that we may experience internationally;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- difficulties in enforcing or defending intellectual property rights;
- exposure to different legal 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 our net sales, results of operations, and financial condition.

The use or misuse of our products and 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 if our products or the tissues we process are found to have caused or contributed to injuries or death, we may become subject to costly litigation by our customers or their patients. Although we offer training for physicians, we do not require that physicians be trained in the use of our products or the tissues we distribute, and physicians may use our products or the tissues we distribute 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, be expensive to defend, and result in sizable damage awards against us. Claims of this nature may also adversely affect our reputation, which could damage our position in the market and subject us to recalls.

We cannot assure you that our product liability insurance coverage will be sufficient to satisfy any claim 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. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing coverage in the future. 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 time and attention and harm our business. Additionally, we could experience adverse effects of litigation even before finally adjudicated if a counterparty is granted intermediate relief such as an injunction. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees. The fact that we operate in international markets also increases the risk that we may face legal exposures 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 business, financial condition and results of operations.

If we fail to convert additional countries or products from distributor sales to direct sales, or encounter difficulties in effecting such conversions, our results of operations could suffer.

We have a history of converting international distributor sales to direct-to-hospital sales by buying out our foreign distributor agreements and selling direct-to-hospital through our own direct sales representatives. In the future, we may elect to convert select additional countries and products from distributor sales to direct-to-hospital sales. Such conversions sometimes result in disruptions in our sales in the applicable geographies. These transitions may also have an adverse effect on our cash flow because distributors, unlike direct sales representatives, pay us for inventory which they store for later sale. In addition, switching to a direct sales force may subject us to longer customer collection times and larger bad debt expense, since we would be required to collect customer payments directly rather than bill and collect from the single distributor.

Our distribution agreements are exclusive, where permissible, with terms of up to five years. These agreements may temporarily constrain our ability to convert certain countries or products from a distributor to a direct-to-hospital model. In order to ensure a successful market transition, we may compensate a distributor in connection with the termination of their distributorship, even where the payment of compensation is not required by contract or local law.

Following termination of any distribution agreement, we may encounter difficulties in transitioning to a direct-to-hospital model. The transition to a direct sales model may require us to meet regulatory requirements that were previously the responsibility of the distributor, which may subject us to additional costs. It also may take us longer than expected to find qualified sales personnel to establish an effective sales force, which could negatively impact projected sales. If a distributor sold our products through a network of sales agents, rather than exclusively through its own personnel, we may not be able to establish relationships with all members of that network, temporarily limiting our access to the existing market. Similarly, failure to maintain or quickly re-establish a distributor's close relationships with the physicians who use our products could reduce sales. Further, it may be difficult or impossible to transfer the assignment of a distributor's rights to sell our products, and as a result, sales to customers may be delayed until a new agreement or approval is obtained. The transition to a direct sales model may also require us to incur additional expenses and may be time-consuming to manage remotely, as is the case with our sales office in China, which consumes a disproportionate amount of resources in view of its sales levels. As a result of these risks, there can be no assurance that we will be successful in transitioning to a direct sales model in the countries that we select, and difficulties that we encounter in these transitions could negatively affect our business.

Fluctuations in the exchange rate of the U.S. dollar and other currencies may adversely impact our results of operations.

Our results of operations are reported in U.S. dollars. While the majority of our revenue is denominated in U.S. dollars, a significant portion of our revenue and costs is denominated in other currencies, such as the Euro, the British pound, the Japanese yen, the Canadian dollar, the Chinese yuan and the Australian dollar. For the year ended December 31, 2020, 42% of our net sales were to customers outside the U.S., largely in currencies other than the U.S. dollar. As a result, we face exposure to movements in currency exchange rates. Our results of operations and our operating expenses are exposed to foreign exchange rate fluctuations as the financial results of those operations are translated from local currency into U.S. dollars upon consolidation. If the U.S. dollar weakens against the local currency, the translation of these foreign currency-based local operations will result in increased net assets, revenue, operating expenses, and net income. Conversely, our local currency-based net assets, revenue, operating expenses, and net income will decrease if the U.S. dollar strengthens against the local currency. Additionally, receivable and payable balances denominated in currencies other than the functional currency may result in gains and losses upon settlement that may adversely impact 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 the means by which companies in the healthcare industry may market their products and services to healthcare professionals and may compete by discounting the prices of their products and services, 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, including, but not limited to, civil and criminal penalties, damages, fines, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. Although in structuring our sales and marketing practices and customer discount arrangements we strive to comply with those laws and regulations, we cannot assure you that government officials charged with responsibility for enforcing those laws will not assert that our sales and marketing practices or customer discount arrangements are in violation of those laws or regulations= or that government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. 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.

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 manufacturing, processing, selling or distributing our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- 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 reputation could suffer.

If we are not successful in obtaining and maintaining clearances and approvals from governmental agencies for our medical devices, we will not be able to sell our products, and our future growth will be significantly 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, or PMA, from the FDA before the product can be marketed or sold. Either process can be lengthy and expensive. The FDA's 510(k) clearance procedure usually takes three to twelve months from the date the FDA receives the application, but may take longer. 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 and required to undergo the more burdensome PMA approval process if they are not found to be substantially equivalent.

The PMA approval process is much more costly, lengthy, and uncertain than the premarket notification process. It generally takes from six months to three years from the date the application is submitted to, and filed with, the FDA, and may take longer. Achieving premarket approval typically requires extensive clinical trials and may require the filing of numerous amendments with the FDA over time. The FDA may also require post-approval studies to continue demonstrating the safe and effective performance of these devices. 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. Additionally, in April 2018, the FDA announced the Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health in which the FDA has proposed limiting the age of predicate devices used in 510(k) applications, thus narrowing the field of available predicates for comparison in the 510(k) process. 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 will be significantly hampered.

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, our sales and profitability could suffer, and we may become subject to a wide 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.

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, which are the FDA regulatory requirements for the processing of human tissue. The FDA enforces its regulations through pre-announced and unannounced inspections. We have been, and anticipate in the future being, subject to such inspections by the FDA and other regulatory bodies. The timing and scope of future audits is unknown and it is possible, despite our belief that our quality systems and the operation of our manufacturing facilities will remain in compliance with U.S, and non-U.S. regulatory requirements, that a future audit 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, and our operations could be disrupted and our manufacturing delayed.

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 force in the U.S. before marketing and selling our products in those countries. If we fail to comply, we would lose our ability to market and sell our products in those foreign countries.

Even after our products have received marketing approval or clearance, our products and the tissue we process may be subject to product recalls. 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. These authorities have been increasing their scrutiny of our industry. If those regulatory bodies feel that we have failed to comply with regulatory standards or if we encounter unforeseen problems following initial approval, licensure or registration, 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 increased scrutiny of our industry by the various regulatory agencies and 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 proves to be defective, we can voluntarily recall, or the FDA or foreign equivalent could require us to implement a recall of or prohibit the sale of, any of our products. For example, in March 2020 we conducted a worldwide recall of a substantial number of our TufTex over-the-wire embolectomy catheters due to a risk of the balloon catheter failing to deflate during use. We experienced backorders for these products while we addressed this issue. Recalls, whether voluntary or required, could result in significant costs to us and significant adverse publicity, which could harm our ability to market our products in the future.

With respect to our RestoreFlow allografts, we may voluntarily recall tissue, and in the event of non-compliance with the regulations governing human tissue, the FDA may issue a warning letter, order the recall and/or destruction of tissues and/or order the suspension or cessation of processing and preservation of new tissues.

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 reputation and 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 for products purchased by our customers, the prices that our customers are willing to pay for those products and the number of procedures using our devices.

Our products and our tissue 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, for the healthcare services provided to their patients. The ability of our customers to obtain appropriate reimbursement for products and services from third-party payors is critical to the success of our products and services because it affects which products customers purchase and the prices they are willing to pay. Reimbursement varies by country and can significantly impact the acceptance of new technology. Implementation of healthcare reforms in the U.S. and in significant overseas markets such as Germany, Japan, France and other countries may limit, reduce or eliminate reimbursement for our products and services and adversely affect both our pricing flexibility and the demand for our products and services. Even when we develop or acquire a promising new product or service, we may find limited demand for the product or service unless reimbursement approval is obtained from private and governmental third-party payors.

Major third-party payors for hospital services in the U.S. and abroad continue to work to contain healthcare costs through, among other things, the introduction of cost containment incentives and closer scrutiny of healthcare expenditures by both private health insurers and employers. For example, in an effort to decrease costs, certain hospitals and other customers may resterilize our products intended for a single use or purchase reprocessed products from third-party reprocessors in lieu of purchasing new products from us.

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 resulting in restrictive reimbursement practices or denials of coverage could have an adverse impact on the acceptance of our products and the prices that our customers are willing to pay for them.

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 obtaining, maintaining, and enforcing our intellectual property rights, trademarks, and other proprietary rights, and our ability to avoid infringing on the proprietary rights of others. 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 afford limited protection and may not prevent our competitors from duplicating our products or services; prevent our competitors from gaining access to our proprietary information and technology; or permit us to gain or maintain a competitive advantage.

The issuance of a patent is not conclusive as to its validity or enforceability. Any patents we have obtained or will obtain in the future might also be invalidated or circumvented by third parties. In addition, any pending patent applications may not issue as patents or, if issued, may not provide commercially meaningful protection, as competitors may be able to design around our patents to produce alternative, non-infringing designs. Should such challenges to our patents be successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. Furthermore, patents expire after a certain duration, depending on the jurisdiction in which 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 and harm our sales and operating results.

Additionally, 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 with us. We also generally require our consultants to assign to us any inventions made during the course of their engagement by 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.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their 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. Whether a product infringes a patent or other intellectual property rights involves complex legal and factual issues, the determination of which is often uncertain. 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 to third parties for past use of the asserted intellectual property;
- harm our reputation;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer, or rebrand our products, which may not be possible and could be costly and time consuming if it is possible to do so at all;
- 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 and Outstanding Debt

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. Shareholders may not be able to resell their shares at or above the price at which they purchased them due to fluctuations in the market price of our common stock caused by changes in our operating performance or prospects, a reduced volume of trading in our common stock, and other factors.

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;
- our announcements or our competitors' announcements of new products;
- public concern as to the safety or efficacy of our products and services;
- 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;
- changes in our growth rates or our competitors' growth rates;
- developments regarding our patents or proprietary rights or those of our competitors;
- our inability to raise additional capital;
- 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;
- changes in stock market analyst recommendations or earnings estimates regarding our common stock, comparable companies, or our industry generally;
- 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.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought. This litigation, if brought 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 and the LeMaitre Family LLC collectively control approximately 14% of our outstanding common stock as of December 31, 2020. As a result, these stockholders, if they were to act together, could have significant influence on many 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 and declared by us based upon a variety of factors deemed relevant by our directors, including, among other things, our financial condition, liquidity, earnings projections and business prospects. 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.

Our level of indebtedness could adversely affect our financial condition and make it more difficult for us to fund our operations.

As of December 31, 2020, we had $39.0 million of indebtedness outstanding under our credit facility. Our level of indebtedness could have important negative consequences to you and us, including:

- we may have difficulty satisfying our obligations under the credit facility;
- we may have difficulty obtaining financing in the future for working capital, capital expenditures, acquisitions or other purposes;
- we will need to use a portion of our available cash flow to pay interest and principal on our debt, which will reduce the amount of money available to finance our operations, dividends and other business activities;
- our debt level increases our vulnerability to general economic downturns and adverse industry conditions;
- our debt level could limit our flexibility in planning for, or reacting to, changes in our business and in our industry in general;
- our leverage could place us at a competitive disadvantage compared to our competitors that have less debt;
- our failure to comply with the financial and other restrictive covenants in our credit agreement, which, among other things, may require us to maintain specified financial ratios and may limit our ability to incur additional debt and sell assets, could result in an event of default that, if not cured or waived, could have a material adverse effect on our business.

Item 1B. Unresolved Staff Comments

None.

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. All five Burlington leases expire in December 2030. 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 16,470 square foot leased facility located in Sulzbach, Germany, with a lease expiring in August 2023. We also lease additional manufacturing, processing, distribution and sales offices in other U.S., Europe, U.K. and Asia/Pacific Rim 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, 2020, 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.

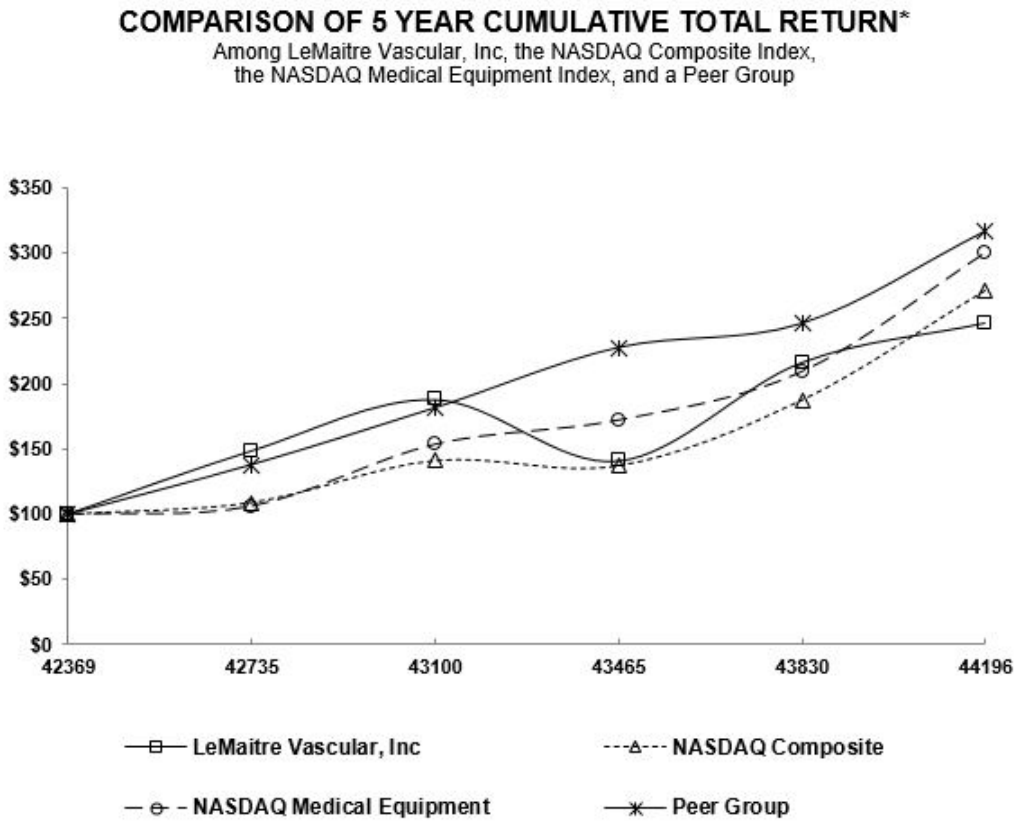
Holders of Record

On March 2, 2021, the closing price per share of our common stock was $51.38 as reported on The Nasdaq Global Market, and we had approximately 162 stockholders of record. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

Stock Price Performance Graph

Set forth below is a graph comparing the cumulative total stockholder return on LeMaitre's common stock with the Nasdaq US Composite Index, the Nasdaq Medical Equipment Index and a peer group for the period covering from December 31, 2015, through the end of LeMaitre's fiscal year ended December 31, 2020. The graph assumes an investment of $100.00 made on December 31, 2015, in (i) LeMaitre's common stock, (ii) the stocks comprising the Nasdaq US Composite Index, (iii) the stocks comprising the Nasdaq Medical Equipment Index and (iv) the stocks comprising our peer group. 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.



	12/15	12/16	12/17	12/18	12/19	12/20
LeMaitre Vascular, Inc	100.00	148.49	187.96	140.73	216.40	246.88
NASDAQ Composite	100.00	108.87	141.13	137.12	187.44	271.64
NASDAQ Medical Equipment	100.00	106.07	153.41	171.99	209.03	300.10
Peer Group	100.00	137.80	181.17	227.29	245.62	316.05

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 2020 peer group includes the following companies: AngioDynamics, Inc., Cardiovascular Systems Inc., Cryolife Inc., Merit Medical Systems, Inc., Penumbra, Inc, Silk Road Medical, Inc, and Shockwave Medical, Inc.

Recent Sales of Unregistered Securities

Not Applicable.

Issuer Purchases of Equity Securities

	Issuer Purchases of Equity Securities			
Period	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, 2020 through October 31, 2020	105	$ 33.21	N/A	N/A
November 1, 2020 through November 30, 2020	-	$ -	N/A	N/A
December 1, 2020 through December 31, 2020	7,301	$ 37.75	N/A	N/A
Total	7,406	$ 37.69	N/A	N/A

(1) For the three months ended December 31, 2020, we repurchased 7,406 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. Selected Financial Data

Omitted.

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 medical device company that develops, manufactures, and markets medical devices and implants largely used in the treatment of peripheral vascular disease. To a lesser extent, our devices are also used to treat diabetes and cardiovascular disease, and are used in neurosurgery applications. We also provide processing and cryopreservation services of peripheral vascular human tissue for implantation into patients. Our principal product offerings are sold throughout the world, primarily in the United States, Europe, the U.K., Canada and Asia/Pacific Rim. We estimate that the annual worldwide market for all of our devices exceeds $5 billion, within which our core product lines address roughly $750 million. We have grown our business 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 and developing complementary devices. We have used acquisitions as a primary means of further penetrating the peripheral vascular device market, and we expect to continue to pursue this strategy in the future. We currently manufacture most of our products in our Burlington, Massachusetts headquarters.

Our products are used primarily by vascular surgeons who treat peripheral vascular disease through both open surgery and endovascular techniques. In contrast to interventional cardiologists and interventional radiologists, vascular surgeons can perform both open surgery and minimally invasive endovascular procedures, and are therefore uniquely positioned to provide a wide range of treatment options to patients.

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

To assist us in evaluating our business strategies, we monitor long-term technology trends in peripheral vascular and other device markets. 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.

Historically we have experienced success in lower-rivalry niche segments, for example the markets for valvulotomes and carotid shunts. In the valvulotome market, our highly differentiated devices have historically allowed us to increase our selling prices while maintaining our unit share. In contrast, we have experienced less success in highly competitive markets such as our AlboGraft vascular graft product line, where we face strong competition from larger companies with greater resources. While we believe that these challenging market dynamics can be mitigated by our relationships with vascular surgeons, there can be no assurance that we will be successful in these highly competitive markets.

In recent years we have also experienced success in international markets, such as Europe, where we sometimes offer comparatively lower average selling prices. If we continue to seek growth opportunities outside of North America, we may experience downward pressure on our gross margin.

Our business opportunities include the following:

- the long-term growth of our direct sales force in North America, Europe and Asia/Pacific Rim;
- the addition of complementary products through acquisitions;

- the introduction of our products in new territories upon receipt of regulatory approvals or registrations in these territories;
- the updating of existing products and introduction of new products through research and development; and
- the consolidation of manufacturing into our Burlington, Massachusetts corporate headquarters.

We sell our products and services primarily through a direct sales force. As of December 31, 2020 our sales force was comprised of 80 sales representatives in North America, Europe and Asia/Pacific Rim, including two 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 sales offices in Milan, Italy; Madrid, Spain; and Hereford, England. Our Asia/Pacific Rim headquarters is located in Singapore, and we have sales offices in Tokyo, Japan; Shanghai, China; and Kensington, Australia. During the years ended December 31, 2020 and 2019, approximately 95% and 94%, respectively, of our net sales were generated in territories in which we employ direct sales representatives. We also sell our products in other countries, including South Korea, Russia and Brazil, through distributors.

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 March 2018, we terminated our master distribution agreement with Sinopharm United Medical Device Co., Ltd. (Sinopharm), under which we sold our TRIVEX devices for distribution in China. In April 2018, we began selling these products to sub-distributors in China. In June 2019, we agreed to purchase at a discount all of Sinopharm’s remaining inventory of our powered phlebectomy devices in settlement of a lawsuit they filed against us in China.
- During 2018, we entered into definitive agreements with several former Applied Medical and Cardial distributors in Europe and Asia in order to terminate their distribution of our recently-acquired embolectomy catheter, polyester graft and valve cutter products, and we began selling direct-to-hospitals in those geographies. The termination fees totaled approximately $0.1 million.
- During 2020, we entered into definitive agreements with, or participated with Anteris in concluding agreements with, several former Anteris distributors in Europe and Canada, in order to terminate their distribution of our recently-acquired bovine cardiac and vascular patch products, and we began selling direct-to-hospitals in those geographies. The termination fees totaled approximately $0.1 million.
- During 2020, we participated with Artegraft in concluding agreements with several of their former U.S. distributors in order to terminate their distribution of our bovine graft products. We now sell Artegraft products direct-to-hospitals throughout the U.S.

Our strategy for growing our business includes the acquisition of complementary product lines and companies and occasionally the discontinuance or divestiture of products or activities that are no longer complementary:

- In April 2018, we divested our Reddick cholangiogram catheter and Reddick-Saye screw product lines to Specialty Surgical Instrumentation for $7.4 million.
- In September 2018, we acquired the assets of the Syntel embolectomy catheter business from Applied Medical for $14.2 million.
- In October 2018, we acquired the assets of Cardial, a subsidiary of Becton, Dickinson, located in Saint-Etienne, France, for €2.0 million. Cardial’s product lines include polyester vascular grafts, valve cutters and surgical glue.
- In July 2019, we entered into an agreement with UreSil, LLC to purchase the remaining assets of their Eze-Sit valve cutter business, including U.S. distribution rights, for $8.0 million.
- In October 2019, we entered into an agreement with Anteris to purchase the assets of their CardioCel biologic patch business for $15.5 million plus additional payments of up to $7.8 million, depending upon the satisfaction of certain contingencies.
- 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, depending upon 2021 – 2023 unit sales.

In addition to relying upon acquisitions for growth, we also rely on internal product development efforts to bring differentiated technology and next-generation products to market:

- In 2018, we expanded the U.S. indications for our Anastoclip GC to include dura tissue repair.
- In 2019, we launched XenoSure *Plus* aimed at a segment of the market that prefers a thicker biologic patch
- In 2019, we also launched DuraSure, a biologic patch indicated for closing or repairing dural defects during open neurosurgical procedures.
- In 2020, we launched RestoreFlow cardiac allografts for use in cardiac repair and restoration.

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 will result in improved control over production quality as well as reduced costs. Our most recent manufacturing transfers included:

- In September 2018, we acquired the embolectomy catheter business from Applied Medical. We initiated a project to transfer production to our Burlington facilities. This transfer is now complete.
- In late 2018 and into 2019, we expanded our Burlington biologic clean room in order to transfer the production of our Omniflow II vascular graft from our North Melbourne, Australia facility to Burlington. This transfer is now complete.
- In October 2019, we acquired the biologic patch business assets from Anteris. In July 2020, we initiated a project to transfer production to our Burlington facilities. We expect this transfer to be complete in 2022 or 2023

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

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, 2020, approximately 42% of our sales took place outside 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 2020, we estimate that the effects of changes in foreign exchange rates increased our reported sales by approximately $0.8 million, as compared to rates in effect for 2019.

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 sell on to hospitals and clinics. In certain cases our products are consigned to 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 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, attendance at vascular 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 includes costs associated with the design, development, testing, enhancement and regulatory approval of our products, principally salaries, laboratory testing and supply costs. It also includes costs associated with design and execution of clinical studies, regulatory submissions and costs to register, maintain, and defend our intellectual property, and royalty payments associated with licensed and acquired intellectual property.

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

In March 2020, we began to experience negative effects on our revenues and operations as a result of the COVID-19 global pandemic. Our revenues increased 7% during the quarter ended March 31, 2020 as compared to the prior year quarter, but for the quarter ended June 30, 2020, sales decreased 16% versus the prior year quarter, with the largest sales impacts in the U.S., Germany, Italy and France. Some of our sales offices were closed during the second quarter of 2020, and in many cases our employees are still working remotely.

During the quarter ended September 30, 2020 revenues increased by $7.3 million, or 25%, compared to the quarter ended September 30, 2019; however, of that increase, $5.4 million was from our recently acquired Artegraft product line, and we estimate that approximately $0.5 million was from changes in foreign currency exchange rates. For the full year 2020 our sales were higher by 10%, or $12.1 million, as compared to 2019, with a substantial portion ($11.1 million) attributable to the Artegraft acquisition. We currently expect to see a continued negative impact from COVID-19 on our revenues, gross profit and gross margin in 2021, but it is difficult to estimate by how much, due to the uncertain duration and severity of the pandemic.

In April 2020, we initiated a plan to reduce our global workforce by approximately 13%, and to temporarily reduce base salaries for certain employees. The salary reduction program applied to all employees earning more than $40,000 per year and was applied outside of the U.S. to the extent permissible under applicable local laws and regulations. These salary reductions remained in place until August 31, 2020, at which point full base salaries were restored. In addition, we have subsequently begun to hire employees into many of the areas previously reduced, and we expect to add personnel in 2021. Annual salary and bonus increases for 2021, which normally occur in January of each year, were brought forward to November 2020.

For reasons described above, we expect that results will continue to be impacted in the near term. These financial statements and management’s discussion and analysis of financial condition and results of operations should be read in that context.

Comparison of the year ended December 31, 2020 to the year ended December 31, 2019

The following tables set forth, for the periods indicated, our results of operations and the change between the specified periods expressed as a percentage increase or decrease:

	2020	2019	$ Change	Percent change
	($ in thousands)			
Net sales	$ 129,366	$ 117,232	$ 12,134	10%
Net sales by geography:				
Americas	$ 81,470	$ 69,359	$ 12,111	17%
Europe, Middle East and Africa	39,193	39,480	(287)	(1%)
Asai/Pacific Rim	8,703	8,393	310	4%
Total	$ 129,366	$ 117,232	$ 12,134	10%

Net sales. Net sales increased 10% or $12.1 million to $129.4 million for the year ended December 31, 2020, compared to $117.2 million for the year ended December 31, 2019. The increase was largely from recently acquired products including Artegraft bovine grafts of $10.8 million and CardioCel bovine cardiac patches of $5.3 million. We also had higher valvulotome sales of $3.9 million, including sales of Eze-Sit in the U.S., which we acquired in July 2019. These sales increases were partly offset by lower OEM sales of $2.2 million, lower sales of carotid shunts of $1.8 million, lower XenoSure bovine carotid patch sales of $1.1 million, lower TRIVEX sales of $1.0 million and lower AnastoClip sales of $0.8 million. All other products decreased on a net basis by $2.0 million. We estimate that changes in foreign exchange rates during the year ended December 31, 2020 increased net sales by $0.8 million.

Direct-to-hospital net sales were 95% of total sales for the year ended December 31, 2020 and 94% for the year ended December 31, 2019.

Net sales by geography. Net sales in the Americas increased $12.1 million or 17% for the year ended December 31, 2020. The increase was driven mainly by recently acquired products including Artegraft of $10.8 million and CardioCel of $3.5 million. We also had higher valvulotome sales of $2.8 million. These increases were partly offset by decreases across most product lines which, with the exception of OEM sales, we believe were due primarily to the impact of the COVID-19 pandemic. Product lines with the largest decreases included carotid shunts and OEM sales, each decreasing by $1.5 million, bovine carotid patches which decreased $0.7 million and vessel closure systems which decreased by $0.9 million. All other products combined decreased by $0.4 million.

Europe, Middle East and Africa net sales were relatively unchanged year-over-year, at $39.2 million for the year ended December 31, 2020 as compared to $39.5 million for the year ended December 31, 2019. Sales of CardioCel cardiac patches increased by $1.4 million and valvulotomes increased by $1.0 million, offset by declines in most other product lines. Products with larger decreases included Omniflow II grafts and OEM sales, which each decreased by $0.7 million, and bovine carotid patches, which decreased by $0.6 million. As discussed under Item 1A. Risk Factors, we have experienced a lapse in CE mark certifications for some products due to one of our Notified Bodies abandoning CE mark certifications services. This caused certain of our products to go on backorder starting in the quarter ended June 30, 2020, including bovine carotid patches and polyester grafts. We received temporary approvals in most European countries, which allowed us to resume sales of those products for a limited time period, pending recertification.

Asia/Pacific Rim net sales increased $0.4 million or 4% for the year ended December 31, 2020. Increased sales of CardioCel cardiac patches of $0.5 million, bovine carotid patches of $0.2 million and embolectomy catheters of $0.2 million were offset in part by declines in sales of TRIVEX of $0.6 million.

	2020	2019	Change	Percent change
	($ in thousands)			
Gross profit	$ 84,618	$ 79,853	$ 4,765	6%
Gross margin	65.4%	68.1%	(2.7%)	*

* Not applicable

Gross Profit. Gross profit increased $4.8 million to $84.6 million for the year ended December 31, 2020, while gross margin decreased by 270 basis points to 65.4% in the period. The decrease in the gross margin was driven primarily by the impact of purchase accounting from the Artegraft acquisition and to a lesser extent by manufacturing inefficiencies, as well as a slightly less favorable product mix, including higher sales of CardioCel cardiac patches and embolectomy catheters.

Operating Expenses.

	2020	2019	$ change	Percent change	2020 as a % of Net Sales	2019 as a % of Net Sales
			($ in thousands)			
Sales and marketing	$ 23,700	$ 30,339	$ (6,639)	(22%)	18%	26%
General and administrative	22,501	19,055	3,446	18%	17%	16%
Research and development	10,099	9,276	823	9%	8%	8%
Gain on sale of building	(470)	-	(470)	*	(0%)	*
	$ 55,830	$ 58,670	$ (2,840)	(5%)	43%	50%

* Not a meaningful percentage.

Sales and marketing. For the year ended December 31, 2020, sales and marketing expense decreased $6.6 million, or 22%, to $23.7 million. The decrease was driven mainly by expense reduction programs implemented in response to the COVID-19 global pandemic, including a reduction in force and temporary base salary cuts in place until August 31. The major components of the sales and marketing expense reduction were salaries and related expenses of $2.3 million, travel and related expenses of $1.9 million, and commission expense of $1.6 million. As a percentage of net sales, sales and marketing expense decreased to 22% for the year ended December 31, 2020 from 26% in the prior period.

General and administrative. For the year ended December 31, 2020, general and administrative expense increased $3.5 million, or 18%, to $22.5 million. Higher acquisition-related costs including consulting and other transaction costs of approximately $1.2 million and increased amortization expense of $2.6 million were partly offset by lower compensation-related costs from our reduction in force and temporary wage cuts of $0.6 million. Other expense categories increased by an additional $0.3 million on a net basis. As a percentage of net sales, general and administrative expense was 17% for 2020 and 16% for 2019.

Research and development. For the year ended December 31, 2020, research and development expense increased $0.8 million, or 9%, to $10.1 million. Product development and process engineering expenses decreased $1.2 million or 22% on a combined basis, in large part due to completion of the manufacturing transfer of certain acquired products to our Burlington facilities. Clinical and regulatory expenses increased $2.3 million or 67%, as a result of consulting and other costs incurred in connection with reinstating or maintaining regulatory approvals, especially in Europe, as well as regulatory submissions for our products in geographies such as China and Japan, and testing related to our biologic products. Royalty expense decreased $0.3 million due to the expiration of underlying royalty agreements. As a percentage of sales, research and development expense were 8% for both 2020 and 2019.

Gain on sale of building. During the first quarter of 2020, in connection with our planned manufacturing transfer of Omniflow II to Burlington, we executed an agreement to sell our land and building in North Melbourne, Australia for A$2.9 million ($2.0 million). The sale closed in September 2020. The building had a net book value of A$1.9 million ($1.4 million). We recognized a $0.5 million gain on the sale, net of applicable sales taxes and administrative costs.

Other income (expense). Other income (expense) primarily includes interest income and expense, foreign currency gains (losses), and other miscellaneous gains (losses). Interest income was $0.2 million and $0.7 million, respectively for 2020 and 2019. The decrease was due to the liquidation of most of our interest-bearing investments to acquire Artegraft. We also incurred debt of $65.0 million in order to complete the acquisition, which generated $1.3 million of interest expense in 2020. Foreign exchange losses on settlements or remeasurement of receivables and payables denominated in foreign currencies were $0.3 million and $0.2 million in 2020 and 2019, respectively.

Income tax expense. We recorded a provision for taxes of $6.1 million on pre-tax income of $27.4 million in 2020 as compared to $3.7 million on pre-tax income of $21.7 million in 2019. The 2020 provision was comprised of a U.S. federal tax provision of $4.2 million, a state tax provision of $0.7 million, and a foreign tax provision of $1.2 million. The 2019 provision was comprised of a U.S. federal tax provision of $2.0 million, a state tax provision of $0.4 million, and a foreign tax provision of $1.3 million. Our effective tax rate differed from the U.S. statutory tax rate in 2020 principally because of stock option exercises, taxes on foreign earnings, valuation allowances, and certain permanent differences. While it is often difficult to predict the final outcome or timing of the resolution of any particular tax matter, we believe that 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, 2020, we have provided a valuation allowance of $1.8 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.

Refer to Note 9 to our consolidated financial statements for additional information about income tax expense (benefit) including information related to U.S. tax reform legislation.

Comparison of the year ended December 31, 2019 to the year ended December 31, 2018

The following tables set forth, for the periods indicated, our results of operations and the change between the specified periods expressed as a percentage increase or decrease:

	2019	2018	$ Change	Percent change
	($ in thousands)			
Net sales	$ 117,232	$ 105,568	$ 11,664	11%
Net sales by geography:				
Americas	$ 69,359	$ 63,649	$ 5,710	9%
Europe, Middle East and Africa	39,480	35,319	4,161	12%
Asai/Pacific Rim	8,393	6,600	1,793	27%
Total	$ 117,232	$ 105,568	$ 11,664	11%

Net sales. Net sales increased 11% or $11.7 million to $117.2 million for the year ended December 31, 2019, compared to $105.6 million for the year ended December 31, 2018. Sales increases were primarily driven by increased sales of our embolectomy catheters of $4.3 million, of which $3.4 million was from our 2018 acquisition of Syntel embolectomy catheters; valvulotomes of $1.6 million, of which $1.2 million was from our Eze-Sit and Chevalier acquisitions in 2019 and 2018, respectively; and polyester grafts of $1.5 million, of which $0.4 million was from our Cardial acquisition. We also had an increase in human tissue cryopreservation service revenues from our RestoreFlow allograft business of $1.4 million. Our recently acquired CardioCel and VascuCel products contributed combined sales of $1.2 million in 2019. These and other product line increases were partially offset by decreased sales of TRIVEX of $0.8 million.

Direct-to-hospital net sales were 94% for the year ended December 31, 2019 and 95% for the year ended December 31, 2018.

Net sales by geography. Net sales in the Americas increased $5.7 million or 9% for the year ended December 31, 2019. The increase was primarily driven by increased sales of embolectomy catheters of $2.6 million, in part due to our acquisition of the Syntel embolectomy catheters, and increased human tissue cryopreservation services of $1.4 million. We also increased sales of valvulotomes by $1.1 million, and our recently acquired CardioCel and VascuCel products contributed sales of $0.9 million in the Americas in 2019. These increases were partially offset by decreased sales of TRIVEX of $0.8 million.

Europe, Middle East and Africa net sales increased $4.2 million or 12% for the year ended December 31, 2019. The increase was primarily driven by increased sales of polyester grafts of $1.3 million, embolectomy catheters of $0.8 million, OEM sales of $0.7 million, valvulotomes of $0.6 million and Omniflow II grafts of $0.4 million.

Asia/Pacific Rim net sales increased $1.8 million or 27% for the year ended December 31, 2019. The increase was driven by increased sales of embolectomy catheters of $0.9 million, AnastoClips of $0.3 million, occlusion catheters of $0.2 million and biologic vascular patches of $0.2 million. These and other increases were offset in part by decreased valvulotome sales of $0.1 million.

	2019	2018	Change	Percent change
	($ in thousands)			
Gross profit	$ 79,853	$ 73,939	$ 5,914	8%
Gross margin	68.1%	70.0%	(1.9%)	*

* Not applicable

Gross Profit. Gross profit increased $5.9 million to $79.9 million for the year ended December 31, 2019, while gross margin decreased by 190 basis points to 68.1% in the period. The gross margin was favorably impacted by higher average selling prices across most product lines, as well manufacturing efficiencies. These increases were more than offset, however, by an unfavorable product mix, including recently acquired products which typically have a lower gross margin prior to being integrated into our Burlington manufacturing operations. Foreign exchange rate changes also had an unfavorable impact in 2019.

	2019	2018	$ change	Percent change	2019 as a % of Net Sales	2018 as a % of Net Sales
			($ in thousands)			
Sales and marketing	$ 30,339	$ 27,318	$ 3,021	11%	26%	26%
General and administrative	19,055	17,689	1,366	8%	16%	17%
Research and development	9,276	8,197	1,079	13%	8%	8%
Gain on divestures and acquisitions	-	(7,474)	7,474	*	0%	*
	$ 58,670	$ 45,730	$ 12,940	28%	50%	43%

* Not a meaningful percentage.

Sales and marketing. For the year ended December 31, 2019, sales and marketing expense increased $3.0 million, or 11%, to $30.3 million. The increase was primarily driven by higher personnel costs, including compensation, commissions and travel expenses associated with expanding our sales force. We also had higher costs due to the implementation of customer relationship management software. As a percentage of net sales, sales and marketing expense was 26% in both 2019 and 2018.

General and administrative. For the year ended December 31, 2019, general and administrative expense increased $1.4 million, or 8%, to $19.1 million. General and administrative expense increases were primarily related to acquisition-related costs including amortization of intangible assets, professional fees, bank and credit card fees, bad debt expense and facilities costs. As a percentage of net sales, general and administrative expense was 16% for 2019 and 17% for 2018.

Research and development. For the year ended December 31, 2019, research and development expense increased $1.1 million, or 13%, to $9.3 million. Product development and process engineering increased $0.8 million on a combined basis, in large part due to transitioning certain acquired products to our Burlington manufacturing operations. Clinical and regulatory expenses increased $0.3 million, related to regulatory submissions for new products in geographies such as China and Japan, and testing related to our biologic products.

Gain on divestitures and acquisitions. The 2018 gains on divestitures and acquisitions relate to the sale of our Reddick cholangiogram catheter and Reddick-Saye screw product lines to Symmetry Surgical, which resulted in a gain of $5.9 million, and also to our purchase of the Cardial assets from Becton Dickinson, which resulted in a bargain purchase gain of $1.6 million.

Other income (expense). Interest income was $0.7 million and $0.6 million, respectively for 2019 and 2018. Foreign exchange losses on settlements or remeasurement of receivables and payables denominated in foreign currencies were $0.2 million and $0.4 million in 2019 and 2018, respectively.

Income tax expense. We recorded a provision for taxes of $3.7 million on pre-tax income of $21.7 million in 2019 as compared to $5.5 million on pre-tax income of $28.4 million in 2018. The 2019 provision was comprised of a U.S. federal tax provision of $2.0 million, a state tax provision of $0.4 million, and a foreign tax provision of $1.3 million. The 2018 provision was comprised of a U.S. federal tax provision of $2.8 million, a state tax provision of $0.5 million and a foreign tax provision of $2.2 million. Our effective tax rate differed from the U.S. statutory tax rate in 2019 principally because of stock option exercises, taxes on foreign earnings, valuation allowances, and certain permanent differences. While it is often difficult to predict the final outcome or timing of the resolution of any particular tax matter, we believe that 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, 2019, we had provided a valuation allowance of $1.4 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.

Refer to Note 8 to our consolidated financial statements for additional information about income tax expense (benefit) including information related to U.S. tax reform legislation.

Liquidity and Capital Resources

At December 31, 2020, we held $26.8 million in cash and cash equivalents and $0.2 million in a short-term managed income mutual fund investment, as compared to $11.8 million in cash and cash equivalents and $20.9 million in the mutual fund investment at December 31, 2019. Our cash and cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase, consist of money market funds, and are stated at cost, which approximates fair value. 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. All of our cash held outside of the U.S. is available for corporate use, with the exception of $2.6 million held by subsidiaries in jurisdictions for which earnings are planned to be permanently reinvested.

On February 23, 2021, our Board of Directors authorized the repurchase of up to $15.0 million of the Company’s common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 22, 2022. The repurchase program may be suspended or discontinued at any time. To date we have not made any repurchases under this program.

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 bear 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. At December 31, 2020 all outstanding borrowings or $39.0 million were designated as Eurodollar loans and had an interest rate of 3.5%.

The term of the revolving line of credit is five years and allows re-borrowing up to $25 million during the term, with all outstanding amounts due on June 22, 2025. The term loan is repayable in increasing quarterly installments of from $0.5 million to $1.0 million commencing September 30, 2020 through March 31, 2025, with the remaining outstanding balance due on June 22, 2025. 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.

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 $28.8 million for the year ended December 31, 2020, $21.2 million for the year ended December 31, 2019 and $28.2 million for the year ended December 31, 2018. 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:

- the revenues generated by product sales;
- payments associated with potential future quarterly cash dividends to our common stockholders;
- payments associated with our stock repurchase program;
- future acquisition-related payments;
- payments associated with U.S income and other taxes;
- the costs associated with expanding our manufacturing, marketing, sales, and distribution efforts;
- the costs associated with our initiatives to sell direct-to-hospital in new countries;

- the costs of obtaining and maintaining FDA, CE mark and other regulatory clearances of our existing and future products; and
- the number, timing, and nature of acquisitions and other strategic transactions.

Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, repay outstanding debt, 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. 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 access our available revolving credit facility. The sale of additional equity and debt securities may result in dilution to our stockholders. 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,		
	2020	**2019**	**2018**
		($ in thousands)	
Cash and cash equivalents	$ 26,764	$ 11,786	$ 26,318
Cash flows provided by (used in):			
Operating activities	$ 34,800	$ 14,179	$ 19,506
Investing activities	(52,891)	(24,100)	(7,055)
Financing activities	32,155	(4,622)	(4,416)

Net cash provided by operating activities. Net cash provided by operating activities was $34.8 million for the year ended December 31, 2020, and consisted of $21.2 million net income, adjusted for non-cash items of $12.7 million (including primarily depreciation and amortization of $8.4 million, stock-based compensation of $3.0 million, provisions for inventory write-offs and doubtful accounts of $1.8 million, and fair value adjustments on contingent consideration for acquisitions of $0.2 million, offset by a benefit from deferred taxes of $0.3 million, and a gain on the sale of a building of $0.5 million) as well as cash from working capital of $0.9 million. The net cash generated from working capital was driven by increases in accounts payable and other liabilities of $4.3 million, offset by increases in inventory and other deferred costs of $2.6 million and accounts receivable of $0.9 million.

Net cash provided by operating activities was $14.2 million for the year ended December 31, 2019, and consisted of $17.9 million net income, adjusted for non-cash items of $10.1 million (including primarily depreciation and amortization of $5.4 million, stock-based compensation of $2.6 million, provisions for inventory write-offs and doubtful accounts of $1.1 million, a provision for deferred taxes of $0.8 million and fair value adjustments on contingent consideration for acquisitions of $0.2 million), as well as working capital uses of $13.6 million. The net cash used for working capital was driven by increases in inventory of $11.3 million, accounts receivable of $1.3 million, and other current assets of $0.7 million, as well as a decrease in accounts payable and other liabilities of $0.3 million.

Net cash provided by operating activities was $19.5 million for the year ended December 31, 2018, and consisted of $22.9 million net income, adjusted for non-cash items of $1.7 million (including primarily depreciation and amortization of $4.3 million, stock-based compensation of $2.3 million, and provisions for inventory write-offs and doubtful accounts of $1.0 million, offset by a benefit for deferred taxes of $2.2 million and gains on acquisitions and divestitures of $7.5 million), as well as working capital uses of $1.7 million. The net cash used for working capital was driven by increases in accounts receivable of $1.3 million, inventory of $4.3 million and other current assets of $0.4 million, offset by an increase in accounts payable and other liabilities of $4.3 million.

Net cash used in investing activities. Net cash used in investing activities was $52.9 million for the year ended December 31, 2020, including acquisition-related payments of $72.6 million primarily associated with the purchase of Artegraft and expenditures on property, equipment and technology of $3.0 million, offset by net sales and purchases of marketable securities of $20.7 million and proceeds from the sale of the North Melbourne, Australia building of $2.0 million.

Net cash used in investing activities was $24.1 million for the year ended December 31, 2019, driven by cash paid for acquisitions of $21.0 million, as well as purchases of property and equipment of $3.8 million primarily associated with biologic clean room build-outs in Burlington. These investments were in part offset by net sales of short-term investments of $0.9 million.

Net cash used in investing activities was $7.1 million for the year ended December 31, 2018, driven by cash paid for acquisitions of $12.3 million, as well as purchases of property and equipment of $3.1 million primarily associated with clean room build-outs in Burlington. These investments were in part offset by proceeds from the Reddick divestiture of $7.4 million and net sales of short-term investments of $0.9 million.

Net cash provided by (used in) financing activities. Net cash provided by financing activities was $32.2 million for the year ended December 31, 2020, consisting primarily of borrowings of $63.2 million net of debt issuance costs and stock option exercises proceeds of $5.4 million, net of shares repurchased to cover employee payroll taxes. These increases to cash were partly offset by dividend payments of $7.7 million, debt payments of $26.0 million and deferred payments for acquisitions of $2.8 million.

Net cash used in financing activities was $4.9 million for the year ended December 31, 2019, driven primarily by dividend payments of $6.7 million and payments related to prior acquisitions of $2.3 million. We had proceeds from stock option exercises of $4.9 million, offset by the acquisition of $0.7 million of treasury shares to cover minimum withholding taxes on restricted stock unit vestings.

Net cash used in financing activities was $4.4 million for the year ended December 31, 2018, driven primarily by dividend payments of $5.4 million and payments related to prior acquisitions of $1.2 million. We had proceeds from stock option exercises of $3.0 million, offset by the acquisition of $0.7 million of treasury shares to cover minimum withholding taxes on restricted stock unit vestings.

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:

Record Date	Payment Date	Per Share Amount	Dividend Payment
			(in thousands)
Fiscal Year 2020			
March 3, 2020	March 19, 2020	$ 0.095	$ 1,917
May 20, 2020	June 4, 2020	$ 0.095	$ 1,917
August 27, 2020	September 10, 2020	$ 0.095	$ 1,925
November 19, 2020	December 3, 2020	$ 0.095	$ 1,936
Fiscal Year 2019			
March 22, 2019	April 5, 2019	$ 0.085	$ 1,672
May 22, 2019	June 6, 2019	$ 0.085	$ 1,672
August 21, 2019	September 5, 2019	$ 0.085	$ 1,691
November 20, 2019	December 5, 2019	$ 0.085	$ 1,701

On February 23, 2021, our Board of Directors approved a quarterly cash dividend on our common stock of $0.11 per share payable on March 25, 2021, to stockholders of record at the close of business on March 9, 2021, which will total approximately $2.2 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, inventories, intangible assets, 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 significant 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. We also occasionally enter into consigned inventory arrangements with either hospitals or distributors on a limited basis. Following our acquisition of the RestoreFlow allograft business, we also derive revenues from human tissue cryopreservation services. These service revenues are recognized when services have been provided and the tissue has been shipped to the customer, provided all other revenue recognition criteria discussed below have been met.

We recognize 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 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 Spain and Italy 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 consists of finished products, work-in-process, and raw materials. We value inventory 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.

In connection with our RestoreFlow allograft business, other deferred costs include costs incurred for the preservation of human vascular tissues available for shipment, tissues currently in active processing, and tissues held in quarantine pending release to implantable status. By U.S. 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 human vascular tissues are instead accumulated and deferred.

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 $58.9 million as of December 31, 2020 and $24.9 million as of December 31, 2019. Goodwill was $65.9 million as of December 31, 2020 and $40.0 million as of December 31, 2019.

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, 2020, 2019, and 2018, 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 amount 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

In June 2016, the FASB issued ASU 2016-13 Financial Instruments – Credit Losses (Topic 326), which requires a financial asset (or group of financial assets) measured at amortized cost to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions and reasonable, supportable forecasts that affect the collectability of the reported amount, and requires judgment in determining relevant information and estimation methods. The new standard was effective for us beginning January 1, 2020. The adoption of this standard did not have a material impact on our financial statements, as the only financial assets we have that are affected by the standard are trade receivables for which we have historically employed a collectability estimation technique.

In August 2018, the FASB issued ASU 2018-13 Fair Value Measurement (Topic 820), which modifies the disclosure requirements for fair value measurements. The new standard was effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard did not have a material impact on our financial statements.

In January 2017, the FASB issued ASU 2017-04 Intangibles – Goodwill and Other (Topic 350), which, among other provisions, eliminates “step 2” from the goodwill impairment test. The annual, or interim, goodwill impairment test will be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The new standard was effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard did not have a material impact on our financial statements.

In December 2019, the FASB issued ASU 2019-12 Income Taxes (Topic 740), which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 as well as clarifying and amending other areas of existing GAAP under Topic 740. The new standard is effective for us beginning January 1, 2021, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our 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 fiscal 2020 and 2019, 42% and 46%, respectively, 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 2020 or 2019. 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, 2020 and 2019, we recorded $0.3 million and $0.2 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 $1.5 million for 2020.

Interest Rate Risk

At December 31, 2020, we held $26.8 million in cash and cash equivalents and $0.2 million in a short-term managed income mutual fund investment. Due to the short maturities on any instruments held, a hypothetical 10% increase or decrease in interest rates would not have a material impact on our financial position, results of operations or cash flows. We also have exposure to floating interest rates through our senior secured credit facility, as the interest expense related to any borrowings will fluctuate with changes in Eurodollar and other benchmark rates. Therefore, increases in interest rates may reduce our net income or loss by increasing the cost of carrying debt.

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, 2020, 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, 2020. 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, 2020.

Our internal control over financial reporting as of December 31, 2020 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

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2020 that has materially affected, or is 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 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, 2020, 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, 2020, 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, 2020, and our report dated March 12, 2021 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
March 12, 2021

Item 9B. Other Information

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 2021 definitive proxy statement (2021 Definitive Proxy Statement) for the 2021 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2020.

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 2021 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 2021 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 2021 Definitive Proxy Statement.

Equity Compensation Plan Information

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2020. 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)
Equity compensation plans approved by security holders	1,078,855	$ 28.50	860,847
Equity compensation plans not approved by security holders	-	-	-
Total	1,078,855	$ 28.50	860,847

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 2021 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 2021 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

		Incorporated By Reference			
Exhibit Number	**Exhibit Description**	**Form**	**Date**	**SEC File Number**	**Filed Herewith**
2.1	Asset Purchase Agreement dated November 10, 2016 between the Registrant, Restore Flow Allografts, LLC and certain individuals named therein.	10-K	3/9/18	001-33092	
2.2	Asset Purchase Agreement dated September 20, 2018 between the Registrant and Applied Medical Resources Corporation	10-Q	11/2/18	001-33092	
2.3	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	
2.1^	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	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	
10.2	Director Compensation Policy	10-K	3/27/12	001-33092	
10.3†	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	
10.4†	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts	S-1/A	6/22/06	333-133532	
10.5†	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino	S-1/A	6/22/06	333-133532	
10.6†	Form of Indemnification Agreement between the Registrant and its directors and executive officers	S-1/A	5/26/06	333-133532	
10.7	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	
10.8	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	
10.9	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	
10.10†	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	
10.11†	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and David Roberts	10-K	3/31/09	001-33092	
10.12†	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	
10.13	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	

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
10.14	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	
10.15	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	
10.16	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	
10.17	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	
10.18	Lease dated December 20, 2013, by and between N.W. Building 3 Trust and Registrant	8-K	12/23/13	001-33092	
10.19	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	
10.20	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	
10.21†	Amended and Restated Management Incentive Compensation Plan	8-K	2/25/14	001-33092	
10.22†	Third Amended and Restated 2006 Stock Option and Incentive Plan	8-K	6/8/15	001-33092	
10.23†	Separation Agreement dated June 7, 2017 between Peter R. Gebauer and LeMaitre Vascular GmbH	8-K	8/3/17	001-33092	
10.24†	Transition and Employment Agreement dated June 7, 2017 between Peter R. Gebauer and the Registrant	8-K	8/3/17	001-33092	
10.25†	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	
10.26†	Form of Incentive Stock Option Agreement under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	10-K	3/9/18	001-33092	
10.27†	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	
10.28	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	
10.29	Asset Purchase Agreement between the Registrant and Specialty Surgical Instrumentation, Inc. dated April 5, 2018.	10-Q	5/4/18	001-33092	
10.30	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	
10.31	First Amendment of Lease dated October 29, 2019 between NWP BUILDING 3 LLC and the Registrant	8-K	11/1/19	001-33092	
10.32	Fifth Amendment of Lease dated October 29, 2019 between NWP BUILDING 4 LLC and the Registrant	8-K	11/1/19	001-33092	
10.33	Seventh Amendment of Lease dated October 29, 2019 between NWP BUILDING 5 LLC and the Registrant	8-K	11/1/19	001-33092	
10.34	Lease dated November 26, 2019 between NWP Retail 18 LLC and the Registrant.	8-K	12/3/19	001-33092	
10.35	Credit Agreement dated June 22, 2020, by and among the Company, the lenders from time to time party thereto and KeyBank National Association, as administrative agent.	8-K	6/24/20	001-33092	
10.36	Security Agreement, dated June 22, 2020, by and among the Company, each additional grantor that becomes a party thereto and KeyBank National Association, as collateral agent.	8-K	6/24/20	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
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 XRBL 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 would likely cause competitive harm to the Registrant if disclosed.

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 March 12, 2021.

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
/s/ GEORGE W. LEMAITRE **George W. LeMaitre**	Chief Executive Officer and Chairman of the Board *(Principal Executive Officer)*	March 12, 2021
/s/ JOSEPH P. PELLEGRINO, JR. **Joseph P. Pellegrino, Jr.**	Chief Financial Officer *(Principal Financial and Accounting Officer)* and Director	March 12, 2021
/s/ LAWRENCE J. JASINSKI **Lawrence J. Jasinski**	Director	March 12, 2021
/s/ JOHN J. O'CONNOR **John J. O'Connor**	Director	March 12, 2021
/s/ DAVID B. ROBERTS **David B. Roberts**	President and Director	March 12, 2021
/s/ JOHN A. ROUSH **John A. Roush**	Director	March 12, 2021
/S/ BRIDGET A. ROSS **Bridget A. Ross**	Director	March 12, 2021

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
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, 2020 and 2019, the related consolidated statements of operations, comprehensive income, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 March 12, 2021 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
The critical audit matters communicated below 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. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of the acquisition-date fair value of contingent consideration
As discussed in Notes 2 and 13 to the consolidated financial statements, on June 22, 2020 the Company acquired Artegraft, Inc. for a total purchase price of $72.9 million. The acquisition agreement included a contingent consideration provision based on the volume of units sold in each of the three years post-acquisition, individually and in the aggregate, with potential total consideration of $17.5 million. We identified the evaluation of the acquisition-date fair value of the contingent consideration as a critical audit matter.

The principal consideration for our determination that the evaluation of the acquisition-date fair value of the contingent consideration is a critical audit matter is that a high degree of subjective auditor judgment was required in evaluating certain inputs to the Monte Carlo model used to determine the fair value of the contingent consideration. Specifically, the key inputs included forecasted unit sales and the volatility of unit sales. There was limited observable market information, and the calculated fair value of the contingent consideration was sensitive to possible changes to these key inputs.

The primary procedures we performed to address this critical audit matter included the following:

- We tested internal controls over the Company's acquisition-date valuation process, including controls over the key inputs listed above.
- In connection with our assessment of the unit sale forecasts used in the valuation, we compared forecasted unit sale growth rates to historical actual results, prior acquisitions and projected industry growth rates.
- In addition, we involved valuation professionals with specialized skills and knowledge, who assisted in:
  - evaluating the valuation approach used by the Company to calculate the fair value of contingent consideration;
  - comparing the selected volatility used against publicly available volatility of comparable companies; and
  - developing estimates of the fair values of the contingent consideration using independently obtained external information and comparing the results to the Company's fair value estimates.

Evaluation of acquisition-date fair value of customer relationships and developed technology intangible assets
As discussed in Note 2 to the consolidated financial statements, on June 22, 2020 the Company acquired Artegraft, Inc. for a total purchase price of $72.9 million. The Company accounted for this acquisition under the acquisition method of accounting for business combinations. In connection with the transaction, the Company recorded customer relationships and developed technology intangible assets (collectively, the "intangible assets") of $21.3 million and $16.5 million, respectively. We identified the evaluation of the acquisition-date fair value of the intangible assets acquired in the Artegraft, Inc. transaction as a critical audit matter.

The principal consideration for our determination that the fair value of the intangible assets is a critical audit matter is that a high degree of subjective auditor judgement was required in evaluating certain assumptions used in the valuation methods to calculate the fair value of the intangible assets. The valuation models included a number of internally developed assumptions for which there was limited observable market information, and the calculated fair value of such assets was sensitive to possible changes to the following key assumptions: obsolescence curve, royalty rates and annual customer attrition rate.

The primary procedures we performed to address this critical audit matter included the following:

- We tested internal controls over the Company's acquisition-date valuation process, including controls over the development of the key assumptions.
- We also evaluated the annual customer attrition rate by examining the Company's historical customer attrition data as well as comparing attrition rates to prior acquisitions.
- In addition, we involved valuation professionals with specialized skills and knowledge, who assisted in:
  - evaluating the valuation approach used by the Company to calculate the fair value of the intangible assets;
  - evaluating the obsolescence curve (and the resulting economic useful life) assumption, based on the qualitative support provided by management and comparing it to market surveys for useful lives of similar assets; and
  - evaluating the selected royalty rate against market data of comparable licensing agreements, and the Company's historical licensing agreements as well as independently analyzed the profit split used.

/s/ GRANT THORNTON LLP

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

Boston, Massachusetts
March 12, 2021

LeMaitre Vascular, Inc.
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$ 26,764	$ 11,786
Short-term marketable securities	214	20,895
Accounts receivable, net of allowances of $623 at December 31, 2020, and $522 at December 31, 2019	19,552	16,572
Inventory and other deferred costs	45,115	39,527
Prepaid expenses and other current assets	2,618	3,312
Total current assets	94,263	92,092
Property and equipment, net	15,036	14,854
Right-of-use leased assets	16,066	15,208
Goodwill	65,945	39,951
Other intangibles, net	58,905	24,893
Deferred tax assets	1,686	1,084
Other assets	909	259
Total assets	$ 252,810	$ 188,341
Liabilities and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 2,500	$ -
Revolving line of credit	-	-
Accounts payable	2,394	2,604
Accrued expenses	17,525	14,014
Acquisition-related obligations	772	2,476
Lease liabilities - short-term	1,954	1,757
Total current liabilities	25,145	20,851
Long-term debt, net	35,532	-
Lease liabilities - long-term	14,791	13,955
Deferred tax liabilities	127	1,179
Other long-term liabilities	4,643	4,215
Total liabilities	80,238	40,200
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 22,061,554 shares at December 31, 2020, and 21,678,927 shares at December 31, 2019	221	217
Additional paid-in capital	114,924	105,934
Retained earnings	70,554	57,029
Accumulated other comprehensive loss	(1,525)	(4,007)
Treasury stock, at cost; 1,538,572 shares at December 31, 2020 and 1,522,035 shares at December 31, 2019	(11,602)	(11,032)
Total stockholders' equity	172,572	148,141
Total liabilities and stockholders' equity	$ 252,810	$ 188,341

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Operations

	Year ended December 31,		
	2020	**2019**	**2018**
	(in thousands, except per share data)		
Net sales	$ 129,366	$ 117,232	$ 105,568
Cost of sales	44,748	37,379	31,629
Gross profit	84,618	79,853	73,939
Sales and marketing	23,700	30,339	27,318
General and administrative	22,501	19,055	17,689
Research and development	10,099	9,276	8,197
Gains on sales of assets and acquisitions	(470)	-	(7,474)
Total operating expenses	55,830	58,670	45,730
Income from operations	28,788	21,183	28,209
Other income (expense):			
Interest income	207	698	631
Interest expense	(1,310)	-	(2)
Foreign currency loss	(329)	(202)	(394)
Income before income taxes	27,356	21,679	28,444
Provision for income taxes	6,136	3,745	5,501
Net income	$ 21,220	$ 17,934	$ 22,943
Earnings per share of common stock:			
Basic	$ 1.05	$ 0.91	$ 1.18
Diluted	$ 1.04	$ 0.88	$ 1.13
Weighted-average shares outstanding:			
Basic	20,246	19,813	19,426
Diluted	20,479	20,326	20,242
Cash dividends declared per common share	$ 0.38	$ 0.34	$ 0.28

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Comprehensive Income

	Year ended December 31,		
	2020	**2019**	**2018**
Net income	$ 21,220	$ 17,934	$ 22,943
Other comprehensive income (loss):			
Foreign currency translation adjustment, net	2,468	(234)	(1,626)
Unrealized gain (loss) on short-term marketable securities	14	127	15
Total other comprehensive income (loss)	2,482	(107)	(1,611)
Comprehensive income	$ 23,702	$ 17,827	$ 21,332

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2017	20,745,041	$ 207	$ 93,127	$ 28,333	$ (2,289)	1,480,101	$ (9,608)	$ 109,770
Net income				22,943				22,943
Other comprehensive income					(1,611)			(1,611)
Issuance of common stock for stock options exercised	303,379	4	2,966					2,970
Vested restricted stock units	61,804	-	-					-
Stock-based compensation expense			2,349					2,349
Repurchase of common stock at cost						21,410	(741)	(741)
Common stock cash dividend paid				(5,445)				(5,445)
Balance at December 31, 2018	21,110,224	211	98,442	45,831	(3,900)	1,501,511	(10,349)	130,235
Net income				17,934				17,934
Other comprehensive income					(107)			(107)
Issuance of common stock for stock options exercised	509,693	6	4,850					4,856
Vested restricted stock units	59,010	-	-					-
Stock-based compensation expense			2,642					2,642
Repurchase of common stock at cost						20,524	(683)	(683)
Common stock cash dividend paid				(6,736)				(6,736)
Balance at December 31, 2019	21,678,927	217	105,934	57,029	(4,007)	1,522,035	(11,032)	148,141
Net income				21,220				21,220
Other comprehensive income					2,482			2,482
Issuance of common stock for stock options exercised	331,958	3	5,968					5,971
Vested restricted stock units	50,669	1	-					1
Stock-based compensation expense			3,022					3,022
Repurchase of common stock at cost						16,537	(570)	(570)
Common stock cash dividend paid				(7,695)				(7,695)
Balance at December 31, 2020	22,061,554	$ 221	$ 114,924	$ 70,554	$ (1,525)	1,538,572	$ (11,602)	$ 172,572

See accompanying notes to consolidated financial statements.

LeMaitre Vascular, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31,		
	2020	**2019**	**2018**
		(in thousands)	
Operating activities			
Net income	$ 21,220	$ 17,934	$ 22,943
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	8,395	5,416	4,324
Stock-based compensation	3,022	2,642	2,349
Fair value adjustments to contingent consideration obligations	182	171	(29)
Provision for doubtful accounts and allowances	293	388	264
Provision for inventory write-downs	1,523	747	671
Provision (benefit) for deferred income taxes	(328)	824	(2,152)
Gains on sale of building, acquisitions and divestitures	(470)	-	(7,474)
Foreign currency transaction gain	100	(57)	259
Changes in operating assets and liabilities:			
Accounts receivable	(939)	(1,301)	(1,283)
Inventory and other deferred costs	(2,609)	(11,335)	(4,262)
Prepaid expenses and other assets	89	(654)	(418)
Accounts payable and other liabilities	4,322	(596)	4,314
Net cash provided by operating activities	34,800	14,179	19,506
Investing activities			
Purchases of property and equipment	(2,982)	(3,761)	(3,054)
Proceeds from sale of building	2,023	-	-
Payments related to acquisitions	(72,627)	(21,240)	(12,282)
Purchases of short-term marketable securities	(2,205)	(22,699)	(19,619)
Proceeds from sales of marketable securities	22,900	23,600	20,500
Proceeds from divestitures	-	-	7,400
Net cash used in investing activities	(52,891)	(24,100)	(7,055)
Financing activities			
Payment of deferred acquisition consideration	(2,800)	(2,059)	(1,199)
Proceeds from revolving line of credit	25,000	-	-
Proceeds from issuance of long-term debt	40,000	-	-
Payments of revolving line of credit	(25,000)	-	-
Payments of long-term debt	(1,000)	-	-
Payment of deferred debt issuance costs	(1,751)	-	-
Proceeds from issuance of common stock	5,971	4,856	2,969
Purchase of treasury stock	(570)	(683)	(741)
Common stock cash dividend paid	(7,695)	(6,736)	(5,445)
Net cash provided by (used in) financing activities	32,155	(4,622)	(4,416)
Effect of exchange rate changes on cash and cash equivalents	914	11	(813)
Net increase (decrease) in cash and cash equivalents	14,978	(14,532)	7,222
Cash and cash equivalents at beginning of year	11,786	26,318	19,096
Cash and cash equivalents at end of year	$ 26,764	$ 11,786	$ 26,318
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, 2019

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, angioscopes, biologic vascular and dialysis grafts, biologic vascular and cardiac patches, carotid shunts, embolectomy catheters, occlusion catheters, powered phlebectomy devices, radiopaque marking tape, remote endarterectomy devices, surgical glue, synthetic vascular grafts and valvulotomes. Our offices and production facilities are located in Burlington, Massachusetts; Fox River Grove, Illinois; North Brunswick, New Jersey (Note 2); Chandler, Arizona; Vaughan, Canada; Sulzbach, Germany; Milan, Italy; Madrid, Spain; Saint-Etienne, France; Hereford, England; Kensington, Australia; Tokyo, Japan; Shanghai, China; and Singapore.

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 SL, LeMaitre Vascular Switzerland GmbH, LeMaitre Vascular ULC, LeMaitre Vascular AS, LeMaitre Vascular Pty Ltd, Bio Nova International Pty Ltd, LeMaitre Vascular, Ltd., LeMaitre Medical Technology (Shanghai) Co. Ltd, LeMaitre Cardial SAS and LeMaitre Vascular Singapore Pte 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 in our consolidated financial statements and accompanying notes. Due to the COVID-19 pandemic, there is heightened volatility and uncertainty in customer demand and the worldwide economy in general. However, the magnitude and duration of the impact on our revenues and operations from COVID-19 is uncertain and cannot currently be reasonably estimated at this time. 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 as of March 12, 2021, the issuance date of this Annual Report on Form 10-K. Actual results could differ from those estimates, particularly if the Company experiences material impacts to the carrying value of its assets and liabilities from COVID-19.

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. With the acquisition of the RestoreFlow allograft business, 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

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,	
	2020	**2019**
Americas	$ 81,470	$ 69,359
Europe, Middle East and Africa	39,193	39,480
Asia/Pacific Rim	8,703	8,393
Total	$ 129,366	$ 117,232

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 Spain and Italy 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.

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,		
	2020	2019	2018
	(in thousands)		
Advertising expense	$ 216	$ 286	$ 299

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.

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 United States 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 United States totaled approximately $13.7 million as of December 31, 2020.

Our accounts receivable are with customers based in the United States and internationally. Accounts receivable generally are due within 30 to 90 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns, other than in certain European markets where longer payment terms are customary and may range from 90 to 240 days. 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 and Spain, may be subject to significant payment delays due to government austerity measures impacting funding and payment practices. As of December 31, 2020 our receivables in Italy and Spain totaled $0.9 million and $0.6 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 large lump sum payments. While we believe our allowance for doubtful accounts in these countries is adequate as of December 31, 2020, 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 doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review our allowance for doubtful accounts on a monthly basis and all past due balances are reviewed individually for collectability. The provision for the allowance for doubtful accounts is recorded in general and administrative expenses. The following is a summary of our allowance for doubtful accounts 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 doubtful accounts and sales returns:				
Year ended December 31, 2020	$ 522	$ 293	$ 192	$ 623
Year ended December 31, 2019	399	388	265	522
Year ended December 31, 2018	349	264	214	399

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 and were not material to our consolidated financial statements for the year ended December 31, 2020.

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.

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
Computers and equipment	3–5 years
Machinery and equipment	3–10 years
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, for acquisitions completed within the past year, 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 two-step goodwill impairment test. The “more likely than not” threshold is defined as having a likelihood of more than 50 percent. If required, the next step of the goodwill impairment test is to determine the fair value of the reporting unit. The implied fair value of goodwill is determined on the same basis as the amount of goodwill recognized in connection with a business combination. Specifically, the fair value of a reporting unit is allocated to all of the assets and liabilities (including any unrecognized intangible assets) as if the reporting unit had been acquired in a business combination as of the date of the impairment review and as if the fair value of the reporting unit was the price paid to acquire the reporting unit. The excess of the fair value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss shall be recognized in an amount equal to that excess. We have determined that no goodwill impairment charges were required for the years ended December 31, 2020, 2019 or 2018.

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 which is 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) as an additional form 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 based upon the continued service to the company. The fair market value of the award is determined based on the number of RSUs 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 are forfeited and canceled as of the date that employment or service to the company terminates. RSUs are settled in shares of our common stock upon vesting. We typically repurchase common stock upon our employees’ vesting in RSUs in order to cover any minimum tax withholding liability as a result of the RSUs having vested.

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 in each matter or changes in approach such as a change in settlement strategy in dealing with these matters. We record charges for the losses we anticipate incurring in connection with litigation and claims against us when we conclude a loss is probable and we can reasonably estimate these losses. During the years ended December 31, 2020, 2019 and 2018, 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 European Union we are required to obtain CE marks for our products, which denote conformity to essential requirements for manufacturers of higher-risk devices. We have CE marks to sell many of our products, though currently there is a lapse in our CE marks for some of our products. 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. There can be no assurance that we will be able to obtain or maintain the required regulatory approvals in these countries.

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, 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, 2020, 2019 or 2018.

Accumulated other comprehensive loss consisted primarily of foreign currency translation adjustment losses of $1.6 million and $4.0 million as of December 31, 2020 and 2019, 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 that will begin within twelve months, 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,		
	2020	2019	2018
	(in thousands, except per share data)		
Basic:			
Net income available for common stockholders	$ 21,220	$ 17,934	$ 22,943
Weighted average shares outstanding	20,246	19,813	19,426
Basic earnings per share	$ 1.05	$ 0.91	$ 1.18
Diluted:			
Net income available for common stockholders	$ 21,220	$ 17,934	$ 22,943
Weighted-average shares outstanding	20,246	19,813	19,426
Common stock equivalents, if dilutive	233	513	816
Shares used in computing diluted earnings per common share	20,479	20,326	20,242
Diluted earnings per share	$ 1.04	$ 0.88	$ 1.13
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	483	468	230

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13 Financial Instruments – Credit Losses (Topic 326), which requires a financial asset (or group of financial assets) measured at amortized cost to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions and reasonable, supportable forecasts that affect the collectability of the reported amount, and requires judgment in determining relevant information and estimation methods. The new standard was effective for us beginning January 1, 2020. The adoption of this standard did not have a material impact on our financial statements, as the only financial assets we have that are affected by the standard are trade receivables for which we have historically employed a collectability estimation technique.

In August 2018, the FASB issued ASU 2018-13 Fair Value Measurement (Topic 820), which modifies the disclosure requirements for fair value measurements. The new standard was effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard did not have a material impact on our financial statements.

In January 2017, the FASB issued ASU 2017-04 Intangibles – Goodwill and Other (Topic 350), which, among other provisions, eliminates “step 2” from the goodwill impairment test. The annual, or interim, goodwill impairment test will be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The new standard was effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard did not have a material impact on our financial statements.

In December 2019, the FASB issued ASU 2019-12 Income Taxes (Topic 740), which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 as well as clarifying and amending other areas of existing GAAP under Topic 740. The new standard is effective for us beginning January 1, 2021, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

2. Acquisitions and Divestitures

Acquisitions are accounted for using the acquisition method and the acquired businesses' results have been included in the accompanying consolidated financial statements from their respective dates of acquisition. In each case for the acquisitions disclosed below, pro forma information assuming the acquisition had occurred at the beginning of the earliest period presented is not included as the impact is immaterial.

Our acquisitions have historically been made at prices above the fair value of the acquired identifiable assets, resulting in goodwill, due to expectations of synergies that will be realized by combining businesses. These synergies include the use of our existing sales channel to expand sales of the acquired businesses' products, consolidation of manufacturing facilities, and the leveraging of our existing administrative infrastructure.

The fair market valuations associated with these transactions fall within Level 3 (see Note 13) of the fair value hierarchy, due to the use of significant unobservable inputs to determine fair value. The fair value measurements were calculated using unobservable inputs, primarily using the income approach, specifically the discounted cash flow method. The amount and timing of future cash flows within our analysis was based on our due diligence models, most recent operational budgets, long range strategic plans and other estimates.

Artegraft Biologic Grafts

On June 22, 2020, we entered into an Asset Purchase Agreement (Artegraft APA) to acquire the biologic graft business from Artegraft, Inc., who subsequent to the closing changed their name to Accidentals, Inc, (Artegraft, Inc.). Under the terms of the Artegraft APA, we agreed to pay Artegraft, Inc. a total of up to $90.0 million for the purchase of substantially all of its assets related to its business of the manufacturing, marketing, sale and distribution of its bovine carotid artery grafts (Products) other than specifically identified excluded assets. The acquired assets included inventory, accounts receivable, machinery and equipment, intellectual property, permits and approvals, data and records, and customer and supplier information. At closing, $72.5 million of the purchase price was paid to Artegraft, Inc. and other parties as specified in the Artegraft APA, including $7.5 million into an escrow account. The escrow amount is to be held until December 31, 2021 to cover any potential claims against LeMaitre or Artegraft, Inc., after which it will be released to Artegraft, Inc. by mutual consent of the parties.

Three earn-out payments of $5,833,333 each are potentially due to Artegraft, Inc. under the Artegraft APA depending on the achievement of specified revenue targets, as follows:

- $5.8 million upon final determination that 20,000 units of Product have been sold to third parties from January 1, 2021 to December 31, 2021;
- $5.8 million upon final determination that 24,000 units of Product have been sold to third parties from January 1, 2022 to December 31, 2022; and
- $5.8 million upon final determination that 28,800 units of Product have been sold to third parties from January 1, 2023 to December 31, 2023.

The Artegraft APA includes a catch-up feature on the earn-outs such that, at the end of the three-year period, if the sum of the unit sales for all three years is greater than or equal to 58,240 unit sales (80% of the combined individual-year targets), Artegraft, Inc. will receive a "catch-up payment" in an amount equal to (a) $17,500,000 times a fraction, the numerator of which is the aggregate number of unit sales for the three-year period, and the denominator of which is 72,800 less (b) any individual-year earn-out previously paid. We recorded this liability at a fair value of $0.4 million to reflect management's estimate of the likelihood of achieving these targets at the time of the closing of the acquisition, as well as the time value of money until payment. This amount will be remeasured each quarter during the earn-out period, with any adjustments recorded in income from operations.

On the date of acquisition, the Company allocated the consideration given to the individual assets acquired and the liabilities assumed based on a preliminary estimate of their fair values. During the three months ended September 30, 2020, the Company obtained and considered additional information related to the assets acquired and liabilities assumed, and recorded measurement period adjustments to the allocation of the purchase price. The following table summarizes the purchase price allocation:

	Allocated Fair Value
	(in thousands)
Inventory	$ 3,859
Accounts receivable	1,789
Equipment and supplies	1,140
Accounts payable and other	(53)
Intangible assets	39,056
Goodwill	27,115
Purchase price	$ 72,906

The goodwill results from expected synergies of combining the acquired products and customer information to our existing operations, and is deductible for tax purposes over 15 years.

The following table reflects the allocation of purchase consideration to the acquired intangible assets and related estimated useful lives:

	Allocated Fair Value	**Estimated Useful Life (Years)**
	(in thousands)	
Customer relationships	$ 20,310	15.0
Intellectual property	16,449	10.0
Non-compete agreement	104	5.0
Tradenames	2,193	10.0
Total intangible assets	$ 39,056	

The weighted-average amortization period of the acquired intangible assets was 12.6 years.

The results of operations of the Artegraft biologic graft business have been included in the results of operations of LeMaitre since the date of acquisition of June 22, 2020. Revenues since the acquisition date through December 31, 2020 were $11.1 million. The following unaudited pro forma financial information presents the results of operations for the years ended December 31, 2020 and 2019 as if the acquisition had occurred at the beginning of 2019. The pro forma financial information presents historical operating results for the combined entities with adjustments for amortization expense, interest, management fees and related tax effects. This information has been prepared for comparative purposes only and is not indicative of what actual results would have been if the acquisitions had taken place at the beginning of fiscal 2019, or of future results.

	Unaudited Pro Forma Financial Information Year ended December 31,	
	2020	**2019**
	($ in thousands)	
Net sales	$ 137,450	$ 131,915
Net income	20,041	15,045
Net income per share		
Basic	$ 0.99	$ 0.76
Diluted	$ 0.98	$ 0.74

CardioCel and VascuCel Biologic Patches

On October 11, 2019 (the Closing Date), we entered into an Asset Purchase Agreement (APA) to acquire the biologic patch business assets and a related technology license from Anteris Technologies Ltd. and various of its subsidiaries (Anteris). The biologic patch business consists of the CardioCel and VascuCel product lines, which are manufactured in a manner intended to reduce the risk of calcification. The products are sold worldwide. On the same date, the parties entered into a Transition Services Agreement (TSA) under which Anteris will manufacture and supply LeMaitre with inventory for a period of up to three years, unless extended in writing by both parties. Revenues from the acquisition date through December 31, 2019 were $1.4 million.

Under the APA we agreed to pay Anteris a total of up to $15.3 million for the purchase of substantially all of its biologic patch business assets, other than specifically identified Excluded Assets, plus $8.0 million for the technology licenses. The acquired assets (in combination with the license) included inventory, intellectual property, permits and approvals, data and records, and customer and supplier information, as well as a small amount of machinery and equipment. At closing, $14.2 million of the purchase price was paid to Anteris. Shortly thereafter another $0.3 million was paid in connection with delivery of audited financial statements of the acquired business to LeMaitre. Additional payments of $0.7 million are due within 15 days of the first and third anniversaries of the closing date; the first such payment was made in October 2020. Additional contingent consideration was or may be payable as follows:

- $2.0 million (the Third Holdback) within 15 days following LeMaitre's receipt of a CE mark on all acquired products;
- $2.5 million if revenues in the first 12-month period following the Closing Date exceed $20 million, OR, $1.2 million if revenues in the first 12-month period following the Closing Date exceed $15 million (this milestone was not met and accordingly no payment was made);
- $2.5 million if revenues in the second 12-month period following the Closing Date exceed $30 million, OR, $1.2 million if revenues in the second 12-month period following the Closing Date exceed $22.5 million; and
- $0.5 million if by the first anniversary of the Closing Date Anteris extends the shelf life of the products from 36 months to at least 60 months (this milestone was not met and accordingly no payment was made).

This contingent consideration of $7.5 million was initially valued in total at $2.3 million and is being re-measured each reporting period until the payment requirement ends, with any adjustments reported in income from operations.

During the quarter ended September 30, 2020, we recorded a $1.3 million adjustment to goodwill with an offsetting adjustment to deferred income taxes to reflect the difference between book basis and tax basis of the technology license. The following table summarizes the purchase price allocation:

	Allocated Fair Value (in thousands)
Inventory and other	$ 1,343
Intangible assets	8,725
Goodwill	7,344
Purchase price	$ 17,412

The goodwill results from expected synergies of combining the acquired products and customer information to our existing operations, and is deductible for tax purposes over 15 years.

The following table reflects the allocation of purchase consideration to the acquired intangible assets and related estimated useful lives:

	Allocated Fair Value	Weighted Average Useful Life (Years)
	(in thousands)	
Customer relationships	$ 5,562	12.0
Intellectual property	2,335	8.0
Non-compete agreement	361	5.0
Tradenames	467	8.0
Total intangible assets	$ 8,725	

The weighted-average amortization period of the acquired intangible assets was 10.4 years.

Tru-Incise Valve Cutter

On July 12, 2019, we entered into an agreement with UreSil, LLC, an Illinois limited liability company, to purchase the remaining assets of their Tru-Incise valve cutter business, including distribution rights in the United States. We also entered into a transition services agreement under which UreSil, LLC would continue to manufacture the acquired products for us for a specified time, until we had transferred the manufacturing process to our Burlington, Massachusetts facilities. Revenues from the acquisition date through December 31, 2019 were $0.8 million.

The purchase price for the acquired assets, which included inventory, machinery and equipment, intellectual property, and customer and supplier information, was $8.0 million. Of this amount, $6.8 million was paid at closing, with three follow-on payments $0.4 million each due on the first, second and third anniversaries of the closing date. The deferred amounts totaling $1.2 million were recorded at an acquisition-date fair value of $1.1 million using a discount rate of 4.19% to reflect the time value of money between the acquisition date and the payment due dates. There are no contingencies associated with these holdback payments, although they may be reduced for certain post-closing claims. The first payment was made without adjustment in July 2020.

The following table summarizes the preliminary purchase price allocation:

	Allocated Fair Value
	(in thousands)
Inventory	$ 276
Equipmentand supplies	70
Intangible assets	4,844
Goodwill	2,748
Purchase price	$ 7,938

The goodwill results from expected synergies of combining the acquired products and customer information to our existing operations, and is deductible for tax purposes over 15 years.

The following table reflects the allocation of purchase consideration to the acquired intangible assets and related estimated useful lives:

	Allocated Fair Value	Weighted Average Useful Life (Years)
	(in thousands)	
Customer relationships	$ 3,945	13.0
Intellectual property	563	7.0
Non-compete agreement	233	5.0
Tradenames	103	7.0
Total intangible assets	$ 4,844	

The weighted-average amortization period of the acquired intangible assets was 11.8 years.

Cardial

On October 22, 2018, we acquired the business assets of Cardial, located in Saint-Etienne, France. The Cardial business consists of the manufacturing of polyester vascular grafts, valvulotomes, surgical glue and original equipment manufacturing (OEM) services.

The purchase price for the acquired assets, including the land and building, inventory, machinery and equipment, intellectual property, permits and approvals, data and records, and customer and supplier information, was €2.0 million ($2.3 million). At closing, €1.1 million ($1.3 million) was paid in cash, and €0.5 million ($0.5 million) of liabilities were assumed by LeMaitre Cardial SAS. Another €0.4 million ($0.4 million) was due in two installments, half to be paid twelve months after the closing date, and half eighteen months after the closing date, subject to possible reductions depending upon the results of a reconciliation of the value of inventory transferred, as outlined in the agreement, or for certain post-closing claims. The first of these two payments was not required to be made based on the inventory reconciliation results. The second payment was made in April 2020, in a reduced amount based on the inventory reconciliation results, as well as other post-closing claims.

The following table summarizes the purchase price allocation:

	Allocated Fair Value
	(in thousands)
Inventory	€ 2,419
Land and building	750
Equipment and supplies	94
Intangible assets	623
Bargain purchase gain	(1,946)
Purchase price	€ 1,940

The bargain purchase gain was recorded to reflect the excess of the net assets acquired over the purchase price. We recorded deferred taxes on this gain of €0.5 million ($0.6 million), resulting in a net gain of €1.4 million ($1.6 million).

The following table reflects the allocation of purchase consideration to the acquired intangible assets and related estimated useful lives:

	Allocated Fair Value	Weighted Average Useful Life (Years)
	(in thousands)	
Customer relationships	€ 250	16.0
Intellectual property	237	5.0
Non-compete agreement	46	5.0
Tradenames	90	5.0
Total intangible assets	€ 623	

The weighted-average amortization period of the acquired intangible assets was 9.4 years.

Applied Medical

On September 20, 2018, we entered into an agreement to acquire the assets of the embolectomy catheter business of Applied Medical Resources Corporation (Applied). The embolectomy catheter business consists of several embolectomy and thrombectomy catheter product lines which are sold worldwide. On the same date, we entered into a transition services agreement under which Applied would supply us with inventory for a period of twelve months, unless extended in writing by both parties. The TSA was not extended.

The purchase price for the acquired assets, which included inventory, machinery and equipment, intellectual property, permits and approvals, data and records, and customer and supplier information, was $14.2 million. Of this amount, $11.0 million was paid at closing, another $2.0 million was paid 12 months following the closing date and the final $1.2 million was paid 24 months following the closing date, in a slightly reduced amount. The deferred amounts totaling $3.2 million were recorded at an acquisition-date fair value of $3.0 million using a discount rate of 3.75% to reflect the time value of money between the acquisition date and the payment due dates.

The following table summarizes the purchase price allocation. The purchase accounting is complete:

	Allocated Fair Value
	(in thousands)
Inventory	$ 739
Equipment and supplies	416
Intangible assets	6,527
Goodwill	6,361
Purchase price	$ 14,043

The goodwill results from expected synergies of combining the acquired products and customer information to our existing operations, and is deductible for tax purposes over 15 years.

The following table reflects the allocation of purchase consideration to the acquired intangible assets and related estimated useful lives:

	Allocated Fair Value	Weighted Average Useful Life (Years)
	(in thousands)	
Customer relationships	$ 4,475	16.0
Intellectual property	1,316	7.0
Non-compete agreement	530	5.0
Tradenames	206	7.0
Total intangible assets	$ 6,527	

The weighted-average amortization period of the acquired intangible assets was 13.0 years.

Reddick Divestiture

On April 5, 2018, we entered into an asset purchase agreement with Specialty Surgical Instrumentation, Inc. to sell the inventory, intellectual property and other assets associated exclusively with our Reddick cholangiogram catheter and Reddick-Saye screw product lines for $7.4 million. Concurrent with this divestiture we entered into a transition services agreement (TSA) under which we will continue to manufacture and supply these products to the buyer for a period of up to two years unless extended by both parties, as well as a balloon supply agreement under which we will supply balloons, a component of the cholangiogram catheters, to the buyer for a period of up to six years unless extended by both parties. We recorded a gain in connection with these agreements of $5.9 million. The following table summarizes the allocation of consideration received:

	Allocated Fair Value
	(in thousands)
Inventory	$ 308
Deferred revenue - transition services agreement	1,081
Goodwill	135
Gain on divestiture	5,876
Consideration received	$ 7,400

Under the terms of the TSA, we agreed to manufacture the Reddick products for the buyer at prices at or in some cases below our cost. We allocated a portion of the consideration received to this agreement to reflect it at fair value and recorded it as deferred revenue. As the products were sold to the buyer, we amortized a portion of the deferred revenue to adjust the gross margin on the sale to fair value on a specific identification basis. Additionally, as the Reddick product lines that were divested constituted a business, we allocated a portion of our goodwill to this divestiture based on the fair value of the business sold in relation to the fair value of the business retained.

3. Inventory and Other Deferred Costs

Inventory and other deferred costs consists of the following:

	December 31, 2020	December 31, 2019
	(in thousands)	
Raw materials	$ 5,044	$ 5,359
Work-in-process	6,004	6,238
Finished products	28,117	23,032
Other deferred costs	5,950	4,898
Total inventory and other deferred costs	$ 45,115	$ 39,527

We had inventory on consignment at customer sites of $2.1 million and $1.9 million as of December 31, 2020 and 2019, respectively.

In connection with our RestoreFlow allograft business, other deferred costs include costs incurred for the preservation of human vascular 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:

	As of December 31,	
	2020	2019
	(in thousands)	
Computers and equipment	$ 5,046	$ 4,623
Machinery and equipment	17,266	16,245
Building and leasehold improvements	12,809	11,758
Gross property and equipment	35,121	32,626
Less accumulated depreciation	(20,085)	(17,772)
Property and equipment, net	$ 15,036	$ 14,854

During the years ended December 31, 2020, 2019 and 2018 we wrote off fully depreciated assets with gross values of $0.6 million, $0.5 million and $1.0 million, respectively.

Depreciation expense is as follows:

	Year ended December 31,		
	2020	2019	2018
		(in thousands)	
Depreciation expense	$ 3,181	$ 2,979	$ 2,564

5. Goodwill and Other Intangibles

Goodwill consists of the following:

	As of December 31,	
	2020	2019
Balance at beginning of year	$ 39,951	$ 29,868
Additions for acquisitions	27,115	10,092
Purchase accounting adjustments	(1,345)	-
Effects of currency exchange	224	(9)
Balance at end of year	$ 65,945	$ 39,951

During the quarter ended September 30, 2020, we recorded a $1.3 million adjustment to goodwill with an offsetting adjustment to deferred income taxes to reflect the difference between book basis and tax basis of the technology license acquired under the CardioCel APA.

Other intangibles consist of the following:

	December 31, 2020			December 31, 2019		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
	(in thousands)					
Product technology and intellectual property	$ 29,951	$ 7,947	$ 22,004	$ 13,502	$ 5,722	$ 7,780
Trademarks, tradenames and licenses	4,000	1,094	2,906	1,807	702	1,105
Customer relationships	38,525	5,424	33,101	18,215	3,364	14,851
Other intangible assets	1,767	873	894	1,725	568	1,157
Total identifiable intangible assets	$ 74,243	$ 15,338	$ 58,905	$ 35,249	$ 10,356	$ 24,893

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, 2020, is 11.7 years. Amortization expense is included in general and administrative expense and is as follows:

	Year ended December 31,		
	2020	2019	2018
	(in thousands)		
Amortization expense	$ 5,043	$ 2,437	$ 1,760

During the year ended December 31, 2019 we wrote off fully amortized intangible assets with a gross values of $4.5 million. Estimated amortization expense for each of the next five fiscal years, based upon the intangible assets at December 31, 2020, is as follows:

	Year ended December 31,				
	2021	2022	2023	2024	2025
	(in thousands)				
Amortization expense	$ 6,179	$ 5,975	$ 5,902	$ 5,706	$ 5,467

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, which 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. Long term debt as of December 31, 2020 is as follows:

	December 31, 2020 (in thousands)
Five-year term loan, net of unamortized debt issuance costs of $968	$ 38,032
Less current portion	(2,500)
	$ 35,532

The following table summarizes the maturities or our long-term debt under the term loan agreement:

Year ending December 31,		
	2021	$ 2,500
	2022	3,000
	2023	3,500
	2024	4,000
	2025	26,000
Total before unamortized issuance costs		39,000
Less unamortized issuance costs		(968)
Less current portion of long-term bebt		(2,500)
Total long-term debt		$ 35,532

The loans bear 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 is 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. At December 31, 2020 all outstanding borrowings were designated as Eurodollar loans and bore interest of 3.5%. We incurred debt issuance costs in connection with this credit arrangement of approximately $1.8 million. The transaction costs were allocated between the revolving line of credit and the term loan, 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 are being amortized into interest expense on a straight-line basis as the result is not materially different from using the interest method, over the five-year term. This results in an effective interest rate of approximately 4.2%. Cash paid for interest during the year ended December 31, 2020 was $0.9 million.

The term of the revolving line of credit is five years, and allows re-borrowing up to $25 million during the term, with all outstanding amounts due on June 22, 2025. The term loan is repayable in increasing quarterly installments of $0.5 million to $1.0 million commencing September 30, 2020 through March 31, 2025, with the remaining outstanding balance due on June 22, 2025.

We must comply with various financial and non-financial covenants, which are set forth in the Credit Agreement. The primary financial covenant consists of a maximum consolidated leverage ratio. The lenders are entitled to accelerate repayment of the loans and terminate the revolving credit commitment upon the occurrence of any of various events of default as described in the Credit Agreement. We were in compliance with the covenants as of December 31, 2020.

Borrowings under the secured credit facility are secured by 100% of the stock of our domestic subsidiaries, portions of the stock of certain of our foreign subsidiaries, and substantially all of our and our subsidiaries' other property and assets, in each case subject to various exceptions.

We are required to make mandatory prepayments of the term loans and any revolving credit loans in various amounts if we have Excess Cash Flow (as defined in the Credit Agreement, and commencing in respect of our fiscal year ending December 31, 2021), if we make certain sales of assets outside the ordinary course of business above certain thresholds or if we suffer certain property loss events above certain thresholds. We may make optional prepayments of the term loans without premium or penalty.

7. Accrued Expenses and Other Long-term Liabilities

Accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
	(in thousands)	
Compensation and related taxes	$ 8,675	$ 8,550
Income and other taxes	2,394	1,003
Professional fees	39	40
Other	6,417	4,421
Total	$ 17,525	$ 14,014

Other long-term liabilities consist of the following:

	December 31, 2020	December 31, 2019
	(in thousands)	
Acquisition-related liabilities	$ 3,700	$ 3,268
Income taxes	813	781
Other	130	166
Total	$ 4,643	$ 4,215

8. Commitments and Contingencies

Leases

We conduct the majority of our operations in leased facilities, all of which are accounted for as operating leases, as they do not meet the criteria for finance leases. Our principal worldwide executive, distribution, and manufacturing operations are located in five leased facilities with square footage totaling 109,354 in Burlington, Massachusetts. All five Burlington leases expire in December 2030. In addition, our European operations are headquartered at a 16,470 square foot leased facility located in Sulzbach, Germany under a lease which expires in August 2023. This lease contains two five-year renewal options. We also lease a 2,258 square foot facility in Hereford, England which houses our United Kingdom sales and distribution business. 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. We also have smaller long-term leased sales, marketing and other facilities located in Arizona, Japan, Canada, Australia, Singapore and China, and short-term leases in Italy, Spain and Illinois. Our lease in Canada contains a five-year renewal option exercisable in February 2023. Our leases in Germany and Australia are subject to periodic rent increases based on increases in the consumer price index as measured each September and May, respectively, with such increases applicable to the subsequent twelve months of lease payments. 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. None of our leases have variable payments. 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 at December 31, 2020.

We also lease automobiles under operating leases in the U.S. as well as certain other countries. The terms of these leases are generally three years, with older vehicles replaced by newer vehicles from time to time.

As discussed above under Recent Accounting Pronouncements, on January 1, 2019 we adopted the provisions of ASU No. 2016-02, *Leases (Topic 842)*, subsequently amended by ASU 2018-11, *Leases (Topic 842): Targeted Improvements*. Under the new guidance, we are required to recognize the following for all leases (with the exception of short-term leases) at the commencement date: a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term.

Our most significant judgment involved in determining the amounts to initially record as lease liabilities and right-of-use assets was the selection of a discount rate; because we had no debt at that time we had no incremental borrowing rate to reference. We therefore estimated an incremental borrowing rate using quotes from potential lenders as the primary inputs, augmented by other available information. The resulting rate selected was 5.25%. We determined that it was appropriate to apply this single rate to our portfolio of leases worldwide, as the lease terms and conditions were substantially similar, and because we believe our subsidiaries would be unable to obtain borrowings on their own without a commitment of parent company support. During 2020 we assumed a building lease in connection with our acquisition of Artegraft biologic graft business, for which we referenced the associated debt agreement entered into for that transaction, in establishing a discount rate.

Additional information with respect to our leases is as follows:

	Year ended December 31, 2020 (in thousands)	**Year ended December 31, 2019** (in thousands)
Lease cost		
Operating lease cost	$ 1,912	$ 1,756
Short-term lease cost	192	291
Total lease cost	$ 2,104	$ 2,047
Other information		
Cash paid for amounts included in the measurement of operating lease liabilities	$ 2,404	$ 1,858
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 2,770	$ 10,571
Weighted average remaining lease term - operating leases (years)	7.8	8.3
Weighted average discount rate - operating leases	5.02%	5.25%

At December 31, 2020, the minimum noncancelable operating lease rental commitments with initial or remaining terms of more than one year are as follows:

Year ending December 31,	
2021	$ 2,763
2022	2,447
2023	2,064
2024	1,866
2025	1,916
Thereafter	9,920
Adjustment to net present value as of December 31, 2020	(4,230)
Minimum noncancelable lease liability	$ 16,746

Purchase Commitments

As part of our normal course of business, we have commitments to purchase $5.2 million of inventory through 2021. 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,		
	2020	2019	2018
		(in thousands)	
United States	$ 25,308	$ 17,989	$ 22,256
Foreign	2,048	3,690	6,188
Total	$ 27,356	$ 21,679	$ 28,444

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,		
	2020	2019	2018
		(in thousands)	
Current:			
Federal	$ 4,594	$ 1,501	$ 4,262
State	806	304	673
Foreign	1,064	1,116	2,718
	6,464	2,921	7,653
Deferred:			
Federal	(397)	538	(1,512)
State	(48)	144	(145)
Foreign	117	142	(495)
	(328)	824	(2,152)
Provision for income taxes	$ 6,136	$ 3,745	$ 5,501

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, 2020, the gross amount of unrecognized tax benefits exclusive of interest and penalties was $0.8 million, which may increase within the twelve months ending December 31, 2021. We recognized a reduction of unrecognized tax benefits in 2020 due to the settlement of a 2013-2016 Corporate Tax audit by the German Tax Authority. 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 2028. A reconciliation of the beginning and ending amount of our unrecognized tax benefits is as follows:

	2020	2019	2018
		(in thousands)	
Unrecognized tax benefits at the beginning of year	$ 848	$ 711	$ 525
Additions for tax positions of current year	-	74	73
Additions for tax positions of prior years	37	63	113
Reductions for settlements with taxing authorities.	(65)	-	-
Reductions for lapses of the applicable statutes of limitations	-	-	-
Unrecognized tax benefits at the end of the year	$ 820	$ 848	$ 711

Deferred taxes are attributable to the following temporary differences:

	As of December 31,	
	2020	2019
	(in thousands)	
Deferred tax assets:		
Inventory	$ 1,629	$ 840
Net operating loss carryforwards	1,348	1,289
Tax credit carryforwards	1,019	944
Capital loss carryforwards	521	277
Reserves and accruals	994	787
Operating lease liabilities	3,664	3,343
Intangible assets	4,386	2,764
Stock options	359	342
Other	105	20
Total deferred tax assets	14,025	10,606
Deferred tax liabilities:		
Property and equipment	(1,831)	(1,520)
Goodwill	(4,055)	(3,459)
Operating lease right-of-use assets	(3,503)	(3,224)
Foreign branch deferred offset	(954)	(923)
Other	(299)	(187)
Total deferred tax liabilities	(10,642)	(9,313)
Net deferred tax assets before valuation allowance	3,383	1,293
Valuation allowance	(1,824)	(1,388)
Net deferred tax liabiltity	$ 1,559	$ (95)
Deferred tax classification		
Long-term deferred tax asset	$ 1,686	$ 1,084
Long-term deferred tax liability	(127)	(1,179)
Net long-term deferred tax liability	$ 1,559	$ (95)

In 2019, we increased our valuation allowance by $0.1 million mainly attributable to Australian net operating loss carry forwards and Massachusetts credit carryforwards. In 2020, we increased our valuation allowance by $0.4 million mainly attributable to Australian net operating loss carry forwards and Massachusetts credit carryforwards.

As of December 31, 2020, we have provided a valuation allowance of $1.8 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, 2020, we have net operating loss carryforwards in Australia of $1.5 million that do not expire, in France of $2.5 million that do not expire, in Spain of $0.9 million that do not expire, and in Norway of $0.1 million that do not expire. We have a capital loss carryforward in Australia of $1.7 million that does not expire. We also have state tax credit carryforwards of approximately $1.6 million that are available to reduce future tax liabilities, which begin to expire in 2021, 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:

	2020	2019	2018
Federal statutory rate	21.0%	21.0%	21.0%
State tax, net of federal benefit	2.2%	1.9%	1.4%
Effect of foreign taxes	1.1%	2.1%	3.8%
Federal tax on foreign income	0.4%	0.8%	1.4%
Valuation allowance	1.4%	0.6%	(3.2%)
Foreign deferred tax liability offset	(0.2%)	(0.4%)	(0.3%)
Manufacturing deduction	0.0%	0.0%	0.0%
Research & development tax credits	(0.6%)	(1.2%)	(0.7%)
Stock options	(2.3%)	(8.8%)	(3.3%)
Uncertain tax positions	0.3%	1.0%	0.8%
Other permanent differences	(0.6%)	0.5%	(0.7%)
Change in tax laws	0.0%	0.0%	0.0%
Deferred tax remeasurement	0.0%	0.0%	0.0%
Other	(0.3%)	(0.2%)	(0.9%)
Effective tax rate	22.4%	17.3%	19.3%

In August 2018, the German tax authority commenced an audit of our German subsidiary for the tax years 2013 through 2016. This audit concluded in 2020 and our German subsidiary settled for an immaterial amount of additional German tax. We are not currently under audit in any other tax jurisdictions.

As of December 31, 2020, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions are:

United States	2017 and forward
Foreign	2013 and forward

Supplemental disclosures of cash flow information are as follows:

	Year ended December 31,		
	2020	2019	2018
	(in thousands)		
Cash paid for income taxes, net	$ 4,470	$ 4,817	$ 5,521

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.

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, 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 or RSUs 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 860,847 remain available for grant as of December 31, 2020.

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

	2020	2019	2018
Dividend yield	1.02%	0.96%	1.20%
Volatility	47.3%	42.8%	41.3%
Risk-free interest rate	0.3%	1.7%	2.7%
Weighted average expected option term (in years)	4.9	4.7	4.8
Weighted average fair value per share of options granted	$ 13.24	$ 12.51	$ 8.28

A summary of option activity as of December 31, 2020 and the year then ended is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance outstanding at December 31, 2019 (1)	1,047,094	$ 23.19	4.31	$ 13,366,595
Granted	222,110	$ 36.67		
Exercised (2)	(331,958)	$ 17.99		$ 5,413,197
Canceled / Expired	(5,406)	$ 27.49		
Balance outstanding at December 31, 2020 (3)	931,840	$ 28.22	4.49	$ 11,442,240
Vested and exercisable at December 31, 2020 (4)	274,411	$ 23.08	3.50	$ 4,780,656
Expected to vest at December 31, 2020	657,429	$ 30.37	4.93	
Total	931,840			

(1) The aggregate intrinsic value represents the difference between the exercise price and $35.95, the closing price of our stock on December 31, 2019, for all in-the-money options outstanding.

(2) The aggregate intrinsic value of shares exercised represents the difference between the exercise price and the closing price of our stock on the date of exercise.

(3) The aggregate intrinsic value represents the difference between the exercise price and $40.50, the closing price of our stock on December 31, 2020, for all in-the-money options outstanding.

(4) The aggregate intrinsic value represents the difference between the exercise price and $40.50, the closing price of our stock on December 31, 2020, for all in-the-money options vested and exercisable as of that date.

Restricted Stock Units

A summary of our RSU activity is as follows:

	Shares	Weighted Average Grant Date Fair Value
Balance outstanding at December 31, 2019	188,681	$ 26.14
Granted	46,146	$ 36.86
Vested (1)	(50,669)	$ 22.76
Canceled	(37,143)	$ 27.88
Balance outstanding at December 31, 2020	147,015	$ 30.24

(1) 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 2020, 2019 and 2018 were $1.8 million, $2.1 million, and $1.9 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:

	2020	2019
Shares of common stock repurchased	16,537	20,524
Average per share repurchase price	$ 34.47	$ 33.28
Aggregage purchase price (in thousands)	$ 570	$ 683

Stock-based Compensation

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

	2020	2019	2018
		(in thousands)	
Stock option awards	$ 1,938	$ 1,580	$ 1,457
Restricted stock units	1,084	1,062	892
Total stock-based compensation	$ 3,022	$ 2,642	$ 2,349

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

	2020	2019	2018
		(in thousands)	
Cost of sales	$ 333	$ 310	$ 272
Sales and marketing	516	544	529
General and administrative	1,883	1,509	1,293
Research and development	290	279	255
Total stock-based compensation	$ 3,022	$ 2,642	$ 2,349

We expect to record the unamortized portion of share-based compensation expense of $10.8 million for existing stock options and RSUs outstanding at December 31, 2020, over a weighted-average period of 3.6 years.

Stock Repurchase Plans

On February 23, 2021, our Board of Directors authorized the repurchase of up to $15.0 million of the Company's common stock through transactions on the open market, in privately negotiated purchases or otherwise until February 22, 2022. 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:

Record Date	Payment Date	Per Share Amount	Dividend Payment
			(in thousands)
Fiscal Year 2020			
March 3, 2020	March 19, 2020	$ 0.095	$ 1,917
May 20, 2020	June 4, 2020	$ 0.095	$ 1,917
August 27, 2020	September 10, 2020	$ 0.095	$ 1,925
November 19, 2020	December 3, 2020	$ 0.095	$ 1,936
Fiscal Year 2019			
March 22, 2019	April 5, 2019	$ 0.085	$ 1,672
May 22, 2019	June 6, 2019	$ 0.085	$ 1,672
August 21, 2019	September 5, 2019	$ 0.085	$ 1,691
November 20, 2019	December 5, 2019	$ 0.085	$ 1,701

On February 23, 2021, our Board of Directors approved a quarterly cash dividend on our common stock of $0.11 per share payable on March 25, 2021, to stockholders of record at the close of business on March 9, 2021, which will total approximately $2.2 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 $0.3 million, $0.4 million and $0.3 million for 2020, 2019 and 2018, 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 reporting purposes.

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

	Year ended December 31,		
	2020	2019	2018
	(in thousands)		
United States	$ 75,222	$ 63,130	$ 59,078
Germany	12,365	12,400	12,445
Other countries	41,779	41,702	34,045
Net sales	$ 129,366	$ 117,232	$ 105,568

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

	As of December 31,	
	2020	2019
	(in thousands)	
United States	$ 27,660	$ 24,885
Australia	115	1,499
France	1,140	1,089
Germany	1,138	1,405
Other countries	1,049	1,184
Total long-term assets	$ 31,102	$ 30,062

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, 2020 included our short-term investment mutual fund account.

We had no Level 2 assets being measured at fair value on a recurring basis as of December 31, 2020.

As discussed in Notes 1 and 2, 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. As discussed more fully in Note 2, the agreement requires us to make potential additional payments to Artegraft of up to $17.5 million depending on the achievement of certain revenue milestones during the first three calendar years following the acquisition. We recorded this liability at a fair value of $0.4 million 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 will be remeasured each quarter during the earn-out period, with any adjustments recorded in income from operations.

During 2019, we recorded contingent liabilities associated with our acquisition of the CardioCel and VascuCel patch business from Anteris. 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 statement of the acquired business to us; $2.0 million contingent on LeMaitre Vascular's success in obtaining CE marks on the acquired products, $0.5 million contingent upon Anteris' success in extending the shelf life of the acquired products, 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 re-measured each reporting period 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 required revenues during the first 12 months following the acquisition were not met, and the portion of the liabilities related to these items was adjusted through income from operations.

The following table provides a rollforward 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,		
	2020	2019	2018
		(in thousands)	
Beginning balance	$ 1,764	$ 72	$ 1,300
Additions	406	1,989	-
Payments	-	(309)	(1,199)
Change in fair value included in earnings	70	12	(29)
Ending balance	$ 2,240	$ 1,764	$ 72

14. Accumulated Other Comprehensive Income (Loss)

	Year ended December 31,		
	2020	2019	2018
	(in thousands)		
Beginning balance	$ (4,007)	$ (3,900)	$ (2,289)
Other comprehensive income (loss) before reclassifications	2,482	(107)	(1,611)
Amounts reclassified from accumulated other comprehensive loss	-	-	-
Ending Balance	$ (1,525)	$ (4,007)	$ (3,900)

Changes to our accumulated other comprehensive loss consisted primarily of foreign currency translation for the years ended December 31, 2020, 2019 and 2018.

15. Quarterly Financial Data (unaudited)

2020	Three months ended March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Total net sales	$ 30,551	$ 24,851	$ 36,416	$ 37,548
Gross profit	20,483	17,029	22,704	24,402
Income (loss) from operations	4,353	4,872	10,018	9,545
Net income	3,174	3,500	7,513	7,033
Earnings per share				
Basic	$ 0.16	$ 0.17	$ 0.37	$ 0.35
Diluted	$ 0.16	$ 0.17	$ 0.37	$ 0.34

2019	Three months ended March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Total net sales	$ 28,479	$ 29,483	$ 29,100	$ 30,170
Gross profit	19,464	20,315	20,166	19,908
Income (loss) from operations	4,435	5,915	5,905	4,928
Net income	3,513	4,624	5,184	4,613
Earnings per share				
Basic	$ 0.18	$ 0.23	$ 0.26	$ 0.23
Diluted	$ 0.17	$ 0.23	$ 0.25	$ 0.23

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

The following is a list of our subsidiaries:

Name	State or Other Jurisdiction of Incorporation	Name Under Which Does Business
LeMaitre Vascular GmbH	Germany	Same
LeMaitre Vascular GK	Japan	Same
LeMaitre Acquisition LLC	Delaware	Same
LeMaitre Vascular SAS	France	Same
LeMaitre Vascular Spain, S.L.	Spain	Same
LeMaitre Vascular S.r.l.	Italy	Same
Vascutech Acquisition LLC	Delaware	Same
LeMaitre Vascular ULC	Canada	Same
LeMaitre Vascular Switzerland GmbH	Switzerland	Same
LeMaitre Vascular AS	Norway	Same
LeMaitre Vascular Pty Ltd	Australia	Same
LeMaitre Medical Technology (Shanghai) Co., Ltd.	China	Same
LeMaitre Vascular, Ltd	United Kingdom	Same
Bio Nova Holdings Pty Ltd	Australia	Same
Bio Nova International Pty Ltd	Australia	Same
LeMaitre Cardial SAS	France	Same
LeMaitre Vascular Singapore Pte Ltd	Singapore	Same

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 12, 2021, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of LeMaitre Vascular, Inc. on Form 10-K for the year ended December 31, 2020. We consent to the incorporation by reference of said reports in the Registration Statements of LeMaitre Vascular, Inc. on Forms S-3 (File No. 333-238541 and File No. 333-195658) and on Forms S-8 (File No. 333-138181, File No. 333-161361, File No. 333-174129, and File No. 333-205360).

/s/ GRANT THORNTON LLP

Boston, Massachusetts
March 12, 2021

EXHIBIT 31.1

CERTIFICATIONS

I, George W. LeMaitre, certify that:

1. I have reviewed this Annual Report on Form 10-K of LeMaitre Vascular, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ GEORGE W. LEMAITRE

George W. LeMaitre
Chairman and Chief Executive Officer

Date: March 12, 2021

EXHIBIT 31.2

CERTIFICATIONS

I, Joseph P. Pellegrino, Jr., certify that:

1. I have reviewed this Annual Report on Form 10-K of LeMaitre Vascular, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ JOSEPH P. PELLEGRINO, JR.

Joseph P. Pellegrino, Jr.
Chief Financial Officer

Date: March 12, 2021

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of LeMaitre Vascular, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph P. Pellegrino, Jr., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being provided pursuant to 18 U.S.C. § 1350 and is not deemed to be a part of the Report, nor is it to deemed to be "filed" for any purpose whatsoever.

/s/ GEORGE W. LEMAITRE

George W. LeMaitre
Chairman and Chief Executive Officer

March 12, 2021

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of LeMaitre Vascular, Inc. (the "Company") on Form 10-K for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph P. Pellegrino, Jr., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being provided pursuant to 18 U.S.C. § 1350 and is not deemed to be a part of the Report, nor is it to deemed to be "filed" for any purpose whatsoever.

/s/ JOSEPH P. PELLEGRINO, JR.

Joseph P. Pellegrino, Jr.
Chief Financial Officer

March 12, 2021