

LEMAITRE VASCULAR INC  
Form 10-K  
March 10, 2016  
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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, 2015

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)

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**Delaware**  
(State or other jurisdiction of incorporation or organization)

**04-2825458**  
(I.R.S. Employer Identification No.)

**63 Second Avenue, Burlington, Massachusetts**  
(Address of principal executive offices)

**01803**  
(Zip Code)

**Registrant's telephone number, including area code 781-221-2266**

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
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 Rule 12b-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 Rule 12b-2 of the Act). Yes:  No:

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2015: \$130,107,007. 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, 2016, the registrant had 18,339,704 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**

**2015 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, although 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, UnBalloon, VascaTape, TRIVEX, XenoSure, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular or one of its subsidiaries, and AlboSure, EndoHelix, Flexcel, Grice, Martin, NovaSil, Periscope, Reddick-Saye 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 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 Expandable LeMaitre Valvulotome, the XenoSure biologic patch, the Pruitt F3 Carotid Shunt and VascaTape 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 \$750 million.

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We sell our products primarily through a direct sales force. As of December 31, 2015 our sales force was comprised of 86 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, 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 2015, approximately 92% of our net sales were generated in territories in which we employ direct sales representatives.

### **The Peripheral Vascular Device 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 2015, 80% to 90% of our net sales were from devices used in open vascular procedures.

### **Our Business Strategies**

We have grown our business by using a multi-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 2015 approximately 80% 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.

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**Low rivalry niche segments.** We seek to build and maintain leading positions in niche product 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 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, however, we have sought to sell complementary products such as the Omniflow biosynthetic graft in larger, more competitive market segments, particularly when we believe that our product offering in that segment is highly differentiated.

**Direct sales force expansion.** 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 86 direct sales representatives. We intend to continue to expand our sales force in 2016 and over time. 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, 2015, 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.

**Addition of complementary products through acquisitions and research and development.** 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 14 product lines.

We have completed 17 acquisitions of complementary products since 1998:

<b>Year</b>	<b>Acquisition</b>	<b>Key Product(s)</b>
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

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With the exception of the remote endarterectomy devices, powered phlebectomy systems, biosynthetic vascular grafts, and the Tru-Incise valvulotome, we have relocated the manufacturing operations associated with these acquisitions to our Burlington, Massachusetts headquarters and we continue to look at ways to make our operations more efficient.



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### **Our Products**

We have a portfolio of 14 product lines, most of which are designed for use in open vascular surgery, and which address various anatomical areas including the carotid, lower extremities, upper extremities (for vascular access), aorta and other areas. In 2015, the carotid and lower extremities product lines comprised more than 10% of our revenues. In 2015, the lower extremities product lines were 53% of revenues, while the carotid product lines were 29%. In 2014, the lower extremities product lines were 51% of revenues while the carotid product lines were 28% of our revenues. In 2013 lower extremities product lines were 51% of revenues while the carotid product lines were 27%. 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 2015, 2014 or 2013.

#### ***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, Inahara-Pruitt, Flexcel and polyurethane carotid shunts are used to temporarily shunt blood to the brain while the surgeon removes plaque from the carotid artery in a carotid endarterectomy surgery. Our Pruitt F3, Pruitt-Inahara, and polyurethane 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 less invasive 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 VascoTape 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. VascoTape 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.

### ***Vascular Patches***

Our XenoSure Biologic Vascular Patch is made from bovine pericardium. In 2008, we obtained exclusive rights to distribute this product under our XenoSure brand in the United States, and in 2012, we exercised our option to acquire this product for worldwide distribution.

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

### ***Vessel Closure Systems***

Our AnastoClip AC and AnastoClip GC vessel closure systems allow surgeons to attach vessels to one another by deploying titanium clips instead of sutures. These vessel closure systems create an interrupted anastomosis which expands and contracts as the vessel pulses, which we believe improves the durability of the anastomosis.

### ***Other Products***

In some hospitals, vascular surgery procedures are 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.

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### **Sales and Marketing**

As of December 31, 2015, we employed 86 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 three 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 October 2013, we agreed to terminate agreements with our distributors in Australia and Norway, and we began selling direct-to-hospital in those territories in January 2014. 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 plan to begin selling our Chinese market products to Meheco in 2016. Meheco will then sell to a layer of sub-distributors who will then sell our products directly to China 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.

### **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 2015, our efforts were focused on launching the elongated AnastoClip AC and the 1.5mm HYDRO LeMaitre Valvulotome, as well as developing a shunt flow monitor.

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.

For 2015, 2014 and 2013, our research and development expenditures were \$5.5 million, \$4.7 million, and \$5.2 million, respectively, representing 7%, 7% and 8% of net sales, respectively. As of December 31, 2015, our research and development staff consisted of 14 full-time engineers and technicians.

### **Manufacturing**

Our manufacturing facilities are located in Burlington, Massachusetts, where most of our product lines are produced, and in North Melbourne, Australia, where our Omniflow II product line is produced.

Following the acquisition of new product lines, we typically integrate manufacturing of the newly acquired lines into our Burlington operations. In 2013, we completed the build-out of our third clean room in Burlington for the production of the XenoSure biologic vascular patch, and in 2014 fully transitioned XenoSure production to our Burlington facility. In 2014, we transferred the manufacturing of the Clinical Instruments devices, which we acquired in 2013, to our Burlington facility. Our TRIVEX, EndoRE, and Tru-Incise valvulotome products are currently manufactured by third parties; however, we expect to transition manufacturing of the Tru-Incise valvulotome to our Burlington facility during 2016.

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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.

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.

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 manufacturing 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 we underwent an audit by the U.S. Food and Drug Administration (FDA), and in November 2014, and July and November 2015, we underwent audits by our European Notified Body. 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., Covidien Medical Supplies (now a part of Medtronic), C.R. Bard, Inc., Edwards Lifesciences Corporation, Getinge AB, 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 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

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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. 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.

## **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 actively 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 2016 to 2032.

Generally, for products that we believe are appropriate for patent protection, we will attempt to obtain patents in the United States and key markets of the 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, VascoTape, 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. Some of our products are not protected by patents. 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.

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

### **Government Regulation**

The products we manufacture and market are subject to regulation by the FDA, and, in some instances, other federal and state authorities and foreign governments.

#### ***United States Regulation***

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

#### ***Premarket Pathways***

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

***510(k) Clearance.*** To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and performance to a predicate device (*i.e.*, a previously 510(k)-cleared class I or class II device or a pre-amendment class III device for which the FDA has not yet called for PMA applications). The FDA's 510(k) clearance pathway usually takes from three to twelve months, but it can take longer. In reviewing a premarket notification, the FDA may request additional information, including clinical data. All of our devices currently sold in the United States are marketed pursuant to the 510(k) clearance.

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.

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

**Clinical Trials.** A clinical trial is typically required to support a PMA application and is sometimes required to support 510(k) clearance. In some cases, one or more smaller feasibility Investigational Device Exemption (IDE) studies may precede a pivotal IDE clinical trial intended to comprehensively demonstrate the safety and effectiveness of the investigational device. All clinical studies of investigational devices must be conducted in compliance with the FDA's extensive requirements. If an investigational device could pose a significant risk to patients (as defined in the regulations), the FDA, prior to initiation of clinical use, must approve an IDE application showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A non-significant risk device does not require submission to the FDA of an IDE application. Both significant risk and non-significant risk investigational devices require approval from institutional review boards (IRBs) at the study centers where the device will be used. The FDA and the IRB at each institution at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk.

During a study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, record keeping, and prohibitions on the promotion of investigational devices. The investigators must obtain patient informed consent, 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. However, if we were to seek approval for our Omniflow II biosynthetic vascular graft, 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;

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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 and 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.

### **Other U.S. Regulations**

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

We are subject to federal, state, and local laws, rules, regulations, and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling, and disposal of certain hazardous and potentially hazardous substances used in connection with our operations. Although we believe that we have complied with these laws and regulations in all material respects and to date have not been required to take any action to correct any noncompliance, there can be no assurance that we will not be required to incur significant costs to comply with environmental regulations in the future.

### ***Non-U.S. Regulation***

Sales of medical devices are subject to regulatory requirements in many countries. The regulatory review process may vary greatly from country to country. For example, 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.



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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 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.

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.

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.

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

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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.

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, 2015, 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 recent formation of our Chinese subsidiary in 2015, we transferred our licenses from our third-party license holders to our subsidiary.

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

## **Third-Party Reimbursement**

### *United States*

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

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

In many instances, third-party payors cover the procedures performed using our products using price fee schedules that do not vary reimbursement to reflect the cost of the products and equipment used in performing those procedures. In other instances, payment or reimbursement is separately available for the products and equipment used, in addition to payment or reimbursement for the procedure itself. Even if coverage is available, third-party payors may place restrictions on the circumstances in which they provide coverage or may offer reimbursement that is not sufficient to cover the cost of our products. Many of the products that compete with ours are less expensive. Therefore, although coverage may be available for our products and the related procedures, the levels of approved coverage may not be sufficient to justify using our products instead of those of competitors.

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

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control the cost of healthcare by authorizing fewer elective surgical procedures. Under current prospective payment systems, such as the diagnosis-related group system and the hospital out-patient prospective payment system, both of which are used by Medicare and in many managed care systems used by private third party payors, the reimbursement for our products will be incorporated into the overall reimbursement of a procedure, and there will be no separate reimbursement for our products. As a result, we cannot be certain that hospital administrators and physicians will purchase our products.

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

### ***Non-U.S.***

Our success in non-U.S. markets will depend largely upon the availability of reimbursement from the third-party payors through which healthcare providers are paid in those markets. Reimbursement and healthcare payment systems in non-U.S. markets vary significantly by country. The main types of healthcare payment systems are government sponsored healthcare and private insurance. As in the United States, reimbursement is subject to legislative and regulatory changes and is susceptible to budgetary pressures. Reimbursement approval must be obtained individually in each country in which our products are marketed. Outside the United States, we may pursue reimbursement approval in those countries in which we sell directly to the hospital. In other markets, we generally rely on the distributors who sell our products to obtain reimbursement approval in those countries in which they will sell our products. There can be no assurance that reimbursement approval will be received.

### **Fraud and Abuse Laws**

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

### **Patient Protection and Affordable Care Act**

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

### **Employees**

We had 356 employees, including 339 full-time employees, at December 31, 2015.

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### **Financial Information by Business Segment and Geographic Data**

We operate in one reportable industry segment: the design, marketing, sales 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 2015.

### **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](http://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](http://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.*

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**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 we sell;

increased product and price competition, due to market conditions, the regulatory landscape or other factors;

changes in the mix of products we sell;

our pricing strategy with respect to different product lines;

strategic actions by us, such as acquisitions of businesses, products, or technologies;

effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;

the divestiture or discontinuation of a product line or other revenue generating activity;

the relocation and integration of manufacturing 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 distributorships;

our ability to collect outstanding accounts receivable in selected countries outside of the United States;

the expiration or utilization of deferred tax assets such as net operating loss carry-forwards;

market reception of our new or improved product offerings; and

the loss of any significant customer, especially in regard to any product that has a limited customer base.

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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.

***Our management and independent auditors have identified a material weakness in our internal controls, and we may be unable to develop, implement and maintain appropriate controls in future periods, which may lead to errors or omissions in our financial statements.***

In connection with the preparation of our 2015 financial statements, our management team and independent registered public accounting firm identified a weakness in our internal controls that was considered to be a material weakness. Specifically, we did not have control activities in revenue recognition that were designed and operating effectively, including controls to validate pricing terms and conditions in our revenue contracts such that the price of a sale is fixed or determinable at the time of shipment for all sales made by the Company. Control activities that were historically in place (i) did not always address relevant risks and (ii) were not performed on all relevant transactions. In addition, the level of precision of the management review controls was not sufficient to identify all potential errors. This material weakness did not result in any adjustments or

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restatements of our audited and unaudited consolidated financial statements or disclosures for any prior period previously reported by the Company. However, if the material weakness is not remediated, then it could result in material financial misstatements in the future.

We are currently designing and implementing new procedures and controls intended to remediate the material weakness described above. While this design and implementation phase is underway, we may rely significantly on manual procedures to assist us with meeting the objectives otherwise fulfilled by an effective control environment. The implementation of new procedures and controls could be costly and distract management from other activities. Prior to the complete remediation of this material weakness, there remains a risk that the transitional controls on which we currently rely will fail to be sufficiently effective, which could result in errors in our financial statements. If the new controls being implemented to address the material weakness and to strengthen the overall internal control are not designed or do not operate effectively, if we are unsuccessful in implementing or following these new processes or we are otherwise unable to remediate this material weakness, it may result in untimely or inaccurate reporting of our financial condition or results of operations.

In addition, although we review and evaluate internal control systems to allow management to report on the sufficiency of our internal controls, we cannot assure you that we will not discover additional weaknesses in our internal control over financial reporting in the future. Any such additional weakness or failure to remediate the existing weakness could materially adversely affect our financial condition or ability to comply with applicable financial reporting requirements, which could result in the imposition of sanctions or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our common stock.

*If we are unable to expand our product 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 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 is affected by our ability to:

identify in a timely manner new market trends and customer needs;

keep pace with technological changes and industry standards;

obtain regulatory clearance or approval of new products and technologies;

successfully develop cost-effective manufacturing processes for such products;

commercially introduce such products and technologies; and

achieve market acceptance.

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

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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 17 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 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;

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;

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 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 is 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 such country for the foreseeable future. Our ability to manage these operations efficiently and effectively may be impaired due to their remoteness from our Burlington, Massachusetts headquarters.

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Additionally, 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 2016; however there can be no assurances that this will be achieved on the expected timetable or that transfer costs will not exceed our expectations.

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.

### ***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, 2015, 42% 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.

### ***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, 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

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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, 2015, 2014 and 2013, 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.

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

if healthcare spending is reduced, particularly in the United States, in response to government-enacted healthcare reform, general economic conditions, or the influence of accountable care organizations;

if the reimbursement rates for the medical procedures in which our products are used are reduced or limited; or

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

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

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

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

We derive a significant portion of our net sales from operations in markets outside of the United States. For the year ended December 31, 2015, 42% 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;

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;

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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;

a shortage of high-quality sales personnel and distributors;

loss of any key personnel who possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;

the imposition of restrictions on the activities of foreign agents, representatives, and distributors;

scrutiny of foreign tax authorities, which could result in significant fines, penalties, and additional taxes being imposed on us;

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles;

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

difficulties in enforcing or defending intellectual property rights;

exposure to different legal and political standards; and

political, economic, and/or social instability.

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

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

We rely on sole- and limited-source suppliers for some of our important product components and certain products. For example, our TRIVEX system and associated disposables, as well as components of our EndoRE remote endarterectomy product line, are manufactured for us by third-party suppliers. Additionally, we rely on a sole-source supplier for the ovine material used for our Omniflow II biosynthetic vascular graft. There are relatively few, or in some cases no, alternative, validated sources of supply for these components and products. And in some cases, we do not have supply agreements with these suppliers, instead placing orders on an as-needed basis. At any time, these suppliers could discontinue or become incapable of the manufacture or supply of these components or products on acceptable terms or otherwise. We do not ordinarily carry a significant inventory of these components and products. Identifying and qualifying additional or replacement suppliers, if

required, may not be accomplished quickly or at all and could involve significant additional costs. Any supply interruption from our suppliers or failure to obtain replacement suppliers would interrupt our ability to manufacture our products and result in production delays and increased costs and may limit our ability to deliver products to our customers. This could lead to customer dissatisfaction and damage to our reputation, and our financial condition or results of operations may be harmed.

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

Our principal worldwide executive, distribution, and manufacturing operations are located in three adjacent leased facilities located in Burlington, Massachusetts. We also have a manufacturing site in North Melbourne, Australia. These facilities and the manufacturing equipment we use to produce our products would be difficult to

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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 to alternate manufacturing facilities, and we would be forced to rely on third-party manufacturers. 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.

***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.***

Though the trend has slowed recently, 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 procedures of the type in which our devices would be used. 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.

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

If our products are defectively designed, manufactured, or labeled, contain defective components, or are misused, or if our products 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 in the use of some of our products, we do not require that physicians be trained in the use of our products, and physicians may use our products incorrectly or in procedures not contemplated by us. We are from time to time involved in product liability claims. Product liability claims could divert management's attention from our core business, 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 product 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.

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*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 other 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.

Our distribution agreements are typically exclusive with terms of up to three 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.

### **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 to healthcare professionals and may compete by discounting the prices of their products, including for example, the federal Anti-Kickback Statute, the federal False Claims Act, the federal Health



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Insurance Portability and Accountability Act of 1996, state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, civil and criminal penalties, damages, fines, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. Although in structuring our sales and marketing practices and customer discount arrangements we strive to comply with those laws and regulations, we cannot assure you that:

government officials charged with responsibility for enforcing those laws will not assert that our sales and marketing practices or customer discount arrangements are in violation of those laws or regulations; or

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

***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 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 are wide-ranging and govern, among other things, the testing, marketing, and premarket clearance or approval of new medical devices, in addition to regulating manufacturing 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 or selling 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

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, we will not be able to sell our products, and our future growth will be significantly hampered.***

## Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

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

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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.

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 post market requirements, our manufacturing operations could be disrupted, our product sales and profitability could suffer, and we may become subject to a wide variety of FDA enforcement actions.***

After a device is placed on the market, numerous regulatory requirements apply. 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. The FDA enforces the Quality System Regulation 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 a Quality System Regulation 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.

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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 may be subject to product recalls or product 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, marketing, sales and development activities, and manufacturing processes are subject to extensive and rigorous regulation by the FDA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. These authorities have been increasing their scrutiny of our industry. If those regulatory bodies feel that we have failed to comply with regulatory standards or if we encounter unforeseen problems following initial approval of our products, there can be no assurance that any approval will not be subsequently withdrawn, suspended or conditioned upon extensive post-market study requirements, even after products have received marketing approval or clearance. 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 product approvals by any single regulatory agency will not precipitate one or more additional regulatory agencies from also withdrawing or suspending approval of any such product.

In the event that any of our products proves to be defective, we can voluntarily recall, or the FDA or foreign equivalent could require us to implement a recall of, any of our products, and, if someone is harmed by a malfunction or a product defect, we may experience product liability claims for such defects. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital and may harm our reputation and financial results. Future recalls or claims could also result in significant costs to us and significant adverse publicity, which could harm our ability to market our products in the future.

In 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 2011, 2012, and 2013, we voluntarily recalled certain lots of our AlboGraft vascular graft. In March 2012, regulatory agencies in France and the UK issued Prohibition Notices, which prohibited us from selling AlboGraft vascular grafts in these countries pending our ability to address their concerns. Though these prohibitions were lifted by the end of 2012 and we believe that the failures associated with those lots were isolated, there can be no assurance that there will not be a recurrence or that other problems related to our AlboGraft vascular graft will not develop in the future.

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%

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excise tax on U.S. sales of most medical devices has been 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. 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. The impact of the PPACA and these proposals 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 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 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 adversely affect both our pricing flexibility and the demand for our products. Even when we develop or acquire a promising new product, we may find limited demand for the product 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 re sterilize 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 periodic 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 registrations and imposed additional requirements for obtaining approval, which includes procedures related to conducting clinical trials in China. Any delay in product registrations could have a negative impact on our results of operations.

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

Our AlboGraft Vascular Graft, AlboSure Vascular Patch, and XenoSure Biologic Patch 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, 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

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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.

### **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;

prevent our competitors from gaining access to our proprietary information and technology; or

permit us to gain or maintain a competitive advantage.

The issuance of a patent is not conclusive as to its validity or enforceability. Any patents we have obtained or will obtain in the future might also be invalidated or circumvented by third parties. In addition, 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

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complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties intellectual property rights, and we cannot assure you that our products or methods do not infringe the patents or other intellectual property rights of third parties. Our efforts to identify and avoid infringing on third parties intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

be expensive and time consuming to defend;

result in us being required to pay significant damages to third parties for past use of the asserted intellectual property;

harm our reputation;

cause us to cease making or selling products that incorporate the challenged intellectual property;

require us to redesign, reengineer, or rebrand our products, which may not be possible and could be costly and time consuming if it is possible to do so at all;

require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;

divert the attention of our management and key personnel from other tasks important to the success of our business; or

result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

It is also possible that 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.

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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;

light volume of trading in our common stock;

public concern as to the safety or efficacy of our products;

the public's reaction to our press releases, our other public announcements, and our filings with the SEC;

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

our determination whether or not to undertake or continue a share repurchase program;

strategic actions by us or our competitors, such as acquisitions, divestitures or restructurings;

dilutive issuances of additional securities;

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 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;

the discontinuation of a product line or other revenue generating activity;

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adverse regulatory actions which may necessitate recalls of our products or warning letters that negatively affect the markets for our products;

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; and

changes in stock market analyst recommendations or earnings estimates regarding our common stock, comparable companies, or our industry generally.

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 directors and executive officers have significant voting power and may take actions that may not be in the best interests of our other stockholders.***

Our directors and executive officers collectively control approximately 25% of our outstanding common stock as of December 31, 2105. As a result, these stockholders, if they were to act together, would have significant influence on most 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.

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*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 August 2016 but which we expect to extend at a fair market renewal rate. We also own a 6,140 square foot manufacturing facility in North Melbourne, Australia. 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.

### **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, 2015, that, in the opinion of management, would be reasonably expected to have a material adverse effect on our financial position, results of operations or cash flows.

### **Item 4. Mine Safety Disclosures**

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**  
**Market Information**

Our common stock 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, 2015:

	High	Low
<b>Year ended December 31, 2015:</b>		
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
<b>Year ended December 31, 2014:</b>		
First quarter ended March 31, 2014	\$ 8.50	\$ 7.42
Second quarter ended June 30, 2014	\$ 8.39	\$ 7.09
Third quarter ended September 30, 2014	\$ 8.35	\$ 6.71
Fourth quarter ended December 31, 2014	\$ 7.65	\$ 6.48

**Holders of Record**

On March 2, 2016, the closing price per share of our common stock was \$14.47 as reported on The NASDAQ Global Market, and we had approximately 220 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 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
Fiscal Year 2014				
	March 20, 2014	April 3, 2014	\$0.035	\$546
	May 22, 2014	June 5, 2014	\$0.035	\$547
	August 21, 2014	September 4, 2014	\$0.035	\$607
	November 20, 2014	December 4, 2014	\$0.035	\$608

On February 22, 2016, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.045 per share payable on April 4, 2016, to stockholders of record at the close of business on March 21, 2016, which will total approximately \$0.8 million in payments.



**Table of Contents****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, 2010, through the end of LeMaitre's fiscal year ended December 31, 2015. The graph assumes an investment of \$100.00 made on December 31, 2010, 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.

	12/31/10	12/31/11	12/31/12	12/31/13	12/31/14	12/31/15
LeMaitre Vascular, Inc	100.00	88.54	87.35	124.08	120.71	276.16
NASDAQ Composite	100.00	100.53	116.92	166.19	188.78	199.95
NASDAQ Medical Equipment	100.00	115.55	128.17	151.89	175.17	190.80
Old Peer Group	100.00	113.98	138.32	227.95	242.57	162.21
New Peer Group	100.00	100.91	121.06	226.10	253.34	173.23

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

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

**Recent Sales of Unregistered Securities**

Not Applicable.

**Issuer Purchases of Equity Securities**

In the quarter ended December 31, 2015, we did not repurchase any shares of our common stock.



**Table of Contents****Item 6. Selected Financial Data**

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements and the related notes which are included elsewhere in this Annual Report and the Management's Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report. We have derived the consolidated statement of operations data for the years ended December 31, 2015, 2014, and 2013 and the consolidated balance sheet data as of December 31, 2015 and 2014, 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, 2012 and 2011, and the consolidated balance sheet data as of December 31, 2013, 2012, and 2011 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.

	2015	Year ended December 31, (in thousands, except per share data)			
	2014	2013	2012	2011	
<b>Consolidated Statements of Operations Data:</b>					
Net sales	\$ 78,352	\$ 71,097	\$ 64,549	\$ 56,735	\$ 57,685
Cost of sales	24,186	22,666	19,434	15,867	17,458
<b>Gross profit</b>	54,166	48,431	45,115	40,868	40,227
<b>Operating expenses:</b>					
Sales and marketing	22,780	22,087	22,143	20,811	19,375
General and administrative	14,010	13,889	12,576	10,973	11,228
Research and development	5,479	4,671	5,243	5,092	4,425
Medical device excise tax	744	689	635		
Restructuring charges		526			2,161
Gain on divestitures	(360)			(248)	(735)
Impairment charges		229			83
Total operating expenses	42,653	42,091	40,597	36,628	36,537
<b>Income from operations</b>	11,513	6,340	4,518	4,240	3,690
<b>Other income (expense):</b>					
Interest income	13	1	4	78	11
Interest expense		(5)	(12)	(1)	
Foreign currency gain (loss)	(102)	(16)	(182)	(324)	51
Other income, net					
<b>Total other income (loss)</b>	(89)	(20)	(190)	(247)	62
<b>Income before income tax</b>	11,424	6,320	4,328	3,993	3,752
<b>Provision for income taxes</b>	3,666	2,405	1,126	1,422	1,609
<b>Net income</b>	\$ 7,758	\$ 3,915	\$ 3,202	\$ 2,571	\$ 2,143
<b>Earnings per share of common stock:</b>					
Basic	\$ 0.44	\$ 0.24	\$ 0.21	\$ 0.17	\$ 0.14
Diluted	\$ 0.42	\$ 0.23	\$ 0.20	\$ 0.16	\$ 0.13
<b>Weighted-average shares outstanding:</b>					
Basic	17,764	16,614	15,317	15,194	15,458
Diluted	18,316	17,008	15,764	15,638	15,989

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Cash dividends declared per common share	\$ 0.16	\$ 0.14	\$ 0.12	\$ 0.10	\$ 0.08
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	2015	2014	December 31, 2013 (in thousands)	2012	2011
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 27,451	\$ 18,692	\$ 14,711	\$ 16,448	\$ 20,132
Current assets	58,184	48,588	41,725	39,131	39,687
Total assets	90,704	81,492	70,492	63,060	59,687
Current liabilities	10,368	10,041	10,220	8,394	6,539
Long-term liabilities	2,452	3,244	3,710	1,778	1,060
Total liabilities	12,820	13,285	13,930	10,172	7,599
Total stockholders' equity	77,884	68,207	56,562	52,888	52,088

**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. 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 \$750 million. We have grown our business by using a multi-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. 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 continue to seek to expand our vascular device offerings through new product development. We currently manufacture most of our product lines in our Burlington, Massachusetts, headquarters.

Our products are used 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, balloon catheters, carotid shunts, biologic vascular patches, radiopaque marking tape, anastomotic clips, remote endarterectomy devices, laparoscopic cholecystectomy devices, prosthetic vascular grafts, biologic vascular grafts, and powered phlebectomy devices.

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

Our business opportunities include the following:

the long-term growth of our sales force in North America, Europe, Asia and the Pacific Rim;

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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 in such territories; and

the consolidation of product manufacturing into our facilities in our Burlington, Massachusetts corporate headquarters.

We sell our products primarily through a direct sales force. As of December 31, 2015 our sales force was comprised of 86 sales representatives in North America, Europe, Japan, China and Australia. We also sell our products in other geographies through distributors. Our worldwide headquarters and main manufacturing facility is located in Burlington, Massachusetts. Our international headquarters are 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 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, our selling prices, mainly due to strong sales service. In the valvulotome market segment, we believe that we have been able to materially increase our selling prices without losing significant market segment share. In contrast, we have experienced less success in highly competitive product segments such as polyester and ePTFE prosthetic 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 radiopaque tape, where we face recently introduced competitive products. 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 other highly competitive market segments.

In recent years we have also experienced comparatively greater success in geographic markets outside of the United States, including Europe and other non-traditional markets for our devices such as China and Saudi Arabia. Sales to these geographies generally feature lower average selling prices. As a result, if we keep seeking 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:

In March 2013, we began shipping directly to Canadian hospitals from our sales office in Mississauga, Canada.

In October 2013, we terminated our existing distribution agreements in Norway and Australia in order to sell directly to hospitals in each country beginning January 2014. The agreements required us to pay approximately \$0.4 million in exchange for the purchase of their customer list for our products and minimal inventory.

In 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.

In 2015, we entered into definitive agreements with seven UreSil, LLC distributors in Europe in order to terminate their distribution of our newly acquired Tru-Incise valvulotome and we began selling direct-to-hospital in those geographies. The termination fee was approximately \$0.2 million



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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.

We anticipate that the expansion of our direct sales organization in China will result in increased sales and marketing expenses during 2016. As of December 31, 2015 we had four 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 July 2013, we acquired substantially all of the assets of Clinical Instruments International, Inc. (Clinical Instruments), a manufacturer of latex and polyurethane shunts and catheters, for \$1.1 million.

In August 2013, we acquired substantially all of the assets of InaVein, LLC (InaVein), a manufacturer of a varicose veins removal system. The purchase price consisted of \$2.5 million plus potential contingent consideration of up to \$1.4 million. In October 2014, we paid \$0.2 million related to a sales milestone.

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 is 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 (Applied Medical) for \$0.4 million.

In September 2014, we terminated our 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 the third quarter of 2015.

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 April 2013, we launched the MultiTASC device.

In May 2013, we launched the 1.5mm Expandable LeMaitre Valvulotome.

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In June 2013, we launched the AlboSure Vascular Patch.

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

In December 2014, we launched the LeMills valvulotome.

In December 2015, we launched the long AnastoClip AC.

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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 the second quarter of 2014.

In March 2015, we initiated the transfer of the manufacturing of our 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 plans to establish a production line for our newly acquired Tru-Incise valvulotome product line at our facility in Burlington. We have been purchasing the devices from UreSil, LLC since the acquisition. We expect the establishment of the production line and transition of manufacturing to be completed in the first quarter of 2016.

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 restructuring and other non-recurring charges, as well as longer term impacts to revenues and operating expenditures. For example, in 2014, we incurred \$0.5 million of restructuring charges related to reductions in force and our Clinical Instruments facility closure and relocation to Burlington, Massachusetts, and in 2015 we recognized a gain of \$0.4 million related to the sale of The UnBalloon, our non-occlusive modeling catheter line.

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, 2015, approximately 42% of our sales occurred 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 local currency, thereby partially mitigating our transaction risk exposure. However, most of our foreign sales are denominated in local currency, and 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 in U.S. dollars than we did before the rate increase went into effect. We estimate that the strong U.S. dollar decreased our 2015 revenues by approximately \$5.6 million, reduced 2015 gross margin by 1.7 percentage points, and reduced 2015 operating income by approximately \$2.8 million as compared to the exchange rates for the year ended December 31, 2014.

## **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, 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.



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**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.

**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 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.

**Restructuring.** Restructuring expense includes costs directly associated with distribution agreement termination expenses, severance and retention costs for terminated employees, factory relocation costs, and other expenses associated with restructuring our operations.

**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, 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 from the U.S. and Europe 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. Recently, we have experienced stronger sales growth in Europe as well as other non-traditional markets such as China and Saudi Arabia as compared to the United States. Sales to these geographies generally feature lower average selling prices. As a result, if revenue continues to grow outside of the United States, it could negatively impact our gross margin.

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

**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. We plan to increase the size of our sales force in 2016, and we expect that selling and marketing expenses will increase commensurately.

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**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 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 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 Federal tax 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 have assessed the need for a valuation allowance against our deferred tax assets and concluded that as of December 31, 2015, we will 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 believe it is more likely than not that such assets will not be realized. Of the \$2.2 million of valuation allowance, \$2 million resulted from the Xenotis acquisition in Australia.

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We expect our effective tax rate to increase in 2016, as our state tax rates will be normalized. In 2015, a Massachusetts valuation allowance was reversed, which lowered our overall effective tax rate by 3.5%.

**Comparison of the year ended December 31, 2014, to the year ended December 31, 2013**

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:

	2014	2013	\$ Change	Percent change
	(\$ in thousands)			
Net sales	\$ 71,097	\$ 64,549	\$ 6,548	10%
Net sales by geography:				
Americas	\$ 43,502	\$ 41,140	\$ 2,362	6%
International	27,595	23,409	4,186	18%
Total	\$ 71,097	\$ 64,549	\$ 6,548	10%

**Net sales.** Net sales increased 10% to \$71.1 million in 2014 from \$64.5 million in 2013. Sales from newly acquired product lines contributed 5.0% to the sales growth.

Net sales increases of \$6.5 million in 2014 were primarily driven by increased sales in biologic vascular patches of \$2.2 million, valvulotomes of \$1.0 million, and catheters of \$0.9 million. In addition, sales of powered phlebectomy systems, acquired in 2013, increased \$1.2 million and our newly acquired biologic vascular graft sales were \$1.0 million. This sales growth was partially offset by decreased sales of vessel closure systems and remote endarterectomy devices. The primary drivers of increased sales were higher average selling prices across nearly all product lines and increases in unit sales.

Direct-to-hospital net sales were 91% of net sales in 2014 compared to 92% in 2013. This decrease was primarily driven by sales to our Chinese distributors which increased \$0.2 million to \$1.2 million in 2014 and consisted of powered phlebectomy systems, vessel closure systems, and radiopaque tape.

**Net sales by geography.** Net sales in the Americas increased \$2.4 million to \$43.5 million in 2014. The increase was largely the result of higher average selling prices across nearly all product lines, as well as increased sales of powered phlebectomy systems, biologic vascular patches, valvulotomes, and catheters. These increases were partially offset by a decrease in vessel closure systems of \$0.6 million and remote endarterectomy devices of \$0.2 million. International net sales increased \$4.2 million to \$27.6 million in 2014. The increase was primarily driven by higher sales of biologic vascular patches, catheters, shunts, and valvulotomes. In addition, our newly acquired biologic vascular graft sales were primarily in Europe.

	2014	2013	\$ Change	Percent change
	(\$ in thousands)			
Gross profit	\$ 48,431	\$ 45,115	\$ 3,316	7%
Gross margin	68.1%	69.9%	*	(1.8%)

\* Not applicable

**Gross profit.** Gross profit increased \$3.3 million to \$48.4 million in 2014 from \$45.1 million in 2013, while our gross margin decreased 1.8% to 68.1% in 2014. The gross margin decrease was largely driven by unfavorable product and geographic mix, certain manufacturing cost increases, and increased inventory write-offs, primarily related to our non-occlusive modeling catheter product line. These decreases were partially offset by higher average selling prices across all product lines and the completion of the biologic vascular patch manufacturing transition in the second quarter of 2014. The gross profit increase was a result of higher sales.



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	2014	2013	\$ change (\$ in thousands)	Percent change	2014 as a % of Net Sales	2013 as a % of Net Sales
Sales and marketing	\$ 22,087	\$ 22,143	\$ (56)	0%	31%	34%
General and administrative	13,889	12,576	1,313	10%	20%	19%
Research and development	4,671	5,243	(572)	(11%)	7%	8%
Medical device excise tax	689	635	54	9%	1%	1%
Restructuring	526		526	*	1%	*
Impairment charges	229		229	*	*	*
	\$ 42,091	\$ 40,597	\$ 1,494	4%	59%	63%

\* Not a meaningful percentage.

**Sales and marketing.** Sales and marketing expenses were \$22.1 million in 2014 and 2013. As a percentage of net sales, sales and marketing expenses were 31% in 2014, down 3% from the prior year. Selling expenses decreased \$0.1 million while marketing expenses increased by \$0.1 million. Selling expense decreases were driven by lower travel and sales meetings and related costs of \$0.4 million, and were partially offset by start-up costs associated with our Shanghai office and increased compensation and other personnel related costs, partly due to additional sales personnel in Norway and Australia. Marketing expense increases were primarily driven by increased compensation costs.

**General and administrative.** General and administrative expenses increased 10% to \$13.9 million in 2014 from \$12.6 million in 2013. The increase was mainly driven by increased compensation related expenses of \$0.5 million, acquisition related expenses of \$0.5 million, increased intangibles amortization of \$0.3 million, increased professional services costs of \$0.2 million, and was partially offset by decreased travel related costs of \$0.1 million. As a percentage of net sales, general and administrative expenses were 20% in 2014 as compared to 19% in the prior year.

**Research and development.** Research and development expenses decreased 11% to \$4.7 million in 2014 from \$5.2 million in 2013. As a percentage of net sales, research and development expenses decreased to 7% in 2014 from 8% in 2013. Product development expenses decreased \$0.4 million primarily due to lower product testing costs of \$0.2 million and lower compensation expenses. Clinical and regulatory costs decreased \$0.2 million, primarily due to compensation related expenses.

**Medical device excise tax.** The medical device excise tax was \$0.7 million in 2014 compared to \$0.6 million in 2013, an increase of approximately \$50,000 driven by increased U.S. sales.

**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.

**Impairment charges.** 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 in 2014.

**Other income (expense).** Foreign exchange losses for 2014 were \$16,000 compared to \$0.2 million for 2013 as the exchange rates between the US dollar and Euro were generally unchanged in 2014 vs. 2013.

**Income tax expense.** We recorded a provision for taxes of \$2.4 million on pre-tax income of \$6.3 million in 2014 compared to \$1.1 million on pre-tax income of \$4.3 million in 2013. The 2014 provision was comprised of

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Federal tax in the United States of \$1.9 million, state taxes of \$0.2 million and foreign taxes of \$0.3 million. The 2013 provision was comprised of Federal tax in the United States of \$2.5 million, state taxes of \$0.1 million and a net foreign benefit of \$1.4 million. Our effective tax rate differed from the U.S. statutory tax rate in 2014 principally due to manufacturing deductions, research and development tax credits, effect of foreign taxes, stock-based compensation, other permanent differences, state taxes and Subpart-F income.

We assessed the need for a valuation allowance against our deferred tax assets and concluded that as of December 31, 2014, we would continue to carry a valuation allowance against \$3.2 million of deferred tax assets, principally foreign net operating loss and capital loss carry-forwards, as based on the weight of available evidence, we believed it to be more likely than not that such assets would not be realized. Of the \$3.2 million of valuation allowance, \$2.2 million resulted from the Xenotis acquisition in Australia.

## **Liquidity and Capital Resources**

At December 31, 2015, our cash and cash equivalents totaled \$27.5 million compared to \$18.7 million at December 31, 2014. Our cash equivalents are highly liquid investments with maturities of 90 days or less at the date of purchase and consist of money market funds, and are stated at cost, which approximates fair value. We did not hold any marketable securities nor any mortgage asset-backed or auction-rate securities in our investment portfolio as of December 31, 2015. All of our cash balances held outside of the United States are available for corporate use, with the exception of \$2.9 million held by subsidiaries in jurisdictions for which earnings are planned to be permanently reinvested.

## ***Operating and Capital Expenditure Requirements***

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

For the year ended December 31, 2015, we reported operating income of \$11.4 million. For the year ended December 31, 2014, we reported operating income of \$6.3 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;

future acquisition related payments;

payments associated with U.S income, sales 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.

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Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, make payments under our quarterly dividend program, 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



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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.

**Share Offering**

On June 4, 2014, we issued 1,644,500 shares of our common stock, \$0.01 par value per share, at a price to the public of \$7.00 per share less underwriting discounts. The net proceeds, after deducting the underwriting discounts and other estimated offering expenses, were approximately \$10.5 million. We have deployed a portion of the net proceeds from the offering towards our recent acquisitions and expect to use the remainder for general corporate purposes, including product development, working capital needs, capital expenditures, payments under our quarterly dividend program, deferred payments related to prior acquisitions, and the funding of future acquisitions.

**Cash Flows**

	Year ended December 31,		
	2015	2014	Net Change
	(\$ in thousands)		
Cash and cash equivalents	\$ 27,451	\$ 18,692	\$ 8,759
Cash flows provided by (used in):			
Operating activities	\$ 11,438	\$ 5,512	\$ 5,926
Investing activities	(3,480)	(7,748)	4,268
Financing activities	1,079	6,662	(5,583)

**Operating activities.** 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 provided by operating activities was \$5.5 million in 2014, and consisted of \$3.9 million in net income, adjusted for non-cash items of \$5.5 million (including depreciation and amortization of \$3.3 million, stock-based compensation of \$1.3 million, provision for inventory write-offs of \$0.7 million, and impairment charges of \$0.2 million) and was offset by working capital increases of \$3.9 million. Working capital increases were driven by increased inventory of \$2.7 million, primarily related to powered phlebectomy devices and biologic vascular patches, increased accounts receivable of \$0.7 million, and decreased accounts payable and other liabilities of \$1.0 million, all of which were partially offset by decreased other assets of \$0.5 million.

**Investing activities.** 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 investing activities was \$7.7 million in 2014. This was driven by acquisition related payments of \$6.6 million, primarily related to Xenotis and Applied Medical, and the purchase of property and equipment of \$1.2 million.

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**Financing activities.** 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.

Net cash provided by financing activities was \$6.7 million in 2014, driven primarily by net proceeds from our stock offering of \$10.5 million and proceeds from stock option exercises of \$0.3 million and partially offset by payments of common stock dividends of \$2.3 million, payment of the debt assumed in the Xenotis acquisition of \$1.1 million, payment of deferred acquisition payments of \$0.7 million, and the acquisition of \$0.2 million of treasury stock to cover minimum withholding taxes of restricted stock unit vestings.

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

Record Date	Payment Date	Per Share Amount	Dividend Payment (in thousands)
Fiscal Year 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
Fiscal Year 2014			
March 20, 2014	April 3, 2014	\$0.035	\$546
May 22, 2014	June 5, 2014	\$0.035	\$547
August 21, 2014	September 4, 2014	\$0.035	\$607
November 20, 2014	December 4, 2014	\$0.035	\$608

On February 22, 2016, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.045 per share payable on April 4, 2016, to stockholders of record at the close of business on March 21, 2016, which will total approximately \$0.8 million in payments.

**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, 2015:

Contractual obligations	Total	Less	1-3	3-5	More
		than	years	years	than
		1 year	(in thousands)		5 years
Operating leases	\$ 7,604	\$ 1,258	\$ 1,969	\$ 1,769	\$ 2,608
Purchase commitments for inventory	2,777	2,556	221		
<b>Total contractual obligations</b>	<b>\$ 10,381</b>	<b>\$ 3,814</b>	<b>\$ 2,190</b>	<b>\$ 1,769</b>	<b>\$ 2,608</b>

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 2016 and which we currently expect to extend; 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; and our Shanghai, China office, expiring in 2017. They also include automobile and equipment leases.

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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 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.

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.

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### ***Accounts Receivable***

Our accounts receivable are with customers based in the United States and internationally. Accounts receivable generally are due within 30 to 90 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns, other than in certain European markets where longer payment terms are customary and may range from 90 to 240 days. We perform ongoing credit evaluations of the financial condition of our customers and adjust credit limits based upon payment history and the current creditworthiness of the customers, as determined by a review of their current credit information. We continuously monitor aging reports, collections, and payments from customers, and maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues we identify.

We closely monitor outstanding receivables for potential collection risks, including those that may arise from economic conditions, in both the U.S. and international economies. Our European sales to government-owned or supported customers such as hospitals, distributors and agents, in 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, 2015 our receivables in Italy and Spain totaled \$1.0 million and \$0.5 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, 2015, 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***

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.

### ***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.

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We also issue restricted stock units (RSUs) as an additional form of equity compensation to our employees, officers, and directors, pursuant to our stockholder-approved Second Amended and Restated 2006 Stock Option and Incentive Plan. RSUs entitle the grantee to an issuance of stock at no cost and generally vest over a period of time determined by our Board of Directors at the time of grant based upon the continued service to the company. The fair market value of the award is determined based on the number of RSUs granted and the market value of our common stock on the grant date and is amortized to expense over the period of vesting. Unvested RSUs are forfeited and canceled as of the date that employment or service to the company terminates. RSUs are settled in shares of our common stock upon vesting. We may repurchase common stock upon our employees vesting in RSUs in order to cover any minimum tax withholding liability as a result of the RSUs having vested.

Share-based compensation charges are recorded net of the estimated forfeitures based upon historical rates and will be adjusted in future periods to reflect the results of actual forfeitures and vesting. 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 \$1.4 million in connection with share-based payment awards for the year ended December 31, 2015. The future expense of non-vested share-based awards of approximately \$3.2 million is to be recognized over a weighted-average period of 3.5 years. During 2015, we granted stock options at a weighted average fair value of \$2.80 and RSUs with weighted average fair value of \$11.32.

***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 \$17.8 million and \$17.3 million as of December 31, 2015 and 2014, 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 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

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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 \$6.3 million as of December 31, 2015 and \$7.2 million as of December 31, 2014. 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, 2015, 2014, and 2013, 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 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

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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 \$2.2 million and \$3.2 million as of December 31, 2015 and 2014, respectively.

### **Recent Accounting Pronouncements**

On February 25, 2016, the Financial Accounting Standards Board (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.

During November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which simplifies the presentation of deferred income taxes. This ASU requires that deferred tax assets and liabilities be classified as non-current in a statement of financial position. We early adopted ASU 2015-17 effective December 31, 2015 on a prospective basis. Adoption of this ASU resulted in a reclassification of our net current deferred tax asset to the net non-current deferred tax asset in our Consolidated Balance Sheet as of December 31, 2015. No prior periods were retrospectively adjusted.

In May 2014, the FASB issued a new accounting standard that provides for a comprehensive model to use in the accounting for revenue arising from contracts with customers that will replace most existing revenue recognition guidance in GAAP. Under this standard, revenue will be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. This standard will be effective for annual reporting periods beginning after December 15, 2017, allows for either full retrospective or modified retrospective application, and early adoption is permitted for annual reporting periods beginning after December 15, 2016. We are assessing the new standard and which adoption method we will apply. We have not yet determined the impact on our results of operations.

### ***Off-Balance Sheet Arrangements***

We did not have any off-balance sheet arrangements as of December 31, 2015. 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.

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### **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.

#### *Foreign Currency Risk*

During fiscal 2015 and 2014, 42% 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 2015 and fiscal 2014. Our largest exposures to foreign currency exchange rates exist primarily with the Euro, Canadian dollar, Australian dollar and Japanese yen.

During fiscal 2015 and fiscal 2014, we recorded \$0.1 million and \$16 thousand 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 \$1.4 million for fiscal 2015.

#### *Interest Rate Risk*

At December 31, 2015, we held \$27.5 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.



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Based on their evaluation as of December 31, 2015, the end of the period covered by this report, our Chief Executive Officer and Chief Financial Officer, with the participation of management, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)) were not effective as of December 31, 2015 due to a material weakness in internal control over financial reporting described below in Management's Report on Internal Control Over Financial Reporting.

Notwithstanding the material weakness discussed below, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that the consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States (US GAAP).

### **Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Under the supervision and with the participation of the principal executive and financial officers of the Company, management assessed our internal control over financial reporting based upon the framework in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our Chief Executive Officer and Chief Financial Officer concluded that, due to the material weakness described below (which was not remediated as of December 31, 2015), we did not maintain effective internal control over financial reporting, specifically with respect to revenue recognition, as of December 31, 2015. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

We concluded that we had a material weakness because we did not have control activities in revenue recognition that were designed and operating effectively, including controls to validate pricing terms and conditions in our revenue contracts such that the price of a sale is fixed or determinable at the time of shipment for all sales made by the Company. Control activities that were historically in place (i) did not always address relevant risks and (ii) were not performed on all relevant transactions. In addition, the level of precision of the management review controls was not sufficient to identify all potential errors.

Notwithstanding the material weaknesses discussed above and management's assessment that internal control over financial reporting was ineffective as of December 31, 2015, our management, including our Chief Executive Officer and Chief Financial Officer, believes that the consolidated financial statements contained in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States. This material weakness did not result in any adjustments or restatements of our audited and unaudited consolidated financial statements or disclosures for any prior period previously reported by the Company.

Our internal control over financial reporting as of December 31, 2015 has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their respective report which is included herein.

### **Management's Plan for Remediation**

Management is in the process of designing and implementing a remediation plan intended to address the control deficiencies which resulted in the material weakness described above. These remediation efforts are expected to include enhancement of automated and management oversight controls to validate pricing terms and conditions. Management will report regularly to the Audit Committee regarding the status of the implementation activities.

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**Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting that occurred during the fiscal quarter ended December 31, 2015, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting. Management is in the process of preparing and implementing a remediation plan to address the material weakness described above.

**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, 2015, 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.

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.

A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment.

As of December 31, 2015, management disclosed a material weakness around the design and effectiveness of its controls over revenue recognition.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control – Integrated Framework* issued by COSO.

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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, 2015. The material weakness identified above was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2015 consolidated financial statements, and this report does not affect our report dated March 10, 2016, which expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Boston, Massachusetts

March 10, 2016

**Item 9B. Other Information**

Not Applicable.

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

The information responsive to this item is incorporated by reference herein from the information to be contained in the sections entitled Directors, Executive Officers and Key Employees, Corporate Governance, and Meetings and Committees of the Board of Directors in our 2016 definitive proxy statement (2016 Definitive Proxy Statement) for the 2016 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the year ended December 31, 2015.

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 2016 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 2016 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 2016 Definitive Proxy Statement.

**Equity Compensation Plan Information**

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2015. 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

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	(a)	(b)	(a) (c)
<i>Equity compensation plans approved by security holders</i>	1,927,325	\$ 8.39	2,329,104
<i>Equity compensation plans not approved by security holders</i>			
<b>Total</b>	<b>1,927,325</b>	<b>\$ 8.39</b>	<b>2,329,104</b>

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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 2016 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 2016 Definitive Proxy Statement.

**Table of Contents****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	



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2.4	Amendment No. 3 to Purchase Option Agreement dated October 1, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.	10-K	3/27/13	001-33092
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
3.1	Amended and Restated By-laws of the Registrant	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	
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	
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	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
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.				X
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
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
101.PRE	XRBL Taxonomy Extension Presentation Linkbase Document.				X

Indicates a management contract or any compensatory plan, contract, or arrangement.

- \* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of LeMaitre Vascular, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 10, 2016.

LEMAITRE VASCULAR, INC.

By: /s/ GEORGE W. LEMAITRE  
**George W. LeMaitre,**

**Chief Executive Officer and Chairman of the Board**

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints George W. LeMaitre and Joseph P. Pellegrino, Jr., and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ GEORGE W. LEMAITRE <b>George W. LeMaitre</b>	Chief Executive Officer and Chairman of the Board ( <i>Principal Executive Officer</i> )	March 10, 2016
/s/ JOSEPH P. PELLEGRINO, JR. <b>Joseph P. Pellegrino, Jr.</b>	Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	March 10, 2016
/s/ LAWRENCE J. JASINSKI <b>Lawrence J. Jasinski</b>	Director	March 10, 2016
/s/ CORNELIA W. LEMAITRE <b>Cornelia W. LeMaitre</b>	Director	March 10, 2016
/s/ JOHN J. O'CONNOR <b>John J. O' Connor</b>	Director	March 10, 2016
/s/ DAVID B. ROBERTS <b>David B. Roberts</b>	President and Director	March 10, 2016
/s/ JOHN A. ROUSH <b>John A. Roush</b>	Director	March 10, 2016
/s/ MICHAEL H. THOMAS <b>Michael H. Thomas</b>	Director	March 10, 2016



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**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders

LeMaitre Vascular, Inc.

We have audited the accompanying consolidated balance sheet of LeMaitre Vascular, Inc. and subsidiaries (the Company) as of December 31, 2015, and the related consolidated statements of operations, comprehensive income, changes in stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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 the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of LeMaitre Vascular, Inc. and subsidiaries as of December 31, 2015, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in the 2013 *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 10, 2016 expressed an adverse opinion thereon.

/s/ GRANT THORNTON LLP

Boston, Massachusetts

March 10, 2016

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of LeMaitre Vascular, Inc.

We have audited the accompanying consolidated balance sheet of LeMaitre Vascular, Inc. (the Company) as of December 31, 2014, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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 the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of LeMaitre Vascular, Inc. at December 31, 2014, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 18, 2015

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Balance Sheets**

	December 31, 2015	December 31, 2014
	(in thousands, except share data)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,451	\$ 18,692
Accounts receivable, net of allowances of \$243 at December 31, 2015, and \$242 at December 31, 2014	11,971	10,803
Inventory	15,205	16,714
Prepaid expenses and other current assets	3,557	2,379
<b>Total current assets</b>	<b>58,184</b>	<b>48,588</b>
Property and equipment, net	7,022	6,878
Goodwill	17,789	17,281
Other intangibles, net	6,336	7,157
Deferred tax assets	1,205	1,418
Other assets	168	170
<b>Total assets</b>	<b>\$ 90,704</b>	<b>\$ 81,492</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,366	\$ 1,127
Accrued expenses	8,837	7,479
Acquisition-related obligations	165	1,435
<b>Total current liabilities</b>	<b>10,368</b>	<b>10,041</b>
Deferred tax liabilities	1,678	2,919
Other long-term liabilities	774	325
<b>Total liabilities</b>	<b>12,820</b>	<b>13,285</b>
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 3,000,000 shares; none outstanding		
Common stock, \$0.01 par value; authorized 37,000,000 shares; issued 19,748,321 shares at December 31, 2015, and 18,778,436 shares at December 31, 2014	197	188
Additional paid-in capital	82,094	75,389
Retained earnings (accumulated deficit)	8,161	3,248
Accumulated other comprehensive loss	(4,049)	(2,365)
Treasury stock, at cost; 1,431,139 shares at December 31, 2015, and 1,407,211 shares at December 31, 2014	(8,519)	(8,253)
<b>Total stockholders' equity</b>	<b>77,884</b>	<b>68,207</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 90,704</b>	<b>\$ 81,492</b>

See accompanying notes to consolidated financial statements.



**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Operations**

	2015	Year ended December 31, 2014 (in thousands, except per share data)	2013
Net sales	\$ 78,352	\$ 71,097	\$ 64,549
Cost of sales	24,186	22,666	19,434
Gross profit	54,166	48,431	45,115
Sales and marketing	22,780	22,087	22,143
General and administrative	14,010	13,889	12,576
Research and development	5,479	4,671	5,243
Medical device excise tax	744	689	635
Restructuring charges		526	
Gain on divestitures	(360)		
Impairment charges		229	
Total operating expenses	42,653	42,091	40,597
Income from operations	11,513	6,340	4,518
Other income (expense):			
Interest income	13	1	4
Interest expense		(5)	(12)
Foreign currency loss	(102)	(16)	(182)
Income before income taxes	11,424	6,320	4,328
Provision for income taxes	3,666	2,405	1,126
Net income	\$ 7,758	\$ 3,915	\$ 3,202
Earnings per share of common stock:			
Basic	\$ 0.44	\$ 0.24	\$ 0.21
Diluted	\$ 0.42	\$ 0.23	\$ 0.20
Weighted-average shares outstanding:			
Basic	17,764	16,614	15,317
Diluted	18,316	17,008	15,764
Cash dividends declared per common share	\$ 0.16	\$ 0.14	\$ 0.12

See accompanying notes to consolidated financial statements.

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Comprehensive Income**

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
Net income	\$ 7,758	\$ 3,915	\$ 3,202
Other comprehensive income (loss):			
Foreign currency translation adjustment, net	(1,684)	(2,112)	180
Total other comprehensive income (loss)	(1,684)	(2,112)	180
Comprehensive income	\$ 6,074	\$ 1,803	\$ 3,382

See accompanying notes to consolidated financial statements.

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Stockholders' Equity**

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2012	16,539,621	\$ 165	\$ 64,694	\$ (3,869)	\$ (433)	1,323,537	\$ (7,669)	\$ 52,888
Net income				3,202				3,202
Other comprehensive income					180			180
Issuance of common stock for stock options exercised	307,425	4	1,214					1,218
Vested restricted stock units	112,284	1						1
Excess tax benefits from stock-based compensation awards			31					31
Stock based compensation expense			1,253					1,253
Repurchase of common stock at cost						56,582	(373)	(373)
Common stock cash dividend paid			(1,838)					(1,838)
Balance at December 31, 2013	16,959,330	\$ 170	\$ 65,354	\$ (667)	\$ (253)	1,380,119	\$ (8,042)	\$ 56,562

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See accompanying notes to consolidated financial statements.

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Stockholders Equity (continued)**

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Total Stockholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2013	16,959,330	\$ 170	\$ 65,354	\$ (667)	\$ (253)	1,380,119	\$ (8,042)	\$ 56,562
Net income				3,915				3,915
Other comprehensive income					(2,112)			(2,112)
Issuance of common stock	1,644,500	16	10,474					10,490
Issuance of common stock for stock options exercised	103,064	1	342					343
Vested restricted stock units	71,542	1						1
Excess tax benefits from stock-based compensation awards			225					225
Stock based compensation expense			1,302					1,302
Repurchase of common stock at cost						27,092	(211)	(211)
Common stock cash dividend paid			(2,308)					(2,308)
Balance at December 31, 2014	18,778,436	\$ 188	\$ 75,389	\$ 3,248	\$ (2,365)	1,407,211	\$ (8,253)	\$ 68,207

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See accompanying notes to consolidated financial statements.



**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Stockholders Equity (continued)**

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders Equity
	Shares	Amount				Shares	Amount	
Balance at December 31, 2014	18,778,436	\$ 188	\$ 75,389	\$ 3,248	\$ (2,365)	1,407,211	\$ (8,253)	\$ 68,207
Net income				7,758				7,758
Other comprehensive income					(1,684)			(1,684)
Issuance of common stock for stock options exercised	906,936	9	4,827					4,836
Vested restricted stock units	62,949							0
Excess tax benefits from stock-based compensation awards			454					454
Stock based compensation expense			1,424					1,424
Repurchase of common stock at cost						23,928	(266)	(266)
Common stock cash dividend paid				(2,845)				(2,845)
Balance at December 31, 2015	19,748,321	\$ 197	\$ 82,094	\$ 8,161	\$ (4,049)	1,431,139	\$ (8,519)	\$ 77,884

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See accompanying notes to consolidated financial statements.

**Table of Contents****LeMaitre Vascular, Inc.****Consolidated Statements of Cash Flows**

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
<b>Operating activities</b>			
Net income	\$ 7,758	\$ 3,915	\$ 3,202
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	3,394	3,334	2,793
Stock-based compensation	1,424	1,302	1,253
Fair value adjustments to contingent consideration obligations		138	57
Impairment charges		229	
Provision (recovery) of doubtful accounts	182	54	(29)
Provision for inventory write-downs	462	667	479
Provision (benefit) for deferred income taxes	(384)	(72)	287
Gain on divestitures	(360)		
Excess tax benefits from stock-based compensation awards	(454)	(225)	(31)
Loss on disposal of property and equipment	5	8	52
Foreign currency transaction gain	100	60	115
Changes in operating assets and liabilities:			
Accounts receivable	(1,879)	(654)	(1,247)
Inventory	608	(2,711)	(2,168)
Prepaid expenses and other assets	(2,035)	553	(236)
Accounts payable and other liabilities	2,617	(1,086)	861
Net cash provided by operating activities	11,438	5,512	5,388
<b>Investing activities</b>			
Purchases of property and equipment	(2,273)	(1,174)	(2,733)
Payments related to acquisitions, net of cash acquired	(1,565)	(6,559)	(3,291)
Proceeds from divestitures, net of expenses	360		
Proceeds from sale of property and equipment	15		
Purchase of intellectual property	(17)	(15)	(164)
Net cash used in investing activities	(3,480)	(7,748)	(6,188)
<b>Financing activities</b>			
Payments of long-term debt		(1,133)	
Payment of deferred acquisition consideration	(1,100)	(745)	
Proceeds from issuance of common stock	4,836	10,834	1,219
Purchase of treasury stock	(266)	(211)	(373)
Common stock cash dividend paid	(2,845)	(2,308)	(1,838)
Excess tax benefits from stock-based compensation awards	454	225	31
Net cash provided by (used in) financing activities	1,079	6,662	(961)
Effect of exchange rate changes on cash and cash equivalents	(278)	(445)	24
Net increase (decrease) in cash and cash equivalents	8,759	3,981	(1,737)
Cash and cash equivalents at beginning of year	18,692	14,711	16,448
Cash and cash equivalents at end of year	\$ 27,451	\$ 18,692	\$ 14,711

Supplemental disclosures of cash flow information (see Note 13).

See accompanying notes to consolidated financial statements.



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**LeMaitre Vascular, Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2015**

**1. Significant Accounting Policies and Related Matters**

***Description of Business***

Unless the context requires otherwise, references to LeMaitre Vascular, we, our, and us refer to LeMaitre Vascular, Inc. and our subsidiaries. We develop, manufacture, and market medical devices and implants used primarily in the field of vascular surgery. We operate in a single segment in which our principal product lines include the following: valvulotomes, balloon catheters, carotid shunts, biologic vascular patches, biologic vascular grafts, radiopaque marking tape, anastomotic clips, remote endarterectomy devices, laparoscopic cholecystectomy devices, vascular grafts, angioscopes, and powered phlebectomy devices. Our offices are located in Burlington, Massachusetts; Mississauga, Canada; Sulzbach, Germany; Milan, Italy; Madrid, Spain; North Melbourne, Australia; Tokyo, Japan; and Shanghai, China.

***Consolidation and Basis of Presentation***

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

***Foreign Currency Translation***

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

***Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to bad debts, inventories, intangible assets, sales returns and discounts, and income taxes are reviewed on an ongoing basis and updated as appropriate. Actual results could differ from those estimates.

***Revenue Recognition***

Our revenue is derived primarily from the sale of disposable or implantable devices used during vascular surgery. We sell primarily directly to hospitals and to a lesser extent to distributors, as described below, and, during the periods presented in our consolidated financial statements, entered into consigned inventory arrangements with either hospitals or distributors on a limited basis.

We 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 assess whether the fee is fixed or determinable based on the terms of

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the agreement associated with the transaction. Sales transactions are based on prices that are determinable at the time the customer's purchase order is accepted by us. Orders that are not accompanied with a purchase order are either confirmed in writing or verbally with the customer.

After the delivery of the product, there is no uncertainty about customer acceptance due to the nature of the product. There is no contingency for acceptance, warranty, or price protection. We do not recognize revenue on consigned sales until the customer notifies us that the products have been used. 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 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 product return history.

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

***Research and Development Expense***

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

***Shipping and Handling Costs***

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

***Advertising Costs***

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

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
Advertising expense	\$ 428	\$ 462	\$ 421

***Cash and Cash Equivalents***

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

**Table of Contents****Concentrations of Credit Risk**

Our financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. Cash equivalents represent highly liquid investments with maturities of 90 days or less at the date of purchase. Credit risk related to cash and cash equivalents are limited based on the creditworthiness of the financial institutions at which these funds are held. We maintain cash balances in several banks. Accounts located in the United States are insured by the Federal Deposit Insurance Corporation (FDIC) up to \$250,000. Certain of our account balances exceed the FDIC limit. Cash balances held outside the United States totaled approximately \$4.7 million as of December 31, 2015.

Our accounts receivable are with customers based in the United States and internationally. Accounts receivable generally are due within 30 to 90 days of invoice and are stated at amounts due from customers, net of an allowance for doubtful accounts and sales returns, other than in certain European markets where longer payment terms are customary and may range from 90 to 240 days. We perform ongoing credit evaluations of the financial condition of our customers and adjust credit limits based upon payment history and the current creditworthiness of the customers, as determined by a review of their current credit information. We continuously monitor aging reports, collections, and payments from customers, and maintain a provision for estimated credit losses based upon historical experience and any specific customer collection issues we identify.

We closely monitor outstanding receivables for potential collection risks, including those that may arise from economic conditions, in both the U.S. and international economies. Our European sales to government-owned or supported customers such as hospitals, distributors and agents, in Southern Europe, specifically Italy and Spain may be subject to significant payment delays due to government austerity measures impacting funding and payment practices. As of December 31, 2015 our receivables in Italy and Spain totaled \$1.0 million and \$0.5 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, 2015, if significant changes were to occur in the payment practices of these European governments or if government funding becomes unavailable, we may not be able to collect on receivables due to us from these customers and our write offs of uncollectible amounts may increase.

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

	<b>Balance at Beginning of Period</b>	<b>Additions (recoveries) charged to Income</b>	<b>Deductions from Reserves</b>	<b>Balance at End of Period</b>
	(in thousands)			
<b>Allowance for doubtful accounts and sales returns:</b>				
Year ended December 31, 2015	\$ 242	\$ 182	\$ 181	243
Year ended December 31, 2014	263	54	75	242
Year ended December 31, 2013	326	(29)	34	263

**Fair Value of Financial Instruments**

Our financial instruments include cash and cash equivalents, accounts receivable and trade payables. The fair value of the majority of these instruments approximates their carrying value based upon their short-term nature or variable rates of interest.

**Table of Contents*****Inventory***

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.

***Property and Equipment***

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

Description	Useful Life
Computers and equipment	3 5 years
Machinery and equipment	3 10 years
Leasehold improvements	The shorter of its useful life or lease term

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

***Valuation of Business Combinations***

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

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

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

***Contingent Consideration***

The Financial Accounting Standards Board (the FASB) requires contingent consideration be recognized at the date of acquisition, based on the fair value at that date, and then re-measured periodically through adjustments to net income.

***Impairment of Long-lived Assets***

We review our long-lived assets (primarily property and equipment and intangible assets) subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Conditions that may indicate impairment





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include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset, a product recall, or an adverse action or assessment by a regulator. If an impairment indicator exists, we test the intangible asset for recoverability. We record impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. Impairment is measured based on the fair market value of the affected asset using discounted cash flows.

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

This impairment adjustment falls within Level 3 of the fair value hierarchy, due to the use of significant unobservable inputs to determine fair value. The fair value measurements were calculated using unobservable inputs, primarily using the income approach, specifically the discounted cash flow method. As the product line was terminated, we concluded there would be no additional future cashflows.

### ***Goodwill***

Goodwill represents the amount of consideration paid in connection with business acquisitions in excess of the fair value of assets acquired and liabilities assumed. Goodwill is evaluated for impairment annually or more frequently if indicators of impairment are present or changes in circumstances suggest that an impairment may exist. We evaluate the December 31 balance of the carrying value of goodwill based on a single reporting unit annually. We perform an assessment of qualitative factors to determine if it is more likely than not that the fair value of our reporting unit is less than its carrying value as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The more likely than not threshold is defined as having a likelihood of more than 50 percent. If required, the next step of the goodwill impairment test is to determine the fair value of the reporting unit. The implied fair value of goodwill is determined on the same basis as the amount of goodwill recognized in connection with a business combination. Specifically, the fair value of a reporting unit is allocated to all of the assets and liabilities (including any unrecognized intangible assets) as if the reporting unit had been acquired in a business combination as of the date of the impairment review and as if the fair value of the reporting unit was the price paid to acquire the reporting unit. The excess of the fair value of a reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss shall be recognized in an amount equal to that excess. We have determined that no goodwill impairment charges were required for the years ended December 31, 2015, 2014, or 2013.

### ***Other Intangible Assets***

Other intangible assets consist primarily of patents, trademarks, technology licenses, and customer relationships acquired in connection with business acquisitions and asset acquisitions and are amortized over their estimated useful lives, ranging from 1 to 13 years.

### ***Stock-based Compensation***

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

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We also issue restricted stock units (RSUs) as an additional form of equity compensation to our employees, officers, and directors, pursuant to our stockholder-approved 2006 Plan. RSUs entitle the grantee to an issuance of stock at no cost and generally vest over a period of time determined by our Board of Directors at the time of grant based upon the continued service to the company. The fair market value of the award is determined based on the number of RSUs granted and the market value of our common stock on the grant date and is amortized to expense over the period of vesting. Unvested RSUs are forfeited and canceled as of the date that employment or service to the company terminates. RSUs are settled in shares of our common stock upon vesting. We 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 are recorded net of the estimated forfeitures based upon historical rates and will be adjusted in future periods to reflect the results of actual forfeitures and vesting. Share-based compensation charges are recorded across the consolidated statement of operations based upon the grantee's primary function.

### ***Commitments and Contingencies***

In the normal course of business, we are subject to proceedings, lawsuits, and other claims and assessments for matters related to, among other things, patent infringement, business acquisitions, employment, and product recalls. We assess the likelihood of any adverse judgments or outcomes to these matters as well as potential ranges of probable losses. A determination of the amount of reserves required, if any, for these contingencies is made after careful analysis of each individual issue. The required reserves may change in the future due to new developments in each matter or changes in approach such as a change in settlement strategy in dealing with these matters. We record charges for the losses we anticipate incurring in connection with litigation and claims against us when we conclude a loss is probable and we can reasonably estimate these losses. During the years ended December 31, 2015, 2014, and 2013, we were not subject to any material litigation or claims and assessments.

### ***Income Taxes***

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

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

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

During November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which simplifies the presentation of deferred income taxes. This ASU requires that deferred tax assets and liabilities be classified as non-current in a statement of financial position. We early adopted ASU 2015-17 effective October 31, 2015 on a prospective basis. Adoption of this ASU resulted in a reclassification of our net current deferred tax asset to the net non-current deferred tax asset in our Consolidated Balance Sheet as of December 31, 2015. No prior periods were retrospectively adjusted.

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A provision has not been made for U.S. or additional non-U.S. taxes on \$2.9 million of undistributed earnings of international subsidiaries that could be subject to taxation if remitted to the U.S. because we plan to keep these amounts permanently reinvested overseas. To the extent such foreign earnings were remitted in the future a deferred tax liability of \$0.8 million would be recorded.

**Comprehensive Income**

Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Other than reported net income, comprehensive income includes foreign currency translation adjustments, which are disclosed in the accompanying consolidated statements of comprehensive income. There were no reclassifications out of comprehensive income for the years ended December 31, 2015 and 2014.

Accumulated other comprehensive loss consisted of foreign currency translation adjustment losses of \$4.0 million and \$2.4 million as of December 31, 2015 and 2014, respectively.

**Restructuring**

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

**Earnings per Share**

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

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

	<b>Year ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
	<b>(in thousands, except per share data)</b>		
<b>Basic:</b>			
Net income available for common stockholders	\$ 7,758	\$ 3,915	\$ 3,202
Weighted average shares outstanding	17,764	16,614	15,317
Basic earnings per share	\$ 0.44	\$ 0.24	\$ 0.21
<b>Diluted:</b>			
Net income available for common stockholders	\$ 7,758	\$ 3,915	\$ 3,202
Weighted-average shares outstanding	17,764	16,614	15,317
Common stock equivalents, if dilutive	552	394	447
Shares used in computing diluted earnings per common share	18,316	17,008	15,764
Diluted earnings per share	\$ 0.42	\$ 0.23	\$ 0.20
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	55	277	373



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**Table of Contents*****Recent Accounting Pronouncements***

On February 25, 2016, the Financial Accounting Standards Board (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.

During November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes*, which simplifies the presentation of deferred income taxes. This ASU requires that deferred tax assets and liabilities be classified as non-current in a statement of financial position. We early adopted ASU 2015-17 effective December 31, 2015 on a prospective basis. Adoption of this ASU resulted in a reclassification of our net current deferred tax asset to the net non-current deferred tax asset in our Consolidated Balance Sheet as of December 31, 2015. No prior periods were retrospectively adjusted.

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 are currently evaluating the impact of ASU 2015-11 on our consolidated financial statements.

On May 28, 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)*, was issued in three parts: (a) Section A, *Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs-Contracts with Customers (Subtopic 340-40)*, (b) Section B, *Conforming Amendments to Other Topics and Subtopics in the Codification and Status Tables* and (c) Section C, *Background Information and Basis for Conclusions*. The standard 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 has not yet selected a transition method and is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

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**Table of Contents****2. Acquisitions and Divestitures**

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

***XenoSure Manufacturing and Distribution Rights***

In October 2012, we entered into an asset purchase agreement (the Neovasc Agreement) with Neovasc, Inc. and its subsidiary, Neovasc Medical Inc. (collectively Neovasc) to acquire the manufacturing and distribution rights of the XenoSure biologic vascular patch. Previously, we were the exclusive distributor of the XenoSure biologic vascular patch through January 26, 2016 and held an option to purchase the manufacturing and distribution rights. Assets acquired in October 2012 include intellectual property, manufacturing know-how, and a five year non-compete agreement. Other provisions of the Neovasc Agreement include transitional assistance from Neovasc and mutual indemnification for losses arising out of or relating to certain breaches of, and misrepresentations under, the Neovasc Agreement. Additionally, we entered into a supply agreement with Neovasc while we transition manufacturing to our Burlington facility.

The purchase price for this acquisition was \$4.6 million. We paid Neovasc \$4.3 million at the closing of the acquisition. The remaining \$0.3 million was paid in October 2013. We accounted for the acquisition as a business combination. We recorded \$2.8 million of intangible assets and \$1.8 million of goodwill. The weighted-average amortization period for the acquired intangible assets as of November 1, 2012 was 12.0 years. The goodwill is deductible for tax purposes over 15 years.

***Clinical Instruments International, Inc.***

In July 2013, we entered into an asset purchase agreement with Clinical Instruments International, Inc. (Clinical Instruments) to acquire substantially all the assets of Clinical Instruments for \$1.1 million. We paid \$0.9 million at the closing and paid the remaining \$0.2 million in October 2014. We accounted for the acquisition as a business combination. Assets acquired include inventory and intellectual property. We recorded \$0.2 million of inventory, \$0.3 million of intangible assets and \$0.6 million of goodwill. The weighted-average amortization period for the acquired intangible assets as of July 31, 2013 was 5.7 years. The goodwill is deductible for tax purposes over 15 years.

***InaVein, LLC***

In August 2013, we entered into an Asset Purchase Agreement with InaVein, LLC (InaVein) to acquire substantially all the assets of InaVein for \$2.5 million and potential acquisition-related contingent consideration totaling \$1.4 million in 2014 and 2015 dependent on the sales performance of the acquired business and the timing of regulatory approval in China. We paid \$2.1 million at the closing and the remaining \$0.4 million fixed payment was made in September 2014. We accounted for the acquisition as a business combination. Assets acquired include receivables, inventory, equipment, and intellectual property. Liabilities assumed include payables and service contracts.

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The following table summarizes the fair value of the assets acquired and liabilities assumed at the date of the acquisition:

	<b>Allocated Fair Value (in thousands)</b>
Current assets	\$ 670
Property and equipment, net	154
Intangible assets	1,143
Goodwill	668
<b>Total assets acquired</b>	<b>2,635</b>
Total liabilities assumed	(100)
	<b>\$ 2,535</b>

The goodwill of \$0.7 million will be deductible for tax purposes over 15 years.

Of the \$1.1 million of acquired intangible assets, the following table reflects the allocation of the acquired intangible assets and related estimated useful lives:

	<b>Allocated Fair Value (in thousands)</b>	<b>Weighted Average Useful Life</b>
Non-compete agreement	\$ 70	5.0 years
Tradenname	163	8.0 years
Technology	354	6.0 years
Customer relationships	556	7.0 years
<b>Total intangible assets</b>	<b>\$ 1,143</b>	

The contingent consideration was initially valued at the date of acquisition and is remeasured each reporting period until the contingency is resolved. Based upon stronger than expected sales to China, we recorded an increase of \$0.1 million related to the contingent consideration, which was dependent on the sales performance of the acquired business in the first year following the closing of the transaction as a charge to general and administrative expense in 2014. In October 2014, we paid \$0.2 million related to the first sales related milestone. Neither the milestone related to the timing of the regulatory approval in China nor the second sales milestone was achieved.

***Xenotis Pty Ltd***

In August 2014, we entered into a stock purchase agreement with the shareholders of Xenotis Pty Ltd (Xenotis) to acquire all of the capital stock of Xenotis for \$6.7 million with a mechanism for a purchase price adjustment based on the net tangible assets of Xenotis at closing. Xenotis is 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. We paid \$5.1 million at the closing and the remaining \$1.4 million was paid in August 2015. The net tangible asset purchase price adjustment of \$0.2 million was paid in November 2014. We accounted for the acquisition as a business combination. Assets acquired include receivables, inventory, equipment, a building, and intellectual property. Liabilities assumed include payables and debt.

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The following table summarizes the fair value of the assets acquired and liabilities assumed at the date of the acquisition:

	<b>Allocated Fair Value (in thousands)</b>
Current assets	\$ 2,110
Property and equipment, net	2,054
Intangible assets	1,794
Goodwill	2,475
<b>Total assets acquired</b>	<b>8,433</b>
Total liabilities assumed	(1,731)
<b>Purchase price</b>	<b>\$ 6,702</b>

Total liabilities assumed of \$1.7 million include \$1.1 million of assumed debt, which we paid in full in August 2014. The purchase accounting is complete.

The goodwill of \$2.5 million will not be deductible for tax purposes. In addition, we acquired deferred tax assets of \$2.4 million which consist primarily of net operating loss carry-forwards and capital loss carry-forwards. We assessed the need for a valuation allowance on the acquired deferred tax assets in Australia. Our assessment considered evidence such as current profitability, utilization of certain available tax assets and liabilities, and projected future earnings. Based on this evidence, we concluded that it was more likely than not that we would not be able to utilize the deferred tax assets in Australia. We recorded a full valuation allowance on these deferred tax assets.

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

	<b>Allocated Fair Value (in thousands)</b>	<b>Weighted Average Useful Life</b>
Non-compete agreement	\$ 135	5.0 years
Tradename	142	7.0 years
Technology	1,465	7.0 years
Customer relationships	52	7.0 years
<b>Total intangible assets</b>	<b>\$ 1,794</b>	

In September 2014, we entered into definitive agreements with eight former Xenotis distributors in Europe to terminate their distribution of our Omniflow II biosynthetic vascular grafts for \$1.3 million. We paid approximately \$1.1 million in 2014 with the remainder due in 2015. We recorded \$0.4 million of inventory and \$0.9 million of intangible assets. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transactions. The weighted-average amortization period for the acquired intangible assets is 5.0 years.

**Angioscope**

In September 2014, we entered into an asset purchase agreement with Applied Medical Resource Corporation (Applied Medical) to acquire substantially all the assets related to Applied Medical's angioscope product line for \$0.4 million. We paid \$0.3 million at closing and the remaining \$0.1 million is payable in December 2015. We accounted for the acquisition as a business combination. Assets acquired include inventory, property and equipment, and intellectual property.





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The following table summarizes the fair value of the assets acquired and liabilities assumed at the date of the acquisition:

	<b>Allocated Fair Value (in thousands)</b>
Inventory	\$ 26
Property and equipment, net	38
Intangible assets	276
Goodwill	80
<b>Total assets acquired</b>	<b>420</b>
Total liabilities assumed	
<b>Purchase price</b>	<b>\$ 420</b>

The goodwill of \$0.1 million is deductible for tax purposes over 15 years.

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

	<b>Allocated Fair Value (in thousands)</b>	<b>Weighted Average Useful Life</b>
Non-compete agreement	\$ 3	2.0 years
Tradenname	28	7.0 years
Technology	163	7.0 years
Customer relationships	82	9.0 years
<b>Total intangible assets</b>	<b>\$ 276</b>	

***Tru-Incise Valvulotome***

In May 2015, we entered into an asset purchase agreement with UreSil, LLC (UreSil) to acquire the production and distribution rights of UreSil's Tru-Incise valvulotome for sales outside the United States for a purchase price of approximately \$1.4 million. We paid \$1.1 million with the remaining \$0.3 million payable at various points in 2016 and 2017. We accounted for the acquisition as a business combination. Assets acquired include inventory and intellectual property. We did not assume any liabilities. The purchase accounting is complete.

The following table summarizes the purchase price allocation at the date of the acquisition:

	<b>Allocated Fair Value (in thousands)</b>
Inventory	\$ 88
Intangible assets	545
Goodwill	742
<b>Purchase price</b>	<b>\$ 1,375</b>

The goodwill is deductible for tax purposes over 15 years.



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

	<b>Allocated Fair Value (in thousands)</b>	<b>Weighted Average Useful Life</b>
Non-compete agreement	\$ 120	5.0 years
Tradename license	17	3.0 years
Technology	391	7.0 years
Customer relationships	17	3.0 years
<b>Total intangible assets</b>	<b>\$ 545</b>	

**Other Items**

Following the Tru-Incise valvulotome acquisition, we entered into definitive agreements with eight UreSil distributors to terminate their distribution of the Tru-Incise valvulotome for aggregated termination fees of \$0.2 million. We recorded approximately \$0.2 million of intangible assets with a weighted-average amortization period of 3.0 years.

In August 2015, we entered into a definitive agreement with Grex Medical Oy (Grex) our then-distributor in Finland in order to terminate its distribution of our products and we began selling direct to hospitals in Finland as of January 1, 2016. The agreement required us to pay approximately \$0.2 million in exchange for the purchase of customer lists and a non-compete agreement.

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

**The UnBalloon Divestiture**

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 our The UnBalloon non-occlusive modeling catheter product line for \$0.4 million which was recognized as a gain on divestiture in the third quarter of 2015. During the year ended December 31, 2014, we had recognized an impairment charge of \$0.2 million on The UnBalloon non-occlusive modeling catheter product line. Additionally, in 2014 we recognized a \$0.3 million charge to cost of sales related to the non-occlusive modeling catheter inventory.

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

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Inventory consists of the following:

	As of December 31, 2015                      2014 (in thousands)	
Raw materials	\$ 3,062	\$ 3,367
Work-in-process	2,681	3,464
Finished products	9,462	9,883
 Total inventory	 \$ 15,205	 \$ 16,714

We held inventory on consignment of \$1.1 million and \$0.8 million as of December 31, 2015 and 2014, respectively.

**4. Property and Equipment**

Property and equipment consists of the following:

	As of December 31, 2015                      2014 (in thousands)	
Computers and equipment	\$ 2,560	\$ 2,399
Machinery and equipment	8,264	7,278
Building and leasehold improvements	6,143	5,721
 Gross property and equipment	 16,967	 15,398
Less accumulated depreciation	(9,945)	(8,520)
 Property and equipment, net	 \$ 7,022	 \$ 6,878

Depreciation expense is as follows:

	Year ended December 31, 2015                      2014                      2013 (in thousands)		
Depreciation expense	\$ 1,881	\$ 1,795	\$ 1,573

**5. Goodwill and Other Intangibles**

Goodwill consists of the following:

	As of December 31, 2015                      2014 (in thousands)	
Balance at beginning of year	\$ 17,281	\$ 15,031
Additions for acquisitions	742	2,555

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Effects of currency exchange	(234)	(305)
Balance at end of year	\$ 17,789	\$ 17,281

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Other intangibles consist of the following:

	2015		Net Carrying Value of Intangible Assets (in thousands)	2014		Net Carrying Value of Intangible Assets
	Gross Carrying Value	Accumulated Amortization		Gross Carrying Value	Accumulated Amortization	
Product technology	\$ 7,113	\$ 3,247	\$ 3,866	\$ 7,134	\$ 2,777	\$ 4,357
Trademarks and licenses	1,560	1,230	330	1,557	1,074	483
Customer relationships	3,801	2,143	1,658	3,694	1,781	1,913
Other intangible assets	1,297	815	482	1,084	680	404
<b>Total identifiable intangible assets</b>	<b>\$ 13,771</b>	<b>\$ 7,435</b>	<b>\$ 6,336</b>	<b>\$ 13,469</b>	<b>\$ 6,312</b>	<b>\$ 7,157</b>

These assets are being amortized over useful lives ranging from 1 to 13 years. The weighted-average amortization period for these intangibles as of December 31, 2015, is 6.0 years. Amortization expense is included in general and administrative expense and is as follows:

	Year ended December 31,		
	2015	2014	2013
Amortization expense	\$ 1,513	\$ 1,539	\$ 1,220

Estimated amortization expense for each of the five succeeding fiscal years, based upon the intangible assets at December 31, 2015, is as follows:

	Year ended December 31,				
	2016	2017	2018	2019	2020
Amortization expense	\$ 1,469	\$ 1,212	\$ 1,025	\$ 838	\$ 585

**6. Accrued Expenses**

Accrued expenses consist of the following:

	As of December 31,	
	2015	2014
Compensation and related taxes	\$ 6,062	\$ 4,819
Income and other taxes	483	444
Professional fees	530	496
Other	1,762	1,720
<b>Total</b>	<b>\$ 8,837</b>	<b>\$ 7,479</b>





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We conduct the majority of our operations in leased facilities, which are accounted for as operating leases. Certain leases include renewal options. In addition, we lease automobiles and equipment under operating leases. There were no assets held under capital leases at December 31, 2015 and 2014. Rent expense was as follows:

	Year ended December 31,		
	2015	2014	2013
		(in thousands)	
Rent expense	\$ 1,506	\$ 1,435	\$ 1,264

At December 31, 2015, the minimum rental commitments under all non-cancelable operating leases with initial or remaining terms of more than one year, for each of the following fiscal years, are as follows:

	Year ended December 31,					Thereafter
	2016	2017	2018	2019	2020	
			(in thousands)			
Operating leases	\$ 1,258	\$ 973	\$ 996	\$ 901	\$ 868	\$ 2,608

**Purchase Commitments**

As part of our normal course of business, we have purchase commitments to purchase \$2.8 million of inventory through 2017. 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.

**8. Income Taxes**

Income (loss) before income taxes is as follows:

	Year ended December 31,		
	2015	2014	2013
		(in thousands)	
United States	\$ 10,469	\$ 5,341	\$ 4,692
Foreign	955	979	(364)
Total	\$ 11,424	\$ 6,320	\$ 4,328

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

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

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
<b>Current:</b>			
Federal	\$ 3,218	\$ 2,058	\$ 504
State	333	238	143
Foreign	499	181	192
	4,050	2,477	839
<b>Deferred:</b>			
Federal	(12)	(176)	1,968
State	(466)	(14)	(84)
Foreign	94	118	(1,597)
	(384)	(72)	287
<b>Provision for income taxes</b>	<b>\$ 3,666</b>	<b>\$ 2,405</b>	<b>\$ 1,126</b>

We have reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. As of December 31, 2015, the gross amount of unrecognized tax benefits exclusive of interest and penalties was \$82,000, which may increase within the twelve months ending December 31, 2016. We remain subject to examination until the statute of limitations expires for each respective tax jurisdiction. The statute of limitations will be open with respect to these tax positions through 2024. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

	2015	2014	2013
	(in thousands)		
Unrecognized tax benefits at the beginning of year	\$ 23	\$ 111	\$ 321
Additions for tax positions of current year		20	
Additions for tax positions of prior years	59		
Reductions for settlements with taxing authorities.		(33)	
Reductions for lapses of the applicable statutes of limitations		(75)	(210)
Unrecognized tax benefits at the end of the year	\$ 82	\$ 23	\$ 111

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Deferred taxes are attributable to the following temporary differences:

	<b>As of December 31,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in thousands)</b>	
<b>Deferred tax assets:</b>		
Inventory	\$ 589	\$ 524
Net operating loss carryforwards	2,786	3,296
Tax credit carryforwards	654	585
Capital loss carryforwards	1,090	1,306
Reserves and accruals	631	434
Intangible assets	996	1,040
Stock options	355	312
Other	16	48
<b>Total deferred tax assets</b>	<b>7,117</b>	<b>7,545</b>
<b>Deferred tax liabilities:</b>		
Property and equipment	(668)	(706)
Goodwill	(3,504)	(3,130)
Foreign branch deferred offset	(1,176)	(1,411)
<b>Total deferred tax liabilities</b>	<b>(5,348)</b>	<b>(5,247)</b>
<b>Net deferred tax assets before valuation allowance</b>	<b>1,769</b>	<b>2,298</b>
<b>Valuation allowance</b>	<b>(2,242)</b>	<b>(3,157)</b>
<b>Net deferred tax liability</b>	<b>\$ (473)</b>	<b>\$ (859)</b>
<b>Deferred tax classification</b>		
Short-term deferred tax asset	\$	\$ 758
Short-term deferred tax liability		(116)
<b>Net short-term deferred tax asset</b>	<b>\$</b>	<b>\$ 642</b>
Long-term deferred tax asset	\$ 1,205	\$ 1,418
Long-term deferred tax liability	(1,678)	(2,919)
<b>Net long-term deferred tax liability</b>	<b>\$ (473)</b>	<b>\$ (1,501)</b>
<b>Net deferred tax liability</b>	<b>\$ (473)</b>	<b>\$ (859)</b>

We have assessed the need for a valuation allowance against our deferred tax assets and continue to carry a valuation allowance against \$2.2 million of foreign deferred tax assets; based on the weight of available evidence, we believe it is more likely than not such assets will not be realized. As of December 31, 2015, \$2.0 million of our valuation allowance related to our Xenotis acquisition in Australia. The valuation allowance against our deferred tax assets may require adjustment in the future based on changes in the mix of temporary differences, changes in tax laws, and operating performance.

In 2015, we released approximately \$400,000 of valuation allowances on certain deferred assets associated with state research and development credits. Our assessment considered evidence such as current profitability, utilization of certain available tax assets and liabilities, and projected future earnings. Based on this evidence, we concluded that it was more likely than not that we would generate sufficient pre-tax income in future periods to utilize all of our deferred tax assets related to state research and development credits.

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Realization of our deferred tax assets is dependent on our generating sufficient taxable income in future periods. Although we believe it is more likely than not that future taxable income will be sufficient to allow us to recover substantially all of the value of our deferred tax assets remaining after we apply the valuation allowances,

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realization is not assured and future events could cause us to change our judgment. In the event that actual results differ from our estimates, or we adjust these estimates in the future periods, further adjustments to our valuation allowance may be recorded, which could materially impact our financial position and net income (loss) in the period of the adjustment. As of December 31, 2015, we have net operating loss carryforwards in Australia of \$4.6 million that do not expire, in France of \$2.7 million that do not expire, in Spain of \$1.1 million that begin to expire in 2029, in Italy of \$0.6 million that do not expire, in Sweden of \$0.1 million that do not expire, in Switzerland of \$0.1 million that begin to expire in 2020 and in Norway of \$0.1 million that do not expire. We have a capital loss carryforward in Australia of \$3.6 million that does not expire. We also have state tax credit carryforwards of approximately \$1.0 million that are available to reduce future tax liabilities, which expire at various dates through 2030, or can be carried forward indefinitely. Approximately \$10,000 of these state tax credits relate to excess stock compensation deductions and as such, the benefit of these tax deductions will be credited to additional paid-in capital when we receive a cash benefit from these credits being utilized. Ownership changes, as defined by the Internal Revenue Code, may limit the amount of net operating losses and research and experimentation credit carryforwards that can be utilized annually to offset future taxable income and taxes payable.

A provision has not been made for U.S. or additional non-U.S. taxes on \$2.9 million of undistributed earnings of international subsidiaries that could be subject to taxation if remitted to the U.S. because we plan to keep these amounts permanently reinvested overseas. To the extent such foreign earnings were remitted in the future a deferred tax liability of \$0.8 million would be recorded.

A reconciliation of the Federal statutory rate to our effective tax rate is as follows:

	2015	2014	2013
Federal statutory rate	34.0%	34.0%	34.0%
State tax, net of federal benefit	(2.1%)	2.3%	0.4%
Effect of foreign taxes	1.4%	(1.4%)	(4.1%)
Subpart F income	2.2%	1.7%	2.2%
Valuation allowance	0.4%	0.1%	(38.2%)
Foreign deferred tax liability offset	(0.9%)	(1.9%)	36.1%
Manufacturing deduction	(2.8%)	(3.5%)	(2.9%)
Research & development tax credits	(1.5%)	(2.4%)	(8.0%)
Stock options	0.6%	4.3%	3.6%
Uncertain tax positions	0.6%	(0.2%)	(5.1%)
Italian permanent differences	0.0%	3.2%	5.2%
Other permanent differences	1.3%	3.1%	3.0%
Other	(1.1%)	(1.3%)	(0.2%)
Effective tax rate	32.1%	38.0%	26.0%

In September 2015 we were notified that our 2013 U.S. federal tax return would be audited by the Internal Revenue Service. As of December 31, 2015, the audit was in the early stages of the audit and no additional taxes have been assessed. We believe that there will be no material changes to our income taxes as a result of this audit. We are not currently under audit in any other tax jurisdictions.

In October 2014, the German tax authority completed an audit of our German subsidiary for the tax years 2009 through 2012. In October 2014, the French tax authority completed an audit of our French subsidiary for the tax years 2011 through 2013. The German audit resulted in additional income taxes of \$39,000. The France audit did not result in any material changes to our income tax liability. As of December 31, 2015, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions are:

United States	2012 and forward
Foreign	2008 and forward

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### **9. Stockholders Equity**

#### *Authorized Shares*

On June 14, 2012, our stockholders approved an amendment (Charter Amendment) to our Second Amended and Restated Certificate of Incorporation to reduce the number of authorized shares of common stock from 100,000,000 to 37,000,000 shares and of undesignated preferred stock from 5,000,000 to 3,000,000 shares. The Charter Amendment was previously approved by our Board of Directors on April 12, 2012, subject to approval by our stockholders. The Charter Amendment was filed with the Secretary of State of the State of Delaware on June 14, 2012.

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

#### *Share Offering*

On June 4, 2014, we issued 1,644,500 shares of our common stock, \$0.01 par value per share, at a price to the public of \$7.00 per share less underwriting discounts. The net proceeds, after deducting the underwriting discounts and other estimated offering expenses, were approximately \$10.5 million. We have deployed a portion of the net proceeds from the offering on our recent acquisitions and expect to use the remainder for general corporate purposes, including continued development of our products, working capital and capital expenditures, payments under our quarterly dividend program, deferred payments related to prior acquisitions, and to fund future acquisitions.

#### *Stock Award Plans*

Under our 1997, 1998, 2000, and 2004 stock option plans, we authorized the granting of options in the form of incentive stock options or non-qualified stock options to employees, directors, and consultants to purchase up to 1,688,702 shares of common stock. The stock options provide the holder the right to purchase common stock at a specific exercise price and the expected term will not exceed ten years. Incentive stock options are required to be issued at not less than fair market value at the date of the grant and generally vest over four or five years. The term of the options is determined by our Board of Directors but in no event will exceed ten years from date of grant, except with respect to one non-qualified option issued under our 1997 stock option plan.

In May 2006 we approved a 2006 Stock Option and Incentive Plan (as subsequently amended, the 2006 Plan), which became effective upon the initial public offering. In 2010 we amended the 2006 Plan to increase the aggregate pool of available shares to 3,000,000 of common stock, and in 2015 the 2006 Plan was amended to increase the aggregate pool to 5,500,000 shares. The 2006 Plan allows for granting of incentive stock options, non-qualified stock options, stock appreciation rights, RSUs, unrestricted stock awards, and deferred stock awards to our officers, employees, directors, and consultants. In connection with the adoption of the 2006 Plan, no further option grants are permitted under the 1997, 1998, 2000, and 2004 stock option plans and any expirations, cancellations, or terminations under the previous plans are available for issuance under the 2006 Plan. We may satisfy awards upon exercise of stock options or RSUs with either newly issued or treasury shares. The total number of shares currently authorized for the 2006 Plan is 7,118,003 shares, of which 2,329,104 remain available for grant as of December 31, 2015.

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

	2015	2014	2013
Dividend yield	1.4%	1.8%	1.8%
Volatility	28.6%	45.2%	57.8%
Risk-free interest rate	1.8%	2.0%	1.5%
Weighted average expected option term (in years)	5.6	5.5	5.5
Weighted average fair value per share of options granted	\$ 2.80	\$ 2.81	\$ 3.01
Aggregate intrinsic value of options exercised	\$ 6,534,800	\$ 819,478	\$ 1,009,726

A summary of option activity as of December 31, 2015 and the year then ended is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance outstanding at December 31, 2014	2,238,734	\$ 6.42	4.41	\$ 3,767,658
Granted	511,227	\$ 11.72		
Exercised (1)	(906,936)	\$ 5.33		\$ 6,534,800
Canceled / Expired	(107,045)	\$ 9.06		
Balance outstanding at December 31, 2015 (2)	1,735,980	\$ 8.39	4.28	\$ 15,381,584
Vested and exercisable at December 31, 2015	517,932	\$ 6.35	2.71	\$ 5,645,756
Expected to vest at December 31, 2015 (3)	902,258	\$ 9.11	4.85	
Total	1,420,190			

- (1) The aggregate intrinsic value represents the difference between the exercise price and the closing price of our stock on the date of exercise.
- (2) The aggregate intrinsic value represents the difference between the exercise price and \$17.25, the closing price of our stock on December 31, 2015, for all in-the-money options outstanding.
- (3) Options outstanding that are expected to vest are net of estimated future option forfeitures

**Restricted Stock Units**

A summary of our RSU activity is as follows:

	Shares	Weighted Average Grant Date Fair Value
Balance outstanding at December 31, 2014	220,298	\$ 7.04
Granted	62,942	\$ 11.32
Vested (1)	(61,362)	\$ 6.84
Canceled	(30,533)	\$ 7.47
Balance outstanding at December 31, 2015	191,345	\$ 8.45

- (1) The number of RSUs vested includes the shares that we withheld on behalf of employees to satisfy minimum statutory tax withholding requirements.

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The fair values of the RSUs that vested during 2015, 2014, and 2013 were \$0.7 million, \$0.5 million, and \$0.8 million, respectively.

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

	2015	2014
Shares of common stock repurchased	23,928	27,092
Average per share repurchase price	\$ 11.12	\$ 7.80
Aggregate purchase price	\$ 266,090	\$ 211,379

**Stock-based Compensation**

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

	2015	2014	2013
		(in thousands)	
Stock option awards	\$ 992	\$ 917	\$ 789
Restricted stock units	432	385	464
<b>Total stock-based compensation</b>	<b>\$ 1,424</b>	<b>\$ 1,302</b>	<b>\$ 1,253</b>

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

	2015	2014	2013
		(in thousands)	
Cost of sales	\$ 165	\$ 150	\$ 148
Sales and marketing	284	309	295
General and administrative	869	757	726
Research and development	106	86	84
<b>Total stock-based compensation</b>	<b>\$ 1,424</b>	<b>\$ 1,302</b>	<b>\$ 1,253</b>

We expect to record the unamortized portion of share-based compensation expense of \$3.2 million for existing stock options and RSUs outstanding at December 31, 2015, over a weighted-average period of 3.5 years.

**Stock Repurchase Plan**

In July 2009, our Board of Directors authorized a repurchase of our common stock from time to time on the open market or in privately negotiated transactions. In November 2011, our Board of Directors increased this authorization to \$10.0 million and extended the program through December 31, 2013. The repurchase program concluded as of December 31, 2013. The following is a summary of the stock repurchase activity for the year ended December 31, 2013:

	December 31, 2013	December 31, 2013
	Shares	Total
	Purchased	Purchased
	(\$ in thousands)	
Share repurchases	15,323	\$ 88



**Table of Contents****Dividends**

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

Record Date	Payment Date	Per Share Amount	Dividend Payment (in thousands)
<b>Fiscal Year 2015</b>			
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
<b>Fiscal Year 2014</b>			
March 20, 2014	April 3, 2014	\$ 0.035	\$ 546
May 22, 2014	June 5, 2014	\$ 0.035	\$ 547
August 21, 2014	September 4, 2014	\$ 0.035	\$ 607
November 20, 2014	December 4, 2014	\$ 0.035	\$ 608

On February 22, 2016, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.045 per share payable on April 4, 2016, to stockholders of record at the close of business on March 21, 2016, which will total approximately \$0.8 million in payments.

**10. Profit-Sharing Plan**

We offer a 401(k) profit-sharing plan (the Plan) covering eligible U.S. employees to make tax deferred contributions, a portion of which are matched by us. We may make discretionary profit sharing contributions to the Plan in an amount determined by our Board of Directors. Our contributions vest ratably over six years of employment and amounted to approximately \$50,000, \$30,000 and \$40,000 for 2015, 2014 and 2013, respectively.

**11. Restructuring Charges**

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 manufacturing to our Burlington headquarters and corresponding closure of our Southbridge manufacturing facility. As a result, we recorded approximately \$0.4 million of severance related restructuring expense during the year ended December 31, 2014.

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 during the year ended December 31, 2014.

The components of the restructuring charges were as follows:

	Year ended December 31, 2014 (in thousands)
Severance	\$ 499
Other	27
<b>Total</b>	<b>\$ 526</b>

The 2014 restructuring plans were paid in full during the year ended December 31, 2014.



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

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

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
United States	\$ 45,177	\$ 41,545	\$ 39,240
Germany	9,090	7,639	6,939
Other countries	24,085	21,913	18,370
Net sales	\$ 78,352	\$ 71,097	\$ 64,549

Total property and equipment held by geography were as follows:

	As of December 31,	
	2015	2014
	(in thousands)	
United States	\$ 5,199	\$ 4,786
Australia	1,593	1,802
Germany	170	186
Other countries	60	104
Total property and equipment	\$ 7,022	\$ 6,878

**13. Supplemental Cash Flow Information**

Supplemental disclosures of cash flow information are as follows:

	Year ended December 31,		
	2015	2014	2013
	(in thousands)		
Cash paid for income taxes, net	\$ 4,792	\$ 2,088	\$ 1,019

**14. Fair Value Measurements**

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

Level 1 Quoted prices in active markets for identical assets or liabilities.

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Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

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Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

Level 1 assets being measured at fair value on a recurring basis as of December 31, 2015 included our money market mutual fund account.

We had no Level 2 assets being measured at fair value on a recurring basis as of December 31, 2015.

As discussed in Notes 1 and 2, several measurements of acquisition-related assets and impairments of intangible assets were measured using Level 3 techniques. The following table provides a rollforward of the fair value, as determined by Level 3 inputs, of the contingent consideration.

	Year ended December 31,	
	2014	2013
	(in thousands)	
Beginning balance	\$ 99	\$
Additions		42
Payments	(237)	
Change in fair value included in earnings	138	57
Ending balance	\$	\$ 99

**15. Quarterly Financial Data (unaudited)**

2015	Three months ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Total net sales	\$ 18,947	\$ 19,897	\$ 19,025	\$ 20,483
Gross profit	13,117	13,130	13,516	14,403
Income from operations	2,309	2,794	3,321	3,089
Net income	1,369	1,767	2,092	2,530
Earnings per share				
Basic	\$ 0.08	\$ 0.10	\$ 0.12	\$ 0.14
Diluted	\$ 0.08	\$ 0.10	\$ 0.11	\$ 0.13

2014	Three months ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Total net sales	\$ 16,754	\$ 18,161	\$ 17,501	\$ 18,681
Gross profit	11,224	12,376	12,003	12,828
Income (loss) from operations	(231)	1,980	1,852	2,739
Net income (loss)	(207)	1,272	934	1,916
Earnings per share				
Basic	\$ (0.01)	\$ 0.08	\$ 0.05	\$ 0.11
Diluted	\$ (0.01)	\$ 0.08	\$ 0.05	\$ 0.11

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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	Amendment No. 3 to Purchase Option Agreement dated October 1, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.	10-K	3/27/13	001-33092	
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	
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	



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

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
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	
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.				X
21.1	List of Subsidiaries				X
23.1	Consent of Grant Thornton LLP				X
23.2	Consent of Ernst & Young LLP				
24.1	Power of Attorney (included on the Signatures page of this Annual Report on Form 10-K)				X

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Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	SEC File Number	
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)				X
32.1*	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
32.2*	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 36 of Title 18 of the United States Code (18 U.S.C. §1350)				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

Indicates a management contract or any compensatory plan, contract, or arrangement.

\* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of LeMaitre Vascular, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.