LEMAITRE VASCULAR INC
Form 10-K
March 11, 2019

Table of Contents

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, 2018
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	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	Nasdaq Global Market

Securities registered under 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 check mark whether the registrant is a shell company (as defined in Rule12b-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, based on the last sale price for such stock on June 30, 2018 was: $372,895,620. 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 1, 2019, the registrant had 19,646,943 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.

Table of Contents

LEMAITRE VASCULAR

2018 ANNUAL REPORT ON FORM 10-K

TABLE OF CONTENTS

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	14
Item 1B.	Unresolved Staff Comments	28
Item 2.	Properties	28
Item 3.	Legal Proceedings	29
Item 4.	Mine Safety Disclosures	29
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	30
Item 6.	Selected Financial Data	32
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	33
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	47
Item 8.	Financial Statements and Supplementary Data	48
Item 9.	Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	48
Item 9A.	Controls and Procedures	49
Item 9B.	Other Information	50
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	51
Item 11.	Executive Compensation	51
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	51
Item 13.	Certain Relationships and Related Transactions, and Director Independence	51
Item 14.	Principal Accounting Fees and Services	52
PART IV		
Item 15.	Exhibits and Financial Statements Schedules	52
Item 16.	Form 10-K Summary	55
SIGNATURES		56

Table of Contents

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties, particularly risks related to the regulatory environment, our intellectual property, our common stock 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 Annual Report on Form 10-K 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,” “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. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section entitled “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or terminations of distribution arrangements that we may make. These statements, like all statements in this report, speak only as of the date of this Annual Report on Form 10-K (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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, Cardial, Dialine, EndoRE, LeMaitre Valvulotome, Eze-Sit, Glow 'N Tell, Inahara-Pruitt, InvisiGrip, LeverEdge, LifeSpan, MollRing Cutter, MultiTASC, Omniflow, ProcCol, Pruitt, Pruitt F3, Pruitt-Inahara, Python, Reddick, RestoreFlow, Syntel, VascuTape, TRIVEX, Wovex, XenoSure, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular or one of its subsidiaries, and AlboSure, Chevalier, Flexcel, Periscope and VCS 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.

Item 1. Business

Overview

LeMaitre Vascular is a global provider of medical devices and human tissue cryopreservation services for the treatment of peripheral vascular disease. We develop, manufacture, and market vascular devices to address the needs of vascular surgeons. Our diversified portfolio of peripheral vascular 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 Pruitt F3 carotid shunt, VascuTape radiopaque tape, and Syntel, Python and Latis embolectomy catheters. Our principal product offerings are sold throughout the world, primarily in the United States, Europe and, to a lesser extent, Asia and the Pacific Rim. We estimate that the annual worldwide market that our core product lines address is approximately $900 million.

We sell our products and services primarily through a direct sales force. As of December 31, 2018 our sales force was comprised of 108 sales representatives in North America, Europe, Japan, China and Australia, including one export manager. We also sell our products in other geographies through distributors. Our worldwide headquarters is located in Burlington, Massachusetts. Our European operations are headquartered in Sulzbach, Germany, and our Asia/Pacific Rim operations are headquartered in Singapore. We also have sales offices located in Fox River Grove, Illinois, Tokyo, Japan; Vaughan, Canada; Madrid, Spain; Milan, Italy; Saint-Etienne, France, Shanghai, China; and North Melbourne, Australia. In 2018, approximately 95% of our net sales were generated in territories in which we employ direct sales representatives.

Table of Contents

The Peripheral Vascular Disease Market

Based on industry statistics, we estimate that peripheral vascular disease affects more than 200 million people worldwide and that the annual worldwide market for all peripheral vascular devices exceeds $5 billion. The disease encompasses a number of conditions in which the arteries or veins that carry blood to or from the legs, arms, or organs other than the heart become narrowed, obstructed, weakened, or otherwise compromised. In many cases peripheral vascular disease goes undetected, sometimes leading to life-threatening events including stroke, ruptured aneurysm, 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 by 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, evolving 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 15,000 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, Asia and the Pacific Rim. In contrast to other medical 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 2018, 91% 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 2018 approximately 78% 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.

- ***Low rivalry niche segments.*** We seek to build and maintain leading positions in niche product and services segments. 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. In recent years we have also sought to sell complementary offerings into larger, more competitive market segments, particularly when we believe that our offerings in those segments are differentiated, such as the Omniflow II biosynthetic graft or the RestoreFlow human tissue cryopreservation services

- ***Direct sales force expansion, and the addition of complementary products through acquisitions and research and development.*** We sell our products primarily through a direct sales force in North America, Europe, Asia and the Pacific Rim. Since 1998, we have built our sales force from zero to 108 direct sales representatives, including one export manager. 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, 2018, 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. We believe our experience in 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.

Table of Contents

Acquisition History

We were founded in 1983 by George D. LeMaitre, M.D., a vascular surgeon who designed and developed the predecessor to our LeMaitre Valvulotome. Through a combination of strategic acquisitions and research and development efforts, we have expanded to 16 product lines. We have completed 21 acquisitions of complementary products 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	Closure system
2005	Endomed	Stent grafts
2007	Vascular Innovations	Contrast injector
2007	Vascular Architects	Remote endarterectomy devices
2007	UnBalloon Technology	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	Angioscope	Fiberoptic catheters
2015	Eze-Sit	Valvulotomes
2016	ProCol	Biologic graft
2016	RestoreFlow	Human tissue cryopreservation services
2018	Syntel/Python	Embolectomy catheters
2018	Cardial	Polyester grafts, valvulotomes, surgical glue

With the exception of the 2018 acquisitions as well as remote endarterectomy devices, powered phlebectomy systems, cryopreserved allograft services and biosynthetic grafts, we have relocated the manufacturing operations associated with our 21 acquisitions to our Burlington, Massachusetts headquarters and we continue to look at ways to make our operations more efficient. The manufacture of our biosynthetic vascular grafts take place in our North Melbourne, Australia facility and 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, and we currently purchase our Syntel, Pythin and Latis catheters from Applied Medical.

3

Table of Contents

Our Products and Services

We have a portfolio of 16 product lines, all of which are designed to treat vascular disease, and most of which are designed for use in open vascular surgery. We also provide services related to the processing and cryopreservation of human vascular tissue. Our products and services address various anatomical areas including the carotid arteries, lower extremities, upper extremities, aorta and other areas. In 2018, the lower extremities product lines and services were 51% of revenues, the carotid artery product lines comprised 34% of revenues, and other areas combined were 15%. In 2017, the lower extremities product lines and services were 51% of revenues, the carotid artery product lines comprised 32% of revenues, and other areas combined were 17%. In 2016, the lower extremities product lines and services were 51% of revenues, the carotid artery product lines comprised 31% of revenues, and other areas combined were 18%. No single product line accounted for more than 25% of our revenues in 2018, 2017 or 2016.

Of our 16 product offerings, four are biologic devices that are implanted in the patient, and one is the service of processing and cryopreserving human tissue for implantation into the patient. These include the XenoSure patch (bovine pericardium), ProCol graft (bovine mesenteric vein), Omniflow II biosynthetic graft (ovine tissue and synthetic mesh), surgical glue (porcine gelatin) and the RestoreFlow Allograft cryopreserved graft (human tissue). As a percentage of sales, these biologic product lines represented 36% in 2018, 34% in 2017, and 27% in 2016.

Angioscopes

The LeMaitre Disposable Angioscope is a fiberoptic catheter used for viewing the lumen of a blood vessel. It also provides direct visualization of valves during in-situ bypass procedures.

Balloon Catheters for Embolectomy, Thrombectomy, Occlusion and Perfusion

Our LeMaitre, NovaSil, Syntel, Python and Latis 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. Occlusion catheters temporarily occlude blood flow to allow the vascular surgeon time and space to complete a given procedure. Perfusion catheters temporarily 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.

Carotid Shunts

Our Pruitt F3, Pruitt F3-S, Pruitt-Inahara and Flexcel carotid shunts are used to temporarily shunt blood to the brain while the surgeon removes plaque from the carotid artery in a carotid endarterectomy surgery. Our Pruitt F3, Pruitt F3-S and Pruitt-Inahara shunts feature internal balloon fixation that eliminates the need for clamps, thereby reducing vessel trauma. Our Flexcel shunt is a non-balloon shunt offered for surgeons who prefer to secure their shunt with externally placed clamps.

Powered Phlebectomy Device

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 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 our proprietary radiopaque ink that is visible both to the eye and to an x-ray machine or fluoroscope. VascuTape Radiopaque Tape is applied externally 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 in the groin. Our EndoRE devices are used to separate the plaque from the vessel, cut the far end of the plaque to free it for removal, and then withdraw it from the vessel.

Valvulotomes

Our LeMaitre valvulotomes, Over-The-Wire LeMaitre valvulotomes, Eze-Sit valvulotomes, Chevalier valvulotomes and LeMills valvulotomes cut valves primarily in the saphenous vein, a vein that runs from the foot to the groin, so the vein can function 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 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.

Table of Contents

Vascular Grafts

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

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 may arise in dialysis access grafts.

Our Omniflow II biosynthetic vascular graft is a composite of cross-linked ovine collagen with a polyester mesh endoskeleton. It is used to bypass or replace diseased leg arteries and to create dialysis access sites.

Our ProCol biologic graft is a bovine mesenteric vein vascular graft used for dialysis access in patients with a previously failed synthetic graft.

Through our RestoreFlow allograft business, we provide human 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, and aortoiliac arteries. These allografts are used in a variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections. Currently they are only available for distribution in the United States and Canada.

Vascular Patches

Our XenoSure biologic vascular patch is made from bovine pericardium, and is 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.

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 surgeons believe improves the durability of the anastomosis. The AnastoClip AC and AnastoClip GC closure systems also facilitate compliant dura closure in neuro applications.

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.

Sales and Marketing

As of December 31, 2018, we employed 108 field sales representatives, including one export manager. We believe the expansion of our sales force since 1998 has been a key factor in our success, and it remains one of our primary long-term strategies. Over 95% of net sales were generated in territories in which we employ direct sales representatives.

Outside our direct markets, we generally sell our products through country-specific distributors.

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

We also provide training to our vascular surgeon customers on specific vascular surgery procedures including in situ or peripheral bypass, carotid endarterectomy, phlebectomy and interrupted anastomosis.

Research and Development

Our research and development has historically focused on developing enhancements and extensions to our existing product lines. Our current product development efforts are primarily focused on the open vascular space. In 2018, our efforts were primarily focused on expanding and enhancing our biologic product lines including XenoSure and Omniflow II, and completing the integration of our ProCol manufacturing into our Burlington facility. With regard to XenoSure, our priorities included attaining an additional indication for use in neurosurgery in 2019, as well as quality-based improvements and research around potential future generations of the product. Efforts were also made in 2018 to complete improvements on the design of the LeMaitre valvulotome as well as our powered phlebectomy

system.

Table of Contents

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, as appropriate. We may use feedback received from independent physicians to demonstrate product functionality before commencing full-scale marketing of any product.

Manufacturing and Processing

Our primary manufacturing facilities are located in Burlington, Massachusetts, where most of our product lines are produced. We also have facilities in North Melbourne, Australia, where our Omniflow II product line is produced, Saint-Etienne, France where our Wovex and Dialine grafts, Chevalier valvulotomes and surgical glue are produced, and Fox River Grove, Illinois where RestoreFlow allografts are processed, cryopreserved, stored and distributed.

We typically integrate manufacturing of the newly acquired lines into our Burlington operations. Our TRIVEX, EndoRE and some of our embolectomy catheters, however, are currently manufactured by third parties. We completed a renovation of our manufacturing facility in Burlington in 2017 and in 2018 moved our ProCol biologic product line into the space. In 2018 and into 2019 we are continuing to expand this biologic clean room.

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, 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 tissue procurement organizations in the United States. Donated human tissue is procured from deceased donors by these organizations. We have strict specifications regarding tissue we will accept for processing relating to, among other things, 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, and shipping and

distribution analysis, as well as various accounting-oriented functions. During day-to-day operations, these systems enable us to track our products from the inception of an order through the manufacturing process and then ultimately through delivery of the product to the customer.

We purchase 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. We do not have contractual arrangements with many of these suppliers and manufacturers, and we order our supplies and product on an as-needed basis. To date, we have not experienced any significant supply disruptions from existing sources of product and components, but there is no guarantee that we will not experience such disruptions in the future.

Our Burlington, North Melbourne 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 non-U.S. regulatory requirements. See “Government Regulation” for further information. In August 2017, our Burlington facilities were audited by the U.S. Food and Drug Administration (FDA), and in January 2018, we underwent inspections by our European Notified Body, LRQA. In February 2018, our Fox River Grove facility was inspected by the FDA, and our Australian operations were inspected by our notified body, TUV Rheinland. In February 2019, our Burlington facilities were audited by the Korean Ministry of Food and Drug Safety. The results of these inspections were satisfactory.

Table of Contents

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, Inc., Edwards Lifesciences Corporation, Getinge AB, LifeNet Health, Inc., Terumo Medical Corporation, 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, our products that are more technologically advanced than those of our competitors are sometimes sold at higher prices than those of our competitors. We believe that our continued success will depend on our ability to broaden and optimize our direct sales channel, acquire or develop additional complementary vascular device products, 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 many of our products are used primarily or exclusively in open vascular surgery. Our ability to compete effectively relies on keeping pace with existing or new product and technology offerings in the vascular device market, and the minimally invasive endovascular procedure segment in particular.

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 further improving products, obtaining regulatory approvals, and manufacturing and marketing such products. In the case of vascular allografts, certain competitors may have an advantage in sourcing tissue due to higher volume purchases and longer term relationships with tissue procurement organizations. Additionally, certain of our competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization before us, any of which could materially 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 patents, trademarks, trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights.

We maintain patents in the United States, Europe and other strategic locations relating to various aspects of our products and/or manufacturing processes. The majority of our issued U.S. patents are set to expire at various times from 2020 to 2032.

Generally, for products that we believe are appropriate for patent protection, we will attempt to obtain patents in the United States and key markets of the EU. However, depending on circumstances, we may not apply for patents in all or any of those jurisdictions.

Certain aspects of our products are covered by patents held by third parties. We manufacture, market, and sell these products pursuant to license agreements with these third parties. These arrangements require us to pay royalties, typically determined as a percentage of our net sales for the underlying product. If we fail to make these payments or otherwise fail to observe the terms of these agreements, we may lose our ability to sell these products. For example, we manufacture, market, and sell our LifeSpan vascular grafts, Periscope Dissectors and TRIVEX phlebectomy products pursuant to licenses with third-parties.

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 United States, 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 where 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 with us. 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.

Table of Contents

The laws of foreign countries generally do not protect our proprietary rights to the same extent as do the laws of the United States 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 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 United States 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 twelve 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 United States are marketed pursuant to the 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.

Table of Contents

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, rigorously 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 market using the 510(k) clearance procedure, and we have not used the more burdensome PMA process for any of the products that we currently market or sell in the United States, other than our ProCol vascular graft, which had PMA approval at the time we acquired the device. If we were to seek Unites States 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:

- 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 2017, the result of which was 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.

Non-U.S. sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, 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.

Table of Contents

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 and establishes donor-eligibility, 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 as required by the regulations. 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, 2021. 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 January 2018, 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 the reasonable payments associated with the removal,

transportation, implantation, processing, preservation, quality control, and storage of a human organ. We believe the compensation we receive for the processing and cryopreservation services we provide 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 a material adverse effect upon our ability to do 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 to date have not been required to take any action 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.

Non-U.S. 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 Directive), which is applicable to our products. Devices that comply with the requirements of the Directive 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 Iceland, Lichtenstein, Norway, 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.

Table of Contents

The Directive defines a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. The Directive also defines the essential requirements that devices must meet before being placed on the market, establishes assessment procedures for approving a device for marketing, and creates mechanisms for national 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 type of the device and other related factors.

A manufacturer of low-risk devices typically may demonstrate conformity to the essential requirements 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.

The European medical device laws also address the advertising and promotion of medical devices, clinical investigations, and requirements for handling adverse events. Post-market surveillance of medical devices in the EU is generally conducted on a country-by-country basis; however, the Directive 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.

In April 2017, the EU adopted new regulations for medical devices (MDR), which replace the Directive and apply after a three year transition period. Our products will 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 under the MDR. For example, as a condition to CE mark approval, clinical evidence from clinical investigations will be required for most Class III and implantable devices. As our Notified Bodies begin 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. If we fail to obtain the CE marks on our products under the MDR in a timely manner, or at all, future sales of our products could be impacted.

The Notified Bodies that issue a majority of our CE marks are located in the United Kingdom. These United Kingdom Notified Bodies are accredited to issue CE marks by the United Kingdom’s health authority, MHRA. As of the date of this report, the United Kingdom (UK) is scheduled to exit the EU on March 29, 2019. There continues to be uncertainty regarding the economic and regulatory impact of the UK’s exit (referred to as “Brexit”). If the United Kingdom were to leave the EU without a signed withdrawal agreement on March 29, 2019, these CE marks would no longer be recognized by the EU countries, and there would be a lapse in our CE marking. As such, only product built and sold to our European subsidiary prior to March 29, 2019 would be eligible for sale to EU countries while we awaited reissuance of the CE marks by a properly accredited Notified Body. In such event, we would expect

reinstatement of the CE marks by the second half of 2019 and until such time, we would expect to continue selling product from our inventory reserves already on the market in Europe prior to March 29, 2019. If our transference of CE marks is materially delayed, it is possible that our revenues could be impacted due to our saleable inventory reserves becoming depleted.

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, 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 our non-U.S. 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. Our Canadian office was most recently inspected in August 2017, the results of which were satisfactory.

Table of Contents

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 TMG in February, 2019, 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 similar requirements 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 of devices. As a holder of Australian device licenses, we are also subject to inspection by TGA in both Australia and the United States. Our Australian facility was most recently inspected in December 2018, the results of which were satisfactory. Australia requires all foreign manufacturers to have an in country 'sponsor' who must have a licensed business inside of Australia. Our licenses are held on our behalf by our sponsor, Emergo Group.

In China, the China Food and Drug Administration (CFDA) Medical Device Division 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 risk 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 CFDA often tests finished devices at its own testing laboratory to confirm each device's specifications. The approval process is typically lengthy and usually requires clinical trials. CFDA 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 CFDA in both China and the United States. Our China facility was most recently inspected in July 2018, the results of which were satisfactory. The CFDA 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 United States, 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.

Table of Contents

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.

Non-U.S.

Our success in non-U.S. 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 United States, 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 in those countries in which they will sell our products. There can be no assurance that reimbursement approval will be received.

Fraud and Abuse Laws

We may directly or indirectly be subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the 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 the “safe harbors.” These 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 each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

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

We had 483 employees, including 457 full-time employees, at December 31, 2018.

Financial Information by Business Segment and Geographic Data

We operate in one reportable industry segment: the design, marketing, sales, service and technical support of medical devices and implants for the treatment of peripheral vascular disease. Our chief operating decision maker is our chief executive officer. Our chief executive officer reviews financial information, accompanied by information about revenue by geographic region for purposes of allocating resources and evaluating financial performance. Information about segment revenue, revenue by geographic area and long-lived assets by geographic area is included in Note 11 to our Consolidated Financial Statements which are included elsewhere in this Annual Report. For information regarding risks associated with our international operations, please refer to the section entitled "Risk Factors" in Item 1A of Part I in this Annual Report on Form 10-K.

Table of Contents

Customers

Our sales are not dependent on any single customer or distributor, and we continue to expand our distribution channel worldwide through direct and indirect sales forces. No single customer accounted for more than 2% of our net sales in 2018.

Corporate Information

We were incorporated in Massachusetts on November 28, 1983, as Vascutech, Inc. On June 16, 1998, we were reincorporated in Delaware, and on April 6, 2001, we changed our name to LeMaitre Vascular, Inc. On October 19, 2006, we executed our initial public offering, and our common stock trades under the symbol “LMAT.” Our principal executive offices are located at 63 Second Avenue, Burlington, Massachusetts 01803, and our telephone number is (781) 221-2266.

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). 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. In addition, our filings with the Securities and Exchange Commission may be accessed through the Securities and Exchange Commission’s Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at www.sec.gov. 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 consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K 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 Annual Report on Form 10-K 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

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, products, or technologies;
- effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- the divestiture or discontinuation of a product line or other revenue generating activity;

- 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;

Table of Contents

- changes to the regulatory status of our products, including suspension or cancellation of licenses or CE marking;
- changes in foreign political relations that add additional barriers to entry;
- our determination whether or not to continue the payment of quarterly cash dividends, and/or the amount and frequency at which to increase them;
- costs incurred by us in connection with the termination of contractual and other relationships, including those of distributors or agents;
- our ability to collect outstanding accounts receivable in selected countries outside of the United States;
- changes in tax 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 substantially. 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.

The treatment of peripheral vascular disease is shifting from open vascular surgery to minimally invasive endovascular procedures, and many of our products are used primarily or exclusively in open vascular surgery procedures. 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 2018, 91% of our net sales were from devices used in open vascular surgery.

We may not be able to compete effectively with our competitors 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.

While we reported growth in operating and net income in each of the years ended December 31, 2018, 2017 and 2016, there can be no assurance we will continue to achieve significant net sales growth and/or profit growth in the future. If, for example, we are unable to effectively manage our operating expenses due to, for example, increased headcount, we may need to reduce our operating expenses in other areas in order to maintain or improve operating 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;

- market acceptance of our new products and services;

- the productivity of our direct sales force and distributors;

- fluctuations in foreign currency exchange rates;

Table of Contents

- 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.

If we do not comply with foreign regulatory requirements to market our products outside the United States, our business will be harmed.

Sales of medical devices outside the United States 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 FDA in the United States. 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 EU under the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC). In order to market our medical devices in the EU, we are required to obtain CE mark certification, which denotes conformity to the essential requirements of the Medical Devices Directive. We have received CE mark certification to sell nearly all of our products. However, in April 2017, the EU adopted new regulations for medical devices (MDR), which replace the Directive and apply after a three year transition period. Our products will 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 under the MDR. For example, 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 begin 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 our Notified Body for the product lines manufactured in our Saint-Etienne, France facility, that they require more clinical data for the renewal of the CE marks for such devices. There can be no assurance that we will be able to obtain or maintain CE marks for our existing products, 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 under the MDR in a timely manner, or at all, future sales of our products could be adversely impacted.

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. There can be no assurance that we will be successful in maintaining the CE mark for any of our current products. In particular, adverse event reporting requirements in the EU 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.

Failure to receive or maintain approval would prohibit us from selling these products in member countries of the EU, and would require significant delays in obtaining individual country approvals. If we do not receive or maintain these approvals, our business could be harmed.

Table of Contents

Our manufacturing facilities are subject to periodic inspection by numerous regulatory authorities, including governmental agencies and Notified Bodies, and we must demonstrate compliance with their applicable medical devices regulations. Our most recent inspections were as follows:

Facility	Agency	Jurisdiction	Date
Burlington	U.S. FDA	United States	August 2017
Canada	Health Canada	Canada	August 2017
Fox River Grove	AATB	Worldwide	January 2018
Fox River Grove	U.S. FDA	United States	January 2018
Burlington	Notified Body (LRQA)	Europe	January 2018
Australia	Notified Body (TUV)	Europe	January 2018
Burlington	Notified Body (LRQA)	United States Medical Device Single Audit Program	October 2018
Burlington	Notified Body (LRQA)	Europe	November 2018
Australia	Notified Body (TUV)	Europe	November 2018
Australia	Therapeutic Goods Administration (TGA)	Australia	December 2018
Burlington	Notified Body (LRQA)	Europe	December 2018
Burlington	Korean FDA	Korea	January 2019
Tokyo	Tokyo Metropolitan Government	Japan	February 2019

Any failure by us to comply with regulatory requirements in this regard 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 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.

We may acquire businesses and assets in the future. We may experience difficulties in completing the integration of these acquisitions into our business, or we may not realize the anticipated benefits of these acquisitions.

In order to expand our product offerings, we have completed 21 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 our management's time and attention from other business concerns;
- higher costs of integration than we 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;

Table of Contents

- 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 2014 in Australia and in 2018 in 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 debt financing required to fund acquisitions, which would be senior to our common stock, would require interest payments to a lender, 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 acquisitions we complete in the future, and could harm our financial condition and results of operations.

We also acquired the processing, preservation and distribution operations of RestoreFlow allografts located in Fox Rover Grove, Illinois. See “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” below for risks associated with our tissue processing and preservation services.

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 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. 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 2018, 91% of our net sales were from devices used in open vascular procedures.

In addition to performing traditional open surgical procedures, vascular surgeons in growing numbers also perform minimally invasive, image-guided interventional procedures for peripheral vascular disease. However, vascular surgeons may not adopt these procedures in the numbers we expect and instead these procedures may be largely performed by interventional cardiologists and interventional radiologists. Many of our competitors have focused their sales efforts on these interventionalists. If interventional cardiologists and interventional radiologists perform a greater percentage of these new procedures than we expect, our net sales may decline.

Moreover, demographic trends and other factors, such as reimbursement rates, are also driving vascular surgeons in the United States and potentially in other markets 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 skills in open vascular procedures. 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.

Table of Contents

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.

In November 2016, we acquired the processing, preservation and distribution operations for the RestoreFlow allograft. Prior to the acquisition, we did not provide any services related to human tissue. Our ability to successfully provide such 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, or changes in those requirements;
- maintenance of our AATB accreditation, FDA establishment registration and state licensures;
- the degree to which our tissue procurement organizations are successful in procuring the gift of tissue donation;
- procurement from tissue procurement organizations of adequate amounts of human tissue of a type and quality that meets our specifications;
- processing human tissue in a cost effective manner;
- controlling turnover in a workforce skilled in tissue processing and cryopreservation and 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 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 product components and certain products. For example, our TRIVEX system and associated disposables, as well as components of our EndoRE remote endarterectomy product line, are manufactured for us by third-party suppliers. Additionally, we rely on a sole-source supplier for the ovine material used for our Omniflow II biosynthetic vascular graft.

There are relatively few, or in some cases no, alternative, validated sources of supply for these components and products. And in some cases, we do not have supply agreements with these 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 components or products on acceptable terms or otherwise. We do not ordinarily carry a significant inventory of these components 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 customer dissatisfaction and damage to our reputation, and our financial condition or results of operations could be harmed.

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 allografts revenues could be adversely affected.

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

Our principal worldwide executive, distribution, and manufacturing operations are located in four leased facilities located in Burlington, Massachusetts. We also have manufacturing sites in North Melbourne, Australia and Saint-Etienne, France and 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.

Table of Contents

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 assure you that we would be able to find an appropriate replacement on a timely basis when the need arises.

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

Our AlboGraft vascular graft, AlboSure vascular patch, Dialine II vascular graft, Wovex vascular graft, XenoSure biologic patch and ProCol vascular graft 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, including food, pharmaceuticals and medical devices, 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 United States have 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.

Recent industry consolidation could make the competitive environment more difficult for smaller companies like ours. 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 of these competitors are able to manufacture at lower costs and may therefore offer comparable products at lower prices. Certain of these competitors may also have greater experience in developing and further improving products, obtaining regulatory approvals, and manufacturing and marketing such products. Certain of these 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. Because of the size of the vascular disease market opportunity, competitors and potential competitors have dedicated significant resources to aggressively promote their products. Also, 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 a different kind of medical device that we do not 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, 2018, 2017 and 2016, 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 sales of our LeMaitre Valvulotome and with respect to sales occurring in the United States. In the past, we have been able to rely upon our intellectual property position, our well-known brands, and our established reputation to implement price increases. We implemented a significant price increase in 2015 for our LeMaitre Valvulotome, and our ability to implement additional price increases with respect to that product in the future may be limited. We also experienced an increase in net sales of our XenoSure biologic patch in 2016, which was due in part to the recall of a competitive product. That recall has since been resolved, and we have only retained a portion of the customers who switched to our product during the recall.

20

Table of Contents

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

- if healthcare spending is reduced, particularly in the United States, 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 in which our products are 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 operations in markets outside of the United States. For the year ended December 31, 2018, 44% of our net sales were derived from operations outside of the United States. 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, company, person, or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person, or entity, whether due to , or in reaction to, changes in U.S. foreign policy under President Trump or otherwise;
- a shortage of high-quality sales personnel and distributors;
- loss of any key personnel who possess proprietary knowledge, or who are otherwise 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 being imposed 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.

Table of Contents

If Brexit results in greater restrictions on imports and exports between the United Kingdom and the European Union or increased regulatory complexity, then our operations and financial results could be negatively impacted.

As of the date of this report, the United Kingdom (UK) is scheduled to exit the European Union (EU) on March 29, 2019. There continues to be uncertainty regarding the economic and regulatory impact of the UK's exit (referred to as "Brexit"). Potential adverse consequences of Brexit such as global market uncertainty, volatility in currency exchange rates, greater restrictions on imports and exports between the UK and the EU and increased regulatory complexity could have a negative impact on our business, financial condition and results of operations.

We currently ship products to the UK from our Sulzbach, Germany location. If Brexit results in greater restrictions on imports and exports between the UK and the EU, we may find it necessary to make operational changes to adapt to those restrictions. We may be unable to make such changes in a commercially reasonable or timely manner or at all. Additionally, this could result in higher costs of doing business in the UK and possibly the EU.

The Notified Bodies that issue a majority of our CE marks are located in the United Kingdom. These United Kingdom Notified Bodies are accredited to issue CE marks by the United Kingdom's health authority, MHRA. If the United Kingdom were to leave the EU without a signed withdrawal agreement on March 29, 2019, these CE marks would no longer be recognized by the EU countries, and there would be a lapse in our CE marking. As such, only product built and sold to our European subsidiary prior to March 29, 2019 would be eligible for sale to EU countries while we awaited reissuance of the CE marks by a properly accredited Notified Body. In such event, we would expect reinstatement of the CE marks by the second half of 2019 and until such time, we would expect to continue selling product from our inventory reserves already on the market in Europe prior to March 29, 2019. Any delay in obtaining, or an inability to obtain or maintain, any regulatory approvals, as a result of Brexit or otherwise, could prevent us from selling our products in the UK and/or the EU and could constrain our ability to generate revenue from those geographies.

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 and preserve are defectively designed, manufactured, processed or labeled, contain defective components, or are misused, or if our products or the tissues we process and preserve 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. For example, although the amount in controversy is not material, a former distributor in China has recently filed suit against us related to the sale of our powered phlebectomy devices in China. 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.

Table of Contents

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 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 that they stock 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 through a 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 in any country in question. 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 sufficient 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. 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 and the Australian dollar. As of December 31, 2018, 44% of our net sales were transacted 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. Similarly, 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

- 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.

Table of Contents

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 United States 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 tissues, 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.

Our products require premarket clearance or approval in the United States and the CE Mark or other approvals in foreign countries where they are sold. Each medical device that we wish to market in the United States 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.

Table of Contents

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 United States 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 2016 and in early 2017, we voluntarily recalled certain lots of our LeMaitre valvulotome due to an issue with the product's closure mechanism. In February 2017, we voluntarily recalled certain lots of our Reddick cholangiogram catheter due to a labeling issue. While we took corrective actions to address these issues, there can be no assurance that there will not be a recurrence or that other problems related to our products will not develop in the future. And though the aggregate cost of these recalls to us was only $0.2 million, recalls 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 United States 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.

25

Table of Contents

Major third-party payors for hospital services in the United States 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 United States and abroad, or adverse decisions relating to our products by administrators of these systems in coverage or reimbursement, could significantly 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 United States. 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.

Table of Contents

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

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;

Table of Contents

- 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 17% of our outstanding common stock as of December 31, 2018. 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 any credit facility to which we become a party may restrict our ability to pay future quarterly dividends. We can provide no assurance of our ability to pay dividends in the future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal worldwide executive, distribution, and manufacturing operations are located at three adjacent 27,098 square foot, 27,289 square foot and 15,642 square foot leased facilities, as well as a fourth nearby 12,878 square foot leased facility, in Burlington, Massachusetts. Each of our Burlington leases expires in December 2023. In addition, our international operations are headquartered at a 13,948 square foot leased facility located in Sulzbach, Germany, with a lease which expires in 2023. We also own a 6,140 square foot manufacturing facility in North Melbourne, Australia, a 6,824 square foot facility in Saint-Etienne, France and lease an 8,732 square foot processing and distribution facility in Fox River Gove, Illinois. In addition, we have smaller leased sales and marketing offices

located in Canada, China, Italy, Japan, Spain and Singapore. Based on our current operating plans, we believe our current facilities are adequate for our needs.

Table of Contents

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, 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, 2018, 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.

Table of Contents

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 1, 2019, the closing price per share of our common stock was $30.63 as reported on The Nasdaq Global Market, and we had approximately 169 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, 2013, through the end of LeMaitre's fiscal year ended December 31, 2018. The graph assumes an investment of $100.00 made on December 31, 2013, 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 groups. This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any filing of LeMaitre under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

	12/13	12/14	12/15	12/16	12/17	12/18
LeMaitre Vascular, Inc	100.00	97.28	222.56	330.49	418.33	313.21
NASDAQ Composite	100.00	114.62	122.81	133.19	172.11	165.84
NASDAQ Medical Equipment	100.00	117.22	131.48	138.45	195.37	221.45
2017 Peer Group	100.00	93.98	59.48	71.64	85.84	103.65
2018 Peer Group	100.00	96.94	69.98	87.21	112.27	138.15

Table of Contents

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 year presented.

The 2017 peer group includes the following companies: AngioDynamics, Inc., Avinger, Inc., Cardiovascular Systems Inc., Cryolife Inc., Endologix, Inc., Penumbra, Inc., and Vascular Solutions, Inc.

The 2018 peer group includes the following companies: AngioDynamics, Inc., Cardiovascular Systems Inc., Cryolife Inc., Endologix, Inc., Merit Medical Systems, Inc., and Penumbra, Inc. This new peer group differs from our old peer group. Specifically, we removed Avinger, Inc. as the company has been experiencing adverse operating results, we removed Vascular Solutions, Inc. because it was acquired by another company and we added Merit Medical Systems, Inc., as the company competes primarily in the open vascular and interventional radiology segments.

Recent Sales of Unregistered Securities

Not Applicable.

Issuer Purchases of Equity Securities

		Issuer Purchases of Equity Securities	
Total	**Average**	**Total Number of Shares (or Units)**	**Maximum Number (or Approximate Dollar Value) of Shares (or Units)**

Period	Number of Shares (or Units) Purchased (1)	Price Paid Per Share (or Unit)	Purchased as Part of Publicly Announced Plans or Program	that may yet be Purchased under the Plans or Program
October 1, 2018 through October 31, 2018	86	$ 27.94	N/A	N/A
November 1, 2018 through November 30, 2018	-	$ -	N/A	N/A
December 1, 2018 through December 31, 2018	2,685	$ 22.23	N/A	N/A
Total	2,771	$ 22.41	N/A	N/A

(1) For the three months ended December 30, 2018, we repurchased 2,771 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.

Table of Contents

Item 6. Selected Financial Data

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and the related notes which are included elsewhere in this Annual Report and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report. We have derived the consolidated statement of operations data for the years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017, from our audited consolidated financial statements, which are included elsewhere in this Annual Report. We have derived the consolidated statement of operations data for the years ended December 31, 2015 and 2014, and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014 from our audited consolidated financial statements, which are not included in this Annual Report. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period.

	Year ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net sales	$105,568	$100,867	$89,151	$78,352	$71,097
Cost of sales	31,629	30,170	26,215	24,186	22,666
Gross profit	73,939	70,697	62,936	54,166	48,431
Operating expenses:					
Sales and marketing	27,318	25,948	26,105	22,780	22,087
General and administrative	17,689	17,010	14,354	14,010	13,889
Research and development	8,197	6,636	6,141	5,479	4,671
Medical device excise tax	-	-	-	744	689
Restructuring charges	-	-	-	-	526
Gain on divestitures and acquisitions	(7,474)	-	-	(360)	-
Impairment charges	-	-	-	-	229
Total operating expenses	45,730	49,594	46,600	42,653	42,091
Income from operations	28,209	21,103	16,336	11,513	6,340
Other income (expense):					
Interest income	631	179	81	13	1
Interest expense	(2)	(21)	(14)	-	(5)
Foreign currency gain (loss)	(394)	(155)	(161)	(102)	(16)
Total other income (loss)	235	3	(94)	(89)	(20)
Income before income tax	28,444	21,106	16,242	11,424	6,320
Provision for income taxes	5,501	3,929	5,652	3,666	2,405
Net income	$22,943	$17,177	$10,590	$7,758	$3,915
Earnings per share of common stock:					
Basic	$1.18	$0.91	$0.57	$0.44	$0.24
Diluted	$1.13	$0.86	$0.55	$0.42	$0.23
Weighted-average shares outstanding:					
Basic	19,426	18,961	18,485	17,764	16,614
Diluted	20,242	20,033	19,241	18,316	17,008
Cash dividends declared per common share	$0.28	$0.22	$0.18	$0.16	$0.14

32

Table of Contents

	Year ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$26,318	$19,096	$24,288	$27,451	$18,692
Short-term marketable securities	21,668	22,564	-	-	-
Current assets	94,017	80,311	59,027	58,184	48,588
Total assets	153,088	126,323	101,924	90,704	81,492
Current liabilities	19,758	13,189	10,482	10,368	10,041
Long-term liabilities	3,095	3,364	3,942	2,452	3,244
Total liabilities	22,853	16,553	14,424	12,820	13,285
Total stockholders' equity	130,235	109,770	87,500	77,884	68,207

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.

Overview

We are a medical device company that develops, manufactures, and markets medical devices and implants for the treatment of peripheral vascular disease. We also provide processing and cryopreservation services of human tissue for implantation into patients. Our principal product offerings are sold throughout the world, primarily in the United States, Europe and, to a lesser extent, Asia and the Pacific Rim. We estimate that the annual worldwide market for all peripheral vascular devices exceeds $5 billion, within which our core product lines address roughly $900 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 vascular devices. We have used acquisitions as a primary means of further accessing the peripheral vascular device market, and we expect to continue to pursue this strategy in the future. Additionally, we have increased our efforts to expand our vascular device offerings through new product development. We currently manufacture most of our product lines 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, neither of

whom are certified to perform open surgical procedures, vascular surgeons can perform both open surgery and minimally invasive endovascular procedures, and are therefore uniquely positioned to provide a wider range of treatment options to patients.

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

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

Our business opportunities include the following:

- the long-term growth of our direct sales force in North America, Europe, Asia and the 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 product manufacturing into our Burlington, Massachusetts corporate headquarters.

Table of Contents

We sell our products and services primarily through a direct sales force. As of December 31, 2018 our sales force was comprised of 108 sales representatives in North America, Europe, Japan, China, Australia and New Zealand, including one export manager. We also sell our products in other countries through distributors. Our worldwide headquarters and principal manufacturing site is located in Burlington, Massachusetts. Our European operations are headquartered in Sulzbach, Germany and our Asia Pacific operations are headquartered in Singapore. We also have sales offices located in Tokyo, Japan; Vaughan, Canada; Madrid, Spain; Milan, Italy; Shanghai, China; and North Melbourne, Australia, and we have a processing facility in Fox River Grove, Illinois and manufacturing facilities in North Melbourne, Australia and Saint-Etienne, France. During the years ended December 31, 2018 and 2017, approximately 95% and 93%, respectively, of our net sales were generated in territories in which we employ direct sales representatives.

Historically we have experienced success in lower-rivalry niche product segments, for example the markets for valvulotome devices and biologic vascular patches. More recently, however, we have faced increased competition in the biologic vascular patch segment, which has inhibited our ability to continue to increase market share or to implement selling price increases.

In the valvulotome market, our highly differentiated devices have historically allowed us to increase our selling prices while maintaining our unit market share. In contrast, we have experienced less success in highly competitive markets such as our ProCol biologic 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.

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 towards our direct sales organization:

- In December 2015, we signed a master distribution agreement with Meheco Yonstron Pharmaceutical Co. Ltd. (Meheco), a Chinese distribution and logistics company, and began selling our Chinese market products to Meheco in 2016. Meheco then sold our products to multiple sub-distributors who then sold to Chinese hospitals. This agreement expired in December 2017, and we are currently in the process of signing distribution agreements with sub-distributors and have begun selling our products to sub-distributors in China. We repurchased $120,000 of our products back from Meheco in the three months ended September 30, 2018, which resulted in a corresponding revenue reversal.

- In March 2018, we terminated our master distribution agreement with Sinopharm United Medical Device Co., Ltd. under which we sold our powered phlebectomy device and related disposable devices for distribution in China. In April 2018 we began selling these products to sub-distributors 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 catheter, polyester graft and valvulotome products, and we began selling direct-to-hospitals in those geographies. The termination fees totaled approximately $0.1 million.

We anticipate that the expansion of our sales organization in China will result in increased sales, marketing and regulatory expenses during 2019. As of December 31, 2018 we had eight employees in China.

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 March 2016, we acquired substantially all of the assets as well as the production and distribution rights of the ProCol business from Hancock Jaffe Laboratories and CryoLife, Inc. for $2.7 million plus 10% of net sales for three years following the closing. ProCol is a biologic vascular graft used for dialysis access and is approved for sale in the United States.

- In November 2016, we acquired substantially all of the assets related to the peripheral vascular allograft operations of Restore Flow Allografts, LLC for $12.0 million plus additional payments of up to $6.0 million depending upon the satisfaction of certain contingencies.

Table of Contents

- In April 2018, we sold our Reddick cholangiogram catheter and Reddick-Saye screw product lines to Specialty Surgical Instrumentation, Inc. for $7.4 million.

- In September 2018, we acquired the assets of the embolectomy catheter business from Applied Medical Resources Corporation for $14.2 million. We have initiated a project to transfer the manufacturing of the acquired devices to our Burlington facility. We expect this transition to be completed in 2019.

- In October 2018, we acquired the assets of Cardial, a subsidiary of Becton, Dickinson & Company, located in Saint-Etienne, France, for €2.0 million. Cardial's product lines include knitted and woven vascular grafts, valvulotomes and surgical glue.

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

- In 2016, we launched additional sizes of our XenoSure patch.

- In 2016, we launched the 7.0mm diameter size Omniflow graft.

- In 2017, we launched XenoSure biologic pledgets.

- In 2017, we launched a new iteration of our anastoclip AC closure system intended for use in neurosurgery applications.

- In 2018, we expanded the indications for our Anastoclip GC closure system in the United States to include dura tissue repair.

In addition to our sales growth strategies, we have also executed several operational initiatives designed to consolidate and streamline manufacturing within our Burlington, Massachusetts facilities. We expect these plant consolidations will result in improved control over our production capacity as well as reduced costs over the long-term. Our most recent manufacturing transitions included:

- In 2016, we initiated a project to transfer the manufacturing of the ProCol biologic product line to our facility in Burlington. This transition was completed in 2018.

-

In 2017, we renovated our manufacturing facility in Burlington, in which many of our biologic offerings, including the XenoSure patch as well as our ProCol biologic grafts, are currently produced or processed. The cost of the facility renovation was approximately $3.0 million. We are currently in the process of further expanding this clean room, which we expect to complete during 2019 at a cost of approximately $0.8 million.

- In September 2018, we acquired the embolectomy catheter business assets from Applied Medical Resources Corporation. We have initiated a project to transfer the manufacturing of the acquired devices to our Burlington facility. We expect this transition to be completed in 2019.

Our execution of these business opportunities may affect the comparability of our financial results from period to period and may cause substantial fluctuations from period to period as we incur related process engineering and other charges, as well as longer term impacts to revenues and operating expenditures.

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies, primarily the Euro, affect our financial results. For the year ended December 31, 2018, approximately 44% of our sales took place outside the United States, and in most cases in currencies other than the U.S. dollar. We expect that foreign currencies will continue to represent a significant percentage of our sales in the future. Selling, marketing, and administrative costs related to these sales are largely denominated in the same respective currency, thereby partially mitigating our exposure to exchange rate fluctuations. However, as most of our foreign sales are denominated in local currency, 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 receive less revenue in U.S. dollars than we did before the rate increase went into effect. For the year ended December 31, 2018, we estimate that the effects of changes in foreign exchange rates increased sales by approximately $1.4 million, as compared to rates in effect for the year ended December 31, 2017.

Net Sales and Expense Components

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

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

Table of Contents

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 United States, 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 United States and foreign subsidiaries, permanent items, discrete items, unrecognized tax benefits, and amortization of goodwill for U.S tax reporting purposes.

Results of Operations

Comparison of the year ended December 31, 2018 to the year ended December 31, 2017

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:

	2018	2017	$ Change	Percent change	
	($ in thousands)				
Net sales	$105,568	$100,867	$ 4,701	5	%
Net sales by geography:					
Americas	$63,649	$62,696	$ 953	2	%
Europe, Middle East and Africa	$35,319	$32,516	$ 2,803	9	%
Asai/Pacific Rim	6,600	5,655	945	17	%
Total	$105,568	$100,867	$ 4,701	5	%

Net sales. Net sales increased 5% or $4.7 million to $105.6 million for the year ended December 31, 2018, compared to $100.9 million for the year ended December 31, 2017. Sales increases were primarily driven by increased sales of our biologic vascular patches of $1.7 million, carotid shunts of $1.2 million, embolectomy catheters of $1.2 million, of which $0.8 million was from our recent acquisition of Syntel and Python products, and valvulotomes of $0.6 million. We also had an increase in human tissue cryopreservation service revenues from our RestoreFlow allograft business of $1.2 million. These and other product line increases were partially offset by decreased sales due to the divestiture of our Reddick cholangiogram catheter product in early Q2 2018 of $1.1 million and decreased sales of our closure systems of $0.7 million.

Direct-to-hospital net sales were 95% for the year ended December 31, 2018 and 93% for the year ended December 31, 2017.

Net sales by geography. Net sales in the Americas increased $1.0 million for the year ended December 31, 2018. The increase was primarily driven by increased human tissue cryopreservation services of $1.2 million related to our RestoreFlow allograft business. We also had increased sales of embolectomy catheters of $0.7 million, in part due to our acquisition of the Syntel and Python products, as well as increased sales of valvulotomes, carotid shunts and biologic vascular patches of $0.5 million each. These increases were partially offset by decreases in sales associated with the divestiture of the Reddick product line of $1.2 million, as well as lower sales of radiopaque tape of $0.5 million and closure systems of $0.4 million.

Table of Contents

Europe, Middle East and Africa net sales increased $2.8 million for the year ended December 31, 2018. The increase was primarily driven by increased sales of our biologic vascular patches of $1.1 million, polyester grafts of $0.4 million, embolectomy catheters of $0.3 million and carotid shunts of $0.2 million. We also had sales of surgical glue of $0.6 million in connection with our recent Cardial acquisition.

Asia/Pacific Rim net sales increased $0.9 million for the year ended December 31, 2018. The increase was primarily driven by increased sales of carotid shunts of $0.5 million, and embolectomy and occlusion catheters of $0.2 million each, and valvulotomes of $0.1 million each. These increases were offset in part by decreased sales of closure systems to China.

	2018	2017	Change	Percent change
	($ in thousands)			
Gross profit	$73,939	$70,697	$3,242	5 %
Gross margin	70.0 %	70.1 %	(0.1%)	*

* Not applicable

Gross Profit. Gross profit increased $3.2 million to $73.9 million for the year ended December 31, 2018, while gross margin decreased by 10 basis points to 70.0% in the period. The gross margin was favorably impacted by higher average selling prices across most product lines, a more favorable product mix, including increased sales of our biologic patch products, and the favorable impact from changes in foreign exchange rates. These increases were offset, however, by manufacturing inefficiencies as well as higher manufacturing overhead costs experienced for certain of our product lines.

	2018	2017	$ change	Percent change	2018 as a % of Net Sales	2017 as a % of Net Sales
	($ in thousands)					
Sales and marketing	$27,318	$25,948	$1,370	5 %	26 %	26 %
General and administrative	17,689	17,010	679	4 %	17 %	17 %
Research and development	8,197	6,636	1,561	24 %	8 %	7 %
Gain on divestures and acquisitions	(7,474)	-	(7,474)	*	(7 %)	*
	$45,730	$49,594	$(3,864)	(8 %)	43 %	49 %

* Not a meaningful percentage.

Sales and marketing. For the year ended December 31, 2018, sales and marketing expense increased $1.4 million, or 5%, to $27.3 million. The increase was primarily driven by higher personnel costs, including compensation, recruiting, sales meeting and travel expenses associated with expanding the sales force. As a percentage of net sales, sales and marketing expense was 26% in both 2018 and 2017.

General and administrative. For the year ended December 31, 2018, general and administrative expense increased $0.7 million, or 4%, to $17.7 million. General and administrative expense increases were primarily related to compensation costs, professional fees and travel expense, offset in part by lower acquisition-related costs and facilities costs. The compensation expense increase in 2018 was in part due to the January 1, 2018 reinstatement of our Chief Executive Officer's compensation, which he had forgone (except as to the amount legally required) beginning in June 2017. As a percentage of net sales, general and administrative expense was 17% for both 2018 and 2017.

Research and development. For the year ended December 31, 2018, research and development expense increased $1.6 million, or 24%, to $8.2 million. Clinical and regulatory expenses increased $1.0 million and product development expense increased $0.6 million. These increases were primarily related to regulatory submissions for new products in geographies such as China and Japan, testing related to our biologic product offerings and for compliance with new medical device regulation (MDR) requirements in the EU.

Gain on divestitures and acquisitions. 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 with our Reddick cholangiogram catheter and Reddick-Saye screw product lines for $7.4 million. During the three months ended June 30, 2018 we recorded a gain in connection with these agreements of $5.9 million. On October 22, 2018, we entered into an agreement to acquire the assets of Cardial, a subsidiary of Becton Dickinson, whose business consists of the manufacture and sale of knitted and woven vascular grafts, valvulotomes and surgical glue, for a purchase price of €1.2 million ($1.4 million). In connection with this asset purchase, we simultaneously entered into an agreement to purchase Cardial's land and building for €0.8 million ($0.9 million), bringing the total price paid for the business to €2.0 million ($2.3 million). During the three months ended December 31, 2018 we recorded a gain of €1.4 million ($1.6 million) in connection with these agreements resulting from the excess value of the assets acquired over the purchase price, subject to finalization of the purchase accounting.

Table of Contents

Other income (expense). Interest income was $0.6 million and $0.2 million, respectively for 2018 and 2017. Foreign exchange losses on settlements or remeasurement of receivables and payables denominated in foreign currencies were $0.4 million and $0.2 million in 2018 and 2017, respectively.

Income tax expense. We recorded a provision for taxes of $5.5 million on pre-tax income of $28.4 million in 2018 as compared to $3.9 million on pre-tax income of $21.1 million in 2017. The 2018 provision was comprised of a federal tax provision in the United States of $2.8 million, a state tax provision of $0.5 million, and a foreign tax provision of $2.2 million. The 2017 provision was comprised of a federal tax provision in the United States of $2.2 million, a state tax provision of $0.7 million and a foreign tax provision of $1.0 million. Our effective tax rate differed from the U.S. statutory tax rate in 2018 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, 2018, we have provided a valuation allowance of $1.3 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.

Comparison of the year ended December 31, 2017 to the year ended December 31, 2016

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:

2017	**2016**	**$ Change**	**Percent change**
($ in thousands)			

Net sales	$100,867	$89,151	$11,716	13	%
Net sales by geography:					
Americas	$62,696	$53,710	$8,986	17	%
International	38,171	35,441	2,730	8	%
Total	$100,867	$89,151	$11,716	13	%

Net sales. Net sales increased 13% or $11.7 million to $100.9 million for the year ended December 31, 2017, compared to $89.2 million for the year ended December 31, 2016. The sales increase was primarily driven by increased sales of our biologic vascular patches of $3.6 million, carotid shunts of $1.0 million, and biologic vascular grafts of $0.8 million. We also had an increase in human tissue cryopreservation service revenues from our RestoreFlow allograft business (acquired in late 2016) of $5.5 million. These and other product line increases were partially offset by decreased sales of powered phlebectomy devices of $0.5 million, radiopaque tape of $0.4 million and ePTFE vascular grafts of $0.4 million.

Direct-to-hospital net sales were 93% of our sales in the year ended December 31, 2017 and 92% in the year ended December 31, 2016.

Table of Contents

Net sales by geography. Net sales in the Americas increased $9.0 million for the year ended December 31, 2017. The increase was primarily driven by increased human tissue cryopreservation services of $5.5 million related to our RestoreFlow allograft business. We also had increased sales of biologic vascular patches of $2.3 million and carotid shunts of $0.7 million. International net sales increased $2.7 million for the year ended December 31, 2017. The increase was primarily driven by increased sales of our biologic vascular patches of $1.3 million, valvulotomes of $0.7 million and biologic vascular grafts of $0.6 million. These and other product line increases were partially offset by decreased sales of ePTFE vascular grafts of $0.4 million.

	2017	2016	Change	Percent change
	($ in thousands)			
Gross profit	$70,697	$62,936	$7,761	12 %
Gross margin	70.1 %	70.6 %	(0.5 %)	*

* Not applicable

Gross Profit. Gross profit increased $7.8 million to $70.7 million for the year ended December 31, 2017, while gross margin decreased by 50 basis points to 70.1% in the period. The gross margin was favorably impacted by higher average selling prices across most product lines, lower per-unit manufacturing costs of our biologic patches and other products, increased sales of biologic patches, and lower sales to China where average selling prices are comparatively lower. These increases were offset, however, by the introduction of the RestoreFlow product line, as well as higher sales into non-direct markets where we typically realize lower gross margins than in our direct-to-hospital markets. The gross profit increase was a result of higher sales offset slightly by the lower gross margin.

	2017	2016	$ change	Percent change	2017 as a % of Net Sales	2016 as a % of Net Sales
	($ in thousands)					
Sales and marketing	$25,948	$26,105	$(157)	(1%)	26 %	29 %
General and administrative	17,010	14,354	2,656	19 %	17 %	16 %
Research and development	6,636	6,141	495	8 %	7 %	7 %
	$49,594	$46,600	$2,994	6 %	49 %	52 %

* Not a meaningful percentage.

Sales and marketing. For the year ended December 31, 2017, sales and marketing expense decreased $0.2 million or 1% to $25.9 million. The decrease was primarily driven by reduced discretionary spending for professional services, sales meetings, trade shows, advertising and product samples, offset in part by increased compensation-related expense. As a percentage of net sales, sales and marketing expense decreased to 26% in 2017 from 29% in 2016.

General and administrative. For the year ended December 31, 2017, general and administrative expenses increased $2.7 million or 19%, to $17.0 million. General and administrative expense increases were primarily related to compensation costs, facilities costs and acquisition-related expenses, and to a lesser extent recruiting costs and professional fees. As a percentage of net sales, general and administrative expense increased to 17% for the year ended December 31, 2017 as compared to 16% for the prior period.

Research and development. For the year ended December 31, 2017, research and development expenses increased $0.5 million or 8%, to $6.6 million. Clinical and regulatory expenses increased $0.5 million primarily due to compensation costs and professional fees, including costs related to regulatory submissions for new products in geographies such as China. Product development expenses in total were unchanged, with decreases in compensation costs offset by increased product testing.

Other income (expense). Interest income was $0.2 million and $0.1 million, respectively for 2017 and 2016. Foreign exchange losses for both 2017 and 2016 were $0.2 million.

Income tax expense**.** We recorded a provision for taxes of $3.9 million on pre-tax income of $21.1 million in 2017 as compared to $5.7 million on pre-tax income of $16.2 million in 2016. The 2017 provision was comprised of a Federal tax provision in the United States of $2.2 million, a state tax provision of $0.7 million and a foreign tax provision of $1.0 million. The 2016 provision was comprised of a Federal tax provision in the United States of $4.6 million, a state tax provision of $0.6 million and a foreign tax provision of $0.5 million. Our effective tax rate differed from the U.S. statutory tax rate in 2017 principally because of stock option exercises, U.S. tax reform legislation, deferred tax remeasurement, 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, 2017, we have provided a valuation allowance of $2.0 million for deferred tax assets primarily related to an Australian net operating loss and capital loss carry forwards as well as 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.

Table of Contents

Liquidity and Capital Resources

At December 31, 2018, we held $26.3 million in cash and cash equivalents and $21.7 million in a short-term managed income mutual fund investment, as compared to $19.1 million in cash and cash equivalents and $22.6 million in the mutual fund investment at December 31, 2017. 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 United States is available for corporate use, with the exception of $4.4 million held by subsidiaries in jurisdictions for which earnings are planned to be permanently reinvested.

On July 25, 2017, our Board of Directors approved a stock repurchase program under which the Company was authorized to repurchase up to $7.5 million of its common stock. This program expired on July 25, 2018. We did not make any repurchases under this program.

On February 14, 2019, our Board of Directors authorized the repurchase of up to $10.0mm of the Company’s common stock through transactions on the open market, in privately negotiated purchases or otherwise. The repurchase program may be suspended or discontinued at any time and will conclude on February 14, 2020, unless extended by the Board. As of March 6, 2019 we had not made any repurchases under this program.

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 $28.2 million for the year ended December 31, 2018, $21.1 million for the year ended December 31, 2017 and $16.3 million for the year ended December 31, 2016. 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 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, make payments under our quarterly dividend program, 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 borrow funds from, or establish a revolving credit facility, with a financial institution. 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.

Table of Contents

Cash Flows

	Year ended December 31,		
	2018	**2017**	**2016**
	($ in thousands)		
Cash and cash equivalents	$26,318	$19,096	$24,288
Cash flows provided by (used in):			
Operating activities	$19,506	$22,868	$16,896
Investing activities	(7,055)	(28,958)	(17,211)
Financing activities	(4,416)	80	(2,577)

Net cash provided by operating activities. 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, provisions for inventory write-offs and doubtful accounts of $1.0 million, 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 provided by operating activities was $22.9 million for the year ended December 31, 2017, and consisted of $17.2 million net income, adjusted for non-cash items of $7.3 million (including primarily depreciation and amortization of $4.1 million, stock-based compensation of $2.3 million, provisions for inventory write-offs and doubtful accounts of $0.6 million, and a provision for deferred taxes of $0.3 million), as well as working capital uses of $1.6 million. The net cash used for working capital was driven by increases in accounts receivable of $1.5 million, inventory of $1.3 million and other current assets of $0.3 million, offset by an increase in accounts payable and other liabilities of $1.5 million.

Net cash provided by operating activities was $16.9 million for the year ended December 31, 2016, and consisted of $10.6 million net income, adjusted for non-cash items of $5.9 million (including depreciation and amortization of $3.6 million, stock-based compensation of $1.7 million, provisions for inventory write-offs and doubtful accounts of $0.5 million and provision for deferred taxes of $0.1 million), as well as changes in working capital of $0.4 million. The net cash provided by changes in working capital was driven by decreases in other current assets of $1.5 million, including primarily prepaid taxes, partially offset by increases in accounts receivable of $0.9 million and inventory of $0.1 million, and a decrease in accounts payable and other liabilities of $0.1 million.

Net cash used in investing activities. 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 at our Burlington, Massachusetts headquarters. 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 used in investing activities was $29.0 million for year ended December 31, 2017, driven by a $22.5 million purchase of a short-term investment, as well as purchases of property and equipment of $6.4 million primarily associated with the clean room build-outs at our Burlington, Massachusetts headquarters.

Net cash used in investing activities was $17.2 million for year ended December 31, 2016, driven by $14.4 million of cash paid in connection with our acquisitions of the ProCol biologic vascular graft and RestoreFlow allograft businesses, as well as purchases of property and equipment of $2.8 million primarily associated with the expansion of our Burlington, Massachusetts headquarters.

Net cash provided by (used in) financing activities. Net cash used in financing activities was $4.4 million for the year ended December 31, 2018, driven primarily by payments of common stock dividends of $5.4 million and payments related to our 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.

Net cash provided by financing activities was $0.1 million for the year ended December 31, 2017, driven primarily by proceeds from stock option exercises of $5.5 million, offset by the acquisition of $0.8 million of treasury shares to cover minimum withholding taxes on restricted stock unit vestings and by payments of common stock dividends of $4.2 million. We also made payments related to our prior acquisitions of $0.4 million.

Net cash used in financing activities was $2.6 million for the year ended December 31, 2016, driven primarily by payments of common stock dividends of $3.3 million, partially offset by proceeds from stock option exercise, net of shares repurchased for taxes, of $1.1 million. We also made payments related to our prior acquisitions of $0.4 million.

Table of Contents

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 2018			
March 22, 2018	April 5, 2018	$ 0.070	$ 1,351
May 22, 2018	June 7, 2018	$ 0.070	$ 1,353
August 22, 2018	September 6, 2018	$ 0.070	$ 1,369
November 20, 2018	December 6, 2018	$ 0.070	$ 1,372
Fiscal Year 2017			
March 22, 2017	April 6, 2017	$ 0.055	$ 1,029
May 24, 2017	June 8, 2017	$ 0.055	$ 1,036
August 23, 2017	September 6, 2017	$ 0.055	$ 1,055
November 22, 2017	December 7, 2017	$ 0.055	$ 1,060

On February 14, 2019, our Board of Directors approved a quarterly cash dividend on our common stock of $0.085 per share payable on April 5, 2019, to stockholders of record at the close of business on March 22, 2019, which will total approximately $1.7 million.

Contractual obligations. Our principal contractual obligations consist of operating leases and inventory purchase commitments. The following table summarizes our commitments under operating leases as of December 31, 2018:

Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
	(in thousands)				
Operating leases	$7,435	$1,826	$3,053	$2,556	$ -
Inventory purchase commitments	$2,195	$2,072	$123	$-	$ -

The commitments under our operating leases consist primarily of lease payments for our corporate headquarters and manufacturing facility in Burlington, Massachusetts, expiring in 2023, our Sulzbach, Germany office, expiring in 2023, our Vaughan, Canada office expiring in 2023, our Tokyo, Japan office, expiring in 2022; and our Shanghai, China office, expiring in 2020. They also include automobile leases.

We also have inventory purchase commitments of approximately $2.2 million as of December 31, 2018. These commitments are for product used in operations in the normal course of business and do not represent excess commitments or loss contracts.

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 bad debts, inventories, intangible assets, sales returns and discounts, 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.

Table of Contents

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.

On January 1, 2018 we adopted the provisions of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. We used the modified retrospective method of adoption under which the comparative information was not restated and will continue to be reported under the standard in effect for those periods. The adoption of this standard was not material to our financial statements and there was no cumulative effect adjustment to the opening balance of retained earnings required. 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 recognize 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.

Table of Contents

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

	Year ended December 31,	
	2018	**2017**
Americas	$63,649	$62,696
Europe, Middle East and Africa	35,319	32,517
Asia/Pacific Rim	6,600	5,654
Total	$105,568	$100,867

Except as discussed in Note 6 to our consolidated financial statements, 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.

Accounts Receivable

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 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, 2018 our receivables in Italy and Spain totaled $1.0 million and $0.7 million, respectively. Receivables balances with certain publicly-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, 2018, if significant changes were to occur in Italy's or Spain's payment practices 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. While such credit losses have historically been within our expectations and allowances, we cannot guarantee the same credit loss rates will be experienced in the future. 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.

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.

Table of Contents

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 human vascular tissues are instead accumulated and deferred.

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. 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 rates, 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 Second Amended and Restated 2006 Stock Option and Incentive 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 may 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.

As disclosed more fully in the notes to our consolidated financial statements, we recorded expense of approximately $2.3 million in connection with share-based payment awards for the year ended December 31, 2018. The future expense of non-vested share-based awards of approximately $9.7 million is to be recognized over a weighted-average period of 3.8 years. During 2018, we granted stock options at a weighted average fair value of $8.28 and RSUs with weighted average fair value of $23.65. Share-based compensation charges are recorded across the consolidated statement of operations based upon the grantee's primary function.

Valuation of Goodwill, and Other Intangibles

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. Our assessment is performed as of December 31 each year based on a single reporting unit. We first 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. Goodwill was $29.9 million and $23.8 million as of December 31, 2018 and 2017, respectively. Our annual impairment testing indicated no significant risk of impairment based upon changes in value that are reasonably likely to occur. However, changes in these estimates and assumptions could materially affect the estimated fair value of our reporting unit.

Other 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. We review intangible assets quarterly to determine if any adverse conditions exist for a change in circumstances has occurred that would indicate impairment. 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 the asset, a change in the operating cash flows associated with the asset, or adverse action or assessment by a regulator. If an impairment indicator exists we test the intangible asset for recoverability. If the carrying value of the intangible asset exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset, we will write the carrying value down to the fair value in the period in which it is identified. 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 $13.7 million as of December 31, 2018 and $8.2 million as of December 31, 2017.

Table of Contents

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, 2018, 2017, and 2016, we were not subject to any material litigation, claims or assessments.

Income Taxes

As part of the process of preparing our consolidated financial statements we are required to determine our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax expense together with assessing temporary differences resulting from recognition of items for income tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. We must then assess the likelihood that our deferred tax assets will be recovered from taxable income during the carryback period or in the future; and to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must reflect this increase as an expense within the tax provision in the statement of operations.

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 operate in multiple taxing jurisdictions, both within the United States and outside of the United States and may be subject to audits from various tax authorities regarding transfer pricing, the deductibility of certain expenses, intercompany transactions, and other matters. Management’s judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets.

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

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU) 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40)*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The new standard is effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

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 is effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In February 2018, the FASB issued ASU 2018-02, *Income Statement – Reporting Other Comprehensive Income (Topic 220)*, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. Consequently, the amendments eliminate the stranded tax effects resulting from the Tax Cuts and Jobs Act and is expected to improve the usefulness of information reported to financial statement users. However, because the amendments only relate to the reclassification of the income tax effects of the Tax Cuts and Jobs Act, the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations is not affected. The amendments in this ASU also require certain disclosures about stranded tax effects. The new standard is effective for us beginning January 1, 2019, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In January 2017, the FASB issued ASU 2017-04, 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 is effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

Table of Contents

In February 2016, the FASB issued its new lease accounting guidance in ASU No. 2016-02, *Leases (Topic 842),* subsequently amended by ASU 2018-11, *Leases (Topic 842): Targeted Improvements*. Under the new guidance, lessees will be 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. Lessees will no longer be provided with a source of off-balance sheet financing. The new lease guidance also simplifies the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. The standard is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years (i.e., January 1, 2019, for a calendar year entity). Early application is permitted. Entities have the option of using either a modified retrospective approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, or else a transition option (which we currently expect to use) allowing lessees to not apply the new lease standard in comparative periods but instead recognize a cumulative-effect adjustment to retained earnings as of the date of adoption. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach. Our assessment of the impact of adopting this standard is nearly complete, and included cataloging all of our leases, performing an analysis of the amounts of lease liabilities and right-of-use assets to be recorded and reviewing potential changes to our disclosures on leases. Based on this assessment we do not expect the adoption of this standard to have a significant impact on our consolidated statement of operations. However, we expect that the recognition of right-of-use assets and corresponding lease liabilities will have a significant impact on our consolidated balance sheet, adding between $6.1 million and $6.7 million to our total assets, and between $6.6 million and $7.2 million to our total liabilities, depending primarily on the discount rate selected.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2018. We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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 2018 and 2017, 44% and 42%, respectively, of our total revenue was from customers outside of the United States. In addition, a significant portion of our operating costs incurred outside the United States 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 have not done so during fiscal 2018 and fiscal 2017. 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, 2018 and 2017, we recorded $0.4 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 $1.9 million for 2018.

Table of Contents

Interest Rate Risk

At December 31, 2018, we held $26.3 million in cash and cash equivalents and $21.7 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.

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.

Table of Contents

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, 2018, 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, 2018. 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, 2018.

Our internal control over financial reporting as of December 31, 2018 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, 2018 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.

Table of Contents

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, 2018, 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, 2018, 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, 2018, and our report dated March 11, 2019 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

Westborough, Massachusetts

March 11, 2019

Item 9B. Other Information

Not Applicable.

Table of Contents

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 2019 definitive proxy statement (2019 Definitive Proxy Statement) for the 2019 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the fiscal year ended December 31, 2018.

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 “Section 16(a) Beneficial Ownership Reporting Compliance” in our 2019 Definitive Proxy Statement.

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 2019 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 2019 Definitive Proxy Statement.

Equity Compensation Plan Information

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2018. 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	1,680,470	$ 17.03	1,212,644
Equity compensation plans not approved by security holders	-	-	-
Total	1,680,470	$ 17.03	1,212,644

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 2019 Definitive Proxy Statement.

Table of Contents

Item 14. Principal Accounting 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 2019 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 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 Registrant and Applied Medical Resources Corporation	10-Q	11/2/2018	001-33092	
3.1	Amended and Restated By-laws of the Registrant	S-1/A	5/26/06	333-133532	
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	

Table of Contents

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
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	

53

Table of Contents

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	10-Q	8/3/2017	001-33092	
10.24†	Transition and Employment Agreement dated June 7, 2017 between Peter R. Gebauer and the Registrant	10-Q	8/3/2017	001-33092	
10.25†	Form of Restricted Stock Unit Award Agreement under the LeMaitre Vascular, Inc. 2006 Stock Option And Incentive Plan	10-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	5/4/2018	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

Table of Contents

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
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	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XRBL Taxonomy Extension Presentation Linkbase Document.				X

† 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.

Item 16. Form 10-K Summary.

Not applicable.

Table of Contents

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 11, 2019.

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	March 11, 2019

	Chairman of the Board *(Principal Executive Officer)*	
/s/ JOSEPH P. PELLEGRINO, JR. **Joseph P. Pellegrino, Jr.**	Chief Financial Officer *(Principal Financial and Accounting Officer)* and Director	March 11, 2019
/s/ LAWRENCE J. JASINSKI **Lawrence J. Jasinski**	Director	March 11, 2019
/s/ JOHN J. O'CONNOR **John J. O'Connor**	Director	March 11, 2019
/s/ DAVID B. ROBERTS **David B. Roberts**	President and Director	March 11, 2019
/s/ JOHN A. ROUSH **John A. Roush**	Director	March 11, 2019
/S/ MICHAEL H. THOMAS **Michael H. Thomas**	Director	March 11, 2019

Table of Contents

INDEX TO FINANCIAL STATEMENTS

	Page
LeMaitre Vascular, Inc.	
Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2018 and 2017	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2018, 2017 and 2016	F-5
Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2018, 2017 and 2016	F-6
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2018, 2017 and 2016	F-7
Consolidated Statements of Cash Flows for the Years Ended December 31, 2018, 2017 and 2016	F-10
Notes to Consolidated Financial Statements	F-11

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

LeMaitre Vascular, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of LeMaitre Vascular, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 20X2, 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 11, 2019 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 supporting 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.

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

/s/ GRANT THORNTON LLP

Westborough, Massachusetts

March 11, 2019

Table of Contents

LeMaitre Vascular, Inc.

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
	(in thousands, except share data)	
Assets		
Current assets:		
Cash and cash equivalents	$26,318	$19,096
Short-term marketable securities	21,668	22,564
Accounts receivable, net of allowances of $399 at December 31, 2018, and $349 at December 31, 2017	15,721	15,000
Inventory and other deferred costs	27,388	21,046
Prepaid expenses and other current assets	2,922	2,605
Total current assets	94,017	80,311
Property and equipment, net	14,102	12,378
Goodwill	29,868	23,844
Other intangibles, net	13,692	8,234
Deferred tax assets	1,215	1,378
Other assets	194	178
Total assets	$153,088	$126,323
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,732	$1,543
Accrued expenses	15,847	9,770
Acquisition-related obligations	2,179	1,876
Total current liabilities	19,758	13,189
Deferred tax liabilities	484	2,176
Other long-term liabilities	2,611	1,188
Total liabilities	22,853	16,553
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 21,110,224 shares at December 31, 2018, and 20,745,051 shares at December 31, 2017	211	207
Additional paid-in capital	98,442	93,127
Retained earnings	45,831	28,333
Accumulated other comprehensive loss	(3,900)	(2,289)
Treasury stock, at cost; 1,501,511 shares at December 31, 2018 and 1,480,101 shares at December 31, 2017	(10,349)	(9,608)

Total stockholders' equity	130,235	109,770
Total liabilities and stockholders' equity	$153,088	$126,323

See accompanying notes to consolidated financial statements.

Table of Contents

LeMaitre Vascular, Inc.

Consolidated Statements of Operations

	Year ended December 31,		
	2018	**2017**	**2016**
	(in thousands, except per share data)		
Net sales	$105,568	$100,867	$89,151
Cost of sales	31,629	30,170	26,215
Gross profit	73,939	70,697	62,936
Sales and marketing	27,318	25,948	26,105
General and administrative	17,689	17,010	14,354
Research and development	8,197	6,636	6,141
Gain on divestitures and acquisitions	(7,474)	-	-
Total operating expenses	45,730	49,594	46,600
Income from operations	28,209	21,103	16,336
Other income (expense):			
Interest income	631	179	81
Interest expense	(2)	(21)	(14)
Foreign currency loss	(394)	(155)	(161)
Income before income taxes	28,444	21,106	16,242
Provision for income taxes	5,501	3,929	5,652
Net income	$22,943	$17,177	$10,590
Earnings per share of common stock:			
Basic	$1.18	$0.91	$0.57
Diluted	$1.13	$0.86	$0.55
Weighted-average shares outstanding:			
Basic	19,426	18,961	18,485
Diluted	20,242	20,033	19,241
Cash dividends declared per common share	$0.28	$0.22	$0.18

See accompanying notes to consolidated financial statements.

F-4

Table of Contents

LeMaitre Vascular, Inc.

Consolidated Statements of Comprehensive Income

	Year ended December 31,		
	2018	**2017**	**2016**
	(in thousands)		
Net income	$22,943	$17,177	$10,590
Other comprehensive income (loss):			
Foreign currency translation adjustment, net	(1,626)	2,294	(534)
Unrealized gain (loss) on short-term marketable securities	15	-	-
Total other comprehensive income (loss)	(1,611)	2,294	(534)
Comprehensive income	$21,332	$19,471	$10,056

See accompanying notes to consolidated financial statements.

Table of Contents

LeMaitre Vascular, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

	Common Stock		Additional Paid-in	Retained	Accumulated Other Comprehensive	Treasury Stock		Total Stockholders'
	Shares	Amount	Capital	Earnings	Income (Loss)	Shares	Amount	Equity
Balance at December 31, 2015	19,748,321	$ 197	$ 82,094	$ 8,161	$ (4,049)	1,431,139	$ (8,519)	77,884
Net income				10,590				10,590
Other comprehensive income					(534)			(534)
Cummaltive effect adjustment to retained earnings			165	(93)				72
Issuance of common stock for stock options exercised	233,798	3	1,439					1,442
Vested restricted stock units	58,229							-
Stock-based compensation expense			1,680					1,680
Repurchase of common stock at cost						21,671	(311)	(311)
Common stock cash dividend paid				(3,323)				(3,323)
Balance at December 31, 2016	20,040,348	$ 200	$ 85,378	$ 15,335	$ (4,583)	1,452,810	$ (8,830)	$ 87,500
Net income				17,177				17,177
Other comprehensive income					2,294			2,294
Issuance of common stock for stock options exercised	635,503	7	5,493					5,500
Vested restricted stock units	69,190							-

Stock-based compensation expense			2,256					2,256
Repurchase of common stock at cost						27,291	(778)	(778)
Common stock cash dividend paid				(4,179)				(4,179)
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	3	2,966					2,969
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

See accompanying notes to consolidated financial statements.

Table of Contents

LeMaitre Vascular, Inc.

Consolidated Statements of Cash Flows

	Year ended December 31,		
	2018	**2017**	**2016**
	(in thousands)		
Operating activities			
Net income	$22,943	$17,177	$10,590
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	4,324	4,055	3,591
Stock-based compensation	2,349	2,256	1,680
Fair value adjustments to contingent consideration obligations	(29)	106	-
Provision for doubtful accounts and allowances	264	230	105
Provision for inventory write-downs	671	396	362
Provision (benefit) for deferred income taxes	(2,152)	300	140
Gain on acquisitions and divestitures	(7,474)	-	-
Foreign currency transaction gain	259	(29)	59
Changes in operating assets and liabilities:			
Accounts receivable	(1,283)	(1,507)	(922)
Inventory and other deferred costs	(4,262)	(1,352)	(134)
Prepaid expenses and other assets	(418)	(288)	1,528
Accounts payable and other liabilities	4,314	1,524	(103)
Net cash provided by operating activities	19,506	22,868	16,896
Investing activities			
Purchases of property and equipment	(3,054)	(6,417)	(2,841)
Payments related to acquisitions	(12,282)	-	(14,368)
Purchases of short-term marketable securities	(19,619)	(22,541)	-
Proceeds from sales of marketable securities	20,500	-	-
Proceeds from divestitures	7,400	-	-
Purchase of intellectual property	-	-	(2)
Net cash used in investing activities	(7,055)	(28,958)	(17,211)
Financing activities			
Payment of deferred acquisition consideration	(1,199)	(463)	(385)
Proceeds from issuance of common stock	2,969	5,500	1,442
Purchase of treasury stock	(741)	(778)	(311)
Common stock cash dividend paid	(5,445)	(4,179)	(3,323)
Net cash provided by (used in) financing activities	(4,416)	80	(2,577)
Effect of exchange rate changes on cash and cash equivalents	(813)	818	(271)
Net increase (decrease) in cash and cash equivalents	7,222	(5,192)	(3,163)
Cash and cash equivalents at beginning of year	19,096	24,288	27,451
Cash and cash equivalents at end of year	$26,318	$19,096	$24,288
Supplemental disclosures of cash flow information (see Note 13).			

See accompanying notes to consolidated financial statements.

Table of Contents

LeMaitre Vascular, Inc.

Notes to Consolidated Financial Statements

December 31, 2018

1. Significant Accounting Policies and Related Matters

Description of Business

Unless the context requires otherwise, references to 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, balloon catheters, biologic vascular grafts, biologic vascular patches, carotid shunts, polyester vascular grafts, powered phlebectomy devices, radiopaque marking tape, remote endarterectomy devices, surgical glue and valvulotomes. Our offices are located in Burlington, Massachusetts; Fox River Grove, Illinois; Vaughan, Canada; Sulzbach, Germany; Milan, Italy; Madrid, Spain; Saint-Etienne, France; North Melbourne, Australia; Tokyo, Japan; and 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 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 bad debts, inventory and other deferred costs, intangible assets, sales returns and discounts, and income taxes are reviewed on an ongoing basis and updated as appropriate. Actual results could differ from those estimates.

Revenue Recognition

Our revenue is derived primarily from the sale of disposable or implantable devices used during vascular surgery. We sell primarily directly to hospitals and to a lesser extent to 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.

On January 1, 2018 we adopted the provisions of ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*. We used the modified retrospective method of adoption under which the comparative information was not restated and will continue to be reported under the standard in effect for those periods. The adoption of this standard was not material to our financial statements and there was no cumulative effect adjustment to the opening balance of retained earnings required. 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

Table of Contents

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 recognize 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 Vascular 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,	
	2018	**2017**
Americas	$63,649	$62,696
Europe, Middle East and Africa	35,319	32,517
Asia/Pacific Rim	6,600	5,654
Total	$105,568	$100,867

Except as discussed in Note 6, 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.

Table of Contents

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,		
	2018	2017	2016
		(in thousands)	
Advertising expense	$299	$ 305	$378

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 $18.8 million as of December 31, 2018.

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, in Southern Europe, specifically Italy and Spain may be subject to significant payment delays due to government austerity measures impacting funding and payment practices. As of December 31, 2018 our receivables in Italy and Spain totaled $1.0 million and $0.7 million, respectively. Receivables balances with certain publicly-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, 2018, 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.

Table of Contents

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, 2018	$349	$ 264	$ 214	$ 399
Year ended December 31, 2017	258	230	139	349
Year ended December 31, 2016	243	105	90	258

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, 2018.

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 (in years)
Computers and equipment	3-5
Machinery and equipment	3-10
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.

Table of Contents

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, 2018, 2017 or 2016.

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.

Table of Contents

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, 2018, 2017 and 2016, we were not subject to any material litigation or claims and assessments.

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, 2018, 2017 or 2016.

Accumulated other comprehensive loss consisted primarily of foreign currency translation adjustment losses of $3.9 million and $2.3 million as of December 31, 2018 and 2017, 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.

Table of Contents

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

	Year ended December 31,		
	2018	2017	2016
	(in thousands, except per share data)		
Basic:			
Net income available for common stockholders	$22,943	$17,177	$10,590
Weighted average shares outstanding	19,426	18,961	18,485
Basic earnings per share	$1.18	$0.91	$0.57
Diluted:			
Net income available for common stockholders	$22,943	$17,177	$10,590
Weighted-average shares outstanding	19,426	18,961	18,485
Common stock equivalents, if dilutive	816	1,072	756
Shares used in computing diluted earnings per common share	20,242	20,033	19,241
Diluted earnings per share	$1.13	$0.86	$0.55
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	230	6	45

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU) 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40)*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The new standard is effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

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 is effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In February 2018, the FASB issued ASU 2018-02, *Income Statement – Reporting Other Comprehensive Income (Topic 220*), which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. Consequently, the amendments eliminate the stranded tax effects resulting from the Tax Cuts and Jobs Act and is expected to improve the usefulness of information reported to financial statement users. However, because the amendments only relate to the reclassification of the income tax effects of the Tax Cuts and Jobs Act, the underlying guidance that requires that the effect of a change in tax laws or rates be included in income from continuing operations is not affected. The amendments in this ASU also require certain disclosures about stranded tax effects. The new standard is effective for us beginning January 1, 2019, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In January 2017, the FASB issued ASU 2017-04, 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 is effective for us beginning January 1, 2020, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

Table of Contents

In February 2016, the FASB issued its new lease accounting guidance in ASU No. 2016-02, *Leases (Topic 842),* subsequently amended by ASU 2018-11, *Leases (Topic 842): Targeted Improvements*. Under the new guidance, lessees will be 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. Lessees will no longer be provided with a source of off-balance sheet financing. The new lease guidance also simplifies the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. The standard is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years (i.e., January 1, 2019, for a calendar year entity). Early application is permitted. Entities have the option of using either a modified retrospective approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, or else a transition option (which we currently expect to use) allowing lessees to not apply the new lease standard in comparative periods but instead recognize a cumulative-effect adjustment to retained earnings as of the date of adoption. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Lessees and lessors may not apply a full retrospective transition approach. Our assessment of the impact of adopting this standard is nearly complete, and included cataloging all of our leases, performing an analysis of the amounts of lease liabilities and right-of-use assets to be recorded and reviewing potential changes to our disclosures on leases. Based on this assessment we do not expect the adoption of this standard to have a significant impact on our consolidated statement of operations. However, we expect that the recognition of right-of-use assets and corresponding lease liabilities will have a significant impact on our consolidated balance sheet, adding between $6.1 million and $6.7 million to our total assets, and between $6.6 million and $7.2 million to our total liabilities, depending primarily on the discount rate selected.

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.

Cardial

On October 22, 2018, through a newly created subsidiary LeMaitre Cardial SAS, we entered into an agreement to acquire the business assets of Cardial, a company located in Saint-Etienne, France and formerly owned by Becton, Dickinson and Company. The Cardial business consists of the manufacturing of polyester vascular grafts, valvulotomes and surgical glue. On the same date, the parties entered into a separate agreement notarial deed under which LeMaitre Cardial SAS purchased the building and land previously owned by Cardial. Revenues from the acquisition date through December 31, 2018 were $1.1 million.

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) is due in two installments, half to be paid twelve months after the closing date, and half eighteen months after the closing date. There are no contingencies associated with these holdback payments, although they may be reduced depending upon the results of a reconciliation of the value of inventory transferred, as outlined in the agreement.

Table of Contents

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

	Allocated Fair Value (in thousands)	**Weighted Average Useful Life** (in years)
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 clot management business consists of several embolectomy and thrombectomy catheter product lines which are sold worldwide (approximately 60% in the U.S. and 40% outside the U.S.). On the same date, we entered into a transition services agreement under which Applied will manufacture and supply us with inventory for a period of twelve months, unless extended in writing by both parties. Revenues from the acquisition date through December 31, 2018 were $0.8 million.

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 million was paid at closing, with another $2 million due 12 months following the closing date, and the final $1.2 million due 24 months following the closing date. The deferred amounts totaling $3.2 million were recorded at an acquisition-date fair value of $3.043 million using a discount rate of 3.75% to reflect the time value of money between the acquisition date and the payment due dates.

Table of Contents

The following table summarizes the preliminary purchase price allocation:

	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 preliminary allocation of purchase consideration to the acquired intangible assets and related estimated useful lives:

	Allocated Fair Value (in thousands)	**Weighted Average Useful Life** (in years)
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 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

Table of Contents

Under the terms of the transition services agreement, we have 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 are sold to the buyer, we amortize 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 that will be retained.

RestoreFlow Allografts

On November 10, 2016, we entered into an agreement to acquire the assets of Restore Flow Allografts, LLC, a provider of human vascular tissue processing and cryopreservation services, for an initial purchase price of $12 million, with three additional payments of up to $2 million each ($6 million in total), depending upon the satisfaction of certain contingencies. One payment of $2 million was due not later than 15 days following the expiration of the 18 month period following the closing date, subject to reductions as specified in the agreement for each calendar month that certain retained employees were not employed by us due to resignation without good reason, or termination for cause, both as defined in the agreement. The portion of this payment that was to be paid to retained employees and that was contingent on their continued employment, estimated at $0.9 million, was being accounted for as post-combination compensation expense rather than purchase consideration. The remaining $1.1 million that was payable to non-employee investors but that was also contingent on the continued employment of the retained employees had been accounted for as contingent purchase consideration, at an acquisition-date fair value of $0.9 million. In May 2018 we paid this $2 million liability as the contingency was met.

There were also two potential earn-out payments under the agreement. The first earn-out was calculated at 50% of the amount by which net revenue in the first 12 months following the closing exceeded $6 million, with such payout not to exceed $2 million. The second earn-out was calculated at 50% of the amount by which net revenue in the second 12 months following the closing exceeded $9 million, with such payout not to exceed $2 million. These earn-outs were accounted for as contingent consideration, at an acquisition-date fair value of $0.1 million for the two earn-outs combined. This valuation was derived by utilizing an option pricing model technique incorporating, among other inputs, management’s forecasts of future revenues, the expected volatility of revenues, and an estimated weighted average cost of capital of 14.1% to account for the risk of achievement of the revenue forecasts as well as the time value of money between acquisition date and the payment date. These milestones were not met, and accordingly no amount was paid out.

The RestoreFlow business derives revenue from human tissue preservation services, in particular the processing and cryopreservation of veins and arteries. By federal law, human tissues cannot be bought or sold. Therefore, the tissues we obtain and preserve are not held as inventory, and the costs we incur to procure and process vascular tissues are instead accumulated and deferred. Revenues are recognized for the provision of cryopreservation services rather than product sales.

The acquired assets included intellectual property, permits and approvals, data and records, equipment and furnishings, accounts receivable, inventory, literature, and customer and supplier information. We also assumed certain accounts payable. We accounted for the acquisition as a business combination.

The following table summarizes the final purchase price allocation:

	Allocated Fair Value (in thousands)
Accounts receivable	$ 394
Deferred cryopreservation costs	2,583
Equipment and supplies	125
Accounts payable	(286)
Intangible assets	4,544
Goodwill	5,599
Purchase price	$ 12,959

The goodwill is deductible for tax purposes over 15 years.

Table of Contents

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

	Allocated Fair Value (in thousands)	Weighted Average Useful Life (in years)
Non-compete agreements	$ 180	5.0
Tradename	271	9.0
Procurement contracts	617	9.0
Technology	2,793	10.5
Customer relationships	683	12.5
Total intangible assets	$ 4,544	

The weighted-average amortization period of the acquired intangible assets was 10.3 years.

ProCol Biologic Graft

On March 18, 2016, we acquired the ProCol biologic vascular graft (“ProCol”) business for $2.7 million from Hancock Jaffe Laboratories, Inc. (HJL) and CryoLife, Inc. (CRY). HJL was the owner and manufacturer of ProCol and CRY was the exclusive distributor of the ProCol graft. CRY also owned an option to purchase the ProCol business, which we acquired from CRY. We bought finished goods inventory and other ProCol related assets from CRY for $2.0 million, which was paid in full at closing. We bought other ProCol assets from HJL for $0.7 million, 50% of which was paid at closing, with the remainder paid at subsequent dates as specified in the agreement. Additional consideration is payable to HJL for a three-year period following the closing, calculated at 10% of ProCol revenues. This additional consideration was initially valued at $0.3 million and is being re-measured each reporting period until the payment requirement ends, with any adjustments reported in income from operations. For the years ended December 31, 2018, 2017 and 2016, the amount of the adjustment was not material to our financial statements.

Assets acquired included inventory, intellectual property and a related license, the ProCol trade name, customer lists, non-compete agreements and certain equipment and supplies. We did not assume any liabilities. We accounted for the acquisition as a business combination.

The following table summarizes the purchase price allocation:

	Allocated Fair Value (in thousands)
Inventory	$ 2,080
Manufacturing equipment and supplies	25
Intangible assets	620
Goodwill	318
Purchase price	$ 3,043

The goodwill is deductible for tax purposes over 15 years.

Table of Contents

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

	Allocated Fair Value	Weighted Average Useful Life
	(in thousands)	(in years)
Non-compete agreement	$ 84	5.0
Tradename	109	9.5
Technology	277	9.0
Customer relationships	150	9.0
Total intangible assets	$ 620	

The weighted-average amortization period of the acquired intangible assets was 8.6 years.

3. Inventory and Other Deferred Costs

Inventory and other deferred costs consists of the following:

	December 31, 2018	December 31, 2017
	(in thousands)	
Raw materials	$4,085	$ 3,200
Work-in-process	5,095	3,745
Finished products	16,391	12,278
Other deferred costs	1,817	1,823

Total inventory and other deferred costs	$27,388	$ 21,046

We held inventory on consignment of $1.7 million and $1.4 million as of December 31, 2018 and 2017, respectively.

In connection with our acquisition of the 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.

Table of Contents

4. Property and Equipment

Property and equipment consists of the following:

	As of December 31,	
	2018	**2017**
	(in thousands)	
Computers and equipment	$4,077	$3,204
Machinery and equipment	13,718	12,223
Building and leasehold improvements	11,651	10,843
Gross property and equipment	29,446	26,270
Less accumulated depreciation	(15,344)	(13,892)
Property and equipment, net	$14,102	$12,378

During the years ended December 31, 2018, 2017 and 2016 we wrote off fully depreciated assets with gross values of $1.0 million, $0.2 million and $0.1 million, respectively.

Depreciation expense is as follows:

	Year ended December 31,		
	2018	2017	2016
		(in thousands)	
Depreciation expense	$2,564	$ 2,266	$1,986

5. Goodwill and Other Intangibles

Goodwill consists of the following:

	As of December 31,	
	2018	**2017**
Balance at beginning of year	$23,844	$23,426
Additions for acquisitions	6,361	-
Purchase accounting adjustments	-	257
Divestiture adjustment	(135)	
Effects of currency exchange	(202)	161
Balance at end of year	$29,868	$23,844

Table of Contents

Other intangibles consist of the following:

	December 31, 2018			December 31, 2017		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
	(in thousands)					
Product technology and intellectual property	$11,728	$ 5,726	$ 6,002	$10,267	$ 4,908	$ 5,359
Trademarks, tradenames and licenses	2,246	1,561	685	1,948	1,468	480
Customer relationships	10,065	3,806	6,259	5,383	3,299	2,084
Other intangible assets	2,145	1,399	746	1,575	1,264	311
Total identifiable intangible assets	$26,184	$ 12,492	$ 13,692	$19,173	$ 10,939	$ 8,234

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, 2018, is 9.5 years. Amortization expense is included in general and administrative expense and is as follows:

	Year ended December 31,		
	2018	2017	2016
		(in thousands)	
Amortization expense	$1,760	$ 1,790	$1,605

Estimated amortization expense for each of the next five fiscal years, based upon the intangible assets at December 31, 2018, is as follows

	Year ended December 31,				
	2019	2020	2021	2022	2023
	(in thousands)				
Amortization expense	$2,088	$1,839	$1,624	$1,420	$1,347

6. Accrued Expenses and Other Long-term Liabilities

Accrued expenses consist of the following:

	December 31, 2018	December 31, 2017
	(in thousands)	
Compensation and related taxes	$7,973	$ 6,494
Income and other taxes	2,927	703
Professional fees	43	35
Deferred revenue	552	-
Other	4,352	2,538
Total	$15,847	$ 9,770

Table of Contents

As discussed in Note 2 above, deferred revenue relates to our divestiture of the Reddick product line and an associated transition services agreement that we entered into contemporaneously with the divestiture, under which we agreed to manufacture and sell product to the buyer at prices at or below our cost. We allocated a portion of the consideration received from the divestiture to this transition services agreement to reflect it at fair value and recorded it as deferred revenue. As the products are sold to the buyer, which we expect will occur over approximately the next nine to twelve months, we amortize a portion of the deferred revenue to adjust the gross margin on the sale to fair value on a specific identification basis. The following table summarizes the changes in the deferred revenue balance during the year ended December 31, 2018:

	December 31, 2018 (in thousands)
Beginning contract liability balance	$ -
Deferred revenue recorded	1,081
Revenue recognized upon satisfaction of performance obligations in the period	(529)
Ending balance	$ 552

Other long-term liabilities consist of the following:

	December 31, 2018	**December 31, 2017**
	(in thousands)	
Acquisition-related liabilities	$1,326	$ 127
Deferred rent	530	561
Income taxes	559	321
Other	196	179
Total	$2,611	$ 1,188

7. Commitments and Contingencies

Leases

We conduct the majority of our operations in leased facilities, which are accounted for as operating leases. Certain leases include renewal options. We also lease automobiles under operating leases. There were no assets held under capital leases at December 31, 2018 and 2017.

Rent expense under all operating leases was as follows:

	Year ended December 31,		
	2018	2017	2016
		(in thousands)	
Rent expense	$2,090	$ 2,190	$1,580

At December 31, 2018, the minimum non-cancelable operating lease rental commitments with initial or remaining terms of more than one year, and outstanding inventory purchase commitments, are as follows:

Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
	(in thousands)				
Operating leases	$7,435	$1,826	$3,053	$2,556	$ -
Inventory purchase commitments	$2,195	$2,072	$123	$-	$ -

As part of our normal course of business, we have commitments to purchase $2.2 million of inventory through 2019. The purchase commitments for inventory are to be used in operations over the normal course of business and do not represent excess commitments or loss contracts.

Table of Contents

8. Income Taxes

Income (loss) before income taxes is as follows:

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
United States	$22,256	$17,778	$12,600
Foreign	6,188	3,328	3,642
Total	$28,444	$21,106	$16,242

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,		
	2018	2017	2016
		(in thousands)	
Current:			
Federal	$4,262	$ 2,451	$4,409
State	673	292	393
Foreign	2,718	886	710
	7,653	3,629	5,512
Deferred:			
Federal	(1,512)	(268)	197
State	(145)	390	166
Foreign	(495)	178	(223)
	(2,152)	300	140
Provision for income taxes	$5,501	$ 3,929	$5,652

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, 2018, the gross amount of unrecognized tax benefits exclusive of interest and penalties was $0.7 million, which may increase within the twelve months ending December 31, 2019. We remain subject to examination until the statute of limitations expires for each respective tax jurisdiction. The statute of limitations will be open with respect to these tax positions through 2026. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

	2018	**2017**	**2016**
	(in thousands)		
Unrecognized tax benefits at the beginning of year	$525	$390	$82
Additions for tax positions of current year	73	83	95
Additions for tax positions of prior years	113	57	213
Reductions for settlements with taxing authorities.	-	-	-
Reductions for lapses of the applicable statutes of limitations	-	(5)	-
Unrecognized tax benefits at the end of the year	$711	$525	$390

Table of Contents

Deferred taxes are attributable to the following temporary differences:

	As of December 31,	
	2018	2017
	(in thousands)	
Deferred tax assets:		
Inventory	$976	$569
Net operating loss carryforwards	1,421	1,898
Tax credit carryforwards	828	760
Capital loss carryforwards	279	1,168
Reserves and accruals	802	629
Intangible assets	2,737	1,138
Stock options	373	322
Other	91	65
Total deferred tax assets	7,507	6,549
Deferred tax liabilities:		
Property and equipment	(1,416)	(1,203)
Goodwill	(3,023)	(2,932)
Foreign branch deferred offset	(1,032)	(1,177)
Other	(50)	(44)
Total deferred tax liabilities	(5,521)	(5,356)
Net deferred tax assets before valuation allowance	1,986	1,193
Valuation allowance	(1,255)	(1,991)
Net deferred tax liabiltity	$731	$(798)
Deferred tax classification		
Long-term deferred tax asset	$1,215	$1,378
Long-term deferred tax liability	(484)	(2,176)
Net long-term deferred tax liability	$731	$(798)

We elected to adopt ASU 2016-09 during the third quarter of 2016. Consequently, we recorded excess tax benefits related to certain stock option exercises of $0.3 million, $3.7 million, and $1.1 million in 2016, 2017, and 2018 respectively.

In 2016, we released approximately $0.3 million of valuation allowances on deferred assets in Spain and Switzerland. Our 2016 assessment considered evidence such as current profitability, utilization of certain available tax assets and liabilities, and projected future earnings. Based on this evidence, we concluded that it was more likely than not that we would generate sufficient pre-tax income in future periods to utilize all of these deferred tax assets for which the valuation allowance was removed. In 2017, we increased our valuation by a net $0.2 million mainly attributable to Massachusetts credit carryforwards. In 2018, we decreased our valuation allowance by a net $0.7 million mainly attributable to Australian net operating loss and capital loss carry forwards that are now expected to be realized.

As of December 31, 2018, we have provided a valuation allowance of $1.3 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.

Table of Contents

As of December 31, 2018, we have net operating loss carryforwards in Australia of $1.3 million that do not expire, in France of $2.7 million that do not expire, in Spain of $0.9 million that do not expire, in Norway of $0.1 million that do not expire, in Italy of $33,000 that do not expire, and in Sweden of $4,000 that do not expire. We have a capital loss carryforward in Australia of $0.9 million that does not expire. We also have state tax credit carryforwards of approximately $1.4 million that are available to reduce future tax liabilities, which begin to expire in 2020, 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 federal statutory rate to our effective tax rate is as follows:

	2018	**2017**	**2016**
Federal statutory rate	21.0 %	35.0 %	35.0 %
State tax, net of federal benefit	1.4 %	1.7 %	1.3 %
Effect of foreign taxes	3.8 %	(0.6%)	(1.9%)
Federal tax on foreign income	1.4 %	1.7 %	1.6 %
Valuation allowance	(3.2%)	0.1 %	(2.6%)
Foreign deferred tax liability offset	(0.3%)	(0.2%)	1.5 %
Manufacturing deduction	0.0 %	(1.5%)	(2.5%)
Research & development tax credits	(0.7%)	(0.6%)	(0.7%)
Stock options	(3.3%)	(15.8%)	(0.7%)
Uncertain tax positions	0.8 %	0.6 %	2.0 %
Other permanent differences	(0.7%)	1.0 %	1.2 %
Change in tax laws	0.0 %	2.9 %	0.0 %
Deferred tax remeasurement	0.0 %	(5.0%)	0.0 %
Other	(0.9%)	(0.7%)	0.5 %
Effective tax rate	19.3 %	18.6 %	34.8 %

In 2016 the Internal Revenue Service completed an audit of our 2013 and 2014 U.S. federal tax returns. As a result of the audit we paid $0.2 million in additional federal income taxes. Additionally, the adjustment settled on for this audit resulted in an additional $0.2 million increase to our uncertain tax provisions for a state carryforward. In August 2018, the German tax authority commenced an audit of our German subsidiary for the tax years 2013 through 2016. While it is difficult to predict the final outcome or timing of the resolution of this audit, at this time we believe there will be no material changes to our German Subsidiary’s income tax liability as a result of the audit. We are not currently under

audit in any other tax jurisdictions.

As of December 31, 2018, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions are:

United States	2015 and forward
Foreign	2011 and forward

Table of Contents

9. 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 1,212,644 remain available for grant as of December 31, 2018.

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

	2018	2017	2016

Dividend yield	1.2 %	0.7 %	1.3 %
Volatility	41.3%	39.1 %	34.5%
Risk-free interest rate	2.7 %	2.2 %	1.2 %
Weighted average expected option term (in years)	4.8	4.6	5.5
Weighted average fair value per share of options granted	$8.28	$10.37	$4.04

A summary of option activity as of December 31, 2018 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, 2017 (1)	1,536,282	$ 13.86	4.15	$27,771,635
Granted	280,423	$ 23.56		
Exercised (2)	(303,379)	$ 9.79		$7,196,175
Canceled / Expired	(50,751)	$ 13.79		
Balance outstanding at December 31, 2018 (3)	1,462,575	$ 16.41	4.54	$12,214,422
Vested and exercisable at December 31, 2018 (4)	504,988	$ 11.51	2.65	$6,482,151
Expected to vest at December 31, 2018	957,587	$ 18.99	5.54	
Total	1,462,575			

(1) The aggregate intrinsic value represents the difference between the exercise price and $31.84, the closing price of our stock on December 31, 2017, 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 $23.64, the closing price of our stock on December 31, 2018, for all in-the-money options outstanding.

(4) The aggregate intrinsic value represents the difference between the exercise price and $23.64, the closing price of our stock on December 31, 2018, for all in-the-money options vested and exercisable as of that date.

Table of Contents

Restricted Stock Units

A summary of our RSU activity is as follows:

	Shares	Weighted Average Grant Date Fair Value
Balance outstanding at December 31, 2017	216,750	$ 18.10
Granted	87,088	$ 23.65
Vested (1)	(63,478)	$ 15.11
Canceled	(22,465)	$ 17.75
Balance outstanding at December 31, 2018	217,895	$ 21.21

(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 2018, 2017, and 2016 were $1.9 million, $1.9 million, and $0.8 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:

	2018	2017
Shares of common stock repurchased	21,410	27,291
Average per share repurchase price	$34.62	$28.51
Aggregage purchase price (in thousands)	$741	$778

Table of Contents

Stock-based Compensation

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

	2018	2017	2016
	(in thousands)		
Stock option awards	$1,457	$1,612	$1,116
Restricted stock units	892	644	564
Total stock-based compensation	$2,349	$2,256	$1,680

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

	2018	2017	2016
	(in thousands)		
Cost of sales	$272	$188	$175
Sales and marketing	529	403	373
General and administrative	1,293	1,484	983
Research and development	255	181	149
Total stock-based compensation	$2,349	$2,256	$1,680

General and administrative stock-based compensation expense for 2017 included a charge of $0.5 million related to a stock option modification associated with the departure of our President of International Operations.

We expect to record the unamortized portion of share-based compensation expense of $9.7 million for existing stock options and RSUs outstanding at December 31, 2018, over a weighted-average period of 3.8 years.

Stock Repurchase Plans

On July 25, 2017, our Board of Directors approved a stock repurchase program under which the Company was authorized to repurchase up to $7.5 million of its common stock. This program expired on July 25, 2018. We did not make any repurchases under this program.

On February 14, 2019, our Board of Directors authorized the repurchase of up to $10.0mm of the Company’s common stock through transactions on the open market, in privately negotiated purchases or otherwise. The repurchase program may be suspended or discontinued at any time and will conclude on February 14, 2020, unless extended by the Board.

Table of Contents

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 2018			
March 22, 2018	April 5, 2018	$ 0.070	$ 1,351
May 22, 2018	June 7, 2018	$ 0.070	$ 1,353
August 22, 2018	September 6, 2018	$ 0.070	$ 1,369
November 20, 2018	December 6, 2018	$ 0.070	$ 1,372
Fiscal Year 2017			
March 22, 2017	April 6, 2017	$ 0.055	$ 1,029
May 24, 2017	June 8, 2017	$ 0.055	$ 1,036
August 23, 2017	September 6, 2017	$ 0.055	$ 1,055
November 22, 2017	December 7, 2017	$ 0.055	$ 1,060

On February 14, 2019, our Board of Directors approved a quarterly cash dividend on our common stock of $0.085 per share payable on April 5, 2019, to stockholders of record at the close of business on March 22, 2019, which will total approximately $1.7 million in payments.

10. 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 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, $0.2 million and $0.1 million for 2018, 2017 and 2016, respectively.

11. 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, Australia and France. Net sales to unaffiliated customers by country were as follows:

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
United States	$59,078	$58,470	$50,439
Germany	12,445	11,576	10,350
Other countries	34,045	30,821	28,362
Net sales	$105,568	$100,867	$89,151

Table of Contents

Total property and equipment held by geography were as follows:

	As of December 31,	
	2018	2017
	(in thousands)	
United States	$11,006	$10,275
Australia	1,460	1,639
France	1,071	-
Germany	430	369
Other countries	135	95
Total property and equipment	$14,102	$12,378

12. Supplemental Cash Flow Information

Supplemental disclosures of cash flow information are as follows:

	Year ended December 31,		
	2018	2017	2016
	(in thousands)		
Cash paid for income taxes, net	$5,521	$3,146	$4,231

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, 2018 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, 2018.

Table of Contents

As discussed in Notes 1 and 2, several of our acquisition-related assets and liabilities were measured using Level 3 techniques. During 2016, we recorded contingent liabilities associated with our acquisitions of the RestoreFlow allograft and ProCol biologic graft businesses. In the case of the Restore Flow allograft acquisition, the agreement included the potential for us to pay up to $5.1 million of additional consideration, with $1.1 million contingent on the continued employment by LeMaitre Vascular of certain retained employees, and another $4.0 million contingent on the achievement of specified levels of revenues in the first 12 and 24 months following the acquisition date. This additional consideration was initially valued in total at $1.0 million and was being re-measured each reporting period until the payment requirement ended, with any adjustments reported in income from operations. The first portion related to continued employment by LeMaitre Vascular of retained individuals was paid during 2018. The amount attributable to achieving specified levels of revenue following the acquisition date was not paid as the associated revenue metrics were not achieved. In the case of ProCol, additional consideration is payable to the former shareholders for a three-year period following the closing, calculated at 10% of ProCol revenues. This additional consideration was initially valued at $0.3 million and is being re-measured each reporting period until the payment requirement ends, with any adjustments reported in income from operations. These arrangements are described more fully in Note 2. 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 these acquired businesses, as well as, in the case of the Restore Flow allograft acquisition, management's estimate of the likelihood of continued employment of certain retained employees.

	Year ended December 31,		
	2018	**2017**	**2016**
	(in thousands)		
Beginning balance	$1,300	$1,320	$-
Additions	-	-	1,301
Payments	(1,199)	(126)	(68)
Change in fair value included in earnings	(29)	106	87
Ending balance	$72	$1,300	$1,320

14. Quarterly Financial Data (unaudited)

2018	**Three months ended**			
	March 31	**June 30**	**September 30**	**December 31**
	(in thousands, except per share data)			
Total net sales	$25,994	$27,020	$ 24,165	$ 28,389
Gross profit	18,474	18,992	17,255	19,218

Income (loss) from operations	4,862	11,541	4,613	7,193
Net income	3,853	8,751	4,314	6,025
Earnings per share				
Basic	$0.20	$0.45	$ 0.22	$ 0.31
Diluted	$0.19	$0.43	$ 0.21	$ 0.30

	Three months ended			
2017	**March 31**	**June 30**	**September 30**	**December 31**
	(in thousands, except per share data)			
Total net sales	$24,139	$25,753	$ 24,822	$ 26,153
Gross profit	17,353	17,516	17,577	18,251
Income (loss) from operations	4,193	5,536	5,053	6,321
Net income (loss)	3,219	4,632	5,042	4,284
Earnings per share				
Basic	$0.17	$0.25	$ 0.26	$ 0.22
Diluted	$0.16	$0.23	$ 0.25	$ 0.21

15. Accumulated Other Comprehensive Income (Loss)

	Year ended December 31,		
	2018	**2017**	**2016**
	(in thousands)		
Beginning balance	$(2,289)	$(4,583)	$(4,049)
Other comprehensive income (loss) before reclassifications	(1,611)	$- 2,294	(534)
Amounts reclassified from accumulated other comprehensive loss	-	-	-
Ending Balance	$(3,900)	$(2,289)	$(4,583)

Changes to our accumulated other comprehensive loss consisted primarily of foreign currency translation for the years ended December 31, 2018, 2017 and 2016.