LEMAITRE VASCULAR INC
Form 10-K
March 09, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer (Do not check if a small reporting company) Smaller reporting company

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, 2016: $180,617,111. For purposes of this calculation, shares held by stockholders whose ownership exceeded 5% of the registrant s common stock outstanding were deemed to be held by affiliates. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant. At March 2, 2017, the registrant had 18,670,632 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.

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LEMAITRE VASCULAR

2016 ANNUAL REPORT ON FORM 10-K

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. 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, will, would, and similar expressions are intended to identify forward-looking statements, althou 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. 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. 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, EndoRE, Expandable LeMaitre Valvulotome, Glow N Tell, Inahara-Pruitt, InvisiGrip, LeverEdge, LifeSpan, MollRing Cutter, MultiTASC, Omniflow, Pruitt, Pruitt F3, Pruitt-Inahara, Reddick, VascuTape, TRIVEX, XenoSure, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular or one of its subsidiaries, and AlboSure, Flexcel, Periscope, RestoreFlow 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 HYDRO Expandable LeMaitre Valvulotome, the XenoSure biologic patch, the Pruitt F3 Carotid Shunt and VascuTape Radiopaque Tape. 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 which our core product lines address is approximately $840 million.

We sell our products and services primarily through a direct sales force. As of December 31, 2016 our sales force was comprised of 96 sales representatives in North America, Europe, Japan, China and Australia. We also sell our products in other geographies through distributors. Our worldwide headquarters is located in Burlington,

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Massachusetts. Our international operations are headquartered in Sulzbach, Germany. We also have sales offices located in Tokyo, Japan; Mississauga, Canada; Madrid, Spain; Milan, Italy; Shanghai, China; and North Melbourne, Australia. In 2016, approximately 92% of our net sales were generated in territories in which we employ direct sales representatives.

The Peripheral Vascular Disease Market

Based on industry statistics, we estimate that peripheral vascular disease affects more than 20 million people worldwide and that the annual worldwide market for all peripheral vascular devices is approximately $4 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 prescribing higher-priced endovascular devices, and the adoption of western healthcare standards by the developing world. 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.

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.

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 2,500 board-certified vascular surgeons and several thousand general surgeons who perform vascular procedures in the United States, and that there are 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 conventional open vascular surgeries and endovascular procedures. Conventional 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 technologies. We estimate that in 2016, 86% 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 2016 approximately 75% of our sales were to this type of customer. In contrast to other medical specialists, such as interventional cardiologists and interventional radiologists, vascular surgeons are uniquely positioned to be able to perform both conventional open vascular surgeries as well as minimally invasive endovascular procedures. We believe that this presents our core customer with an opportunity to gain procedural market share against competing specialists, while offering us the ability to 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 our larger competitors who may have greater resources than we do, as well as the differentiated features

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and consistent quality of our products, allow for us to establish both higher selling prices and market share gains in these markets. In recent years we have also sought to sell complementary offerings such as the Omniflow biosynthetic graft or the RestoreFlow human tissue cryopreservation services, in larger, more competitive market segments, particularly when we believe that our offerings in those segments are highly differentiated.

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 96 direct sales representatives. 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 also sell our products through distributors. For the year ended December 31, 2016, however, approximately 92% 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 significant 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.

Acquisition History

We were founded in 1983 by George D. LeMaitre, M.D., a vascular surgeon who designed and developed the predecessor to our 1.5mm HYDRO LeMaitre Valvulotome. Through a combination of strategic acquisitions and research and development efforts, we have expanded to 15 product lines.

We have completed 19 acquisitions of complementary products since 1998:

Year	Acquisition	Key Product(s) and Services
1998	Whittaker Screen Printing	Radiopaque tape manufacturing operations
1999	Vermed	Balloon catheters
2001	Ideas for Medicine	Carotid shunts, balloon catheters, and laparoscopic cholecystectomy devices
2003	Credent	Polycarbonate grafts
2004	VCS Clip	Vessel 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	Tru-Incise (for sale outside of the US)	Valvulotomes
2016	ProCol	Biologic vascular graft
2016	RestoreFlow Allografts	Human tissue cryopreservation services

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With the exception of the remote endarterectomy devices, powered phlebectomy systems, the Tru-Incise valvulotome, cryopreserved allograft services, biosynthetic grafts and our ProCol biologic vascular grafts, we have relocated the manufacturing operations associated with our 19 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.

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Our Products and Services

We have a portfolio of 15 product lines, 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, lower extremities, upper extremities, aorta and other areas. In 2016, the lower extremities product lines and services were 51% of revenues, the carotid product lines comprised 31% of our revenues, and other areas combined were 18%. In 2015, the lower extremities product lines were 53% of revenues while the carotid product lines were 29%. In 2014, the lower extremities were 51% of revenues while the carotid product lines were 28%. The average selling price of valvulotomes, which are included in our lower extremities product lines, increased significantly in 2015 with the introduction of our 1.5mm HYDRO LeMaitre Valvulotome. No single product line accounted for more than 25% of our revenues in 2016, 2015 or 2014.

Of our 15 product offerings, three 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 biosynthetic graft (ovine tissue and synthetic mesh) and the RestoreFlow Allograft cryopreserved graft (human tissue). As a percentage of sales, these product lines represented 27% in 2016, 21% in 2015 and 15% in 2014.

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, Occlusion and Perfusion

Our LeMaitre line of embolectomy catheters are used to remove blood clots from arteries or veins. We manufacture single-lumen latex and latex-free embolectomy catheters as well as dual-lumen latex embolectomy catheters. The dual-lumen embolectomy catheter allows clot removal and simultaneous irrigation or guide-wire trackability. 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-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 and Inahara-Pruitt, 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 Devices

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.

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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 1.5mm HYDRO LeMaitre Valvulotomes, Over-The-Wire LeMaitre Valvulotomes, Tru-Incise valvulotomes, and LeMills Valvulotomes cut valves 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 less invasive 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.

Vascular Grafts

Our AlboGraft woven and knitted 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. They are 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 recently acquired RestoreFlow allograft business, we provide human tissue cryopreservation services, in particular the processing and cryopreservation of peripheral vascular 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 variety of vascular reconstructions such as peripheral bypass, hemodialysis access, and aortic infections. Currently they are only available for distribution in the United States.

Vascular Patches

Our XenoSure Biologic Vascular Patch is made from bovine pericardium, and is used for precision endarterectomy vascular reconstruction.

Our AlboSure Vascular Patch is a polyester patch. Vascular surgeons use patches in conjunction with carotid endarterectomy, femoral endarterectomy, and other vascular reconstructions.

Vessel Closure Systems

Our AnastoClip AC and AnastoClip GC vessel closure systems attach vessels to one another with titanium clips instead of sutures. These vessel closure systems create an interrupted anastomosis which expands and contracts

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as the vessel pulses, which surgeons believe improves the durability of the anastomosis. The AnastoClip AC closure system also facilitates compliant dura closure in neuro applications. Surgeons believe it does not penetrate the dura, which eliminates cerebrospinal fluid leakage from suture holes allowing for reduced operating room time.

Other Products

In some hospitals, vascular surgery procedures are sometimes performed by general surgeons. We also sell general surgery devices, primarily laparoscopic cholecystectomy devices. Our leading general surgery product is the Reddick Cholangiogram Catheter, which is used to inject dye into the cystic duct during laparoscopic cholecystectomy. In this procedure, the gall bladder is dissected and removed through small punctures in the abdomen. We also offer a laparoscopic accessory used in laparoscopic gall bladder removal.

Sales and Marketing

As of December 31, 2016, we employed 96 field sales representatives. We believe that the expansion of our direct sales force since 1998 has been a key factor in our success, and it remains one of our primary long-term strategies.

Outside our direct markets, we generally sell our products through country-specific distributors. We typically sign exclusive distribution agreements with distributors for terms of up to five years, frequently specifying minimum annual sales volumes and pricing. These agreements are renewable by mutual agreement between us and the distributor. From time to time, when we determine that it would be financially advantageous for us to sell directly in a country, we terminate our distributor(s) in that country. In August 2015, we agreed to terminate our agreement with a distributor in Finland in order to begin selling direct-to-hospital in Finland as of January 1, 2016. In December 2015, we signed a master distribution agreement with Meheco Yonstron Pharmaceutical Co. Ltd., a Chinese distribution and logistics company, and began selling our Chinese market products to Meheco in 2016. Meheco then sells to multiple sub-distributors who then sell our products to Chinese hospitals.

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 and continued success. We believe that direct marketing allows us to market to vascular surgeons beyond the reach of our direct sales force.

We also provide training to medical professionals as means of promoting our products. We aim to add value to our vascular surgeon customers by providing training opportunities on specific vascular surgery procedures including, among others, in situ bypass, 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 and are largely improvements to our existing devices. In 2016, our efforts were focused on expanding and enhancing our biologic product lines including Xenosure and Omniflow, as well as integrating newly acquired product lines. We continued work begun in 2015 on the development of a shunt flow monitor and furthered our efforts around approval of our elongated anastoclip device for neurosurgery in various geographies. We also made design changes to our powered phlebectomy device product line.

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 procedures 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.

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For 2016, 2015 and 2014, our research and development expenditures were $6.1 million, $5.5 million, and $4.7 million, respectively, representing 7% of net sales in each of the three years. As of December 31, 2016, our research and development staff consisted of 14 full-time engineers and technicians.

Manufacturing and Processing

Our 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, and Fox River Grove, Illinois where RestoreFlow allografts are processed, cryopreserved, stored and distributed.

Following the acquisition of new product lines, we typically integrate manufacturing of the newly acquired lines into our Burlington operations. In 2014 we fully transitioned XenoSure production to our Burlington facility, and we also transferred the manufacturing of the Clinical Instruments devices, which we acquired in 2013, to our Burlington facility. Our TRIVEX, EndoRE, Tru-Incise valvulotome and ProCol biologic graft products are currently manufactured by third parties; however, we expect to complete the transition of manufacturing the Tru-Incise valvulotome to our Burlington facility during 2017 and we expect the transition of manufacturing the ProCol biologic graft products to be complete in 2018, subject to regulatory approval. In addition, we expect to complete the renovation of our manufacturing facility in Burlington in 2017, in which we expect most of our biologic product lines will be produced or processed.

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 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 material disruption in the adequate supply from existing sources of product and components, but there is no guarantee that we will not experience such disruptions in the future.

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Our Burlington and North Melbourne manufacturing facilities have been certified to ISO 13485:2003 quality management system standards, which enables us to satisfy certain regulatory requirements of the European Union, 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 February 2013, our Burlington facilities were audited by the U.S. Food and Drug Administration (FDA), and in November 2014, and July and November 2015, we underwent inspections by our European Notified Body. In February 2016, our Fox River Grove facility was inspected by the FDA. The results of these inspections were satisfactory.

Competition

The segments in which our product lines compete are characterized by 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 Applied Medical Resources Corporation, Baxter International, Inc., Boston Scientific Corporation, Cardiovascular Systems, Inc., Medtronic, C.R. Bard, Inc., 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, obtain patent or other product protections and attract 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 procedures. Our ability to compete effectively with our competitors 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 dacron and ePTFE 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 from 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 us.

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 and pursue 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.

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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 European Union. However, depending on circumstances, we may not apply for patents in all or any of those jurisdictions, or we may pursue patent protection elsewhere.

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 products pursuant to licenses with third-parties.

We believe that our strong brands have been an important factor in our success. We rely on common law and registered trademarks to protect our product brands. Some of our registered trademarks are LeMaitre, XenoSure, Pruitt, VascuTape, Glow N Tell, and Reddick, each of which is registered in the United States and the European Union, and in certain cases in other foreign countries.

We rely on trade secret protection for certain unpatented aspects of other proprietary technology. Many 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 ProCol vascular graft. In the past, other companies have independently developed or otherwise acquired comparable or substantially equivalent proprietary information and techniques, and there can be no assurance that others will not do so in the future 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.

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

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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. 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.

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

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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 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. Our most recent FDA inspection was in February 2013, 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.

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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 manufacture 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 is 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 2016 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, 2018. The AATB is entitled to inspect accredited members at any time. The AATB most recently inspected our Fox River Grove, Illinois facility in January 2015, and the results of that inspection 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 vascular 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

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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 European Union 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 European Union, as well as Iceland, Lichtenstein, Norway, and Switzerland. Each member state of the European Union has implemented the directives into its respective national law and has each established a Competent Authority to apply the directive in its territory.

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 European Union is generally required in order for a manufacturer to commercially distribute the product throughout the European Union. 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 European Union 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 European Union.

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

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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, which are typically processed relatively quickly. Higher classification risk devices (Class III and IV) require filing of dossiers that resemble US 510(k) applications. These applications can range in cost and typically take longer for approval.

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.

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. Australia requires all foreign manufacturers to have an in country sponsor who must have a licensed business inside of Australia. After the formation of our Australian subsidiary in 2013, we transferred out licenses from our third-party license holders to our subsidiary.

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 (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. As of December 31, 2016, CFDA licenses are valid for five years from date of issuance and require renewal prior to expiration. 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

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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.

In addition, particularly in concert with the Patient Protection and Affordable Care Act, 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.

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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). In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed. While the future of PPACA is uncertain as of the date of the filing of this Annual Report due to the Budget Resolution and President Trump s executive order, we continue to comply with its requirements. For example, we continue to comply with 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 and may continue to do so regardless of the repeal or replacement the PPACA.

Employees

We had 397 employees, including 380 full-time employees, at December 31, 2016.

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 is included in Note 12 to our Consolidated Financial Statements which are included elsewhere in this Annual Report.

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 2016.

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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. You may also read and copy any materials filed with the Commission at the SEC s Public Reference Room at 100 F Street, NE., Washington, DC 20549, on official business days during the hours of 10 a.m. to 3 p.m. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. 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

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 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;

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;

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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;

our determination whether or not to continue the payment of quarterly cash dividends;

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 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 an indication of our future performance.

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, 2016, 2015 and 2014, 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 associated with the increase in the number of our sales personnel in 2016, 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 expenditures;

market acceptance of our new products and services;

the productivity of our direct sales force and distributors;

fluctuations in foreign currency exchange rates;

our ability to successfully build direct sales organizations in new markets;

our ability to successfully acquire and develop competitive products;

our ability to successfully integrate acquired businesses, products, services or technologies;

the impact on our business of competing products, technologies, and procedures;

our ability to obtain or maintain regulatory approvals for our products in new and existing markets;

the cost of litigation, if any; and

changes in tax laws.

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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 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.

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.

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 of 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.

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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 19 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;
- 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;
- challenges in complying with new regulatory requirements to which we were not previously subject;
- increased regulatory scrutiny;
- 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;
- 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 acquisition costs, which would be senior to our common stock and would require interest payments to a lender.

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.

For instance, in August 2014, we acquired all of the capital stock of Xenotis Pty Ltd, the parent company of Bio Nova International, which was the manufacturer of our Omniflow II biosynthetic vascular graft. Bio Nova s operations are located in North Melbourne, Australia, and we currently expect to continue operations in Australia for the foreseeable future. Our ability to manage these operations efficiently and effectively may be impaired due to their distance from our Burlington, Massachusetts headquarters.

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In 2014 and 2015, we acquired two product lines for which we have since then been transitioning manufacturing to our Burlington facility. We expect to complete the transfer of manufacturing of these product lines to Burlington in 2017; however there can be no assurances that this will be achieved on the expected timetable or that transfer costs will not exceed our expectations.

In 2016, we acquired the ProCol vascular graft, which continues to be manufactured by the company from which we acquired the device. While we currently rely on the former owners to continue to supply product to us, we have initiated the transfer of manufacturing in 2016, and we expect it to be complete in 2018, subject to regulatory approval.

We also acquired the processing, preservation and distribution operations of RestoreFlow allografts in 2016, and we intend to continue conducting such operations at our Fox Rover Grove, Illinois facility. 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 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 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

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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, and the ProCol vascular graft continues to be manufactured by the company from which we acquired the device.

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 may 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 several 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 revenues from allografts 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 three adjacent leased facilities located in Burlington, Massachusetts. We also have a manufacturing site in North Melbourne, Australia and a tissue processing and preservation facility in Fox River Grove, Illinois. These facilities and the manufacturing equipment we use to produce 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.

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

Our AlboGraft vascular graft, AlboSure vascular patch, XenoSure biologic patch and ProCol vascular graft products contain bovine tissue or material derived from bovine tissue, and our Omniflow II Biosynthetic Vascular Graft contains ovine tissue. 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.

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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, and we believe will continue to dedicate, 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, 2016, 2015 and 2014, 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 1.5mm HYDRO 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 in the vascular surgery device marketplace to implement price increases. We implemented a significant price increase in 2015 for our 1.5mm HYDRO 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 pendency of the recall. If we are unable to retain those customers, then our XenoSure biologic patch sales could be lower than expected.

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;

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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, 2016, 44% of our net sales were derived from our 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 under President Trump or otherwise;

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;

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difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

difficulties in enforcing or defending intellectual property rights;

exposure to different legal and political standards; and

political, economic, and/or social instability.

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

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

If our products or the tissue we process 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. 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 and harm our business. The fact that we operate in international markets also increases the risk that we may face legal exposures as we seek to comply with a large number of varying legal and regulatory requirements. If any such proceedings were to result in an unfavorable outcome, it could adversely affect our business, financial condition and results of operations.

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

We have a history of converting international distributor sales to direct-to-hospital sales by buying out our foreign distributor agreements and selling directly to hospitals through our own established sales representatives. In the future, we may elect to convert select additional countries and products from distributor sales to direct 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 from operations because distributors, unlike direct sales personnel, 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.

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Our distribution agreements are typically exclusive 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 sales 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-sales model in any country in question. It 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 meet regulatory requirements that were previously the responsibility of the distributor. 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 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, 2016, 44% of our net sales were derived from our operations outside of the United States. 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 local currency. Additionally, transactions denominated in currencies other than the functional currency may result in gains and losses 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

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government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. Federal and state laws are also sometimes open to interpretation, and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

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

The production and marketing of our products and services and our ongoing research and development are subject to extensive regulation and review by numerous governmental authorities both in the 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 from three to twelve months from the date the FDA receives the application, but may take significantly longer. Although 510(k) clearances have been obtained for nearly all of our current products that require 510(k) 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 marketed 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 even longer. Achieving premarket approval typically requires extensive clinical trials and may require the filing of numerous amendments with the FDA over time. We do not have significant experience in obtaining PMA approval for our products.

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

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

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with all regulatory requirements. If the FDA finds that we have failed to comply with any regulatory requirements, it can institute a wide variety of enforcement actions.

We and some of our suppliers must comply with the FDA s Quality System Regulation, which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage, and shipping of medical devices. Our Fox River Grove operations must comply with the FDA s current Good Tissue Practices, which are the FDA regulatory requirements for the processing of human tissue. The FDA enforces its regulations through pre-announced and unannounced inspections. We have been, and anticipate in the future being, subject to such inspections by the FDA and other regulatory bodies. The timing and scope of future audits is unknown and it is possible, despite our belief that our quality systems and the operation of our manufacturing facilities will remain in compliance with U.S, and non-U.S. regulatory requirements, that a future audit may result in one or more unsatisfactory results. If we or one of our suppliers fails an inspection, or if a corrective action plan adopted by us or one of our suppliers is not sufficient, the FDA may bring an enforcement action against us, and our operations could be disrupted and our manufacturing delayed.

We are also subject to the FDA s general prohibition against promoting our products for unapproved or off-label uses and to the medical device reporting, or MDR, 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

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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 European Union, 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 HYDRO LeMaitre valvulotome due to an issue with the product s closure mechanism. We were able to address the issue and we believe the recall, affecting approximately 5,500 units, will be substantially complete by June 30, 2017. While the affected lots remain on recall, we have continued to sell unaffected lots and we believe that we will be able to rework returned valvulotomes at minimal expense. In February 2017, we voluntarily recalled certain lots of our Reddick cholangiogram catheter due to a labeling issue. We are able to fix the labeling issue by placing additional stickers on the affected product, and we believe the recall will be substantially complete by June 30, 2017. While we have taken corrective action 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.

The adoption of healthcare reform in the United States may adversely affect our business, results of operations and/or financial condition.

In March 2010, significant reforms to the U.S. healthcare system were adopted in the form of the Patient Protection and Affordable Care Act (PPACA). The PPACA included provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes (including the medical device excise tax in effect in 2013, 2014 and 2015). While the requirement that the medical device industry subsidize healthcare reform in the form of a 2.3% excise tax on U.S. sales of most medical devices was suspended for 2016 and 2017, there is no guarantee that the moratorium will be approved for subsequent years. In 2015, we paid an excise tax of approximately $0.7 million.

In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the PPACA that are repealed.

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Various healthcare reform proposals have also emerged at the state level. The PPACA and these proposals could reduce medical procedure volumes and impact the demand for our products or the prices at which we sell our products. In addition, the excise tax increases our cost of doing business. While the future of PPACA is uncertain due to the Budget Resolution and President Trump s executive order, the impact of the PPACA, or any replacement plan, and these proposals, as well as new state-level proposals in reaction to the executive order, could harm our operating results and liquidity.

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.

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.

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 non-U.S. 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.

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Our products are regulated in the European Union under the European Medical Devices Directive (93/42/EC as amended by 2007/47/EC). In order to market our medical devices in the European Union, 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, there can be no assurance that we will be able to obtain a CE mark for new products in the future or for modifications to our existing products or in the manufacturing of our products, and obtaining a CE mark 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.

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 European Union 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 European Union, and would require significant delays in obtaining individual country approvals. If we do not receive or maintain these approvals, our business could be harmed.

Our manufacturing facilities are subject to periodic inspection by European regulatory authorities and Notified Bodies, and we must demonstrate compliance with the Medical Devices Directive. Our most recent inspections by our European Notified Bodies were conducted in July and November 2015. Any failure by us to comply with European 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 on most new products in China. Any delay in product registrations could have a negative impact on our results of operations.

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 patents, 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.

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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, our 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.

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 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.

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It is also possible that one of our competitors could claim that our manufacturing process violates an existing patent. 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 with 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 with a third party patent holder that covers a product we offer, 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 your 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. You may not be able to resell your shares at or above the price at which you 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 specific factors that may have a significant effect on our common stock market price include:

- actual or anticipated fluctuations in our operating results or future prospects;
- our announcements or our competitors announcements of new products;
- public concern as to the safety or efficacy of our products and services;
- the public s reaction to our press releases, our other public announcements, and our filings with the SEC;
- our determination whether or not to continue the payment of quarterly cash dividends;
- our determination whether or not to undertake or continue a share repurchase program;
- strategic actions by us or our competitors, such as acquisitions, divestitures or restructurings;
- dilutive issuances of additional securities;
- changes in our growth rates or our competitors growth rates;

developments regarding our patents or proprietary rights or those of our competitors;

our inability to raise additional capital;

changes in financial markets or general economic conditions, including those resulting from significant changes in governmental policy, war, incidents of terrorism, and responses to such events;

new laws or regulations or new interpretations of existing laws or regulations applicable to our business;

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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; and

light volume of trading in our common stock;

In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. This litigation, if instituted against us, could result in substantial costs and a diversion of our management s attention and resources.

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

Our chief executive officer and his family collectively control approximately 23% of our outstanding common stock as of December 31, 2016. As a result, these stockholders, if they were to act together, would 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 our 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 in Burlington, Massachusetts. Each of our Burlington leases expires in 2023. In addition, our international operations are headquartered at a 12,841 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 and lease a 6,722 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, and Spain. Based on our current operating plans, we believe our current facilities are adequate for our needs.

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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, 2016, 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.

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PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Market under the symbol LMAT on October 19, 2006. The following table sets forth the high and low sales prices of our common stock as reported on The NASDAQ Global Market for the eight quarters ended December 31, 2016:

	High	Low
Year ended December 31, 2016:		
First quarter ended March 31, 2016	$ 16.44	$ 12.50
Second quarter ended June 30, 2016	$ 16.72	$ 13.89
Third quarter ended September 30, 2016	$ 21.78	$ 13.56
Fourth quarter ended December 31, 2016	$ 25.46	$ 18.95
Year ended December 31, 2015:		
First quarter ended March 31, 2015	$ 8.38	$ 7.29
Second quarter ended June 30, 2015	$ 12.06	$ 8.20
Third quarter ended September 30, 2015	$ 14.30	$ 11.13
Fourth quarter ended December 31, 2015	$ 17.77	$ 12.01

Holders of Record

On March 2, 2017, the closing price per share of our common stock was $22.12 as reported on The NASDAQ Global Market, and we had approximately 204 stockholders of record. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in street name.

Dividend Policy

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 2016			
March 21, 2016	April 4, 2016	$0.045	$825
May 25, 2016	June 8, 2016	$0.045	$829
August 22, 2016	September 2, 2016	$0.045	$833
November 21, 2016	December 5, 2016	$0.045	$836
Fiscal Year 2015			
March 20, 2015	April 3, 2015	$0.040	$700
May 22, 2015	June 5, 2015	$0.040	$705
August 20, 2015	September 3, 2015	$0.040	$715
November 20, 2015	December 4, 2015	$0.040	$725

On February 16, 2017, our Board of Directors approved a quarterly cash dividend on our common stock of $0.055 per share payable on April 6, 2017, to stockholders of record at the close of business on March 22, 2017, which will total approximately $1.0 million in payments.

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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, 2011, through the end of LeMaitre s fiscal year ended December 31, 2016. The graph assumes an investment of $100.00 made on December 31, 2011, in (i) LeMaitre s common stock, (ii) the stocks comprising the NASDAQ US Composite Index, (iii) the stocks comprising the NASDAQ Medical Equipment Index and (iv) the stocks comprising our peer group. 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.

	12/31/11	12/31/12	12/31/13	12/31/14	12/31/15	12/31/16
LeMaitre Vascular, Inc	100.00	98.65	140.14	136.33	311.90	463.14
NASDAQ Composite	100.00	116.41	165.47	188.69	200.32	216.54
NASDAQ Medical Equipment	100.00	109.53	131.61	152.86	168.58	180.31
2015 Peer Group	100.00	120.03	224.17	251.17	174.01	231.50
2016 Peer Group	100.00	127.39	203.66	216.64	135.58	168.81

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 2015 peer group included the following companies: AtriCure, Inc., AngioDynamics, Inc., Cardiovascular Systems Inc., Cryolife Inc., Endologix, Inc., Spectranetics Corp., Lombard Medical Systems Inc. and Vascular Solutions, Inc.

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The 2016 peer group includes the following companies: AngioDynamics, Inc., Avinger, Inc., Cardiovascular Systems Inc., Cryolife Inc., Endologix, Inc., Spectranetics Corp., Lombard Medical Systems Inc., Penumbra, Inc., and Vascular Solutions, Inc. This new peer group differs from our old peer group. Specifically, we removed AtriCure, Inc. since its products extend beyond peripheral vascular use, and we added Avinger, Inc. and Penumbra, Inc., based upon their product offerings and recent public stock issuances.

Recent Sales of Unregistered Securities

Not Applicable.

Issuer Purchases of Equity Securities

In the quarter ended December 31, 2016, we did not repurchase any shares of our common stock.

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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, 2016, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016 and 2015, 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, 2013 and 2012, and the consolidated balance sheet data as of December 31, 2014, 2013 and 2012 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,				
	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net sales	$ 89,151	$ 78,352	$ 71,097	$ 64,549	$ 56,735
Cost of sales	26,215	24,186	22,666	19,434	15,867
Gross profit	62,936	54,166	48,431	45,115	40,868
Operating expenses:					
Sales and marketing	26,105	22,780	22,087	22,143	20,811
General and administrative	14,354	14,010	13,889	12,576	10,973
Research and development	6,141	5,479	4,671	5,243	5,092
Medical device excise tax		744	689	635	
Restructuring charges			526		
Gain on divestitures		(360)			(248)
Impairment charges			229		
Total operating expenses	46,600	42,653	42,091	40,597	36,628
Income from operations	16,336	11,513	6,340	4,518	4,240
Other income (expense):					
Interest income	81	13	1	4	78
Interest expense	(14)		(5)	(12)	(1)
Foreign currency gain (loss)	(161)	(102)	(16)	(182)	(324)
Total other income (loss)	(94)	(89)	(20)	(190)	(247)
Income before income tax	16,242	11,424	6,320	4,328	3,993
Provision for income taxes	5,652	3,666	2,405	1,126	1,422
Net income	$ 10,590	$ 7,758	$ 3,915	$ 3,202	$ 2,571
Earnings per share of common stock:					
Basic	$ 0.57	$ 0.44	$ 0.24	$ 0.21	$ 0.17
Diluted	$ 0.55	$ 0.42	$ 0.23	$ 0.20	$ 0.16
Weighted-average shares outstanding:					
Basic	18,485	17,764	16,614	15,317	15,194
Diluted	19,241	18,316	17,008	15,764	15,638
Cash dividends declared per common share	$ 0.18	$ 0.16	$ 0.14	$ 0.12	$ 0.10

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	2016	2015	December 31, 2014	2013	2012
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 24,288	$ 27,451	$ 18,692	$ 14,711	$ 16,448
Current assets	59,027	58,184	48,588	41,725	39,131
Total assets	101,924	90,704	81,492	70,492	63,060
Current liabilities	10,482	10,368	10,041	10,220	8,394
Long-term liabilities	3,942	2,452	3,244	3,710	1,778
Total liabilities	14,424	12,820	13,285	13,930	10,172
Total stockholders equity	87,500	77,884	68,207	56,562	52,888

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 to 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 approximates $4 billion, within which our core product lines address roughly $840 million. We have grown our business by using a three-pronged strategy: 1) pursuing a focused call point, 2) competing for sales of low-rivalry niche products, and 3) expanding our worldwide direct sales force while acquiring and developing complementary vascular devices. We have used acquisitions as a primary means of further accessing the larger 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 at our Burlington, Massachusetts headquarters.

Our products are used primarily by vascular surgeons who treat peripheral vascular disease through both open surgical methods and endovascular techniques. In contrast to interventional cardiologists and interventional radiologists, neither of whom are certified to perform open surgical procedures, vascular surgeons can perform both open surgical 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, laparoscopic cholecystectomy devices, prosthetic vascular grafts, and remote endarterectomy devices. With the November 10, 2016 acquisition of the RestoreFlow allografts business from Restore Flow Allografts, LLC, 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.

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

We sell our products and services primarily through a direct sales force. As of December 31, 2016 our sales force was comprised of 96 sales representatives in North America, Europe, Japan, China, Australia and New Zealand. We also sell our products in other countries through distributors. Our worldwide headquarters is located in Burlington, Massachusetts. Our international operations are headquartered in Sulzbach, Germany. We also have sales offices located in Tokyo, Japan; Mississauga, Canada; Madrid, Spain; Milan, Italy; Shanghai, China; and North Melbourne, Australia, and we have a processing facility in Fox River Grove, Illinois and a manufacturing facility in North Melbourne, Australia. During both of the years ended December 31, 2016 and 2015, approximately 92% 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 market segments for biologic vascular patches and valvulotome devices. In the biologic vascular patch market segment the number of competitors is limited, and we believe that we have been able to increase segment share and to a lesser extent increase selling prices, mainly due to strong sales service. In the valvulotome market segment, we believe we have been able to materially increase our selling prices without losing significant market share. In contrast, we have experienced less success in highly competitive segments such as laparoscopic cholecystectomy devices and polyester grafts, where we face stronger competition from larger companies with greater resources and lower production costs. We have also experienced less success in segments such as carotid shunts, where unit sales in the overall market may be declining. While we believe that these challenging market dynamics can be mitigated by our strong relationships with vascular surgeons, there can be no assurance that we will be successful in these highly competitive market segments.

In recent years we have also experienced success in geographic markets outside of the United States, such as Europe, where we generally offer comparatively lower average selling prices. If we continue to seek growth opportunities outside of the United States, we will likely 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 to our direct sales organization:

- During 2014, we entered into definitive agreements with eight former Xenotis distributors in Europe in order to terminate their distribution of our Omniflow II biosynthetic vascular grafts and we began selling direct to hospitals in those geographies. The agreements required us to pay approximately $1.3 million in exchange for the purchase of customer lists and inventory.
- During 2015, we entered into definitive agreements with seven former UreSil, LLC distributors in Europe in order to terminate their distribution of our Tru-Incise valvulotome and we began selling direct-to-hospital in those geographies. The termination fee was approximately $0.2 million

In August 2015, we entered into a definitive agreement with Grex Medical Oy (Grex), our distributor in Finland, in order to terminate their distribution of our products and we began selling direct-to-hospital in Finland as of January 1, 2016. The termination fee was approximately $0.2 million.

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We anticipate that the expansion of our direct sales organization in China will result in increased sales, marketing and regulatory expenses during 2017. As of December 31, 2016 we had seven 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 August 2014, we acquired all of the capital stock of Xenotis Pty Ltd (Xenotis) for $6.7 million plus the assumption of $1.1 million of debt. Xenotis was the parent company of Bio Nova International, the manufacturer and marketer of the Omniflow II biosynthetic vascular graft for lower extremity bypass and AV access.

- In September 2014, we acquired substantially all of the assets related to the angioscope product line from Applied Medical Resource Corporation for $0.4 million.

- In September 2014, we terminated our UnBalloon non-occlusive modeling catheter product line.

- In May 2015, we acquired the production and distribution rights of UreSil LLC s Tru-Incise valvulotome for sales outside of the United States for $1.4 million.

- In July 2015, we entered into an asset sales agreement with Merit Medical Ireland Limited to sell our inventory, intellectual property and customer lists associated with The UnBalloon, our non-occlusive modeling catheter product line for $0.4 million.

- In December 2015, we terminated our InvisiGrip vein stripper product line, and wrote down $0.1 million of related inventory in Q3 2015.

- 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 million depending upon the satisfaction of certain contingencies.

In addition to relying upon acquisitions to grow our business, we also rely on our product development efforts to bring differentiated technology and next-generation products to market. These efforts have led to the following recent product developments:

- In June 2014, we launched the 1.5mm HYDRO LeMaitre Valvulotome.

- In October 2014, we launched the LeMaitre Aortic Occlusion Catheter.

- In December 2014, we launched the LeMills Valvulotome.

In December 2015, we launched the 15-cm AnastoClip AC.

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

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

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 that 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 January 2014, we initiated a project to transfer the manufacturing of the newly acquired Clinical Instruments devices to our facility in Burlington. We closed the Clinical Instruments facility in March 2014 and completed the manufacturing transfer during Q2 2014.

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In March 2015, we initiated a project to transfer the manufacturing of the newly acquired angioscope product line to our facility in Burlington. We had been purchasing the devices from Applied Medical since the September 2014 acquisition and completed the transition of manufacturing to our Burlington facility in December 2015.

In May 2015, we initiated a project to transfer the manufacturing of the newly acquired Tru-Incise valvulotome product line to our facility in Burlington. We have been purchasing the devices from UreSil, LLC since the acquisition. We expect the transition of manufacturing to be completed in 2017.

In March 2016, we initiated a project to transfer the manufacturing of the newly acquired ProCol biologic product line to our facility in Burlington. We have an agreement to purchase the product from the seller, Hancock Jaffe Laboratories, for up to three years following the closing. We initiated the transfer of the production line and transition of manufacturing in 2016, and we expect it to be complete in 2018, subject to regulatory approval.

In 2017 we expect to complete the renovation of our manufacturing facility in Burlington, in which we expect most of our biologic offerings, including the XenoSure patch as well as certain biologic grafts, will be produced or processed. We believe the cost of the facility renovation will be approximately $2.0 million.

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, 2016, approximately 44% of our sales took place outside the United States. We expect that foreign currencies will continue to represent a similarly 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, 2016, we estimate that the effects of changes in foreign exchange rates decreased sales by approximately $0.2 million, as compared to rates in effect for the year ended December 31, 2015.

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 generated by shipments to distributors, who in turn sell to hospitals and clinics. In certain cases our products are held on consignment at a hospital or clinic prior to purchase; in those instances we recognize revenue at the time the product is used in surgery rather than at shipment.

Cost of sales. We manufacture nearly all 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 medical society meetings, training programs, advertising and product promotions, direct mail and other marketing costs.

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General and administrative. General and administrative expense consists primarily of executive, finance and human resource expense, 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 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, 2016 to the year ended December 31, 2015

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:

	2016	2015	$ Change	Percent change
		($ in thousands)		
Net sales	$ 89,151	$ 78,352	$ 10,799	14%
Net sales by geography:				
Americas	$ 53,710	$ 47,975	$ 5,735	12%
International	35,441	30,377	5,064	17%
Total	$ 89,151	$ 78,352	$ 10,799	14%

Net sales. Net sales increased 14% or $10.8 million to $89.2 million for the year ended December 31, 2016, compared to $78.4 million for the year ended December 31, 2015. Sales increases were primarily driven by increased sales of our biologic vascular patches of $5.2 million (of which we estimate that $2.3 million was related to a safety alert initiated by a competitor), valvulotomes of $1.9 million, vessel closure systems of $1.5 million and our recently acquired ProCol biologic vascular graft of $1.0 million. We also had human tissue cryopreservation service revenues from our recently acquired RestoreFlow allograft business of $0.5 million. These and other product line increases were partially offset by decreased sales of radiopaque tape of $0.4 million (related primarily to the inclusion in 2015 of $0.6 million of OEM tape sales).

Direct-to-hospital net sales were 92% for both of the years ended December 31, 2016 and December 31, 2015.

Net sales by geography. Net sales in the Americas increased $5.7 million for the year ended December 31, 2016. The increase was primarily driven by biologic vascular patches, valvulotomes, vessel closure systems and our recently acquired ProCol biologic vascular graft, and was partially offset by decreased sales of carotid shunts and radiopaque tape. We also had human tissue cryopreservation service revenues in the U.S. from our recently acquired RestoreFlow allograft business of $0.5 million. International net sales increased $5.1 million for the

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year ended December 31, 2016. The increase occurred across most product lines but was primarily driven by sales of our biologic vascular patches and grafts, valvulotomes, ePTFE vascular grafts and shunts.

	2016	2015	$ Change	Percent change
		($ in thousands)		
Gross profit	$ 62,936	$ 54,166	$ 8,770	16%
Gross margin	70.6%	69.1%	*	1.5%

* Not applicable

Gross Profit. Gross profit increased $8.8 million to $62.9 million for the year ended December 31, 2016, while gross margin increased by 150 basis points to 70.6% in the period. The gross margin was favorably impacted by higher average selling prices across nearly all product lines, increased sales of XenoSure and valvulotome devices, and lower per-unit manufacturing costs of our biologic patch products as well as other products. These increases were partially offset by higher sales in Europe as well as other markets where we sometimes realize lower gross margins than in the United States. The gross profit increase was a result of higher sales and the improved gross margin.

	2016	2015	$ change	Percent change	2016 as a % of Net Sales	2015 as a % of Net Sales
			($ in thousands)			
Sales and marketing	$ 26,105	$ 22,780	$ 3,325	15%	29%	29%
General and administrative	14,354	14,010	344	2%	16%	18%
Research and development	6,141	5,479	662	12%	7%	7%
Medical device excise tax		744	(744)	(100%)	0%	1%
Gain on divestitures		(360)	360	*	*	*
	$ 46,600	$ 42,653	$ 3,947	9%	52%	54%

* Not a meaningful percentage.

Sales and marketing. For the year ended December 31, 2016, sales and marketing expense increased $3.3 million or 15% to $26.1 million. The increases were primarily driven by compensation-related expenses and travel, due to an increase in the number of sales representatives from 81 at January 1, 2015 to 96 at December 31, 2016. As a percentage of net sales, sales and marketing expense was 29% for both comparative periods.

General and administrative. For the year ended December 31, 2016, general and administrative expense increased $0.3 million or 2%, to $14.4 million. General and administrative expense increases were primarily related to compensation costs and acquisition-related expenses, which were partially offset by decreases in recruiting costs, professional fees and bad debt expense. As a percentage of net sales, general and administrative expense decreased to 16% for the year ended December 31, 2016 as compared to 18% for the prior period.

Research and development. For the year ended December 31, 2016, research and development expense increased $0.7 million or 12%, to $6.1 million. Product development expenses increased $0.3 million primarily driven by compensation costs, including costs to support efforts to transition the manufacturing of certain acquired product lines to our Burlington, Massachusetts headquarters. These increases were partially offset by lower spending on supplies and testing. Clinical and regulatory expenses increased $0.3 million primarily related to compensation costs and professional fees, including costs related to regulatory submission for new products in geographies such as China.

Medical device excise tax. The medical device excise tax was $0.7 million in 2015. On December 18, 2015, the Consolidated Appropriations Act of 2016 was signed into law, which suspended the medical device tax for the period beginning January 1, 2016 and ending December 31, 2017.

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Other income (expense). Foreign exchange losses for 2016 were $0.2 million as compared to $0.1 million for 2015.

Income tax expense. We recorded a provision for taxes of $5.7 million on pre-tax income of $16.2 million in 2016 as compared to $3.7 million on pre-tax income of $11.4 million in 2015. The 2016 provision was comprised of Federal tax provision in the United States of $4.6 million, state tax provision of $0.6 million and a foreign tax provision of $0.5 million. The 2015 provision was comprised of Federal tax in the United States of $3.2 million, a state tax benefit of $0.1 million and foreign taxes of $0.6 million. Our effective tax rate differed from the U.S. statutory tax rate in 2016 principally due to the release of valuation allowances on foreign deferred tax assets, manufacturing deductions, uncertain tax positions, effect of foreign taxes, Subpart-F income, foreign deferred tax liability offset, state taxes, other permanent differences, and other. 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 have assessed the need for a valuation allowance against our deferred tax assets and concluded that as of December 31, 2016, we will continue to carry a valuation allowance against $1.8 million of deferred tax assets, principally foreign net operating loss and capital loss carry-forwards; based on the weight of available evidence, we believe it is more likely than not that such assets will not be realized.

We expect our effective tax rate to decrease slightly in 2017, as audit adjustments and uncertain tax positions normalize. The state rate increased in 2016 because there was a release of valuation allowance in 2015. We expect the state rate to normalize in 2017.

In 2016, a federal tax audit resulted in a $0.2 million tax adjustment, which also required a $0.2 million increase to our uncertain tax positions for a Massachusetts tax credit.

Comparison of the year ended December 31, 2015 to the year ended December 31, 2014

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:

	2015	2014	$ Change	Percent change
		($ in thousands)		
Net sales	$ 78,352	$ 71,097	$ 7,255	10%
Net sales by geography:				
Americas	$ 47,975	$ 43,502	$ 4,473	10%
International	30,377	27,595	2,782	10%
Total	$ 78,352	$ 71,097	$ 7,255	10%

Net sales. Net sales increased 10% to $78.4 million in 2015 from $71.1 million in 2014. Sales from newly acquired product lines contributed 4.5% to the sales growth.

The increase in net sales of $7.3 million in 2015 was primarily driven by increased sales in biologic vascular patches of $2.9 million, valvulotomes of $1.7 million and powered phlebectomy systems of $0.8 million. In addition, sales of biological vascular grafts, which were acquired in 2014, increased net sales in 2015 by $2.9 million. This sales growth was partially offset by decreased sales of occlusion catheters of $0.8 million. Across all product lines, we estimate that the strengthening U.S. dollar as compared to 2014 decreased our net sales by $5.6 million. Average selling prices increased across nearly all product lines, particularly in the valvulotome segment, as the 1.5mm HYDRO valvulotome was introduced in Europe.

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Direct-to-hospital net sales were 92% of net sales in 2015 compared to 91% in 2014. This increase was primarily driven by proportionately lower export sales to China of $0.3 million.

Net sales by geography. Net sales in the Americas increased by $4.5 million to $48.0 million in 2015. This increase was primarily driven by increased sales of biologic vascular patches of $1.9 million, valvulotomes of $1.0 million and vessel closure systems of $0.8 million. These increases were partially offset by decreased sales of occlusion catheters of $0.5 million and cholangiogram catheters of $0.4 million. International net sales increased by $2.8 million to $30.4 million in 2015. This increase was primarily driven by higher sales of biologic vascular grafts of $2.8 million, biologic vascular patches of $0.9 million, valvulotomes of $0.6 million and powered phlebectomy systems of $0.5 million. These increases were offset by decreased sales of vessel closure systems of $0.7 million, radiopaque tape of $0.3 million and catheters of $0.3 million.

	2015	2014	$ Change	Percent change
		($ in thousands)		
Gross profit	$ 54,166	$ 48,431	$ 5,735	12%
Gross margin	69.1%	68.1%	*	1.0%

* Not applicable

Gross profit. Gross profit increased by $5.7 million to $54.2 million in 2015 from $48.4 million in 2014, and our gross margin increased by 1.0% to 69.1% in 2015. The gross margin increase in 2015 was largely driven by average selling price increases, particularly with respect to the introduction of our 1.5mm HYDRO valvulotome, as well as increased manufacturing efficiencies, particularly with respect to the XenoSure and AlboGraft product lines. These improvements were partially offset by unfavorable changes in foreign currency exchange rates, as well as increased sales to lower margin geographies such as China and Saudi Arabia. The gross profit increase was also a result of higher sales.

	2015	2014	$ change	Percent change	2015 as a % of Net Sales	2014 as a % of Net Sales
			($ in thousands)			
Sales and marketing	$ 22,780	$ 22,087	$ 693	3%	29%	31%
General and administrative	14,010	13,889	121	1%	18%	20%
Research and development	5,479	4,671	808	17%	7%	7%
Medical device excise tax	744	689	55	8%	1%	1%
Restructuring		526	(526)	*	*	1%
Gain on divestitures	(360)		(360)	*	*	*
Impairment charges		229	(229)	*	*	*
	$ 42,653	$ 42,091	$ 562	1%	54%	59%

* Not a meaningful percentage.

Sales and marketing. Sales and marketing expenses increased to $22.8 million in 2015 from $22.1 million in 2014. As a percentage of net sales, sales and marketing expenses were 29% in 2015, down 2% from the prior year. Selling expenses increased $0.7 million while marketing expenses were unchanged. Selling expense increases in 2015 were driven by higher compensation and related expenses of $0.7 million and travel and sales meetings and related costs of $0.3 million. These increases were partially offset by lower consulting costs and other expenses. Additionally, changes in foreign currency exchange rates reduced our sales and marketing expense as compared to 2014.

General and administrative. General and administrative expenses increased by 1% to $14.0 million in 2015 from $13.9 million in 2014. As a percentage of net sales, general and administrative expenses were 18% in 2015 as compared to 20% in the prior year. General and administrative expense increases for 2015 were mainly driven

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by increased compensation related expenses of $0.6 million, partially offset by decreases in acquisition related expenses of $0.5 million as compared to the prior year. Additionally, changes in foreign currency exchange rates reduced our general and administrative expense as compared to 2014.

Research and development. Research and development expenses increased 17% to $5.5 million in 2015 from $4.7 million in 2014. As a percentage of net sales, research and development expenses were 7% in both 2015 and 2014. Product development expenses increased $0.8 million primarily due to higher compensation and related expense of $0.3 million, higher product testing costs of $0.2 million and higher professional services and other expenses. Clinical and regulatory costs were unchanged.

Medical device excise tax. The medical device excise tax was $0.7 million in 2015 and 2014. On December 18, 2015, the Consolidated Appropriations Act of 2016 was signed into law. The Consolidated Appropriations Act of 2016 suspends the medical device tax for the period beginning January 1, 2016 and ending December 31, 2017.

Restructuring. In February 2014, we committed to a plan intended to improve operational efficiencies, which included a reduction in force of approximately 10% of our workforce and other cost-cutting measures, including the transfer of our Clinical Instruments operations to our Burlington headquarters. As a result, we recorded approximately $0.4 million of severance related restructuring expense. In April 2014, we committed to an additional reduction in force of approximately seven employees. As a result, we recorded approximately $0.1 million of severance related restructuring expense. The cost of these plans was paid in full in 2014. There were no restructuring charges in 2015.

Gain on divestitures. In July 2015, we entered into an asset sales agreement with Merit Medical Ireland Limited to sell our inventory, intellectual property and customer lists associated with The UnBalloon, our non-occlusive modeling catheter product line for $0.4 million.

Impairment charges. In 2014 we recognized impairment charges of $0.2 million related to trademarks, technology, and manufacturing equipment upon the termination of The UnBalloon, our non-occlusive modeling catheter product line.

Other income (expense). Foreign exchange losses for 2015 were $0.1 million as compared to $16,000 for 2014.

Income tax expense. We recorded a provision for taxes of $3.7 million on pre-tax income of $11.4 million in 2015 as compared to $2.4 million on pre-tax income of $6.3 million in 2014. The 2015 provision was comprised of a Federal tax provision in the United States of $3.2 million, a state tax benefit of $0.1 million and a foreign tax provision of $0.6 million. The 2014 provision was comprised of a Federal tax provision in the United States of $1.9 million, state taxes of $0.2 million and foreign taxes of $0.3 million. Our effective tax rate differed from the U.S. statutory tax rate in 2015 principally due to manufacturing deductions, Subpart-F income, state taxes, research and development tax credits, effect of foreign taxes, other permanent differences, and other. 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 assessed the need for a valuation allowance against our deferred tax assets and concluded that as of December 31, 2015, we would continue to carry a valuation allowance against $2.2 million of deferred tax assets, principally foreign net operating loss and capital loss carry-forwards; based on the weight of available evidence, we believed it was more likely than not that such assets would not be realized. Of the $2.2 million of valuation allowance, $2 million resulted from the Xenotis acquisition in Australia.

In 2015, a Massachusetts valuation allowance was reversed, which lowered our overall effective tax rate by 3.5%.

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Liquidity and Capital Resources

At December 31, 2016, our cash and cash equivalents were $24.3 million as compared to $27.5 million at December 31, 2015. 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. All of our cash held outside of the United States is available for corporate use, with the exception of $4.6 million held by subsidiaries in jurisdictions for which earnings are planned to be permanently reinvested.

On July 25, 2016, our Board of Directors approved a stock repurchase program under which the Company is authorized to repurchase up to $5 million of its common stock through transactions on the open market, in privately negotiated purchases or otherwise. This program may be suspended or discontinued at any time, and expires on the earlier of July 25, 2017 or when the authorized aggregate $5 million repurchase limit is reached. To date we have 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 $16.3 million for the year ended December 31, 2016. For the year ended December 31, 2015, we recognized operating income of $11.5 million. 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 sales of our products;
- 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.

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Cash Flows

	Year ended December 31,		
	2016	2015	Net Change
	($ in thousands)		
Cash and cash equivalents	$ 24,288	$ 27,451	$ (3,163)
Cash flows provided by (used in):			
Operating activities	$ 16,896	$ 11,438	$ 5,458
Investing activities	(17,211)	(3,480)	(13,731)
Financing activities	(2,577)	1,079	(3,656)

Net cash provided by operating activities. 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 provided by operating activities was $11.4 million in 2015, and consisted of $7.8 million in net income, adjusted for non-cash items of $4.3 million (including depreciation and amortization of $3.4 million, stock-based compensation of $1.4 million, and provision for inventory write-offs of $0.5 million) and was offset by working capital increases of $0.7 million. Working capital increases were driven primarily by increased prepaid expenses, including primarily prepaid taxes, of $2.0 million and accounts receivable of $1.9 million, offset by increased accounts payable and other liabilities of $2.6 million.

Net cash used in investing activities. 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 used in investing activities was $3.5 million in 2015. This was driven by the purchase of property and equipment of $2.3 million and acquisition related payments of $1.6 million, primarily related to the Tru-Incise acquisition and related distributor buyouts, partially offset by proceeds from the sale of the UnBalloon modeling catheter assets of $0.4 million.

Net cash used in financing activities. 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.

Net cash provided by financing activities was $1.1 million in 2015, driven primarily by proceeds from stock option exercises of $4.8 million partially offset by payments of common stock dividends of $2.8 million, payment of deferred acquisition payments of $1.1 million, and the acquisition of $0.3 million of treasury stock to cover minimum withholding taxes of restricted stock unit vestings.

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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 2016			
March 21, 2016	April 4, 2016	$0.045	$825
May 25, 2016	June 8, 2016	$0.045	$829
August 22,2016	September 2, 2016	$0.045	$833
November 21, 2016	December 5, 2016	$0.045	$836
Fiscal Year 2015			
March 20, 2015	April 3, 2015	$0.040	$700
May 22, 2015	June 5, 2015	$0.040	$705
August 20, 2015	September 3, 2015	$0.040	$715
November 20, 2015	December 4, 2015	$0.040	$725

On February 16, 2017, our Board of Directors approved a quarterly cash dividend on our common stock of $0.055 per share payable on April 6, 2017, to stockholders of record at the close of business on March 22, 2017, which will total approximately $1.0 million in payments.

Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(in thousands)		
Operating leases	$ 8,498	$ 1,546	$ 2,703	$ 2,217	$ 2,032
Purchase commitments for inventory	2,418	2,393	25		
Total contractual obligations	$ 10,916	$ 3,939	$ 2,728	$ 2,217	$ 2,032

***Contractual obligations*.** Our principal contractual obligations consist of operating leases and inventory purchase commitments. The following table summarizes our commitments to settle contractual obligations as of December 31, 2016:

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 Mississauga, Canada office, expiring in 2018; our Sulzbach, Germany office, expiring in 2023; our Tokyo, Japan office, expiring in 2016 at which point it becomes automatically renewable for specified periods; our Milan, Italy office, expiring in 2020; our Madrid, Spain office, expiring in 2017; our two Australia facilities expiring in 2020; our Shanghai, China office, expiring in 2020; and our Fox River Grove offices, expiring in 2018. They also include automobile and equipment leases.

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.

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

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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.

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

Revenue Recognition

Our revenue is derived primarily from the sale of disposable or implantable devices used during vascular surgery. We sell primarily directly to hospitals and to a lesser extent to distributors, as described below. We also occasionally enter into consigned inventory arrangements with either hospitals or distributors on a limited basis. In connection with our recent acquisition of the RestoreFlow allograft business, we also derive revenues from human tissue cryopreservation services. 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 below have been met.

We recognize revenue when four basic criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. We generally use customer purchase orders or contracts to determine the existence of an arrangement. Sales transactions are based on prices that are determinable at the time that the customer s purchase order is accepted by us. In order to determine whether collection is reasonably assured, we assess a number of factors, including past transaction history with the customer and the creditworthiness of the customer. If we determine that collection is not reasonably assured, we would defer the recognition of revenue until collection becomes reasonably assured, which is generally upon receipt of payment. We provide for product returns at the time revenue is recognized based on our historical product return history. Based on these policies, we recognize revenue, net of allowances for returns and discounts, as products are shipped, based on shipping point terms, or at the time consigned inventory is consumed at which time title passes to customers. We recognize revenue net of allowances for returns and discounts as well as any sales and value added taxes required to be invoiced, at the time of shipment of our products to our distributors.

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.

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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, 2016 our receivables in Italy and Spain totaled $0.8 million and $0.4 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, 2016, if significant changes were to occur in the payment practices of these European governments or if government funding becomes unavailable, we may not be able to collect on receivables due to us from these customers and our write offs of uncollectible amounts may increase.

We write off accounts receivable when they become uncollectible. 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.

In connection with our recent 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 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.

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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.

Share-based compensation charges had in prior years been recorded net of the estimated forfeitures based upon historical forfeiture rates, and was adjusted in subsequent periods to reflect the results of actual forfeitures and vesting. In March 2016, the Financial Accounting Standards Board (FASB) issued a new standard that changes the accounting for certain aspects of share-based payments to employees, including a provision allowing companies to make an election to account for award forfeitures as they occur, rather than estimating them at the time of grant. We early-adopted the new guidance in the third quarter of fiscal year 2016, which required us to reflect any adjustments as of January 1, 2016, the beginning of the annual period that includes the interim period of adoption. In connection with this early adoption we made the election to account for award forfeitures as they occur, and we recorded a cumulative-effect adjustment to beginning retained earnings of $0.1 million, net of tax. Share-based compensation charges are recorded across the consolidated statement of operations based upon the grantee s primary function.

As disclosed more fully in the notes to our consolidated financial statements, we recorded expense of approximately $1.7 million in connection with share-based payment awards for the year ended December 31, 2016. The future expense of non-vested share-based awards of approximately $6.1 million is to be recognized over a weighted-average period of 3.8 years. During 2016, we granted stock options at a weighted average fair value of $4.04 and RSUs with weighted average fair value of $14.14.

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 $23.4 million and $17.8 million as of December 31, 2016 and 2015, 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 1 to 13 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

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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 $9.9 million as of December 31, 2016 and $6.3 million as of December 31, 2015. In 2014, we recognized an impairment charge of $0.2 million related to trademarks and technology upon the termination of our non-occlusive modeling catheter product line.

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, 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, 2016, 2015, and 2014, we were not subject to any material litigation, claims or assessments.

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.

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 do not provide for income taxes on undistributed earnings of foreign subsidiaries, as our current intention is to permanently reinvest these earnings.

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. Within specific countries, we may be subject to audit by various tax authorities operating within the country and may be

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subject to different statutes of limitation expiration dates. 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. We will continue to monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly. We have recorded a valuation allowance on our net deferred tax assets of $1.8 million and $2.2 million as of December 31, 2016 and 2015, respectively.

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board (FASB) issued an accounting standards update, ASU 2017-01, which changes the definition of a business for purposes of determining whether a business has been acquired or sold. The amendment is intended to help companies evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new standard is effective for us beginning January 1, 2018, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In August 2016, the FASB issued an accounting standards update, ASU 2016-15, which changes the classification of certain cash receipts and cash payments within the statement of cash flows. The new standard is effective for us beginning January 1, 2018, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation Stock Compensation, Improvements to Employee Share-Based Payment Accounting, which the Company elected to early adopt during the third quarter of 2016. ASU 2016-09 requires an entity to recognize all excess tax benefits and tax deficiencies in connection with stock-based compensation as income tax expense or benefit in the income statement (previously, excess tax benefits were recognized in additional paid-in capital). We adopted the standard prospectively, and we recorded excess tax benefits of $0.3 million within income tax expense for the year ended December 31, 2016. The adoption of the standard requires the Company to adjust its deferred tax assets to account for the benefit of excess tax benefits and any adjustments to forfeitures in historical periods and record the adjustment to retained earnings. Accordingly, the Company has recorded an adjustment of approximately $0.1 million to retained earnings to adjust its deferred tax assets. In addition, the amendments require recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. Furthermore, the amendments require that excess tax benefits be classified as an operating activity in the statement of cash flows (such amounts were previously included as a financing activity in the statement of cash flows); the Company also adopted this provision of ASU 2016-09 prospectively. As allowed by the standard, we also made an election to account for award forfeitures as they occur, rather than estimating them at the time of grant. In connection with this election we recorded a cumulative-effect adjustment to beginning retained earnings of $0.1 million, net of taxes.

In February 2016, the FASB issued its new lease accounting guidance in Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842).* 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. The new lease guidance simplifies the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities. Lessees will no longer be provided with a source of off-balance sheet financing. 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. Lessees (for capital and operating leases) and lessors (for sales-type, direct financing, and operating leases) must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. 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. We have not yet determined the impact on our consolidated financial statements.

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In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory,* or ASU 2015-11. ASU 2015-11 requires an entity to measure in-scope inventory at the lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years. A reporting entity should apply ASU 2015-11 prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We do not expect the adoption of this ASU to have a material impact on our consolidated financial statements.

In May 2014, the FASB and the International Accounting Standards Board (the IASB) issued substantially converged final standards on revenue recognition. The FASB s Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), as amended from time to time, outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The new revenue recognition guidance becomes effective for the Company on January 1, 2018, with early adoption permitted for the Company on January 1, 2017. Entities have the option of using either a full retrospective or a modified approach to adopt the guidance in the ASU. The Company does not currently expect that adoption of the updated standard will have a material impact on its consolidated financial statements and related disclosures.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2016. 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. We manage our exposure to these market risks through our regular operating and financing activities and, if considered appropriate, we may enter into derivative financial instruments such as forward currency exchange contracts, although we have not done so in 2016 or in recent years.

Foreign Currency Risk

During fiscal 2016 and 2015, 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 2016 and fiscal 2015. Our largest exposures to foreign currency exchange rates exist primarily with the Euro, British Pound, Canadian dollar, Australian dollar and Japanese yen.

During fiscal 2016 and fiscal 2015, we recorded $0.2 million and $0.1 million of net foreign currency exchange losses 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 $1.7 million for fiscal 2016.

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Interest Rate Risk

At December 31, 2016, we held $24.3 million in cash and cash equivalents. 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.

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

Not Applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the company s internal control over financial reporting was effective as of December 31, 2016.

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, 2016. 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. In November 2016, we acquired substantially all of the assets of the RestoreFlow allograft business from Restore Flow Allografts LLC. This acquired business, which during 2016 comprised 0.6% of our revenues and as of December 31, 2016 comprised 3.3% of our total assets, is excluded from our report on internal control over financial reporting.

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, 2016.

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Our internal control over financial reporting as of December 31, 2016 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their respective report which is included herein.

Remediation of Prior Year Material Weakness

The material weakness that was previously disclosed as of December 31, 2015 was remediated as of December 31, 2016. See Management s Report on Internal Control over Financial Reporting above. As disclosed in the quarterly reports on Form 10-Q for the first three quarters of 2016, the Company has implemented and executed the Company s remediation plans, and as of December 31, 2016, such remediation plans were successfully tested and the material weakness was deemed remediated.

Changes in Internal Control over Financial Reporting

Except for the acquisition of the RestoreFlow allograft business noted above under Management s Report on 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, 2016, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting. Management is in the process of assessing the effectiveness of internal control over financial reporting for the acquired business.

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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

LeMaitre Vascular, Inc.

We have audited the internal control over financial reporting of LeMaitre Vascular, Inc. (a Delaware corporation) and subsidiaries (the Company) as of December 31, 2016, based on criteria established in the 2013 *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). 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 , (Management s Report). Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit. Our audit of, and opinion on, the Company s internal control over financial reporting does not include the internal control over financial reporting of the RestoreFlow allograft business, whose financial statements reflect total assets and revenues constituting 3.3 percent and 0.6 percent, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2016. As indicated in Management s Report, the RestoreFlow allograft business was acquired during the fourth quarter of 2016. Management s assertion on the effectiveness of the Company s internal control over financial reporting excluded internal control over financial reporting of the RestoreFlow allograft business.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, 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), the consolidated financial statements of the Company as of and for the year ended December 31, 2016, and our report dated March 8, 2017 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Boston, Massachusetts

March 8, 2017

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Item 9B. Other Information

Not Applicable.

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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 2017 definitive proxy statement (2017 Definitive Proxy Statement) for the 2017 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the year ended December 31, 2016.

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 2017 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 2017 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 2017 Definitive Proxy Statement.

Equity Compensation Plan Information

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2016. 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)	(b)	(a)) (c)
Equity compensation plans approved by security holders	2,218,783	$ 10.25	1,745,953
Equity compensation plans not approved by security holders			
Total	2,218,783	$ 10.25	1,745,953

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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 2017 Definitive Proxy Statement.

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 2017 Definitive Proxy Statement.

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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) Exhibits

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
1.1	Underwriting Agreement dated as of May 30, 2014, among the Registrant, Canaccord Genuity Inc. and Stifel, Nicolaus & Company, Incorporated.	8-K	5/30/14	001-33092	
2.1	Purchase Option Agreement dated December 30, 2008 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.	10-K	3/27/13	001-33092	
2.2	Amendment No. 1 to Exclusive Distribution Agreement and Purchase Option Agreement dated January 22, 2009 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.	10-K	3/27/13	001-33092	
2.3	Amendment No. 2 to Purchase Option Agreement dated January 5, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.	10-K	3/27/13	001-33092	
2.4		10-K	3/27/13	001-33092	

	Amendment No. 3 to Purchase Option Agreement dated October 1, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.			
2.5	Amendment No. 4 to Purchase Option Agreement dated October 1, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.	10-Q	8/7/14	001-33092
2.6	Asset Purchase Agreement dated August 28, 2013 between Registrant and InaVein, LLC	10-Q	11/7/13	001-33092
2.7	Share Purchase Deed dated August 14, 2014 among Xenotis Pty Ltd, the shareholders of Xenotis Pty Ltd, Vinogopal Ramayah (as the Selling Shareholder Representative), the Registrant and LeMaitre Vascular Pty Ltd.	10-Q	11/6/14	001-33092

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
2.8	Asset Purchase Agreement dated November 10, 2016 between Registrant, Restore Flow Allografts, LLC and certain individuals named therein.				X
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	
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	Registration Rights Agreement dated June 17, 1998, by and between the Registrant and Housatonic Equity Investors, L.P.	S-1/A	5/26/06	333-133532	
10.3	Director Compensation Policy	10-K	3/27/12	001-33092	
10.4	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	
10.5	Managing Director Employment Agreement dated October 1, 2008, by and between LeMaitre Vascular GmbH and Peter Gebauer, as amended	10-K	3/31/09	001-33092	
10.6	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts	S-1/A	6/22/06	333-133532	
10.7	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino	S-1/A	6/22/06	333-133532	
10.8	1997 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	333-133532	
10.9	1998 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	333-133532	
10.10	2000 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	333-133532	
10.11	2004 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	333-133532	
10.12	Second Amended and Restated 2006 Stock Option and Incentive Plan and form of agreements thereunder	8-K	6/18/10	001-33092	
10.13	Form of Indemnification Agreement between the Registrant and its directors and executive officers	S-1/A	5/26/06	333-133532	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
10.14	Form of Restricted Stock Unit Award Agreement under the Registrant s 2006 Stock Option and Incentive Plan	8-K	12/26/06	001-33092	
10.15	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	
10.16	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	
10.17	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	
10.18	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	
10.19	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and David Roberts	10-K	3/31/09	001-33092	
10.20	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	
10.21	Fifth Amendment of Lease dated March 23, 2010, by and between Rodger P. Nordblom and Peter C. Nordblom, as Trustees of Northwest Associates, and Registrant	10-K	3/29/10	001-33092	
10.22	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	
10.23	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	
10.24	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	
10.25	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	
10.26	Lease dated December 20, 2013, by and between N.W. Building 3 Trust and Registrant	8-K	12/23/13	001-33092	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
10.27	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	
10.28	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	
10.29	Amended and Restated Management Incentive Compensation Plan	8-K	2/25/14	001-33092	
10.30	Third Amended and Restated 2006 Stock Option and Incentive Plan	8-K	6/8/15	001-33092	
10.31	Executive Retention and Severance Agreement dated October 26, 2015, by and between the Registrant and Michael T. Wijas.	10-K	3/10/16	001-33092	
21.1	List of Subsidiaries				X
23.1	Consent of Grant Thornton LLP				X
23.2	Consent of Ernst & Young LLP				X
24.1	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K)				X
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X