

LEMAITRE VASCULAR INC  
Form 10-K  
March 27, 2013  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2012

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)

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

**Delaware**  
(State or other jurisdiction of incorporation or organization)  
**63 Second Avenue, Burlington, Massachusetts**  
(Address of principal executive offices)  
**Registrant's telephone number, including area code 781-221-2266**

**04-2825458**  
(I.R.S. Employer Identification No.)  
**01803**  
(Zip Code)

**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	The NASDAQ Stock Market LLC

**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 29, 2012: \$41,122,284. For purposes of this calculation, shares held by stockholders whose ownership exceeded 5% of the registrant's common stock outstanding based on Schedules 13G filed by such stockholders for the year ended December 31, 2012 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 15, 2013, the registrant had 15,245,054 shares of common stock, par value \$0.01 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

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

**Table of Contents**

**LEMAITRE VASCULAR**

**2012 FORM 10-K ANNUAL REPORT**

**TABLE OF CONTENTS**

**PART I**

Item 1.	<u>Business</u>	1
Item 1A.	<u>Risk Factors</u>	17
Item 1B.	<u>Unresolved Staff Comments</u>	34
Item 2.	<u>Properties</u>	34
Item 3.	<u>Legal Proceedings</u>	34
Item 4.	<u>Mine Safety Disclosures</u>	34

**PART II**

Item 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	35
Item 6.	<u>Selected Financial Data</u>	38
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	39
Item 7A.	<u>Quantitative and Qualitative Disclosure About Market Risk</u>	57
Item 8.	<u>Financial Statements and Supplementary Data</u>	57
Item 9.	<u>Changes In and Disagreements With Accountants on Accounting and Financial Disclosure</u>	57
Item 9A.	<u>Controls and Procedures</u>	57
Item 9B.	<u>Other Information</u>	58

**PART III**

Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	59
Item 11.	<u>Executive Compensation</u>	59
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	59
Item 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	60
Item 14.	<u>Principal Accounting Fees and Services</u>	60

**PART IV**

Item 15.	<u>Exhibits and Financial Statements Schedules</u>	61
<u>SIGNATURES</u>		64

**Table of Contents**

**PART I**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. 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, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, will, would, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, our actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. 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, or investments 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, 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, Pruitt, Pruitt F3, Pruitt-Inahara, Reddick, UnBalloon, VascuTape, XenoSure, and the LeMaitre Vascular logo are registered trademarks of LeMaitre Vascular, and AlboSure, EndoHelix, Flexcel, Grice, Martin, MultiTASC, 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.*

**Item 1. Business  
Overview**

LeMaitre Vascular is a global provider of medical devices and implants 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, including the Expandable LeMaitre Valvulotomes, the Pruitt F3 Carotid Shunt, VascuTape Radiopaque Tape and the XenoSure biologic patch.

We have grown our business by using a three-pronged strategy: competing in niche markets, expanding our worldwide direct sales force, and acquiring and developing complementary vascular devices. Since 1998 we have built our sales force from zero to 81 direct sales representatives as of December 31, 2012 and we have completed a number of vascular device acquisitions.

## **Table of Contents**

We estimate that peripheral vascular disease affects more than 20 million people worldwide. We estimate that the annual worldwide market for all peripheral vascular devices is approximately \$3 billion and that the annual worldwide market addressed by our core product lines approximates \$750 million. We believe that this market will grow due to the increase in the incidence and diagnosis of peripheral vascular disease, a shift to 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 devices, and broad network of vascular surgeon customers position us to capture an increasing share of this large and growing market.

We sell 12 product lines, most of which are used in open vascular surgery and some of which are used in endovascular procedures. For 2012, 2011 and 2010, our valvulotomes, balloon catheters, and carotid shunt product lines have each comprised more than 10% of our revenues. Additionally, our radiopaque tape comprised 10% of our revenues in 2012 compared to 9% in 2011 and 2010. Finally, our XenoSure biologic patches comprised 9% of our revenues in 2012 compared to 5% in 2011. In none of those years, including 2012 did any single product line account for more than 25% of our revenues.

Historically, we have been a leading provider of vascular surgery products in niche product markets characterized by low or limited competition. More recently we have sought to leverage our market leadership in these niche product markets by selling complementary products in more competitive, larger market segments. In addition, our vascular surgeon customers are increasingly performing minimally invasive endovascular procedures, presenting us with attractive opportunities to sell new devices that address their changing product needs.

We sell our products primarily through a direct sales force. Our sales force was comprised of 81 field sales representatives in North America, the European Union, and Japan as of December 31, 2012. We also sell our products through distributors in countries where we do not have a direct sales force. For the year ended December 31, 2012, approximately 94% of our net sales were generated through our direct sales force, and no single customer accounted for more than 2% of our net sales.

### **The Peripheral Vascular Device Market**

We estimate that peripheral vascular disease affects more than 20 million people worldwide. 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 such as stroke, ruptured aneurysm, or pulmonary embolism or death.

Clinical studies have identified several factors that increase the risk of peripheral vascular disease, including smoking, diabetes, obesity, high blood pressure, lack of exercise, coronary artery disease, high cholesterol, and being over the age of 65. Demographic trends suggest an increase in the prevalence of peripheral vascular disease over time, driven primarily by rising levels of obesity and diabetes and an aging population.

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 2,000 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 and Japan. In contrast to other medical specialists, such as interventional cardiologists and interventional radiologists, vascular surgeons perform both conventional vascular surgeries and endovascular procedures. Conventional 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.

## Table of Contents

### Our History

We were founded in 1983 by George D. LeMaitre, M.D., a vascular surgeon who designed and developed the predecessor to our Expandable LeMaitre Valvulotomes and Over-The-Wire LeMaitre Valvulotome. Through a combination of strategic acquisitions and research and development efforts, we have expanded to 12 product lines.

We have completed twelve acquisitions of complementary products since 1998:

Year	Acquisition	Key Product(s)
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	Vascular access grafts
2004	VCS Clip	Vessel closure system
2005	Endomed	Thoracic and abdominal 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(1)	Biologic vascular patch(1)

(1) In 2008, we obtained exclusive rights to distribute this product under our XenoSure brand in the United States and most of Europe, and in 2012, we exercised our purchase option to acquire this product.

We have relocated most of 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.

In 1999, we began building a direct sales organization that we have continued to expand, most recently into Switzerland in 2012.

### Our Business Strategies

Our goal is to be a leading global provider of medical devices to vascular surgeons.

To achieve this objective, we are utilizing the following long-term strategies:

**Focus on niche markets.** We seek to build and maintain market-leading share positions in niche product markets. We believe that the relative lack of competitive focus on these markets by our larger competitors with greater resources, and the differentiated features and consistent quality of our products, allow for higher selling prices in these markets. In recent years we have sought to leverage these market-leading share positions by selling complementary products in more competitive, larger market segments.

**Expand our direct sales force.** We sell our products primarily through a direct sales force in North America, the European Union, and Japan. We intend to further expand our sales force over time. We believe that direct-to-hospital sales build closer customer relationships, allow for higher selling prices, and are not subject to the risk of customer churn resulting from distributor turnover.

**Add complementary products through acquisitions, research and development, and additional regulatory approvals.** 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 actively track industry developments and evaluate the acquisition of additional product lines and businesses that may be complementary to our product

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

offerings on a opportunistic basis, refine our current product lines, develop new applications for our existing technologies, and obtain regulatory approvals for our devices in new markets in order to further access the broader peripheral vascular device market.



**Table of Contents****Our Products**

The following table describes the primary use and availability of each of our product lines as of March 1, 2013:

Product Line	Primary Use	Generally Available for Sale in(1)		
		United States	European Union	Japan
Balloon Catheters	Removal of blood clots; occlusion, and facilitation of blood flow	ü	ü	ü
- LeMaitre Embolectomy Catheters				
- Over-the-Wire Embolectomy Catheters				
- NovaSil Embolectomy Catheters				
- Pruitt Occlusion Catheters				
- Distal Perfusion Catheter	Facilitation of blood flow to brain during carotid plaque removal	ü	ü	ü
Carotid Shunts				
- Pruitt F3 Carotid Shunts				
- Pruitt- Inahara Carotid Shunts				
- Flexcel Carotid Shunts	Introduction of dye into the cystic duct; related uses	ü	ü	
Laparoscopic Cholecystectomy Devices				
- Reddick Cholangiogram Catheter				
- Reddick-Saye Screw Retractor Kit				
- Grice Laparoscopic Suture Needle	Injection of contrast media into blood vessels	ü	ü	
Manual Contrast Injectors				
- LeverEdge Contrast Injector	Improvement in the seal of aortic stent grafts	ü	ü	
Modeling Catheters				
- The UnBalloon Non-Occlusive Modeling Catheter				
Radiopaque Tape	Improvement in precision of vascular and endovascular procedures	ü	ü	ü
- Glow n Tell Tape				
- LeMaitre Stent Guide	Removal of blockages in the major arteries of the leg	ü	ü	Application submitted
Remote Endarterectomy Devices(2)				
- MollRing Cutter Transection Device				
- Martin Dissector				
- EndoHelix Retrieval Device				
- Periscope Dissector				

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

- Ring Stripper				
- MultiTASC Dissection/Transection Device Valvulotomes	Destruction of vein valves to create vein bypass grafts	ü	ü	ü
- Expandable LeMaitre Valvulotomes				
- Over-The-Wire LeMaitre Valvulotome Vascular Grafts	Synthetic vessels for use in bypass and replacement procedures	ü	ü	ü
- AlboGraft Knitted Vascular Grafts				
- AlboGraft Woven Vascular Grafts				
- LifeSpan ePTFE Vascular Grafts Vascular Patches(2)	Synthetic and biological patches for use in closing incisions in a blood vessel	ü	ü	
- XenoSure Biologic Patches				
- AlboSure Vascular Patches Vein Strippers	Single-incision removal of varicose veins	ü	ü	ü
- InvisiGrip Vein Stripper Vessel Closure Systems	Attachment of blood vessels, primarily for dialysis access	ü	ü	ü
- AnastoClip VCS Vessel Closure System				
- AnastoClip GC Vessel Closure System				
- Accessory Devices				

## **Table of Contents**

- (1) Due to varying regulatory schemes and product introduction timelines, it may be that only some models within the applicable product line are approved for sale in the indicated market. For example, in our vascular grafts product line, our LifeSpan ePTFE Vascular Graft is available for sale in the United States, the European Union and Japan, but our AlboGraft products are not available for sale in Japan.
- (2) Neither the MultiTASC device nor our synthetic patch, the AlboSure Vascular Patch, is commercially available. We intend to begin selling these products in 2013.

### ***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 tractability. 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 liquids into the vasculature. Our Pruitt line of occlusion and perfusion catheters reduces vessel trauma by using internal balloon fixation rather than traditional external clamp fixation.

### ***Carotid Shunts***

Our Pruitt F3, Pruitt-Inahara and Flexcel Carotid Shunts are used to temporarily divert, or 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 Inahara-Pruitt shunts feature internal balloon fixation that eliminates the need for clamps, thereby reducing vessel trauma. Our Flexcel shunt is a non-balloon shunt offered for surgeons who prefer to secure their shunt using externally placed clamps.

### ***Modeling Catheters***

Our UnBalloon Non-Occlusive Modeling Catheter is used to apply radial pressure to the inside of an aortic stent graft in order to seal the outer lining of the stent graft against either the aorta or an adjacent stent graft. The physician expands the device's nitinol mesh cage inside of the stent graft in order to appose the stent graft lining against the vessel or stent graft wall. An adequate seal will exclude blood flow from the aneurysm, thereby preventing an endoleak, a condition in which blood continues to enter the aneurysmal sac, increasing the risk of aneurysm rupture and death. Unlike a traditional balloon catheter, The UnBalloon catheter dilates the aortic stent graft without occluding blood flow, allowing the physician more time to repair an endoleak or model the stent graft while minimizing the risk of stent graft migration during modeling.

### ***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.

### ***Remote Endarterectomy Devices***

Our EndoRE line of remote endarterectomy devices are used to remove severe atherosclerotic blockages from the major arteries of the leg in a minimally invasive procedure requiring a single incision in the groin. Our EndoRE devices are used to separate the sclerotic blockage from the vessel, cut the far end of the blockage to free it for removal, and then withdraw the blockage from the vessel.

## **Table of Contents**

### ***Valvulotomes***

Our Expandable LeMaitre Valvulotomes and our Over-The-Wire LeMaitre Valvulotome cut valves in the saphenous vein, a vein that runs from the foot to the groin, so that the vein can function as a bypass vessel to carry blood past diseased arteries to the lower leg or the foot. We believe that 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. The Expandable LeMaitre Valvulotome is the sixth generation of the original valvulotome developed by our founder, George D. LeMaitre, M.D.

### ***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 to increase resistance to compression or kinking. Our stepped and quick tapered LifeSpan models are designed to reduce the risk of steal syndrome and high cardiac output, which are complications that may arise in dialysis access grafts.

### ***Vascular Patches***

We sell the XenoSure Biologic Vascular Patch, a patch 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.

Our AlboSure Vascular Patch is a polyester patch used in conjunction with endarterectomy and vascular reconstructions. We have received regulatory clearance to market our AlboSure Vascular Patch in the United States and intend to begin selling this device in 2013. We expect to receive regulatory clearance in the European Union in 2013 for our AlboSure Vascular Patch. Vascular surgeons use patches in conjunction with carotid endarterectomy, remote endarterectomy, and other vascular reconstructions.

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

Our AnastoClip VCS and AnastoClip GC Vessel Closure Systems allow surgeons to attach vessels to one another by deploying titanium clips in place of suturing. These vessel closure systems create an interrupted anastomosis, or a vessel attachment that expands and contracts as the vessel pulses, which we believe improves the durability of the anastomosis. In 2010 we released the next-generation AnastoClip GC Vessel Closure System, with a new clip design that is intended to provide additional security and ease of use.

### ***Other Products***

In some hospitals, vascular surgery procedures are performed by general surgeons. We sell non-vascular medical devices used in general surgery procedures, primarily laparoscopic cholecystectomy. 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 offer two laparoscopic accessories used in laparoscopic gall bladder removal.

### **Sales and Marketing**

As of December 31, 2012, we employed 81 field sales representatives. Notable developments in 2012 include our initiative to sell direct-to-hospital in Switzerland, with the hiring of two Swiss sales representatives,

## **Table of Contents**

and the opening of a sales office near Toronto, Ontario, Canada in November 2012. We believe that the expansion of our direct sales force 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 terms of up to three years specifying minimum annual sales volumes and pricing. These agreements are renewable by mutual agreement. From time to time, when we determine that it would be financially advantageous for us to sell directly in a market, we terminate one or more of our distributors in that market. In December 2012, we agreed to terminate our distributor for a certain Japanese territory, and we will begin selling direct-to-hospital in this territory through our existing eight person Japanese sales force in 2013.

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 recent years we have increased investment in product research and development, with the goal of more rapidly developing new products, line extensions, and next-generation devices. In 2012 our development efforts were focused on the MultiTASC, a two-in-one tool for dissecting, cutting and removing total occlusions of the superficial femoral artery, and the 1.5mm valvulotome, a smaller-size of our classic valvulotome.

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 2012, 2011 and 2010, our research and development expenditures, including clinical study expenditures, were \$5.1 million, \$4.4 million and \$5.5 million, respectively, representing between 8% and 10% of net sales. As of December 31, 2012, our research and development staff consisted of 17 full-time engineers and technicians.

## **Manufacturing**

Our manufacturing facilities are located in Burlington, Massachusetts, where most of our product lines are produced in two ISO 14644-1 Class 8 clean rooms, each approximately 5,500 square feet. We expect the build-out of a third clean room to these manufacturing facilities for our XenoSure product line to continue into the second half of 2013. Further, the production of the XenoSure biological patch will be our first experience in manufacturing biological tissues. There can be no assurance that we will not experience delays or additional expenses associated with the transfer of this patch and there can be no assurance that our current supply agreement with Neovasc Inc. and its subsidiary, Neovasc Medical Inc. (collectively Neovasc) will be sufficient to meet sales demand during the transition. Our most recent manufacturing consolidations into Burlington, Massachusetts were the relocation of our AlboGraft Vascular Graft manufacturing operations from Brindisi, Italy and our LifeSpan ePTFE Vascular Graft manufacturing operations from Laguna Hills, California, both in 2011. Although almost all of our product lines are produced in Burlington, Massachusetts, our XenoSure products are currently manufactured by a third-party as well as EndoRE remote endarterectomy devices.

## **Table of Contents**

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 that we can maintain better quality control, ensure compliance with applicable regulatory standards and our 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 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 most 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.

Any disruption in our manufacturing capacity could impact our ability to produce sufficient inventory and meet the demands of our customers, which could adversely affect our financial condition and results of operations.

Our 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. If we were to lose these certifications, we would no longer be able to sell our products in these countries until we made the necessary corrections to our operations. Our manufacturing facilities are subject to periodic inspections by regulatory authorities and our Notified Body (described below) to ensure compliance with domestic and non-U.S. regulatory requirements. See Government Regulation. In January, June, and October 2012 as well as in March 2013, we underwent audits from our European Notified Body and the FDA. Although the results of these inspections were satisfactory, 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.

## **Competition**

The markets in which our product lines compete are characterized by rapid change resulting from technological advances and scientific discoveries. No one company competes against all of our product lines. Rather, we compete with a range of companies, from large to small, including publicly traded and privately held device companies. Notable competitors include Applied Medical Resources Corporation, Cardiovascular Systems Inc., Cook Group Incorporated, C.R. Bard, Inc., Edwards Lifesciences Corporation, Getinge AB, Jotec GmbH, Medtronic, Inc., Terumo Medical Corporation, Uresil, LLC, and W. L. Gore & Associates.

Our products compete primarily on the basis of their innovative technology, quality, reliability, ease of use, cost-effectiveness, physician familiarity, brand recognition, and service support. While we compete, where appropriate, on the basis of price, several of our products are sold at higher prices than those of our competitors.

## **Table of Contents**

We believe that our continued success will depend on our ability to broaden and optimize our direct sales channel, acquire or develop additional vascular device product lines, obtain patent or other product protections, obtain regulatory and reimbursement approvals, maintain sufficient inventory to meet customer demand, and attract and retain skilled personnel.

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. 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 2015 to 2022.

We intend to file and prosecute patent applications for our technology in jurisdictions where we believe that patent protection is effective and advisable. 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.

Notwithstanding the foregoing, the patent positions of medical device companies, including our company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or whether any existing or future patent will be dominated by a more basic patent, thus possibly requiring us to obtain a license to produce and sell the product.

Third parties may claim that our products infringe on their patents and other intellectual property rights. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses, or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product designs, license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third-party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management's time and effort. Such claims could also cause our customers or potential customers to defer or limit their purchase or use of the affected products until resolution of the claim. See **Risk Factors** for a description of risks associated with our intellectual property.

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

## **Table of Contents**

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 Grice Suture Needle, LifeSpan Vascular Graft, MollRing Cutter Transection Device, Reddick-Saye Screw, and Periscope Dissector products pursuant to licenses with third-party patent holders.

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 key 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.

## **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, manufacture, 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.



## **Table of Contents**

**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 last longer. In reviewing a premarket notification, the FDA may request additional information, including clinical data. For example, in reviewing our premarket notification for the AlboGraft Vascular Graft, the FDA requested, and we submitted, clinical data from the use of the device in other countries where it was then already approved for sale. Nearly all of our devices sold in the United States to date are marketed pursuant to the 510(k) process.

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

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

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

**Clinical Trials.** A clinical trial is typically required to support a PMA application and is sometimes required to support 510(k) clearance. In some cases, one or more smaller feasibility 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,

## **Table of Contents**

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.

## **Postmarket Regulation**

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

manufacturing establishment registration and device listing with the FDA;

the QSR, which requires finished device manufacturers, including third-party or contract manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures in all aspects of manufacturing;

labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label uses and other requirements related to promotional activities;

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

corrections and removal reporting regulations, which require that manufacturers report to the FDA any field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. Our most recent FDA inspection was in March 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



## **Table of Contents**

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.

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.

## **Table of Contents**

In late 2011 and again in 2012, we received complaints of the failure of several of our AlboGraft Vascular Grafts. In reaction to those failures, we voluntarily recalled two production lots and implemented corrective actions. Subsequent to those recalls, we received several additional complaints in 2012, which we believe were unrelated to the prior product failures.

As a result of the complaints described above, in March 2012, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the National Security Agency for Medicines and Health Products (ANSM) in France issued Prohibition Notices, which prohibited our ability to sell AlboGraft Vascular Grafts in these countries pending our ability to address their concerns. In July 2012, the ANSM rescinded its Prohibition Notice without qualification, and the MHRA rescinded its Prohibition Notice with the qualification that all AlboGraft devices must be tested prior to implant. As of January 1, 2013, the MHRA removed the prior test qualification in the United Kingdom. See **Risk Factors** for the risks associated with the regulatory environment in which we operate.

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 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.

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.

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. 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. Alternatively, third-party payors may reimburse patients for all or part of the charges that patients pay for procedures and the products used in connection with those procedures. In either case, our sales volumes depend on the extent to which third-party payors cover our

## **Table of Contents**

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.

Finally, the advent of contracted fixed rates per procedure has made it difficult to receive separate reimbursement for disposable products, even if the use of these products improves clinical outcomes. In addition, many third-party payors are moving to managed care systems in which providers contract to provide comprehensive healthcare for a fixed cost per person. Managed care providers often attempt to control the cost of healthcare by authorizing fewer elective surgical procedures. Under current prospective payment systems, such as the diagnosis-related group system and the hospital out-patient prospective payment system, both of which are used by Medicare and in many managed care systems used by private third party payors, the reimbursement for our products will be incorporated into the overall reimbursement of a procedure, and there will be no separate reimbursement for our products. As a result, we cannot be certain that hospital administrators and physicians will purchase our products.

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

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

Our success in non-U.S. markets will depend largely upon the availability of reimbursement from the third-party payors through which healthcare providers are paid in those markets. Reimbursement and healthcare payment systems in non-U.S. markets vary significantly by country. The main types of healthcare payment systems are government sponsored healthcare and private insurance. As in the United States, reimbursement is subject to legislative and regulatory changes and is susceptible to budgetary pressures. Reimbursement approval must be obtained individually in each country in which our products are marketed. Outside the United States, we generally 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

## **Table of Contents**

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.

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 PPACA includes provisions that, among other things, require detailed disclosure of gifts and other remuneration made to health care professionals beginning in 2013.

### **Employees**

We had 301 full-time employees at December 31, 2012. We believe that our employee relations are generally satisfactory.

### **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. The information included in Note 13 of the Notes to Consolidated Financial Statements is hereby incorporated by reference.

### **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.

### **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. 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, or 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 obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. All statements made

## **Table of Contents**

in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law. In addition, our Corporate Governance Guidelines, Code of Business Conduct and Ethics and Charters of our Audit, Compensation and Nominating and Corporate Governance Committees are available on our website and are available in print to any stockholder who requests such information.

### **Item 1A. Risk Factors**

*The following important factors, among others, could cause our actual operating results to differ materially from those indicated or suggested by forward-looking statements made in this Form 10-K or presented elsewhere by management from time to time. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are not material may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.*

#### **Risks Related to Our Business**

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

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

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

the divestiture or discontinuation of a product line or other revenue generating activity, such as our stent grafts;

the relocation and integration of manufacturing operations and other strategic restructuring, such as the transfer of AlboGraft production and the transfer of XenoSure production;

adverse regulatory actions which may necessitate recalls of our products or warning letters that negatively affect the markets for our products, such as the AlboGraft Prohibition Notices in the United Kingdom and France in 2012;

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

our determination whether or not to continue share repurchases;

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;

changes in the mix of products we sell;



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

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

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

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

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

## **Table of Contents**

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.

*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. The transactions we completed in 2011 have further concentrated our focus on open vascular procedures. For instance, in 2011 we divested a large portion of our endovascular product portfolio, our TAArget Thoracic Stent Graft and our UniFit Abdominal Stent Graft, and also ended our relationship with Endologix, Inc. for distribution of its Powerlink stent graft in Europe. Furthermore, notwithstanding periodic product updates and next-generation iterations, many of our devices have been on the market for several years or longer. 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 market, 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 could suffer.

*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 twelve 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 and develop products from uncommercialized intellectual property that we acquire. If we are unable to complete acquisitions on satisfactory terms, our growth objectives 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;

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

difficulties in integrating manufacturing operations into our existing business or successfully replicating manufacturing processes at new manufacturing facilities;

difficulties or delays in transitioning clinical studies or unfavorable results from such clinical studies;

**Table of Contents**

difficulties or delays in commercializing intellectual property that we acquire;

the sudden reduction in volume or loss of orders from a key customer, particularly where the acquired company has concentrated sales;

diversion of our management's time and attention from other business concerns;

challenges resulting from limited or no prior experience in new markets or countries we may enter;

higher costs of integration than we anticipated;

unknown or unanticipated liabilities included as part of the acquisition;

the need to improve an acquired product in order to gain broader market acceptance;

difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions;

difficulties in acquiring the rights to and protecting intellectual property;

difficulties if the acquired company is remote or inconvenient to our Burlington, Massachusetts, headquarters;

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 outstanding shares of capital stock, and which 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 October 2012, we acquired the manufacturing and distribution rights of the XenoSure biological patch from Neovasc Inc. and its wholly-owned subsidiary. We have begun the transfer of the production to our Burlington, Massachusetts headquarters. We expect this transition to continue into the second half of 2013 resulting in a negative impact to our gross profit. Once the transition is complete, we expect the gross margins on our XenoSure biologic vascular patch to improve beginning in 2014; however, there can be no assurance that these results will be achieved, if at all. Further, the production of the XenoSure biological patch will be our first experience in manufacturing biological tissues. There can be no assurance that we will not experience delays or additional expenses associated with the transfer of this patch and there can be no assurance that our current supply agreement with Neovasc will be sufficient to meet sales demand during the transition. For any of these reasons or as a result of other factors, we may not realize the anticipated benefits of this acquisition and our operating results may be harmed.

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

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

The markets 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

## Table of Contents

effective than ours. Our competitors could elect to devote additional resources to the markets in which we currently enjoy less competition. Also, although we currently have leading market positions in the markets for some of our products, this is not true for the markets for all of our products. We have from time to time experienced difficulties competing against very large companies.

Recent industry consolidation could make the competitive environment more difficult for smaller companies like ours. 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. Certain of these competitors may also have greater experience in developing and further improving products, obtaining regulatory approvals, and manufacturing and marketing such products. Certain of these competitors may obtain patent protection or regulatory approval or clearance, or achieve product commercialization, before us, any of which could materially adversely affect us. Further, if the trend towards endovascular procedures versus open vascular procedures continues or accelerates, our competitors may be better poised to take advantage of that trend, since our main product lines are used primarily in open vascular procedures. Because of the size of the vascular disease market opportunity, competitors and potential competitors have dedicated, and we believe will continue to dedicate, significant resources to aggressively promote their products. Also, new product developments that could compete with us more effectively are likely because the vascular disease market is characterized by extensive research efforts and technological progress. Competitors may develop technologies and products that are safer, more effective, easier to use, less expensive, or more readily accepted than ours. Their products could make our technology and products obsolete or noncompetitive. Our competitors may also be able to achieve more efficient manufacturing and distribution operations than we can. In addition, many of our products face competition from alternative procedures that utilize a different kind of medical device that we do not currently sell. Increased competition could also result in price reductions and loss of market share, any of which could result in lower revenues and reduced gross profits.

***If we 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.***

In 2012, we converted Switzerland from distributor sales to direct sales. In the future, we also intend to convert select other countries and products from distributor sales to direct sales, including in Japan where we recently agreed to terminate our distributor for a certain territory. Such conversions typically 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. Further, even where the payment of compensation is not required by contract or local law, it may be prudent to make such a payment in order to assure a successful market transition. For example, we paid consulting and transition services fees to our former distributor in Japan in connection with the conversion to direct sales in a specific territory in Japan even though not required under an existing contract, because the absence of cooperation by a distributor may result in the sudden erosion of our customer base, which could materially harm our ability to sell our product in that country.

Following termination of any distribution relationship, 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

## **Table of Contents**

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 cause a drop in 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 Spain, Denmark, or any other countries that we select, and difficulties that we encounter in these transitions could negatively affect our business.

### ***Current economic instability may harm our operating results.***

Since 2011, financial markets and the economies in the European Union have experienced disruption and volatility and conditions could worsen. As a result, the economic environment may, among other things:

create downward pressure on the pricing of our products;

adversely affect the collection of accounts receivable, particularly in regions of southern Europe such as Italy, Spain, and Greece;

increase the sales cycle for certain of our products, resulting in higher levels of inventory;

slow the adoption of new technology;

adversely affect our customers, causing them to reduce spending; and

adversely affect our suppliers, which could disrupt our ability to produce our products.

Any of these conditions could harm our operating results and liquidity.

### ***If we are unable to increase our selling prices to customers, our rate of net sales growth might be reduced and our operating results could suffer.***

In the fiscal years ended December 31, 2012, 2011 and 2010, 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 occurring in the United States. We have in the past been able to rely upon our intellectual property position, our well-known brands, our established reputation in the vascular surgery device marketplace, and, in some cases, an absence of competition, to implement price increases. If healthcare spending is reduced, particularly in the United States, in response either to government-enacted healthcare reform or to general economic conditions, if the reimbursement rates for the medical procedures in which our products are used are reduced or constrained, or if competitors introduce lower-priced products of comparable safety and efficacy, we may become unable to implement further increases in the selling prices of our products. If we become unable to raise selling prices, it might reduce our rate of net sales growth, which could harm our operating results.

### ***Our devices may not achieve market acceptance, which could adversely affect our business.***

Some of our devices have been recently introduced into the market, including The UnBalloon Non-Occlusive Modeling Catheter and the Over-The-Wire LeMaitre Valvulotome, and we cannot assure you that any of those devices will achieve market acceptance. The same is true of new devices that we may acquire or internally develop in the future. The marketing of our products requires a significant amount of time and expense in order to identify and develop relationships with the physicians who may use our products, invest in training and education with these physicians, and employ a sales force that is large enough to interact with the targeted physicians, with no assurance of success. In some cases, our devices may face competition from devices marketed by our competitors, and our customers may not prefer our devices. In other cases, our devices may be used in new procedures and techniques, and if physicians do not adopt these procedures and techniques, demand





**Table of Contents**

for these devices would fail to develop. For example, in 2010 we launched The UnBalloon Non-Occlusive Modeling Catheter in Europe, but it did not achieve widespread market adoption because of user convenience and design issues. This catheter was subsequently withdrawn from the market, redesigned by our research and development department, and then re-released into European and United States markets in the fourth quarter of 2011. Notwithstanding the redesign, sales of the UnBalloon did not meet our expectations in 2012. If our products do not gain market acceptance, our business could be adversely affected.

***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 full year ended December 31, 2012, 33% of our net sales were derived from our operations outside of the Americas. 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;

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.

---

**Table of Contents**

***We depend on single- and limited-source suppliers for some of the components to our products, as well as for acquired products that have not been transitioned to in-house manufacture, and if any of those suppliers are unable or unwilling to supply them on acceptable terms or otherwise, it could limit our ability to deliver our products to our customers on a timely basis or at all.***

We rely on single- and limited-source suppliers for some of our important product components, as well as for products we have acquired that are not manufactured in-house. For example, our EndoRE remote endarterectomy product line is manufactured for us by third-party suppliers. There are relatively few, or in some cases no, alternative, validated sources of supply for these components and products. We do not have supply agreements with most of these suppliers, and instead place orders on an as-needed basis. These suppliers could discontinue or be rendered incapable of the manufacture or supply of these components or products at any time. We do not 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 vendors or failure to obtain additional vendors for any of the components used to manufacture our products would limit our ability to manufacture our products, may result in production delays and increased costs, and may limit our ability to deliver products to our customers. If we are unable to identify alternate sources of supply for the components, we would have to modify our products to use substitute components, which may cause delays in shipments, increase design and manufacturing costs, and increase prices for our products. We cannot assure you that any such modified products would be as effective as the predecessor products, or that such modified products would gain market acceptance. This could lead to customer dissatisfaction and damage to our reputation and our financial condition or results of operations may be harmed.

***If we cannot extend the leases for our manufacturing facilities in Burlington, Massachusetts, then we will need to relocate to suitable facilities elsewhere, which could represent a significant expense and harm our results of operations.***

We are subject to risks associated with our current and future real estate leases. We lease our executive offices and manufacturing facilities in Burlington, Massachusetts, and we have made, and continue to make, substantial investments in those facilities in order to manufacture our products, and new products we acquire, there. For example, we are currently in the process of building a clean room and making other improvements to our Burlington, Massachusetts facility in order to move the manufacture of XenoSure to that facility. The costs of these improvements are significant and we expect that they will continue through 2013.

The leases for our Burlington facilities expire in 2017. If we are unable to renew those leases on acceptable terms or at all, then we will need to relocate to suitable facilities elsewhere. The costs of relocation could be significant, which could harm our results of operations. Additionally, those new manufacturing facilities would need to be modified to our specifications in order to permit us to manufacture our products, which could be costly, and would need to be certified to certain management system standards in order to enable us to satisfy certain regulatory requirements of the European Union, Canada, and other foreign jurisdictions. If we were to lose these certifications, we would no longer be able to sell our products in those countries until we made the necessary corrections to our operations, which could represent a delay in manufacturing and result in losses to us.

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

Our principal worldwide executive, distribution, and manufacturing operations are located at adjacent 27,098 square foot and 27,289 square foot leased facilities located in Burlington, Massachusetts. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace in the event of a natural or man-made disaster. In such event, we could not shift production to alternate manufacturing facilities, and we would be forced to rely on third-party manufacturers. Although we possess insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses, including potential damage to our reputation, and may not continue to be available to us on acceptable terms, or at all.

**Table of Contents**

***Our focus on the needs of vascular surgeons could harm our business if interventional cardiologists and interventional radiologists perform a greater percentage of new procedures that replace those procedures traditionally performed by vascular surgeons, or if vascular surgeons increasingly specialize in procedures for which we do not sell devices.***

The treatment of peripheral vascular disease is increasingly shifting 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. The transactions we completed in 2011 have further concentrated our focus on open vascular procedures. For instance, in 2011 we divested a large portion of our endovascular product portfolio, our TAArget Thoracic Stent Graft and our UniFit Abdominal Stent Graft, and further ended our relationship with Endologix, Inc. for distribution of its Powerlink stent graft.

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 market factors, such as reimbursement rates, are driving vascular surgeons in the United States and potentially in other markets to increasingly specialize in certain kinds of procedures, such as endovascular therapies, the creation and maintenance of dialysis access sites, and the treatment of varicose veins. Sometimes these physicians will discontinue performing other vascular procedures. 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 would 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.

---

**Table of Contents**

**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 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 we exercise care in structuring our sales and marketing practices and customer discount arrangements 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.

In January 2004, AdvaMed, the principal United States trade association for the medical device industry, put in place a model code of conduct that sets forth standards by which its members should abide in the promotion of their products. AdvaMed issued a revised code of conduct effective July 1, 2009. We have in place policies and procedures for compliance that we believe are at least as stringent as those set forth in the revised AdvaMed Code, and we provide routine training to our sales and marketing personnel on our policies regarding sales and marketing practices. Nevertheless, the sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. For example, recent federal legislation and state legislation require detailed disclosure of gifts and other remuneration made to health care professionals. In addition, prosecutorial scrutiny and governmental oversight, on the state and federal levels, over device companies regarding the retention of healthcare professionals as consultants has limited the manner in which medical device companies may retain healthcare professionals as consultants. Various hospital organizations, medical societies and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies or ban or restrict certain marketing and sales practices such as gifts and business meals.

*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;

**Table of Contents**

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.***

Our products require premarket clearance or approval in the United States and the CE Mark or other approvals in foreign countries where they are sold. Each medical device that we wish to market in the United States generally must receive either 510(k) clearance or approval of a premarket application, or PMA, from the FDA before the product can be marketed or sold. Either process can be lengthy and expensive. The FDA's 510(k) clearance procedure usually takes from three to twelve months from the date the FDA receives the application, but may take significantly longer. Although 510(k) clearances have been obtained for nearly all of our current products that require 510(k) clearances, the FDA may condition, limit or prohibit our sales of these products if safety or effectiveness problems develop with the devices. Our new products or significantly modified marketed products could be denied 510(k) clearance and required to undergo the more burdensome PMA approval process if they are not found to be substantially equivalent.

The PMA approval process is much more costly, lengthy, and uncertain than the premarket notification process. It generally takes from six months to three years from the date the application is submitted to, and filed with, the FDA, and may take even longer. Achieving premarket approval typically requires extensive clinical trials and may require the filing of numerous amendments with the FDA over time. We do not have significant experience in obtaining PMA approval for our products.

The FDA has 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



## Table of Contents

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. In December 2011, January 2012, June 2012, October 2012 and March 2013, we underwent audits from our European Notified Body, MHRA, and the FDA. Although the results of these inspections were generally satisfactory, 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.

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 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 October 2011, we received complaints of two AlboGraft device failures which resulted in a voluntary recall of one production lot of our AlboGraft Vascular Graft. In February 2012, we received complaints of two additional AlboGraft device failures, which resulted in a voluntary recall of one additional production lot. We believe that we isolated the root cause of these device failures and implemented corrective actions beginning with



**Table of Contents**

lots produced in November 2011. Subsequent to the February 2012 recall, we received four additional complaints regarding our AlboGraft Vascular Graft. Although the investigation was inconclusive, we believe these complaints were unrelated to the product failures which resulted in the recalls and were isolated manufacturing defects. In October 2012, we received a fifth complaint regarding our AlboGraft Vascular Graft. We believe this complaint was unrelated to the product failures which resulted in the previous recalls and was an isolated manufacturing defect, which we have subsequently addressed through corrective actions implemented in April 2012. However, there can be no assurance that these product failures and manufacturing defects will not reoccur or that other problems related to our AlboGraft Vascular Graft will not develop 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, 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.

As a result of the complaints described above, in March 2012, the MHRA issued a Medical Device Alert advising doctors to use caution when implanting our AlboGraft Vascular Grafts. In April 2012, the MHRA and ANSM issued Prohibition Notices, which prohibited our ability to sell AlboGraft Vascular Grafts in the UK and France pending our ability to address the concerns of these regulatory agencies. In July 2012, the ANSM rescinded its Prohibition Notice without qualification, and MHRA rescinded its Prohibition Notice with the qualification that all AlboGraft devices must be tested prior to implant. As of January 1, 2013, the MHRA removed the prior test qualification in the United Kingdom. Although the Prohibition Notices have been lifted and sales have resumed in the United Kingdom and France, they will likely continue to adversely affect sales in these countries, which could adversely affect our results of operations. The United Kingdom and France represented approximately 40% of our AlboGraft Vascular Graft sales volume in 2011. Sales of AlboGraft in the United Kingdom and France were \$0.5 million in 2012 compared to \$1.0 million in 2011. Additionally, there can be no assurance that additional countries will not also issue their own prohibitions against sales of our AlboGraft devices, which could adversely affect our results of operations.

***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 includes 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. Specifically, the law also requires the medical device industry to subsidize healthcare reform in the form of a 2.3% excise tax on U.S. sales of most medical devices beginning in 2013. In 2013, we believe we will pay 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 will increase 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

## **Table of Contents**

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 resterilize our products intended for a single use or purchase reprocessed products from third-party reprocessors in lieu of purchasing new products from us.

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

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

Sales of medical devices outside the United States are subject to international regulatory requirements that vary from country to country. These requirements and the amount of time required for approval may differ from our experiences with the FDA in the United States. In some cases, we rely on our non-U.S. distributors to obtain premarket approvals, complete product registrations, comply with clinical trial requirements, and complete those steps that are customarily taken in the applicable jurisdictions to comply with governmental and quasi-governmental regulation. In the future, we expect to continue to rely on distributors in this manner in those countries where we continue to market and sell our products through them. Failure to satisfy these foreign regulations would impact our ability to sell our products in these countries and could cause our business to suffer. There can be no assurance that we will be able to obtain or maintain the required regulatory approvals in these countries.

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. For instance, we initiated

## **Table of Contents**

voluntary recalls of two lots of our AlboGraft vascular graft in October 2011 and February 2012, respectively, in response to customer complaints of a manufacturing defect. 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 inspection by our European Notified Body was in December 2012. 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.

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 Japanese regulations have resulted in longer lead times for product development.

Any such 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. 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 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 countries, such as Japan, have issued regulations that require our products be processed from bovine tissue sourced from countries where no cases of BSE have occurred. Products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of infectious agents. Significant new regulation, or a ban of our products, could impair our current business or our ability to expand our business.

### **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;

---

**Table of Contents**

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

permit us to gain or maintain a competitive advantage.

Furthermore, the patents associated with the Expandable LeMaitre Valvulotomes will expire in 2015, and our patent applications associated with the Over-The-Wire Valvulotome are still pending (and we cannot predict when they will issue, if at all). Valvulotomes were our highest net sales product line in 2012. With the pending expiration of patents associated with the Expandable LeMaitre Valvulotomes in 2015, it is possible that other manufacturers will attempt to market and sell valvulotomes substantially similar, or identical, to the Expandable LeMaitre Valvulotomes. To the extent any of these manufacturers are successful this could have an adverse impact on our business and harm our sales and operating results.

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.

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

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

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

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

be expensive and time consuming to defend;

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

harm our reputation;

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

**Table of Contents**

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. For example, in 2005 and 2006, respectively, Boston Scientific Corporation initiated opposition proceedings in the European Patent Office claiming that we were not the first to file a patent application on certain material. As a result of these opposition proceedings, some of our patent claims were canceled.

**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 has been 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 low volume of trading in our common stock, and other factors.

Some specific factors that may have a significant effect on our common stock market price include:

actual or anticipated fluctuations in our operating results or future prospects;

our announcements or our competitors' announcements of new products;

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

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

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

**Table of Contents**

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

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

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;

changes in accounting standards, policies, guidance, interpretations, or principles;

low volume of trades of our common stock;

the discontinuation of a product line or other revenue generating activity, such as our stent grafts;

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;

our relatively small public float; and

changes in stock market analyst recommendations or earnings estimates regarding our common stock, other 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. A securities class action suit against us could result in substantial costs and divert our management's attention and resources that would otherwise be used to benefit the future performance of our business.

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

Our directors, officers, and affiliated stockholders holding more than 5% of our common stock collectively control almost a majority of our outstanding common stock, assuming the exercise of all options held by such persons. As a result, these stockholders, if they act together, would

be able to control the management and affairs of our company and 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 in the best interests of our other stockholders.

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

In February 2011, our Board of Directors adopted a quarterly dividend program for the purpose of returning capital to our stockholders. However, we have not established a minimum dividend payment level for our common stockholders and our ability to pay dividends may be harmed by the risks and uncertainties described in this Annual Report on Form 10-K and in the other documents we file from time to time with the SEC. Future dividends, if any, will be authorized by our Board of Directors and declared by us based upon a variety of factors deemed relevant by our directors, including, among other things, our financial condition, liquidity, earnings projections and business prospects. In addition, financial covenants in any credit facility to which we become a party may restrict our ability to pay future quarterly dividends. We can provide no assurance of our ability to pay dividends in the future.



## **Table of Contents**

### ***Our Board of Directors may decide not to continue our share repurchase program.***

In July 2009, our Board of Directors authorized the repurchase of up to \$1.0 million of our common stock from time to time on the open market or in privately negotiated transactions. In October 2009, our Board of Directors increased this amount to \$2.0 million, and in July 2010, our Board of Directors further increased this amount to \$5.0 million. In November 2011, our Board of Directors further increased this amount to \$10.0 million and extended the program through December 31, 2013. The timing and number of any shares repurchased will be determined based on our evaluation of market conditions and other factors. Repurchases may also be made under a Rule 10b5-1 plan, which would permit shares to be repurchased when we might otherwise be precluded from doing so under insider trading laws. The repurchase program may be suspended or discontinued at any time and will conclude no later than December 31, 2013, unless otherwise extended by our Board of Directors. If the Board of Directors withdraws authority for our share repurchase program, our stock price may be negatively affected.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

Our principal worldwide executive, distribution, and manufacturing operations are located at adjacent 27,098 square foot and 21,929 square foot leased facilities located in Burlington, Massachusetts. In addition, our international operations are headquartered at a 12,841 square foot leased facility located in Sulzbach, Germany, and our Asian operations are located at a 2,140 square foot leased facility located in Tokyo, Japan. In addition, we have an Italian sales office located in a 1,400 square foot leased facility located in Milan, Italy, a Spanish sales office located in an 800 square foot leased facility located in Madrid, Spain and a Canadian sales office located in a 1,739 square foot leased facility located in Mississauga, Ontario, Canada.

The leases for our Burlington, Sulzbach, Milan, Madrid, Tokyo and Mississauga facilities expire in 2017, 2016, 2016, 2014, 2013 and 2018, respectively. Based on our current operating plan, we believe our current facilities are adequate.

### **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 and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, there are no matters, as of December 31, 2012, that, in the opinion of management, might 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 National Market for the eight quarters ended December 31, 2012:

	High	Low
<b>Year ended December 31, 2011:</b>		
First quarter ended March 31, 2011	\$ 7.26	\$ 6.30
Second quarter ended June 30, 2011	\$ 7.19	\$ 6.33
Third quarter ended September 30, 2011	\$ 7.50	\$ 5.03
Fourth quarter ended December 31, 2011	\$ 6.53	\$ 5.15
<b>Year ended December 31, 2012:</b>		
First quarter ended March 31, 2012	\$ 6.20	\$ 5.42
Second quarter ended June 30, 2012	\$ 6.00	\$ 4.79
Third quarter ended September 30, 2012	\$ 6.50	\$ 5.61
Fourth quarter ended December 31, 2012	\$ 6.50	\$ 5.69

**Holders of Record**

On March 15, 2013, the closing price per share of our common stock was \$6.00 as reported on The NASDAQ Global Market, and we had approximately 339 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**

On February 24, 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 year ended December 31, 2012 is as follows:

	Record Date	Payment Date	Per Share Amount	Dividend Payment (in thousands)
Fiscal Year 2012				
	March 20, 2012	April 3, 2012	\$0.025	\$381
	May 18, 2012	June 4, 2012	\$0.025	\$379
	August 17, 2012	August 31, 2012	\$0.025	\$380
	November 20, 2012	December 4, 2012	\$0.025	\$378
Fiscal Year 2011				
	March 22, 2011	April 5, 2011	\$0.02	\$309
	May 20, 2011	June 6, 2011	\$0.02	\$310
	August 19, 2011	September 6, 2011	\$0.02	\$310
	November 23, 2011	December 6, 2011	\$0.02	\$308

On February 21, 2013, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.03 per share payable on April 3, 2013, to stockholders of record at the close of business on March 20, 2013, which will total approximately \$0.5 million.



**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, 2007, through the end of LeMaitre's fiscal year ended December 31, 2012. The graph assumes an investment of \$100.00 made on December 31, 2007, in (i) LeMaitre's common stock, (ii) the stocks comprising the NASDAQ US Composite Index, (iii) 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.

	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11	12/31/12
LeMaitre Vascular, Inc	100.00	37.23	80.65	109.19	96.68	95.38
NASDAQ Composite	100.00	59.03	82.25	97.32	98.63	110.78
NASDAQ Medical Equipment	100.00	53.91	75.19	78.88	89.14	97.76
Peer Group	100.00	78.78	89.68	100.53	93.38	114.80

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.

**Table of Contents**

The peer group includes the following companies: AngioDynamics, Inc., Cardiovascular Systems Inc., Cryolife Inc., Endologix, Inc., Integra Lifesciences Holdings Corporation, Merit Medical Systems Inc., Spectranetics Corp., and Vascular Solutions, Inc.

**Recent Sales of Unregistered Securities**

Not Applicable.

**Issuer Purchases of Equity Securities**

In the quarter ending December 31, 2012, we repurchased 5,665 shares of our common stock in conjunction with the forfeiture of shares to satisfy the employees' obligations with respect to withholding taxes in connection with the vesting of shares of restricted stock.

Period	Issuer Purchases of Equity Securities		
	Total Number of Shares (or Units) Purchased(1)	Average Price Paid Per Share (or Unit)	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that may yet be Purchased under the Plans or Program
October 1, 2012 through October 31, 2012		\$	\$ 3,570,591
November 1, 2012 through November 30, 2012	5,665	\$ 6.40	\$ 3,570,591
December 1, 2012 through December 31, 2012		\$	\$ 3,570,591
Total	5,665	\$ 6.40	\$ 3,570,591

- (1) For the three months ended December 31, 2012, we repurchased 5,665 shares of our common stock to satisfy the employees' obligations with respect to withholding taxes in connection with the vesting of restricted stock units.
- (2) In July 2009, our Board of Directors authorized the repurchase of up to \$1.0 million of our common stock from time to time on the open market or in privately negotiated transactions. In October 2009, our Board of Directors increased this amount to \$2.0 million, in July 2010, our Board of Directors further increased this amount to \$5.0 million, and in November 2011, our Board of Directors further increased this amount to \$10.0 million. The expiration date of this program is December 31, 2013.

**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, 2012, 2011, and 2010 and the consolidated balance sheet data as of December 31, 2012 and 2011, 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, 2009 and 2008, and the consolidated balance sheet data as of December 31, 2010, 2009, and 2008 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.

	2012	Year ended December 31,			2008
		2011	2010	2009	
		(in thousands, except per share data)			
<b>Consolidated Statements of Operations Data:</b>					
Net sales	\$ 56,735	\$ 57,685	\$ 56,060	\$ 50,908	\$ 48,720
Cost of sales	15,867	17,458	14,341	13,604	14,817
<b>Gross profit</b>	<b>40,868</b>	<b>40,227</b>	<b>41,719</b>	<b>37,304</b>	<b>33,903</b>
<b>Operating expenses:</b>					
Sales and marketing	20,811	19,375	19,409	17,710	19,762
General and administrative	10,973	11,228	10,506	9,852	9,999
Research and development	5,092	4,425	5,488	5,910	5,328
Restructuring charges		2,161	1,816	1,777	1,147
Gain on divestitures	(248)	(735)			
Impairment charge		83	485	106	597
Total operating expenses	36,628	36,537	37,704	35,355	36,833
<b>Income (loss) from operations</b>	<b>4,240</b>	<b>3,690</b>	<b>4,015</b>	<b>1,949</b>	<b>(2,930)</b>
<b>Other income (expense):</b>					
Interest income	78	11	31	38	530
Interest expense	(1)		(5)	(26)	(61)
Investment impairment					(168)
Foreign currency gain (loss)	(329)	51	(30)	280	(139)
Other income (expense), net	5		14	(26)	(53)
<b>Total other income</b>	<b>(247)</b>	<b>62</b>	<b>10</b>	<b>266</b>	<b>109</b>
<b>Income (loss) before income tax</b>	<b>3,993</b>	<b>3,752</b>	<b>4,025</b>	<b>2,215</b>	<b>(2,821)</b>
<b>Provision (benefit) for income taxes</b>	<b>1,422</b>	<b>1,609</b>	<b>(1,988)</b>	<b>617</b>	<b>493</b>
<b>Net income (loss)</b>	<b>\$ 2,571</b>	<b>\$ 2,143</b>	<b>\$ 6,013</b>	<b>\$ 1,598</b>	<b>\$ (3,314)</b>
<b>Earnings (loss) per share of common stock:</b>					
Basic	\$ 0.17	\$ 0.14	\$ 0.38	\$ 0.10	\$ (0.21)
Diluted	\$ 0.16	\$ 0.13	\$ 0.37	\$ 0.10	\$ (0.21)
<b>Weighted-average shares outstanding:</b>					
Basic	15,194	15,458	15,627	15,687	15,572
Diluted	15,638	15,989	16,114	15,916	15,572

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

Cash dividends declared per common share	\$ 0.10	\$ 0.08	\$	\$	\$
--	---------	---------	----	----	----

**Table of Contents**

	2012	2011	December 31, 2010 (in thousands)	2009	2008
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 16,448	\$ 20,132	\$ 22,614	\$ 23,192	\$ 15,895
Marketable securities				808	5,359
Current assets	39,131	39,687	42,911	39,550	37,116
Total assets	63,060	59,687	63,274	56,906	54,399
Current liabilities (excluding revolving line of credit and current portion of long-term debt)	8,394	6,539	10,389	6,548	6,933
Long-term liabilities	1,778	1,060	529	2,145	1,718
Total liabilities	10,172	7,599	10,918	8,693	8,651
Total stockholders' equity	52,888	52,088	52,356	48,213	45,748

**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, the European Union and, to a lesser extent, Japan. We estimate that the annual worldwide market for all peripheral vascular devices approximates \$3 billion, within which our core product lines address roughly \$750 million. We have grown our business by using a three-pronged strategy: competing in niche markets, expanding our worldwide direct sales force, and acquiring and developing complementary vascular devices. We have used acquisitions as a primary means of further accessing the larger peripheral vascular device market, and we expect to continue to pursue this strategy in the future. Additionally, we have increased our efforts to expand our vascular device offerings through new product development efforts. 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: balloon catheters, biologic patches, carotid shunts, a contrast injection device, laparoscopic cholecystectomy devices, non-occlusive modeling catheters, radiopaque marking tape, remote endarterectomy devices, valvulotomes, vascular grafts, and vessel closure systems. We divested our aortic stent grafts in June 2011 and terminated our distribution of the Endologix products in August 2011.

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.



**Table of Contents**

Our business opportunities include the following:

the long-term growth of our sales force in North America, Europe and Japan, sometimes in connection with terminations of certain distributor relationships in order to expand our sales presence in new countries;

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 markets upon obtainment of regulatory approvals in these markets; 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, 2012 our sales force was comprised of 81 sales representatives in North America, the European Union and Japan. We also sell our products in other countries through distributors. Our worldwide headquarters is located in Burlington, Massachusetts. Our international operations are headquartered in Sulzbach, Germany. We also have sales offices located in Tokyo, Japan, Toronto, Canada, Madrid, Spain, and Milan, Italy. In 2012, approximately 94% of our net sales were generated in markets in which we employ direct sales representatives.

In recent years we have experienced comparatively greater success in product markets characterized by low or limited competition, for example the markets for biologic patches and valvulotome devices. In the biologic patch market, we believe that we have been able to increase market share. In the valvulotome market, we believe that we have been able to increase selling prices without compromising market share. There can be no assurance that we will not meet resistance to increased selling prices in the future. In contrast, we have experienced comparatively lesser success in highly competitive product markets such as such as prosthetic polyester and ePTFE grafts, where we face stronger competition from larger companies with greater resources. While we believe that these challenging market dynamics can be mitigated by our strong relationships with our vascular surgeon customers, there can be no assurance that we will be successful in highly competitive markets.

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 October 2012, we entered into a definitive agreement with Schaublin Medica SA (Schaublin) to terminate its distribution of our products in Switzerland effective January 1, 2013. The agreement required us to pay approximately \$0.2 million in exchange for the purchase of their customer list for our products, certain customer contracts, sales and marketing transition services, and minimal inventory.

In December 2012, we entered into a definitive agreement with Trytech Corporation to terminate its distribution of our products in a certain Japanese territory effective as of April 1, 2013. The agreement required us to pay approximately \$0.1 million in exchange for the purchase of their customer list for our products, certain customer contracts, sales and marketing transition services, and minimal inventory.

In March 2013, we began shipping directly to our Canadian customers from our sales office in Toronto, Canada. We anticipate that the expansion of our direct sales organization in Canada and Switzerland will result in increased sales and marketing expenses during 2013.



## Table of Contents

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 November 2010, we acquired our LifeSpan ePTFE Vascular Graft from Angiotech Pharmaceuticals, Inc. for \$2.8 million and related assets from Edwards LifeSciences for \$1.2 million.

In June 2011, we divested our TAArget and UniFit stent grafts to Duke Vascular, Inc. for \$0.6 million. In addition, Duke Vascular, Inc. assumed our future obligations for the associated UNITE and ENTRUST clinical trials.

In August 2011, we terminated our distribution of Endologix's aortic stent graft products in Europe in exchange for \$1.3 million.

In November 2012, we acquired the manufacturing rights manufacturing and distribution rights of the XenoSure biologic vascular patch from Neovasc, Inc. for \$4.6 million, having previously been an exclusive distributor of the XenoSure biologic vascular patch since 2008.

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 December 2011, we launched the Over-The-Wire LeMaitre Valvulotome.

In December 2012, we completed first-in-man procedures with the MultiTASC device and the 1.5mm LeMaitre Valvulotome. These two products are scheduled to launch in mid-2013.

In addition to our sales growth strategies, we have also executed several operational initiatives designed to consolidate and streamline manufacturing within our Burlington, MA 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 October 2010, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2007 acquisition of Biomateriali and to improve efficiencies in manufacturing operations. We have completed the transition of AlboGraft vascular graft manufacturing into our existing corporate headquarters in Burlington, Massachusetts.

In May 2011, we adopted a reorganization plan that was designed to eliminate redundant costs resulting from our 2010 acquisition of the LifeSpan vascular graft and to improve efficiencies in manufacturing operations. We have completed the transition of LifeSpan vascular graft manufacturing into our existing corporate headquarters in Burlington, Massachusetts.

In November 2012, we initiated a project to build a third clean room for our newly acquired XenoSure biologic patch. We expect this transition to our Burlington facility to continue into the second half of 2013 resulting in a negative impact to our gross profit. Once the transition is complete, we expect the gross margins on our XenoSure biologic vascular patch to improve beginning in 2014; however, there can be no assurance that these results will be achieved, if at all. Further, the production of the XenoSure biological patch will be our first experience in manufacturing biological tissues. There can be no assurance that we will not experience delays or additional expenses associated with the transfer of this patch and there can be no assurance that our current supply agreement with Neovasc will be sufficient to meet sales demand during the transition.

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

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

to revenues and operating expenditures. For example, in 2011 we exited the stent graft business, and realized gains of approximately \$0.7 million in 2011 and

---

## **Table of Contents**

\$0.2 million in 2012 in connection with that exit. We recognized \$4.0 million of stent graft related revenue during the year ended December 31, 2011, and also incurred sales, marketing, and research and development expenditures in connection with these product lines. Separately, we recognized \$1.1 million and \$1.8 million of restructuring expenses in 2011 and 2010, respectively, related to the Biomateriali plant closure and relocation to Burlington, MA.

In late 2011 and again in 2012, we received complaints of the failure of several of our AlboGraft Vascular Grafts. In reaction to those failures, we voluntarily recalled two production lots and implemented corrective actions. Subsequent to those recalls, we received several additional complaints in 2012, which we believe were unrelated to the prior product failures. As a result of the recalled lots, we recognized \$0.2 million of inventory write-offs, which we recorded to cost of sales during the year ended December 31, 2011.

As a result of the complaints described above, in March 2012, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the National Security Agency for Medicines and Health Products (ANSM) in France issued Prohibition Notices, which prohibited our ability to sell AlboGraft Vascular Grafts in these countries pending our ability to address their concerns. In July 2012, the ANSM rescinded its Prohibition Notice without qualification, and the MHRA rescinded its Prohibition Notice with the qualification that all AlboGraft devices must be tested prior to implant. As of January 1, 2013, the MHRA removed the prior test qualification in the United Kingdom. The United Kingdom and France represented approximately 40% of our AlboGraft Vascular Graft sales volume in 2011. Sales of AlboGraft in the United Kingdom and France were \$1.0 million for the year ended December 31, 2011 and \$0.5 million for the year ended December 31, 2012. As of December 31, 2012, we have approximately \$2.7 million of inventory and \$0.5 million of intangible assets related to the AlboGraft Vascular Graft. See **Risk Factors** for the risks associated with the regulatory environment in which we operate.

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, 2012, approximately 33% of our sales were from outside the Americas. We expect that foreign currencies will continue to represent a similarly significant percentage of our sales in the future. Selling, marketing, and administrative costs related to these sales are largely denominated in the same respective currency, thereby partially mitigating our 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.

### **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 those cases where our products are held on consignment at a hospital or clinic, we generate sales at the time the product is used in surgery rather than at shipment.

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

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

**Table of Contents**

**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, investment impairment charges, 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 German, French, Italian, Spanish, and Japanese subsidiaries. Our consolidated tax expense is affected by the mix of our taxable income (loss) in the United States, Germany, France, Italy, Spain, Switzerland, and Japan, 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, 2012, to the year ended December 31, 2011**

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

	2012	2011	\$ Change	Percent change
	(\$ in thousands)			
Net sales	\$ 56,735	\$ 57,685	\$ (950)	(2%)
Net sales by geography:				
Americas	\$ 38,273	\$ 36,958	\$ 1,315	4%
International	18,462	20,727	(2,265)	(11%)
Total	\$ 56,735	\$ 57,685	\$ (950)	(2%)

**Net sales.** Net sales decreased 2% to \$56.7 million in 2012 from \$57.7 million in 2011. Divestitures, primarily of the TAArget and UniFit stent graft product lines as well as the termination of the Endologix aortic stent graft distribution agreement, resulted in a decrease in sales of 8% from the prior year. Changes in foreign currency exchange rates reduced year over year sales by 2%.

Net sales decreases of \$1.0 million in 2012 were primarily driven by the 2011 divestiture of our stent graft product lines which accounted for \$4.0 million of sales during 2011, a \$0.6 million decrease in polyester graft sales, and a weakening of the Euro, which negatively impacted sales by \$1.3 million. These decreases were partially offset by higher average selling prices across nearly all product lines, increased sales in biologic patches of \$2.0 million, increased sales of radiopaque tape of \$0.6 million and increased sales of catheters of \$0.5 million, which was partially driven by selected pricing discounts in new geographies.

Direct-to-hospital net sales were 94% of net sales in 2012, compared to 93% in 2011.

**Table of Contents**

**Net sales by geography.** Net sales in the Americas increased \$1.3 million to \$38.3 million in 2012. The increase was largely the result of higher average selling prices across nearly all product lines, as well as increased sales of biologic patches, radiopaque tape of \$0.5 million, catheters of \$0.3 million, and vascular closure systems of \$0.2 million. These increases were partially offset by the divestiture of our stent graft product lines which accounted for \$0.5 million in 2011. International net sales decreased \$2.3 million to \$18.5 million in 2012. The decrease was primarily driven by the divestiture of our stent graft product lines which accounted for \$3.5 million in 2011, a decrease in polyester graft sales, and the negative effects of foreign currency exchange rates, which were partially offset by increased sales of biologic patches of \$1.1 million and catheters of \$0.3 million. Biologic patches became available for sale in Europe in July 2011.

In April 2012, the regulatory agencies in the United Kingdom and France issued Prohibition Notices which prohibited us from selling our AlboGraft polyester grafts in those countries until further notice. In July 2012, the regulatory agencies substantially rescinded the Prohibition Notices allowing the products to return to market. See [Overview](#) above for a further discussion regarding these notices. Sales of AlboGraft in France and the United Kingdom were \$0.5 million in 2012 compared to \$1.0 million in 2011.

International direct-to-hospital net sales were 85% in 2012 compared to 82% in 2011. The increase was primarily driven by distributor terminations in Spain and Denmark in 2011.

	2012	2011	\$ Change	Percent change
	(\$ in thousands)			
Gross profit	\$ 40,868	\$ 40,227	\$ 641	2%
Gross margin	72.0%	69.7%	*	2.3%

\* Not applicable

**Gross profit.** Gross profit increased \$0.6 million to \$40.9 million in 2012 from \$40.2 million in 2011, while our gross margin increased 2.3% to 72.0%. The gross margin increase was largely the result of a reduction in costs related to the closure of our factory in Brindisi, Italy in March 2011, a reduction in costs associated with the 2011 manufacturing start-up and transition activities related to the AlboGraft and Lifespan product lines, increased selling prices across most of our product lines, and favorable product and geographic mix driven largely by our exit from stent grafts. The gross margin increase was partially offset by manufacturing inefficiencies as well as increased sales of XenoSure. The gross profit increase was largely the result of the increase in the gross margin, which was partially offset by our exit from the stent graft product lines, which generated \$4.0 million of revenue in 2011.

In November 2012, we acquired the manufacturing and distribution rights of the XenoSure biologic vascular patch, which we expect will negatively affect gross profit in 2013 as we transition production to our Burlington facility. We expect to realize efficiencies, which may improve XenoSure gross margins beginning in 2014.

	2012	2011	\$ change	Percent change	2012 as a % of Revenue	2011 as a % of Revenue
	(\$ in thousands)					
Sales and marketing	\$ 20,811	\$ 19,375	\$ 1,436	7%	37%	34%
General and administrative	10,973	11,228	(255)	(2%)	19%	19%
Research and development	5,092	4,425	667	15%	9%	8%
Restructuring charges		2,161	(2,161)	(100%)	0%	4%
Gain on divestitures	(248)	(735)	487	*	*	*
Impairment charge		83	(83)	*	*	*
	\$ 36,628	\$ 36,537	\$ 91	0%	65%	63%

\* Not a meaningful percentage.





---

**Table of Contents**

Commencing in 2013, we will be subject to a 2.3% medical device excise tax on sales within the United States. We estimate this tax to negatively affect income from operations by approximately \$0.7 million.

**Sales and marketing.** Sales and marketing expenses were \$20.8 million in 2012 compared to \$19.4 million in 2011. As a percentage of net sales, sales and marketing expenses were 37% in 2012, up 3% from the prior year. Selling expenses increased \$1.0 million while marketing expenses increased by \$0.4 million. The increase in selling expenses was primarily driven by increased sales personnel compensation of \$0.8 million and \$0.2 million of additional sales meetings and travel costs. These increases were partially offset by \$0.2 million of 2011 transition services related to the LifeSpan acquisition and the buy-out of our former Spanish distributor. Marketing expense increases were largely driven by \$0.3 million of additional advertising costs. Changes in foreign currency exchange rates reduced 2012 expenses by \$0.6 million compared to the prior year period. At December 31, 2012, we employed 81 sales representatives worldwide, compared to 78 in the prior year period. We plan to increase the size of our sales force in 2013, primarily related to the hiring of additional Canadian sales representatives, and we expect that selling and marketing expenses will increase commensurately.

**General and administrative.** General and administrative expenses decreased 2% to \$11.0 million in 2012 from \$11.2 million in 2011. The decrease was largely driven by a decrease in compensation costs of \$0.3 million, the closure of our Biomateriali facility in March 2011, which incurred general and administrative costs of \$0.1 million in the prior year period, and by changes in foreign currency exchange rates of \$0.3 million. These decreases were partially offset by the settlement of an employee matter of \$0.1 million and bad debt expense relating to certain European markets of \$0.1 million. As a percentage of net sales, general and administrative expenses were 19% in both 2012 and 2011. We expect general and administrative expenses to increase in 2013 primarily due to our direct sales efforts in Canada.

**Research and development.** Research and development expenses increased 15% to \$5.1 million in 2012 from \$4.4 million in 2011. As a percentage of net sales, research and development expenses increased to 9% in 2012 from 8% in 2011. Product development expenses increased \$1.0 million primarily due to increased product engineer compensation and additional testing and sample costs. Clinical and regulatory expenses increased \$0.1 million, primarily due to an increase in compensation expenses. Process engineering expenses decreased \$0.2 million. Royalty expenses decreased \$0.2 million, primarily due to our exit from our stent graft product lines. We expect research and development costs to increase marginally in 2013 as we continue to invest in new product development efforts.

**Restructuring.** We did not incur restructuring charges in 2012 compared to \$2.2 million of restructuring charges in the prior year. In 2011, we closed our Biomateriali manufacturing facility in Brindisi, Italy and transitioned production to our existing corporate headquarters in Burlington, Massachusetts. In 2011, we also closed our Lifespan manufacturing facility in Laguna Hills, California and transitioned production to Burlington. Finally, we terminated our Spanish and Danish distribution agreements and reorganized our European administrative and sales personnel as a result of our exit from the stent graft business in 2011.

**Gain on divestitures.** In 2012, we recognized a gain on divestitures of \$0.2 million resulting from payments on a promissory note related to the divestiture of our TAArget and UniFit stent graft product lines to Duke Vascular, Inc. in 2011. In July 2011, we terminated our Endologix distribution agreement for \$1.3 million and recognized a gain of \$0.7.

**Impairment charges.** We did not incur impairment charges in 2012. We incurred \$0.1 million of impairment charges in 2011 related to patents deemed to have no value based on future expected economic benefits.

**Table of Contents**

**Other income (expense).** Foreign exchange losses for 2012 were \$0.3 million compared to foreign exchange gains for 2011 of \$51,000. Foreign exchange gains were due to the comparative strengthening of the U.S. dollar versus the euro during the year. Net interest income and other income (expense) increased by approximately \$67,000 primarily due to the interest earned from the promissory note related to our stent graft divestiture in 2011.

**Income tax expense.** We recorded a provision for taxes of \$1.4 million on pre-tax income of \$4.0 million in 2012 compared to \$1.6 million on pre-tax income of \$3.8 million in 2011. The 2012 provision was comprised of Federal tax in the United States of \$1.4 million, state taxes of \$0.1 million and a net foreign tax benefit of \$0.1 million. The 2011 provision was comprised of Federal tax in the United States of \$1.1 million, taxes in certain foreign subsidiaries that are profitable of \$0.4 million and state taxes of \$0.1 million. Our effective tax rate differed from the U.S. statutory tax rate in 2012 principally due to permanent items, changes in our valuation allowances, specific manufacturing deductions, state taxes, and release of uncertain tax position reserves. 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, 2012, we will continue to carry a valuation allowance against \$3.1 million of deferred tax assets, principally foreign net operating loss carry-forwards, which based on the weight of available evidence, we believe it is more likely than not that such assets will not be realized.

We expect that our effective tax rate in 2013 will be comparable to our effective tax rate in 2012. We will be able to utilize Federal research and development tax credits in 2013 from both 2012 and 2013 as a result of legislation enacted in January 2013.

**Comparison of the year ended December 31, 2011, to the year ended December 31, 2010**

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

	2011	2010	\$ Change	Percent change
	(\$ in thousands)			
Net sales	\$ 57,685	\$ 56,060	\$ 1,625	3%
Net sales by geography:				
Americas	\$ 36,958	\$ 34,575	\$ 2,383	7%
International	20,727	21,485	(758)	(4%)
Total	\$ 57,685	\$ 56,060	\$ 1,625	3%

**Net sales.** Net sales increased 3% to \$57.7 million in 2011 from \$56.1 million in 2010. Acquisitions, primarily the LifeSpan vascular graft, increased sales 2% compared to 2010. Divestitures, primarily of the TAArget and UniFit stent graft product lines as well as the termination of the Endologix aortic stent graft distribution agreement, decreased sales 4% from the prior year. Changes in foreign currency exchange rates added 2% to year over year sales growth.

Sales increases in 2011 were largely driven by higher average selling prices across nearly all product lines, as well as stronger sales of biologic patches of \$0.9 million, catheters of \$0.6 million and vessel closure systems of \$0.5 million, in addition to full-year LifeSpan vascular graft sales and favorable changes in foreign currency exchange rates. These gains were partially offset by a \$2.6 million decrease in stent grafts, primarily due to the decline of, and subsequent exit from, these product lines.

Direct-to-hospital net sales were 93% in 2011 and 2010.

**Table of Contents**

**Net sales by geography.** Net sales in the Americas increased \$2.4 million to \$37.0 million in 2011. The increase was largely the result of higher average selling prices across nearly all product lines as well as increased sales of biologic patches and vessel closure systems. International net sales decreased to \$20.7 million in 2011. The decrease was primarily driven by the divestitures of the TAArget and UniFit stent graft product lines and the termination of the Endologix aortic stent graft distribution agreement. Sales of these products decreased to \$4.0 million in 2011 compared to \$6.8 million in 2010. The decrease in international sales was partially offset by full-year LifeSpan sales of \$1.2 million and \$1.1 million of favorable changes in foreign currency exchange rates.

International direct-to-hospital net sales were 82% in 2011 and 2010.

	2011	2010	\$ Change	Percent change
	(\$ in thousands)			
Gross profit	\$ 40,227	\$ 41,719	\$ (1,492)	(4%)
Gross margin	69.7%	74.4%	*	(4.7%)

\* Not applicable

**Gross profit.** Gross profit decreased 4% to \$40.2 million in 2011 from \$41.7 million in 2010, while our gross margin decreased 4.7% to 69.7%. The gross margin decrease was the result of manufacturing inefficiencies in Burlington, Massachusetts largely related to the AlboGraft product line and its transfer from Italy to the United States, as well as a \$0.2 million charge related to a voluntary recall of two AlboGraft production lots in the fourth quarter of 2011. The gross margin decrease was partially offset by higher average selling prices across nearly all product lines and improved product mix due to the termination of the Endologix distribution agreement.

	2011	2010	\$ change	Percent change	2011 as a % of Revenue	2010 as a % of Revenue
	(\$ in thousands)					
Sales and marketing	\$ 19,375	\$ 19,409	\$ (34)	0%	34%	35%
General and administrative	11,228	10,506	722	7%	19%	19%
Research and development	4,425	5,488	(1,063)	(19%)	8%	10%
Restructuring charges	2,161	1,816	345	19%	4%	3%
Gain on divestitures	(735)		(735)	*	*	*
Impairment charge	83	485	(402)	*	*	*
	\$ 36,537	\$ 37,704	\$ (1,167)	(3%)	63%	67%

\* Not a meaningful percentage.

**Sales and marketing.** Sales and marketing expenses were \$19.4 million in 2011, flat versus 2010. As a percentage of net sales, sales and marketing expenses were 34% in 2011, down 1% from the prior year. Compared to 2010, sales and marketing expenses were negatively affected by increases in foreign currency exchange rates of \$0.5 million, transition services related to business development activities of \$0.3 million, and recruiting expenses of \$0.2 million, which were offset by a decrease in sales personnel compensation of \$1.0 million. At December 31, 2011, we employed 78 sales representatives worldwide, compared to 67 in the prior year period.

**General and administrative.** General and administrative expense increased 7% to \$11.2 million in 2011 from \$10.5 million in 2010. The increase was largely the result of higher administrative costs associated with our French and Spanish subsidiaries of \$0.5 million, higher amortization costs of \$0.3 million related to the LifeSpan Vascular Graft acquisition and our Spanish distributor buy-out, and changes in foreign currency exchange rates of \$0.2 million, partially offset by a reduction in administrative costs associated with our closure of the Biomateriali subsidiary of \$0.2 million. As a percentage of net sales, general and administrative expenses were 19% in both 2011 and 2010.



---

**Table of Contents**

**Research and development.** Research and development expenses decreased 19% to \$4.4 million in 2011 from \$5.5 million in 2010. As a percentage of net sales, research and development expenses decreased to 8% in 2011 from 10% in 2010. The decrease was largely driven by a reduction in regulatory and clinical affairs costs of \$0.8 million in 2011, related to the suspension of our UNITE and ENTRUST trials in October 2010. In addition, product development costs decreased \$0.4 million in 2011 as we reduced animal testing associated with new products approvals. On June 30, 2011, Duke Vascular, Inc. assumed all future obligations of the UNITE and ENTRUST trials as part of our stent graft divestiture agreement. Process engineering expenses increased by \$0.2 million in 2011 as we increased staffing levels.

**Restructuring.** Restructuring charges were \$2.2 million in 2011 compared to \$1.8 million in 2010. In 2010, we commenced the closure of our Biomateriali manufacturing facility in Brindisi, Italy and the related transition of production to our existing corporate headquarters in Burlington, Massachusetts. In 2011, we incurred an additional \$1.1 million in restructuring charges related to this project. These charges consisted of approximately \$0.3 million for the transfer of manufacturing equipment, \$0.1 million of charges associated with repayment of a development grant and loan from the Italian government, and \$0.7 million related to deferred rent charges upon exiting the Biomateriali facility in March 2011. In March 2012, we completed the Biomateriali liquidation and dissolution process.

In 2010, we incurred a \$1.8 million restructuring charge related to the closure of our Biomateriali manufacturing facility in Brindisi, Italy, and the related transition of production to our existing corporate headquarters in Burlington, Massachusetts. The restructuring charge consisted of \$1.4 million of employee-related severance charges, \$0.3 million of charges associated with repayment of a development grant and loan from the Italian government, and \$0.1 million of charges related to the abandonment of fixed assets and legal fees.

In May 2011, we adopted a reorganization plan (the LifeSpan Plan) that was designed to eliminate redundant costs resulting from our 2010 acquisition of the LifeSpan vascular graft and to improve efficiencies in our manufacturing operations. We transitioned the production of our LifeSpan vascular graft from Laguna Hills, California to our existing corporate headquarters in Burlington, Massachusetts. The LifeSpan Plan resulted in the termination of 7 employees at the Laguna Hills facility, relocation of manufacturing equipment, and the hiring of approximately 4 employees to staff the required functions in Burlington. We incurred approximately \$0.1 million related to the closure of the Laguna Hills facility and the related relocation of the manufacturing equipment during the year ended December 31, 2011. We incurred approximately \$33,000 of severance charges related to this project during year ended December 31, 2011.

On June 30, 2011, we terminated our relationship with our Spanish distributor resulting in a contract termination charge of \$0.5 million which we recorded as restructuring charges. On June 30, 2011, we terminated our relationship with our Danish distributor resulting in a contract termination charge of \$0.1 million which we recorded as restructuring charges.

In July 2011, we adopted a reorganization plan of our European administrative and stent graft sales personnel as a result of our exit from the stent graft business. We terminated 6 employees and recorded severance charges of \$0.3 million during the year ended December 31, 2011. The final severance payments were made in March 2012.

In 2010 and 2011, we initiated a series of strategic initiatives including the transition of AlboGraft manufacturing from Italy to Burlington, the transition of LifeSpan manufacturing from California to Burlington, the sale of our TAArgent and Unifit assets, the termination of our Endologix distribution agreement in Europe, and the termination of our distributors in Spain and Denmark.

**Gain on divestitures.** In July 2011, we terminated our Endologix distribution agreement for \$1.3 million, and recognized a gain of \$0.7 million as a result of the transaction.

---

## **Table of Contents**

**Impairment charges.** We incurred \$0.1 million of impairment charges in 2011 related to patents deemed to have no value based on future expected economic benefits. We incurred \$0.5 million of impairment charges in 2010 of which \$0.4 million was due to the write-down of certain technology, customer lists, and fixed assets related to our aortic stent graft product line. Additionally, we incurred a \$0.1 million impairment charge associated with a Biomateriali private label customer relationship, which we subsequently terminated.

**Other income (expense).** Foreign exchange gains for 2011 were \$51,000 compared to foreign exchange losses for 2010 of \$30,000 in 2010. Foreign exchange gains were due to the comparative weakening of the U.S. dollar versus the euro during the year. Net interest income and other income (expense) was comparatively flat in 2011 versus 2010.

**Income tax expense.** We recorded a provision for taxes of \$1.6 million on pre-tax income of \$3.8 million in 2011 compared to a tax benefit of \$2.0 million on pre-tax income of \$4.0 million in 2010. The 2011 provision was comprised of Federal tax in the United States of \$1.1 million, taxes in certain foreign subsidiaries that are profitable of \$0.4 million and state taxes of \$0.1 million. The 2010 benefit was primarily due to the release of our U.S. deferred tax asset valuation allowance of \$3.3 million, and was partially offset by U.S. deferred provision of \$0.9 million, taxes in certain foreign subsidiaries that are profitable of \$0.2 million, Federal tax in the United States of \$0.1 million, and state taxes of \$0.1 million. The valuation allowance reversal was to the result of achieving three year cumulative profitability which occurred in the fourth quarter of 2010 as well as our expectation of future taxable income in the United States. Our effective tax rate differed from the U.S. statutory tax rate in 2011 principally due to permanent items, true-up of historical deferred tax assets, a valuation allowance recorded against foreign deferred tax assets and state credits, change in our reserve for uncertain tax positions, and state taxes. 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.

## **Liquidity and Capital Resources**

At December 31, 2012, our cash, cash equivalents and marketable securities were \$16.4 million as compared to \$20.1 million at December 31, 2011. Our cash and 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, 2012. All of our cash held outside of the United States is available for corporate use.

## **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, 2012, we recognized operating income of \$4.2 million. For the year ended December 31, 2011, we recognized operating income of \$3.7 million. We expect to fund any increased costs and expenditures from our existing cash and cash equivalents and marketable securities, though our future capital requirements depend on numerous factors. These factors include, but are not limited to, the following:

the revenues generated by sales of our products;

payments associated with potential future quarterly cash dividends to our common stockholders;

payments associated with our stock repurchase plan;

payments associated with U.S income and other taxes, such as the medical device tax which we estimate will be approximately \$0.7 million in 2013;

**Table of Contents**

the costs associated with the facility build out and manufacturing transfer related to the acquisition of the XenoSure manufacturing rights;

the costs associated with expanding our manufacturing, marketing, sales, and distribution efforts;

the rate of progress and cost of our research and development activities;

the costs of obtaining and maintaining FDA and other regulatory clearances of our existing and future products;

the effects of competing technological and market developments; and

the number, timing, and nature of acquisitions and other strategic transactions

Our cash balances may decrease as we continue to use cash to fund our operations, make acquisitions, make purchases under our share repurchase program, 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 from a financial institution. The sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, such securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. 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.

**Italian loan and grant**

As part of the purchase of Biomateriali S.r.l, we assumed a loan from the Italian government under a program that provided funding to certain businesses in Italy through a combination of grants and loans if certain requirements are met. The loan was stated to be payable in ten annual payments through 2018 of principal and interest at an interest rate of 0.74%. The present value of the loan was recorded as of the date the proceeds were received using our incremental borrowing rate. Interest was being imputed on the loan and the amortization was recorded as interest expense. The Italian government informed us the loan and grant will become due in full as a result of the Biomateriali S.r.l plant closure. As a result, in December 2011, we incurred approximately \$0.1 million of restructuring charges related to additional interest and penalties charges, and we made the final payment to the Italian government of \$0.5 million in December 2011. In 2010, we had previously recorded approximately \$0.3 million of restructuring charges related to the expected repayment of the grants, the imputed interest on the outstanding loan balance, and certain additional interest and penalties.

**Cash Flows**

	Year ended December 31,		Net
	2012	2011	Change
Cash and cash equivalents	\$ 16,448	\$ 20,132	\$ (3,684)
Cash flows provided by (used in):			
Operating activities	\$ 4,722	\$ 3,170	\$ 1,552
Investing activities	(5,198)	(1,822)	(3,376)
Financing activities	(3,157)	(3,800)	643

**Operating activities.** Net cash provided by operating activities was \$4.7 million in 2012 and consisted of \$2.6 million in net income, adjusted for non-cash items of \$4.9 million (including depreciation and amortization of \$2.2 million, stock-based compensation of \$1.2 million, and provision for inventory write-offs of \$0.9 million), and net cash used by changes in working capital of \$2.7 million. The net cash used by changes in working capital was principally the result of increased inventories of \$3.7 million and partially offset by increased accounts payables.





**Table of Contents**

Net cash provided by operating activities was \$3.2 million in 2011 and consisted of \$2.1 million in net income, adjusted for non-cash items of \$5.3 million (including depreciation and amortization of \$2.0 million, provision for deferred income taxes of \$1.1 million, stock-based compensation of \$1.0 million, provision for inventory write-offs of \$1.0 million, and noncash restructuring charges of \$0.7 million, all of which were partially offset by a gain on the termination of the Endologix distribution agreement of \$0.7 million), and net cash used by changes in working capital of \$4.2 million. The net cash used by changes in working capital was principally the result of a decrease in accounts payables as well as an increase in accounts receivable, inventories and other current assets.

**Investing activities.** Net cash used in investing activities was \$5.2 million in 2012. This was due to the \$4.4 million of acquisition related payments, primarily related to the XenoSure biologic patch acquisition, certain distributor buyouts, and the purchase of new property and equipment of \$1.2 million. These cash uses were partially offset by a \$0.5 million repayment of a promissory note from Duke Vascular related to our stent graft divestiture in 2011.

Net cash used in investing activities was \$1.8 million in 2011. This was due to the purchase of new property and equipment of \$2.0 million, as a result of the transfer of manufacturing from Brindisi, Italy and Laguna Hills, California to Burlington, Massachusetts and \$1.2 million of acquisition related payments, primarily related to the LifeSpan Vascular Graft acquisition and the Spanish and Danish distributor buyouts. These cash uses were partially offset by a \$1.3 million distribution termination payment from Endologix.

**Financing activities.** Net cash used in financing activities was \$3.2 million in 2012. This was primarily due to the purchase of \$1.7 million of treasury stock under our stock repurchase plan, payment of common stock dividends of \$1.5 million, and the purchase of \$0.3 million of treasury stock to cover minimum withholding taxes of restricted stock unit vestings, and was partially offset by \$0.4 million received from the exercise of stock options. As of December 31, 2012, we were able to purchase up to an additional \$3.6 million of common stock through December 31, 2013 under our stock repurchase plan.

Net cash used in financing activities was \$3.8 million in 2011. This was primarily due to the purchase of \$1.9 million of treasury stock under our stock repurchase plan, payment of common stock dividends of \$1.2 million, and the purchase of \$0.3 million of treasury stock to cover minimum withholding taxes of restricted stock unit vestings, and was partially offset by \$0.1 million received from the exercise of stock options.

**Dividends.** On February 24, 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 year ended December 31, 2012 is as follows:

Record Date	Payment Date	Per Share Amount	Dividend Payment (in thousands)
Fiscal Year 2012			
March 20, 2012	April 3, 2012	\$0.025	\$381
May 18, 2012	June 4, 2012	\$0.025	\$379
August 17, 2012	August 31, 2012	\$0.025	\$380
November 20, 2012	December 4, 2012	\$0.025	\$378
Fiscal Year 2011			
March 22, 2011	April 5, 2011	\$0.02	\$309
May 20, 2011	June 6, 2011	\$0.02	\$310
August 19, 2011	September 6, 2011	\$0.02	\$310
November 23, 2011	December 6, 2011	\$0.02	\$308

On February 21, 2013, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.03 per share payable on April 3, 2013, to stockholders of record at the close of business on March 20, 2013, which will total approximately \$0.5 million.

**Table of Contents**

**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, 2012:

Contractual obligations	Total	Less	1-3	3-5	More
		than	years	years	than
		1 year	(in thousands)		5 years
Operating leases	\$ 4,032	\$ 1,158	\$ 1,763	\$ 1,106	\$ 5
Purchase commitments for inventory	1,516	1,511	5		
<b>Total contractual obligations</b>	<b>\$ 5,548</b>	<b>\$ 2,669</b>	<b>\$ 1,768</b>	<b>\$ 1,106</b>	<b>\$ 5</b>

The commitments under our operating leases consist primarily of lease payments for our Burlington, Massachusetts, corporate headquarters and manufacturing facility, expiring in 2017; our Toronto, Ontario, Canada office, expiring in 2018; our Sulzbach, Germany office, expiring in 2016; our Tokyo, Japan office, expiring in 2013; our Milan, Italy office, expiring in 2016; and our Madrid, Spain office, expiring in 2014. They also include automobile and equipment leases.

The purchase commitments for inventory are to be used in operations over the normal course of business and do not represent excess commitments or loss contracts.

**Critical Accounting Policies and Estimates**

We have adopted various accounting policies to prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles (GAAP). Our most significant accounting policies are described in note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The preparation of our consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and 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 directly to hospitals and 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.

---

**Table of Contents**

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 return product 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, at the time of shipment of our products to our distributors.

***Accounts Receivable***

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

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, 2012 our receivables in Italy and Spain totaled \$1.3 million and \$0.3 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, 2012, 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

---

**Table of Contents**

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, dividend yield, and expected term over which the stock options will be outstanding. The computation of expected volatility is based on the historical volatility of the company's stock. The interest rate for periods within the contractual life of the award is based on the U.S. Treasury risk-free interest rate in effect at the time of grant. Historical data on exercise patterns is the basis for estimating the expected life of an option. The expected annual dividend rate was calculated by dividing our annual dividend, based on the most recent quarterly dividend rate, by the closing stock price on the grant date.

We also issue restricted stock units (RSUs) as an additional form of equity compensation to our employees, officers, and directors, pursuant to our stockholder-approved 2006 Plan. RSUs entitle the grantee to an issuance of stock at no cost and generally vest over a period of time determined by our Board of Directors at the time of grant based upon the continued service to the company. The fair market value of the award is determined based on the number of RSUs granted and the market value of our common stock on the grant date and is amortized to expense over the period of vesting. Unvested RSUs are forfeited and canceled as of the date that employment or service to the company terminates. RSUs are settled in shares of our common stock upon vesting. We 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 \$1.2 million in connection with share-based payment awards for the year ended December 31, 2012. The future expense of non-vested share-based awards of approximately \$2.3 million is to be recognized over a weighted-average period of 3.3 years. During 2012, we granted stock options at a weighted average fair value of \$2.91 and restricted stock units with weighted average fair value of \$6.23.

***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. 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

---

**Table of Contents**

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 \$13.7 million and \$11.9 million as of December 31, 2012 and 2011, 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 15 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 identified. We generally calculate 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 \$5.2 million as of December 31, 2012, and \$3.0 million as of December 31, 2011. We recognized impairment charges on our intangible assets of \$0.1 million in 2011 and \$0.5 million in 2010.

***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, 2012, 2011, and 2010, 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, 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, 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

## **Table of Contents**

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 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 \$3.1 million and \$4.4 million as of December 31, 2012 and 2011, respectively.

### **Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (FASB) amended existing rules covering fair value measurement and disclosure to clarify guidance and minimize differences between GAAP and International Financial Reporting Standards (IFRS). The new guidance requires us to provide information about valuation techniques and unobservable inputs used in Level 3 fair value measurements and provide a narrative description of the sensitivity of Level 3 measurements to changes in unobservable inputs. The guidance became effective on January 1, 2012. The adoption of this standard did not have a material impact on our results of operations or financial position.

In June 2011, new guidance was issued pertaining to the presentation of comprehensive income. The new rule eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to provide a more consistent method of presenting non-owner transactions that affect the company's equity. Under the new guidance, an entity can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive, statements. The new guidance was effective for fiscal years that begin after December 15, 2011. The adoption of this standard did not have a material impact on our results of operations or financial position.

In February 2013, the FASB issued new guidance which requires disclosure of information about significant reclassification adjustments from accumulated other comprehensive income in a single note or on the face of the financial statements. This guidance will be effective in 2013. We believe the adoption of this standard, which is related to disclosure only, will not have an impact on our results of operations or financial position.

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

We did not have any off-balance sheet arrangements as of December 31, 2012. 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.

## **Table of Contents**

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

This item is not applicable to us as a smaller reporting company.

### **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**

Based on their evaluation as of December 31, 2012, 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) were effective at reasonable assurance levels.

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

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

Management assessed the effectiveness of our internal controls over financial reporting as of December 31, 2012. Management based its assessment on criteria established in the *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment.

Based on this assessment under the criteria set forth in the *Internal Control Integrated Framework*, management has concluded that our internal control over financial reporting was effective as of December 31, 2012.

Pursuant to Item 308 of Regulation S-K, this management's report on internal control over financing reporting shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section.

#### **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, 2012, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

#### **Inherent Limitations of Internal Controls**

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

**Table of Contents**

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.

**Item 9B. Other Information**  
**Not Applicable.**



**Table of Contents**

**PART III**

The information responsive to this item is incorporated by reference herein from the information to be contained in our 2013 definitive proxy statement (2013 Definitive Proxy Statement) for the 2013 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the year ended December 31, 2012.

**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 the 2013 Definitive Proxy Statement.

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 2013 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 2013 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 2013 Definitive Proxy Statement.

**Table of Contents****Equity Compensation Plan Information**

The following table sets forth information regarding our equity compensation plans in effect as of December 31, 2012. 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.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
<i>Equity compensation plans approved by security holders</i>	2,290,991	\$ 5.60	1,028,667
<i>Equity compensation plans not approved by security holders</i>			
<b>Total</b>	<b>2,290,991</b>	<b>\$ 5.60</b>	<b>1,028,667</b>

**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 2013 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 section entitled Ratification of Independent Registered Public Accounting Firm in our 2013 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 Comprehensive Income

(v) Consolidated Statements of Changes in Stockholders' Equity

(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	Number	
2.1	Purchase Option Agreement dated December 30, 2008 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.				X
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.				X
2.3	Amendment No. 2 to Purchase Option Agreement dated January 5, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.				X
2.4	Amendment No. 3 to Purchase Option Agreement dated October 1, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.				X
3.1	Amended and Restated By-laws of the Registrant	S-1/A	5/26/06	3.1	

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

3.2	Second Amended and Restated Certificate of Incorporation of the Registrant	10-K	3/29/10	3.2
3.3	Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant	8-K	6/15/12	3.3
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	6/22/06	4.1
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	10.1
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	10.2
10.3	Director Compensation Policy	10-K	3/27/12	10.27

**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	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	10.7	
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	10.8	
10.6	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts	S-1/A	6/22/06	10.24	
10.7	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino	S-1/A	6/22/06	10.10	
10.8	1997 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.11	
10.9	1998 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.12	
10.10	2000 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.13	
10.11	2004 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.14	
10.12	Second Amended and Restated 2006 Stock Option and Incentive Plan and form of agreements thereunder	8-K	6/18/10	10.1	
10.13	Form of Indemnification Agreement between the Registrant and its directors and executive officers	S-1/A	5/26/06	10.17	
10.14	Form of Restricted Stock Unit Award Agreement under the Registrant's 2006 Stock Option and Incentive Plan	8-K	12/26/06	99.1	
10.15	Management Incentive Compensation Plan	8-K	4/27/07	10.1	
10.16	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	10.1	
10.17	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	10.1	
10.18	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	10.36	
10.19	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	10.37	
10.20	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and David Roberts	10-K	3/31/09	10.38	
10.21	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and Joseph P. Pellegrino	10-K	3/31/09	10.39	

**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	Number	
10.22	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	10.33	
10.23	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	10.34	
10.24	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	10.28	
10.25	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	10.29	
10.26	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.				X
21.1	List of Subsidiaries				X
23.1	Consent of Ernst & Young LLP				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
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.

**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 27, 2013.

LEMAITRE VASCULAR

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

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

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 27, 2013
/s/ JOSEPH P. PELLEGRINO, JR. <b>Joseph P. Pellegrino, Jr.</b>	Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	March 27, 2013
/s/ RUSSELL D. HAYS <b>Russell D. Hays</b>	Director	March 27, 2013
/s/ LAWRENCE J. JASINSKI <b>Lawrence J. Jasinski</b>	Director	March 27, 2013
/s/ CORNELIA W. LEMAITRE <b>Cornelia W. LeMaitre</b>	Vice President, Human Resources and Director	March 27, 2013
/s/ JOHN J. O'CONNOR <b>John J. O' Connor</b>	Director	March 27, 2013
/s/ DAVID B. ROBERTS <b>David B. Roberts</b>	President and Director	March 27, 2013
/s/ WILLIAM N. THORNDIKE, JR. <b>William N. Thorndike, Jr.</b>	Director	March 27, 2013

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

	<b>Page</b>
<b>LeMaitre Vascular, Inc.</b>	
<i>Consolidated Financial Statements</i>	
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	F-3
<u>Consolidated Statements of Operations for the Years Ended December 31, 2012, 2011 and 2010</u>	F-4
<u>Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2012, 2011 and 2010</u>	F-5
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2012, 2011 and 2010</u>	F-6
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010</u>	F-9
<u>Notes to Consolidated Financial Statements</u>	F-10



**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying consolidated balance sheets of LeMaitre Vascular, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2012. 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, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 27, 2013

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

	December 31, 2012	December 31, 2011
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,448	\$ 20,132
Accounts receivable, net of allowances of \$326 at December 31, 2012, and \$211 at December 31, 2011	9,048	8,541
Inventory	10,859	8,003
Prepaid expenses and other current assets	2,776	3,011
<b>Total current assets</b>	<b>39,131</b>	<b>39,687</b>
Property and equipment, net	4,544	4,661
Goodwill	13,749	11,917
Other intangibles, net	5,191	2,985
Deferred tax assets	273	6
Other assets	172	431
<b>Total assets</b>	<b>\$ 63,060</b>	<b>\$ 59,687</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,060	\$ 981
Accrued expenses	6,777	5,539
Acquisition-related obligations	557	19
<b>Total current liabilities</b>	<b>8,394</b>	<b>6,539</b>
Deferred tax liabilities	1,673	989
Other long-term liabilities	105	71
<b>Total liabilities</b>	<b>10,172</b>	<b>7,599</b>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.01 par value; authorized 3,000,000 shares; none outstanding		
Common stock, \$0.01 par value; authorized 37,000,000 shares; issued 16,539,621 shares at December 31, 2012, and 16,303,155 shares at December 31, 2011	165	163
Additional paid-in capital	64,694	64,619
Accumulated deficit	(3,869)	(6,440)
Accumulated other comprehensive loss	(433)	(606)
Treasury stock, at cost; 1,323,537 shares at December 31, 2012, and 975,700 shares at December 31, 2011	(7,669)	(5,648)
<b>Total stockholders' equity</b>	<b>52,888</b>	<b>52,088</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 63,060</b>	<b>\$ 59,687</b>

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,		
	2012	2011	2010
	(in thousands,		
	except per share data)		
Net sales	\$ 56,735	\$ 57,685	\$ 56,060
Cost of sales	15,867	17,458	14,341
Gross profit	40,868	40,227	41,719
Sales and marketing	20,811	19,375	19,409
General and administrative	10,973	11,228	10,506
Research and development	5,092	4,425	5,488
Restructuring charges		2,161	1,816
Gain on divestitures	(248)	(735)	
Impairment charges		83	485
Total operating expenses	36,628	36,537	37,704
Income from operations	4,240	3,690	4,015
Other income (expense):			
Interest income	78	11	31
Interest expense	(1)		(5)
Foreign currency gain (loss)	(329)	51	(30)
Other income, net	5		14
Income before income taxes	3,993	3,752	4,025
Provision (benefit) for income taxes	1,422	1,609	(1,988)
Net income	\$ 2,571	\$ 2,143	\$ 6,013
Earnings per share of common stock:			
Basic	\$ 0.17	\$ 0.14	\$ 0.38
Diluted	\$ 0.16	\$ 0.13	\$ 0.37
Weighted-average shares outstanding:			
Basic	15,194	15,458	15,627
Diluted	15,638	15,989	16,114
Cash dividends declared per common share	\$ 0.10	\$ 0.08	\$

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Net income	\$ 2,571	\$ 2,143	\$ 6,013
Other comprehensive income:			
Foreign currency translation adjustment, net	173	(177)	(519)
Unrealized loss on available for sale securities			(4)
Total other comprehensive income	173	(177)	(523)
Comprehensive income	\$ 2,744	\$ 1,966	\$ 5,490

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			Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders Equity
	Shares	Amount	Additional Paid-in Capital			Shares	Amount	
Balance at December 31, 2009	15,911,619	\$ 159	\$ 63,475	\$ (14,596)	\$ 94	210,938	\$ (919)	\$ 48,213
Net income				6,013				6,013
Other comprehensive income					(523)			(523)
Issuance of common stock for stock options exercised	73,497	1	130					131
Vested restricted stock units	132,085	1						1
Tax benefits from stock-based compensation awards			70					70
Stock based compensation expense			967					967
Repurchase of common stock at cost						426,978	(2,516)	(2,516)
Balance at December 31, 2010	16,117,201	\$ 161	\$ 64,642	\$ (8,583)	\$ (429)	637,916	\$ (3,435)	\$ 52,356

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			Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders Equity
	Shares	Amount	Additional Paid-in Capital			Shares	Amount	
Balance at December 31, 2010	16,117,201	\$ 161	\$ 64,642	\$ (8,583)	\$ (429)	637,916	\$ (3,435)	\$ 52,356
Net income				2,143				2,143
Other comprehensive income					(177)			(177)
Issuance of common stock for stock options exercised	56,751	1	67					68
Vested restricted stock units	129,203	1						1
Tax benefits from stock-based compensation awards			50					50
Stock based compensation expense			1,097					1,097
Repurchase of common stock at cost						337,784	(2,213)	(2,213)
Common stock cash dividend paid			(1,237)					(1,237)
Balance at December 31, 2011	16,303,155	\$ 163	\$ 64,619	\$ (6,440)	\$ (606)	975,700	\$ (5,648)	\$ 52,088

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			Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders Equity
	Shares	Amount	Additional Paid-in Capital			Shares	Amount	
Balance at December 31, 2011	16,303,155	\$ 163	\$ 64,619	\$ (6,440)	\$ (606)	975,700	\$ (5,648)	\$ 52,088
Net income				2,571				2,571
Other comprehensive income					173			173
Issuance of common stock for stock options exercised	113,207	1	357					358
Vested restricted stock units	123,259	1						1
Tax benefits from stock-based compensation awards			23					23
Stock based compensation expense			1,213					1,213
Repurchase of common stock at cost						347,837	(2,021)	(2,021)
Common stock cash dividend paid			(1,518)					(1,518)
Balance at December 31, 2012	16,539,621	\$ 165	\$ 64,694	\$ (3,869)	\$ (433)	1,323,537	\$ (7,669)	\$ 52,888

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
<b>Operating activities</b>			
Net income	\$ 2,571	\$ 2,143	\$ 6,013
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	2,234	2,037	1,376
Stock-based compensation	1,213	1,097	967
Impairment charges		83	485
Provision for losses in accounts receivable	153	56	55
Provision for inventory write-downs	863	1,011	836
Provision (benefit) for deferred income taxes	287	1,159	(2,380)
Gain on divestitures	(248)	(735)	
Tax benefits from stock-based compensation awards	(23)	(50)	(70)
Loss on disposal of property and equipment	8	30	51
Non cash restructuring charges		732	108
Foreign currency transaction gain (loss)	369	(156)	37
Changes in operating assets and liabilities, net of effect of business acquisitions:			
Accounts receivable	(640)	(174)	(972)
Inventory	(3,725)	(998)	(1,735)
Prepaid expenses and other assets	303	105	(846)
Accounts payable and other liabilities	1,357	(3,170)	3,127
Net cash provided by operating activities	4,722	3,170	7,052
<b>Investing activities</b>			
Purchases of property and equipment	(1,209)	(2,021)	(2,471)
Payments related to acquisitions	(4,373)	(1,151)	(3,520)
Receipts related to divestitures	500	1,414	40
Purchase of technology and licenses	(116)	(64)	(87)
Sales and maturities of marketable securities			803
Net cash used in investing activities	(5,198)	(1,822)	(5,235)
<b>Financing activities</b>			
Proceeds from issuance of common stock	359	69	132
Purchase of treasury stock	(2,021)	(2,213)	(2,516)
Tax benefits from stock-based compensation awards	23	50	70
Common stock cash dividend paid	(1,518)	(1,237)	
Payments of Italian government loan and grant		(469)	(21)
Net cash used in financing activities	(3,157)	(3,800)	(2,335)
Effect of exchange rate changes on cash and cash equivalents	(51)	(30)	(60)
Net decrease in cash and cash equivalents	(3,684)	(2,482)	(578)
Cash and cash equivalents at beginning of year	20,132	22,614	23,192
Cash and cash equivalents at end of year	\$ 16,448	\$ 20,132	\$ 22,614

Supplemental disclosures of cash flow information (see Note 14).

See accompanying notes to consolidated financial statements.





**Table of Contents**

**LeMaitre Vascular, Inc.**

**Notes to Consolidated Financial Statements**

**December 31, 2012**

**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 are balloon catheters, carotid shunts, laparoscopic cholecystectomy devices, radiopaque tape, remote endarterectomy devices, valvulotomes, vascular grafts, vascular patches, and vessel closure systems. In addition, we held rights to exclusively distribute in the United States, Canada, and most of Europe a biologic vascular patch manufactured by a third party. In October 2012, we acquired this product line and the associated manufacturing rights. Our offices are located in Burlington, Massachusetts, Toronto, Ontario, Canada, Sulzbach, Germany, Milan, Italy, Madrid, Spain, and Tokyo, Japan.

***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, and LeMaitre Vascular ULC. Our wholly-owned subsidiary Biomateriali S.r.l. was dissolved in March 2012. 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 directly to hospitals and 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.

**Table of Contents**

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 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 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, and must have at least 18 months remaining prior to its expiration date, or twelve months for our hospital customers in Europe. 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,		
	2012	2011	2010
		(in thousands)	
Advertising expense	\$ 406	\$ 284	\$ 316

***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, marketable securities, accounts receivable, and notes receivable. Cash equivalents represent highly liquid investments with maturities of 90 days or less at the date of purchase. Marketable securities are investment grade, interest-earning securities and are diversified by type and industry. Credit risk related to cash, cash equivalents, and marketable securities are limited based on the creditworthiness of the financial institutions at which these funds are held. Credit risk related to notes receivable is assessed based upon the individual payor as of the original fair value determination and updated periodically as required.

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, 2012 our receivables in Italy and Spain totaled \$1.3 million and \$0.3 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, 2012, 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 Charged to Income</b>	<b>Deductions from Reserves</b>	<b>Balance at End of Period</b>
	(in thousands)			
Allowance for doubtful accounts and sales returns:				
Year ended December 31, 2012	\$ 211	\$ 153	\$ 38	\$ 326
Year ended December 31, 2011	184	56	29	211
Year ended December 31, 2010	159	55	30	184

**Fair Value of Financial Instruments**

Our financial instruments include cash and cash equivalents, marketable securities, accounts receivable, trade payables, and notes payable. 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.

Beginning January 1, 2009, 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***

For business combinations completed after January 1, 2009, 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. We have not completed an acquisition with contingent consideration subsequent to January 1, 2009.

---

**Table of Contents*****Impairment of Long-lived Assets***

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

As a result of the AlboGraft Vascular Graft Prohibition Notices discussed in Note 8, we assessed the AlboGraft intangible assets by performing a recoverability test which determined that the future cash flows associated AlboGraft Vascular Grafts significantly exceeded our \$0.5 million carrying value of AlboGraft related intangible assets. As a result, we concluded the intangible assets were not impaired as of December 31, 2012.

In 2011, we determined that certain patents within our portfolio in the United States and Europe had no value based upon an analysis of expected economic benefits. As a result, we recorded an impairment charge of \$0.1 million for the write-down of these patents.

In 2010, we recognized impairment charges of \$0.4 million related to our TAArget and UniFit products associated with certain technology, customer lists, and fixed assets. We determined that an impairment indicator existed with respect to these products as we suspended enrollment into our UNITE and ENTRUST clinical trials and ceased development efforts related to these products in October 2010. The fair value of the residual intangible assets of \$0.2 million was determined by projected future cash flows discounted to their net present value. Additionally, we incurred a \$0.1 million impairment charge associated with a Biomateriali private label customer relationship, which we subsequently terminated.

These impairment adjustments 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 most recent operational budgets, long range strategic plans and other estimates.

***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, 2012, 2011, or 2010.

## **Table of Contents**

### ***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 15 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.

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, 2012, 2011, and 2010, 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

## **Table of Contents**

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, which is consistent with that of prior years.

### ***Comprehensive Income***

Comprehensive income is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Other than reported net income, comprehensive income includes foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities, which are disclosed in the accompanying consolidated statements of comprehensive income.

Accumulated other comprehensive loss consisted of foreign currency translation adjustment losses of \$0.4 million and \$0.6 million as of December 31, 2012 and 2011, respectively.

### ***Restructuring***

We record restructuring charges incurred in connection with consolidation or relocation of operations, exited business lines, shutdowns of specific sites, 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, employee separation arrangements, or other costs directly related to the restructuring. If the actual cost incurred exceeds the estimated cost, an additional charge to earnings will result. If the actual cost is less than the estimated cost, a credit to earnings will be recognized.

### ***Earnings per Share***

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



**Table of Contents**

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

	Year ended December 31,		
	2012	2011	2010
	(in thousands, except per share data)		
<b>Basic:</b>			
Net income available for common stockholders	\$ 2,571	\$ 2,143	\$ 6,013
Weighted average shares outstanding	15,194	15,458	15,627
Basic earnings per share	\$ 0.17	\$ 0.14	\$ 0.38
<b>Diluted:</b>			
Net income available for common stockholders	\$ 2,571	\$ 2,143	\$ 6,013
Weighted-average shares outstanding	15,194	15,458	15,627
Common stock equivalents, if dilutive	444	531	487
Shares used in computing diluted earnings per common share	15,638	15,989	16,114
Diluted earnings per share	\$ 0.16	\$ 0.13	\$ 0.37
Shares excluded in computing diluted earnings per share as those shares would be anti-dilutive	106	355	58

**Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (FASB) amended existing rules covering fair value measurement and disclosure to clarify guidance and minimize differences between GAAP and International Financial Reporting Standards (IFRS). The new guidance requires us to provide information about valuation techniques and unobservable inputs used in Level 3 fair value measurements and provide a narrative description of the sensitivity of Level 3 measurements to changes in unobservable inputs. The guidance became effective on January 1, 2012. The adoption of this standard did not have a material impact on our results of operations or financial position.

In June 2011, new guidance was issued pertaining to the presentation of comprehensive income. The new rule eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. The standard is intended to provide a more consistent method of presenting non-owner transactions that affect the company's equity. Under the new guidance, an entity can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive, statements. The new guidance was effective for fiscal years that begin after December 15, 2011. The adoption of this standard did not have a material impact on our results of operations or financial position.

In February 2013, the FASB issued new guidance which requires disclosure of information about significant reclassification adjustments from accumulated other comprehensive income in a single note or on the face of the financial statements. This guidance will be effective in 2013. We believe the adoption of this standard, which is related to disclosure only, will not have an impact on our results of operations or financial position.

**2. Acquisitions and Divestitures*****LifeSpan Vascular Graft***

In November 2010, we entered into an Asset Purchase Agreement (the Angiotech Agreement) with Angiotech Pharmaceuticals (US), Inc., and Angiodevice International GmbH (together, Sellers), to acquire substantially all the assets associated with the LifeSpan Vascular Graft and related manufacturing business. Assets acquired include inventory, fixed assets, select contractual commitments, permits and approvals, legal



**Table of Contents**

rights, and intellectual property. Other provisions of the Angiotech Agreement include transitional assistance from Sellers and mutual indemnification for losses arising out of or relating to certain breaches of, and misrepresentations under, the Angiotech Agreement.

The purchase price for this acquisition was \$2.8 million. We paid Angiotech \$2.5 million at the closing of the acquisition. We paid the remaining \$0.3 million in November 2011. We accounted for the acquisition as a business combination. The following table summarizes the final purchase accounting for 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	\$ 765
Property and equipment	209
Intangible assets	931
Goodwill	895
<b>Total assets acquired</b>	<b>2,800</b>
Total liabilities assumed	
	<b>\$ 2,800</b>

The goodwill of \$0.9 million will be deductible for tax purposes over 15 years.

Of the \$0.9 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>
Patents	\$ 863	6.0 years
Customer and contract relationships	68	4.0 years
<b>Total intangible assets</b>	<b>\$ 931</b>	

In a related transaction, on November 30, 2010, we entered into an Asset Purchase Agreement and a Transition Agreement (together, the Edwards Agreements), each with Edwards Lifesciences Corporation (Edwards), and certain of Edwards' affiliates, for an orderly transition of Edwards' distribution business of the LifeSpan Vascular Graft in Europe and Japan from Edwards to LeMaitre, and to acquire from Edwards certain assets related to Edwards' distribution of the product, including inventory, detailed customer lists for Europe and Japan, transfer of certain registrations, and the LifeSpan trademark. Under the Edwards Agreements, Edwards provided sales and marketing cooperation through assignment of most assignable customer contracts and other transition assistance.

We paid Edwards \$1.0 million on the closing date and paid \$0.2 million in March 2011. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. As such, we recorded \$0.6 million of inventory and \$0.5 million of intangible assets. The weighted-average amortization period for these intangibles as of December 31, 2010 was 4.4 years. In addition, we recorded \$0.1 million as prepaid transition services which were amortized over its contractual life of three months.

**Table of Contents*****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 have 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 is payable in October 2013. We accounted for the acquisition as a business combination. The following table summarizes the final purchase accounting for 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	\$ 12
Intangible assets	2,756
Goodwill	1,832
Total assets acquired	4,600
Total liabilities assumed	
	\$ 4,600

The goodwill of \$1.8 million will be deductible for tax purposes over 15 years.

Of the \$2.8 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>
Patents	\$ 2,450	13.0 years
Non-compete agreement	306	5.0 years
Total intangible assets	\$ 2,756	

***Cardiva, S.L. Distribution Agreement***

In December 2010, we entered into a definitive agreement with Cardiva, S.L. (Cardiva) to terminate its distribution of our products in Spain and to acquire certain assets and rights from Cardiva effective as of June 30, 2011. We paid approximately \$1.2 million in exchange for this early termination, the purchase of their Spanish customer list for our products, certain customer contracts, their provision of sales and marketing services, and most of their remaining inventory. We recorded \$0.4 million of intangible assets, recognized a \$0.5 million restructuring charge related to the early termination of the distribution agreement, expensed \$0.1 million of transition services as selling expense, and recorded \$0.3 million of inventory. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. The weighted-average amortization period for these intangibles as of June 30, 2011 was 5.5 years. Additionally, we entered into a one-year consulting agreement beginning July 1, 2011 with an employee of Cardiva for \$0.2 million which had been paid in full as of December 31, 2011.



---

**Table of Contents*****Marcom Medical ApS Distribution Agreement***

In December 2010, we entered into a definitive agreement with Marcom Medical ApS (Marcom) to terminate its distribution of our products in Denmark and to acquire certain assets and rights from Marcom effective as of June 30, 2011. We paid approximately \$0.2 million in exchange for this early termination, the purchase of their Danish customer list for our products, certain customer contracts, and minimal inventory. We recorded \$0.1 million of intangible assets and recognized a \$0.1 million restructuring charge related to the early termination of the distribution agreement. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. The weighted-average amortization period for these intangibles as of June 30, 2011 was 2.9 years.

***Schaublin Medica SA Distribution Agreement***

In October 2012, we entered into a definitive agreement with Schaublin Medica SA (Schaublin) to terminate its distribution of our products in Switzerland and to acquire certain assets and rights from Schaublin effective as of January 1, 2013 for \$0.2 million. The purchase price is due in three equal installments with the first paid in October 2012 and the remaining two payments due in January 2013 and January 2014. We recorded \$0.1 million of intangible assets and recognized a \$0.1 million of transition services as selling expense. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. The weighted-average amortization period for these intangibles as of December 31, 2012 is 7.0 years.

***TryTech Distribution Agreement***

In December 2012, we entered into a definitive agreement with TryTech Corporation (TryTech) to terminate its distribution of our products in a certain Japanese territory and to acquire certain assets and rights from TryTech effective as of April 1, 2013 for \$0.1 million. The purchase price is due in three equal installments with the first paid in December 2012 and the remaining two payments due in March 2013 and March 2014. We recorded \$0.1 million of intangible assets and recognized \$20,000 of transition services as selling expense. We allocated the payment to the tangible and intangible assets acquired based on the estimated fair value of each of these elements to the transaction. The weighted-average amortization period for these intangibles as of December 31, 2012 is 3.0 years.

***OptiLock Implantable Port***

On June 1, 2010, we sold our OptiLock Implantable Port product line to Minvasive Ltd. (Minvasive). In exchange for consideration of approximately \$0.2 million, Minvasive received our existing inventory, tangible and intangible assets, and a customer list associated with the product line. Payment terms included \$30,000 due at signing, with the remaining balance to be paid in the form of a royalty of 30% of Minvasive's OptiLock Implantable Port sales until the total consideration is paid in full. In 2014, any outstanding balance will become due in full. As a result of the transaction, we recorded the estimated present value of amounts due as a \$0.1 million receivable in other long term assets. All royalty payments received from Minvasive were applied to the receivable. In May 2012, Minvasive provided notice that it was filing for insolvency protection under German law. As a result, we wrote-off the remaining balance of approximately \$52,000 as a loss on divestitures during the three months ended June 30, 2012. We had received approximately \$60,000 under the terms of this agreement prior to the write-off.

***TAArget and UniFit Stent Grafts***

On June 30, 2011, we sold our TAArget and UniFit stent graft product lines to Duke Vascular, Inc. (Duke). In exchange for consideration of approximately \$0.1 million in cash and a \$0.5 million promissory note, Duke received most of our existing inventory, tangible and intangible assets, and a customer list associated with the

**Table of Contents**

product lines. In addition, Duke assumed our future obligations associated with the UNITE and ENTRUST clinical trials. We received the initial cash payment on June 30, 2011. The \$0.5 million promissory note bore interest at 7% and was payable on June 30, 2012. We recorded the estimated fair value of the promissory note as \$0.2 million receivable in other long term assets. As a result of this transaction we recorded a net charge of approximately \$0.4 million in cost of sales during the year ended December 31, 2011. In 2012, we received \$0.5 million which was applied to the outstanding promissory note balance of \$0.2 million, interest income, and as a gain on divestiture of \$0.3 million.

**Endologix Stent Grafts**

On July 6, 2011, we entered into an early termination agreement for our distribution rights of Endologix's aortic endovascular products in Europe. Under the terms of the agreement, we received \$1.3 million in exchange for the early termination of our distribution agreement on August 31, 2011, certain customer contracts, our provision of sales and marketing services, and most of our remaining inventory. Previously, we held distribution rights in certain European countries for Endologix's Powerlink System, and related products, through June 30, 2013. We recognized a gain of \$0.7 million upon the termination of the distribution agreement during the year ended December 31, 2011.

The fair market valuations associated with the Lifespan, XenoSure, Cardiva, Marcom, Schaublin, TryTech, and Duke 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.

**3. Inventory**

Inventory consists of the following:

	<b>As of December 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(in thousands)</b>	
Raw materials	\$ 2,471	\$ 2,034
Work-in-process	2,084	1,308
Finished products	6,304	4,661
Total inventory	\$ 10,859	\$ 8,003

We held inventory on consignment of \$0.7 million and \$0.5 million as of December 31, 2012 and 2011, respectively.

**Table of Contents****4. Property and Equipment**

Property and equipment consists of the following:

	As of December 31,	
	2012	2011
	(in thousands)	
Computers and equipment	\$ 2,196	\$ 2,007
Machinery and equipment	5,599	5,077
Leasehold improvements	2,968	2,949
Gross property and equipment	10,763	10,033
Less accumulated depreciation	(6,219)	(5,372)
Property and equipment, net	\$ 4,544	\$ 4,661

Depreciation expense is as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Depreciation expense	\$ 1,319	\$ 1,047	\$ 693

**5. Goodwill and Other Intangibles**

Goodwill consists of the following:

	As of December 31,	
	2012	2011
	(in thousands)	
Balance at beginning of year	\$ 11,917	\$ 11,917
Additions for acquisitions	1,832	
Balance at end of year	\$ 13,749	\$ 11,917

Other intangibles consist of the following:

	2012			2011		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value of Intangible Assets	Gross Carrying Value	Accumulated Amortization	Net Carrying Value of Intangible Assets
	(in thousands)					
Patents	\$ 5,108	\$ 1,339	\$ 3,769	\$ 2,546	\$ 909	\$ 1,637
Trademarks and technology licenses	1,157	821	336	1,154	723	431
Customer relationships	1,757	1,001	756	1,528	712	816
Other intangible assets	673	343	330	332	231	101



Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

Total identifiable intangible assets	\$ 8,695	\$ 3,504	\$ 5,191	\$ 5,560	\$ 2,575	\$ 2,985
--------------------------------------	----------	----------	----------	----------	----------	----------

F-22

**Table of Contents**

These assets are being amortized over useful lives ranging from 1 to 15 years. The weighted-average amortization period for these intangibles as of December 31, 2012, is 6.3 years. Amortization expense is included in general and administrative expense and is as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Amortization expense	\$ 915	\$ 990	\$ 683

Estimated amortization expense for each of the five succeeding fiscal years, based upon the intangible assets at December 31, 2012, is as follows:

	2013	Year ended December 31,			2017
		2014	2015	2016	
	(in thousands)				
Amortization expense	\$ 1,051	\$ 870	\$ 660	\$ 563	\$ 320

**6. Financing Arrangements**

As part of the purchase of Biomateriali S.r.l., we assumed a loan from the Italian government under a program that provided funding to certain businesses in Italy through a combination of grants and loans if certain requirements are met. The loan was stated to be payable in ten annual payments through 2018 of principal and interest at an interest rate of 0.74%. The present value of the loan was recorded as of the date the proceeds were received using our incremental borrowing rate. Interest was being imputed on the loan and the amortization was recorded as interest expense. The loan and grant became due in full as a result of the Biomateriali S.r.l. plant closure. As a result, in December 2011, we incurred approximately \$0.1 million of restructuring charges related to additional interest and penalties charges, and we made the final payment to the Italian government of \$0.5 million in December 2011. In 2010, we had previously recorded approximately \$0.3 million of restructuring charges related to the expected repayment of the grants, the imputed interest on the outstanding loan balance, and certain additional interest and penalties.

**7. Accrued Expenses**

Accrued expenses consist of the following:

	As of December 31,	
	2012	2011
	(in thousands)	
Compensation and related taxes	\$ 3,860	\$ 3,250
Income and other taxes	963	530
Restructuring		101
Professional fees	521	360
Other	1,433	1,298
Total	\$ 6,777	\$ 5,539

**Table of Contents****8. Commitments and Contingencies****Leases**

We conduct certain 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, 2012 and 2011. Rent expense was as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Rent expense	\$ 1,030	\$ 1,182	\$ 1,089

At December 31, 2012, 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:

	2013	2014	Year ended December 31,			Thereafter
			2015	2016	2017	
	(in thousands)					
Operating leases	\$ 1,158	\$ 934	\$ 829	\$ 615	\$ 491	\$ 5

**Purchase Commitments**

As part of our normal course of business, we have purchase commitments to purchase \$1.5 million of inventory through 2016. 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.

**Other Commitments**

In 2007, we purchased certain patent applications and in-process research and development which included earn-out payments associated with the commercialization of The UnBalloon Non-Occlusive Modeling Catheter in the European Union and the United States as part of the consideration. The earn-out payments are payable quarterly at approximately the rate of two times sales for the four quarters. The European earn-out period was measured from December 23, 2009 through December 22, 2010. We recorded an intangible asset of approximately \$27,000 related to earn-out payments made on European sales. The United States earn-out period was measured from January 1, 2012 through December 31, 2012. We recorded an intangible asset of approximately \$0.1 million related to earn-out payments made on United States sales. We consider the earn-out payments associated with the commercialization of the products in Europe and the United States to be contingent consideration that were recorded as additional intangible assets in the periods that the contingency was resolved.

**AlboGraft Recall**

In late 2011 and again in 2012, we received complaints of the failure of several of our AlboGraft Vascular Grafts. In reaction to those failures, we voluntarily recalled two production lots and implemented corrective actions. Subsequent to those recalls, we received several additional complaints in 2012, which we believe were unrelated to the prior product failures. As a result of the recalled lots, we recognized \$0.2 million of inventory write-offs, which we recorded to cost of sales during the year ended December 31, 2011.

As a result of the complaints described above, in March 2012, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and the National Security Agency for Medicines and Health Products (ANSM) in France issued Prohibition Notices, which prohibited our ability to sell AlboGraft Vascular Grafts in these countries pending our ability to address their concerns. In July 2012, the ANSM rescinded its Prohibition Notice without qualification, and the MHRA rescinded its Prohibition Notice with the qualification



**Table of Contents**

that all AlboGraft devices must be tested prior to implant. As of January 1, 2013, the MHRA removed the prior test qualification in the United Kingdom. The United Kingdom and France represented approximately 40% of our AlboGraft Vascular Graft sales volume in 2011. Sales of AlboGraft in the United Kingdom and France were \$1.0 million for the year ended December 31, 2011 and \$0.5 million for the year ended December 31, 2012. As of December 31, 2012, we have approximately \$2.7 million of inventory and \$0.5 million of intangible assets related to the AlboGraft Vascular Graft.

**9. Income Taxes**

Income (loss) before income taxes is as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
United States	\$ 3,918	\$ 3,511	\$ 7,171
Foreign	75	241	(3,146)
<b>Total</b>	<b>\$ 3,993</b>	<b>\$ 3,752</b>	<b>\$ 4,025</b>

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

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

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
<b>Current:</b>			
Federal	\$ 881	\$ 309	\$ 147
State	100	9	60
Foreign	154	132	185
	1,135	450	392
<b>Deferred:</b>			
Federal	503	831	(2,105)
State	12	116	(257)
Foreign	(228)	212	(18)
	287	1,159	(2,380)
<b>Provision (benefit) for income taxes</b>	<b>\$ 1,422</b>	<b>\$ 1,609</b>	<b>\$ (1,988)</b>

**Table of Contents**

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, 2012, the gross amount of unrecognized tax benefits exclusive of interest and penalties was \$321,000. We have identified no uncertain tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within the 12 months ending December 31, 2013. We remain subject to examination until the statute of limitations expires for each respective tax jurisdiction. The Federal statute of limitations will be open with respect to these tax positions until 2016. A reconciliation of beginning and ending amount of our unrecognized tax benefits is as follows:

	2012	2011	2010
	(in thousands)		
Unrecognized tax benefits at the beginning of year	\$ 329	\$ 277	\$ 299
Additions for tax positions of current year		52	
Additions for tax positions of prior years	6		
Reductions for tax positions of prior years			(22)
Reductions for lapses of the applicable statutes of limitations	(14)		
Unrecognized tax benefits at the end of the year	\$ 321	\$ 329	\$ 277

Deferred taxes are attributable to the following temporary differences:

	As of December 31,	
	2012	2011
	(in thousands)	
Deferred tax assets:		
Inventory	\$ 772	\$ 516
Net operating loss carryforwards	2,561	3,997
Tax credit carryforwards	555	1,054
Reserves and accruals	263	150
Intangible assets	916	791
Deferred gain on sale of assets		160
Other	468	367
Total deferred tax assets	5,535	7,035
Deferred tax liabilities:		
Property and equipment	(692)	(810)
Other intangibles		(103)
Goodwill	(2,374)	(2,068)
Other	(26)	
Total deferred tax liabilities	(3,092)	(2,981)
Net deferred tax assets before valuation allowance	2,443	4,054
Valuation allowance	(3,053)	(4,370)
Net deferred tax liability	\$ (610)	\$ (316)
Deferred tax classification		
Short-term deferred tax asset	\$ 850	\$ 809
Short-term deferred tax liability	(60)	(142)
Net short-term deferred tax asset	\$ 790	\$ 667

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

Long-term deferred tax asset	\$ 273	\$ 6
Long-term deferred tax liability	(1,673)	(989)
Net long-term deferred tax liability	\$ (1,400)	\$ (983)
Net deferred tax asset (liability)	\$ (610)	\$ (316)

F-26

**Table of Contents**

We have assessed the need for a valuation allowance against our deferred tax assets and continue to carry a valuation allowance against \$3.1 million of foreign deferred tax assets and state credits; based on the weight of available evidence, we believe it is more likely than not such assets will not be realized. The valuation allowance against our deferred tax assets may require adjustment in the future based on changes in the mix of temporary differences, changes in tax laws, and operating performance.

As of December 31, 2012, we have net operating loss carryforwards in France of \$3.7 million that have no expiration, Japan of \$1.9 million that begin to expire in 2013, Italy of \$1.1 million related to our Italian sales subsidiary that have no expiration, Spain of \$1.0 million that begin to expire in 2029 and Switzerland of \$0.1 million that begin to expire in 2019. We also have Federal alternative minimum tax credit carryforwards of approximately \$0.1 million and state tax credit carryforwards of approximately \$0.7 million that are available to reduce future tax liabilities, which expire at various dates through 2027, or can be carried forward indefinitely. The benefit of these tax deductions will be credited to additional paid-in capital when we receive a cash benefit from the stock options 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.

In January 2013, legislation was signed into law which retroactively reinstated various tax provisions which had previously expired to January 1, 2012, principally related to the Federal R&D credit. As this legislation was enacted in January 2013, our financial statements do not consider the effects of the legislation. Had this tax legislation been enacted in 2012, we would have recognized an additional \$0.2 million of additional U.S. tax credits in our consolidated financial statements.

We consider undistributed earnings of our foreign subsidiaries to be indefinitely reinvested; therefore, no amount for U.S. income tax has been provided. In the event of distribution of those earnings in the form of dividends or otherwise, we would be subject to both U.S. income taxes, subject to an adjustment, if any, for foreign tax credits, and foreign withholding taxes payable to certain foreign tax authorities.

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

	2012	2011	2010
Federal statutory rate	34.0%	34.0%	34.0%
State tax, net of federal benefit	2.3%	1.7%	1.8%
Effect of foreign taxes	0.0%	(1.6%)	(0.8%)
Valuation allowance	(6.6%)	3.6%	(87.7%)
Permanent differences	9.1%	6.8%	6.4%
Other	(3.2%)	(1.6%)	(3.1%)
Effective tax rate	35.6%	42.9%	(49.4%)

We are not currently under audit in any tax jurisdictions. As of December 31, 2012, a summary of the tax years that remain subject to examination in our most significant tax jurisdictions are:

United States Federal	2009 and forward
Germany	2007 and forward
Italy	2007 and forward
Japan	2006 and forward



**Table of Contents****10. 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.

*Stock Award Plans*

Under our 1997, 1998, 2000, and 2004 stock option plans, we authorized for 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 (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. The 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 stock award plans is 4,618,003 of which approximately 1,028,667 remain available for grant as of December 31, 2012.

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

	2012	2011	2010
Dividend yield	1.6%	1.1%	0.0%
Volatility	61.8%	66.1%	72.1%
Risk-free interest rate	0.6%	1.4%	1.6%
Weighted average expected option term (in years)	5.5	4.8	4.8
Weighted average fair value per share of options granted	\$ 2.91	\$ 3.57	\$ 3.43
Aggregate intrinsic value of options exercised	\$ 340,678	\$ 321,584	\$ 343,185

**Table of Contents**

A summary of option activity as of December 31, 2012 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, 2011	2,017,338	\$ 5.54	4.80	\$ 3,057,342
Granted(1)	304,172	\$ 6.42		
Exercised(2)	(113,207)	\$ 3.17		\$ 340,678
Canceled / Expired	(196,243)	\$ 7.21		
Balance outstanding at December 31, 2012(3)	2,012,060	\$ 5.64	4.47	\$ 2,589,588
Vested and exercisable at December 31, 2012	1,240,801	\$ 5.59	4.27	\$ 2,154,440
Expected to vest at December 31, 2012(4)	578,757	\$ 5.53	4.68	
Total	1,819,558			

- (1) The aggregate intrinsic value represents the difference between the exercise price and the closing price of our stock on the day of grant.
- (2) The aggregate intrinsic value represents the difference between the exercise price and the closing price of our stock on the day of exercise.
- (3) The aggregate intrinsic value represents the difference between the exercise price and \$5.74, the closing price of our stock on December 31, 2012, for all in-the-money options outstanding.
- (4) Options outstanding that are expected to vest are net of estimated future option forfeitures in accordance with the provisions set forth by the FASB.

**Restricted Stock Units**

A summary of our RSU activity, which is subject to fair value accounting requirements, is as follows:

	Shares	Weighted Average Grant Date Fair Value
Balance outstanding at December 31, 2011	329,786	\$ 4.76
Granted	98,929	\$ 6.23
Vested(1)	(123,259)	\$ 4.47
Canceled	(26,525)	\$ 5.82
Balance outstanding at December 31, 2012	278,931	\$ 5.30

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

The fair values of the RSUs that vested during 2012, 2011, and 2010 were \$0.7 million, \$0.9 million, and \$0.5 million, respectively.

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

Edgar Filing: LEMAITRE VASCULAR INC - Form 10-K

	2012	2011
Shares of common stock repurchased	42,991	45,175
Per share repurchase price	\$ 6.11	\$ 6.83
Aggregate purchase price	\$ 262,719	\$ 308,377

F-29

**Table of Contents****Stock-based Compensation**

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

	2012	2011	2010
	(in thousands)		
Stock option awards to employees	\$ 692	\$ 591	\$ 436
Restricted common stock awards	521	506	531
<b>Total stock-based compensation</b>	<b>\$ 1,213</b>	<b>\$ 1,097</b>	<b>\$ 967</b>

We expect to record the unamortized portion of share-based compensation expense of \$2.3 million for existing stock options and RSUs outstanding at December 31, 2012, over a weighted-average period of 3.3 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 timing and number of any shares repurchased will be determined based on our evaluation of market conditions and other factors. Repurchases may also be made under a Rule 10b5-1 plan, which would permit shares to be repurchased when we might otherwise be precluded from doing so under insider trading laws. The repurchase program may be suspended or discontinued at any time and will conclude no later than December 31, 2013, unless otherwise extended by our Board of Directors. The repurchase program is being funded using our available cash and cash equivalents. We have the authority to purchase \$3.6 million of shares of our common stock remaining under the repurchase program as of December 31, 2012. The following is a summary of the stock repurchase activity for the year ended.

	December 31, 2012		December 31, 2011		December 31, 2010	
	Shares Purchased	Total Purchased (\$ in thousands)	Shares Purchased	Total Purchased (\$ in thousands)	Shares Purchased	Total Purchased (\$ in thousands)
Share repurchases	304,846	\$ 1,759	300,326	\$ 1,904	378,528	\$ 2,245

**Dividends**

On February 24, 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 2012</b>			
March 20, 2012	April 3, 2012	\$ 0.025	\$ 381
May 18, 2012	June 4, 2012	\$ 0.025	\$ 379
August 17, 2012	August 31, 2012	\$ 0.025	\$ 380
November 20, 2012	December 4, 2012	\$ 0.025	\$ 378
<b>Fiscal Year 2011</b>			
March 22, 2011	April 5, 2011	\$ 0.02	\$ 309
May 20, 2011	June 6, 2011	\$ 0.02	\$ 310
August 19, 2011	September 6, 2011	\$ 0.02	\$ 310
November 23, 2011	December 6, 2011	\$ 0.02	\$ 308



---

**Table of Contents**

On February 21, 2013, our Board of Directors approved a quarterly cash dividend on our common stock of \$0.03 per share payable on April 3, 2013, to stockholders of record at the close of business on March 20, 2013, which will total approximately \$0.5 million.

**11. Profit-Sharing Plan**

We offer a 401(k) profit-sharing plan (the Plan) covering eligible U.S. employees to make tax deferred contributions, a portion of which are matched by us. We may make discretionary profit sharing contributions to the Plan in an amount determined by our Board of Directors. Our contributions vest ratably over six years of employment and amounted to approximately \$0.1 million for 2011 and \$0.2 million for 2010. Effective September 1, 2012, we resumed our discretionary matching on employee contributions which we previously ceased effective April 1, 2011; however, our contributions were funded from employee forfeitures for 2012.

**12. Restructuring Charges**

In October 2010, we adopted a reorganization plan (Biomateriali Plan) that was designed to eliminate redundant costs resulting from our 2007 acquisition of Biomateriali and to improve efficiencies in our manufacturing operations. We transitioned the production of our AlboGraft Vascular Graft to our existing corporate headquarters in Burlington, Massachusetts. The Biomateriali Plan provided for the termination of 29 employees at our Biomateriali subsidiary, relocation of manufacturing equipment, the eventual dissolution of our Biomateriali subsidiary, and the hiring of additional employees to staff the required functions in Burlington. In 2010, we incurred \$1.4 million of severance charges, of which \$0.9 million was paid in December 2010, \$0.3 million of charges related to the repayment of grants and loans received from the Italian government associated with business incentive programs for the Biomateriali facility (see Note 6), and \$0.1 million of charges related to the abandonment of fixed assets and legal fees associated with the negotiation of the severance agreements. In 2011, we incurred \$0.3 million of charges associated with the transfer of manufacturing equipment to our Burlington factory and \$0.7 million of non-cash charges related to the write-down of an asset for deferred rent, which was triggered by our exit of the Biomateriali facility in March 2011, and \$0.1 million related to the repayment of grants and loans received from the Italian government associated with business incentive programs for the Biomateriali facility. We paid \$0.4 million of severance related charges in 2011 and paid remaining \$0.2 million in February 2012. We made the final payment to the Italian government of \$0.5 million in December 2011. In March 2012, we completed the Biomateriali liquidation and dissolution process.

In May 2011, we adopted a reorganization plan (LifeSpan Plan) that was designed to eliminate redundant costs resulting from our 2010 acquisition of the LifeSpan vascular graft and to improve efficiencies in our manufacturing operations. We transitioned the production of our LifeSpan vascular graft from Laguna Hills, California to our existing corporate headquarters in Burlington, Massachusetts. The LifeSpan Plan resulted in the termination of 7 employees at the Laguna Hills facility, relocation of manufacturing equipment, and the hiring of 4 employees to staff the required functions in Burlington. We incurred approximately \$0.1 million related to the closure of the Laguna Hills facility and the related relocation of the manufacturing equipment during the year ended December 31, 2011. We incurred approximately \$33,000 of severance charges related to this project during year ended December 31, 2011.

On June 30, 2011, we terminated our relationship with our Spanish distributor resulting in a contract termination charge of \$0.5 million which we recorded as restructuring charges (see Note 2 for further details regarding the transaction).

On June 30, 2011, we terminated our relationship with our Danish distributor resulting in a contract termination charge of \$0.1 million which we recorded as restructuring charges (see Note 2 for further details regarding the transaction).

**Table of Contents**

In July 2011, we adopted a reorganization plan of our European administrative and stent graft sales personnel as a result of our exit from our stent graft business. We terminated 6 employees and recorded severance charges of \$0.3 million during the year ended December 31, 2011. The final severance payments were made in March 2012.

The components of the restructuring charges are as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Distributor termination charges	\$	\$ 572	\$
Transfer of manufacturing equipment		446	
Employee severance costs		291	1,431
Italian government loan and grant termination charge		79	250
Non cash asset write-off		732	108
Other		41	27
<b>Total</b>	<b>\$</b>	<b>\$ 2,161</b>	<b>\$ 1,816</b>

Activity related to accrued restructuring costs is as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Balance at beginning of year	\$ 101	\$ 922	\$
Plus:			
Current year restructuring costs		2,161	1,816
Other			155
Less:			
Payment for termination of contractual obligations		572	
Payment of employee severance costs	101	680	941
Payment related to transfer of manufacturing equipment		446	
Payment of Italian loan and grant		469	
Other		83	
Non-cash fixed asset write-off		732	108
Balance at end of year	\$	\$ 101	\$ 922

**13. Segment and Enterprise-wide Disclosures**

The FASB establishes standards for reporting information regarding operating segments in annual financial statements. Operating segments are identified as components of an enterprise about which separate, discrete financial information is available for evaluation 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 other than product sales is prepared by us, except by geographic location, for local reporting purposes.

**Table of Contents**

Most of our revenues were generated in the United States, Europe, and Japan, and substantially all of our assets are located in the United States. We analyze our sales using a number of approaches, including sales by geography. Our German subsidiary (LeMaitre Vascular GmbH) records all sales in Europe excluding direct sales in France (LeMaitre Vascular SAS); Italy (LeMaitre Vascular S.r.l.); and Spain (LeMaitre Vascular Spain SL) beginning July 1, 2011, and to distributors worldwide, excluding distributor sales in North, South and Central America (LeMaitre Vascular, Inc.), France (LeMaitre Vascular SAS), Portugal (LeMaitre Vascular Spain SL), and Korea and Taiwan (LeMaitre Vascular GK). Net sales to unaffiliated customers by country were as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
United States	\$ 36,542	\$ 35,366	\$ 33,386
Germany	5,647	7,276	7,769
Japan	2,674	2,283	1,820
Other countries	11,872	12,760	13,085
Net sales	\$ 56,735	\$ 57,685	\$ 56,060

Total property and equipment held by geography were as follows:

	As of December 31,	
	2012	2011
	(in thousands)	
United States	\$ 4,162	\$ 4,241
Germany	232	253
Other countries	150	167
Total property and equipment	\$ 4,544	\$ 4,661

**14. Supplemental Cash Flow Information**

Supplemental disclosures of cash flow information are as follows:

	Year ended December 31,		
	2012	2011	2010
	(in thousands)		
Cash paid for income taxes, net	\$ 544	\$ 717	\$ 835
<b>Supplemental non-cash financing activities:</b>			
Common stock repurchased for RSU tax withholdings	\$ 263	\$ 308	\$ 271

**15. 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.



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

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

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

F-33

**Table of Contents**

As of December 31, 2012, we had cash equivalents in a money market fund that was valued using Level 1 inputs (quoted market prices for identical assets) at a fair value of \$13.0 million.

We had no Level 2 or Level 3 assets being measured at fair value on a recurring basis as of December 31, 2012. As discussed in Notes 1 and 2, several measurements of acquisition-related assets and impairments of intangible assets were measured using Level 3 techniques.

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

2012	March 31	Three months ended		
		June 30	September 30	December 31
		(in thousands, except per share data)		
Total net sales	\$ 13,928	\$ 14,361	\$ 13,645	\$ 14,801
Gross profit	9,870	10,545	10,015	10,438
Income from operations	854	1,455	1,001	930
Net income	386	824	663	698
Earnings per share				
Basic	\$ 0.03	\$ 0.05	\$ 0.04	\$ 0.05
Diluted	\$ 0.02	\$ 0.05	\$ 0.04	\$ 0.04

2011	March 31	Three months ended		
		June 30	September 30	December 31
		(in thousands, except per share data)		
Total net sales	\$ 14,598	\$ 15,112	\$ 14,564	\$ 13,411
Gross profit	10,151	10,370	10,183	9,523
Income (loss) from operations	(30)	897	1,991	832
Net income	64	519	1,214	346
Earnings per share				
Basic	\$	\$ 0.03	\$ 0.08	\$ 0.02
Diluted	\$	\$ 0.03	\$ 0.08	\$ 0.02

**Table of Contents****EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	Number	
2.1	Purchase Option Agreement dated December 30, 2008 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.				X
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.				X
2.3	Amendment No. 2 to Purchase Option Agreement dated January 5, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.				X
2.4	Amendment No. 3 to Purchase Option Agreement dated October 1, 2012 by and among the Registrant, Neovasc Inc. and Neovasc Medical Inc.				X
3.1	Amended and Restated By-laws of the Registrant	S-1/A	5/26/06	3.1	
3.2	Second Amended and Restated Certificate of Incorporation of the Registrant	10-K	3/29/10	3.2	
3.3	Amendment to Second Amended and Restated Certificate of Incorporation of the Registrant	8-K	6/15/12	3.3	
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	6/22/06	4.1	
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	10.1	
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	10.2	
10.3	Director Compensation Policy	10-K	3/27/12	10.27	
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	10.7	
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	10.8	
10.6	Employment Agreement dated June 20, 2006, by and between the Registrant and David Roberts	S-1/A	6/22/06	10.24	
10.7	Employment Agreement dated April 20, 2006, by and between the Registrant and Joseph P. Pellegrino	S-1/A	6/22/06	10.10	
10.8	1997 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.11	
10.9	1998 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.12	
10.10	2000 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.13	
10.11	2004 Stock Option Plan and form of agreements thereunder	S-1	4/25/06	10.14	

**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	Number	
10.12	Second Amended and Restated 2006 Stock Option and Incentive Plan and form of agreements thereunder	8-K	6/18/10	10.1	
10.13	Form of Indemnification Agreement between the Registrant and its directors and executive officers	S-1/A	5/26/06	10.17	
10.14	Form of Restricted Stock Unit Award Agreement under the Registrant's 2006 Stock Option and Incentive Plan	8-K	12/26/06	99.1	
10.15	Management Incentive Compensation Plan	8-K	4/27/07	10.1	
10.16	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	10.1	
10.17	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	10.1	
10.18	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	10.36	
10.19	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	10.37	
10.20	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and David Roberts	10-K	3/31/09	10.38	
10.21	First Amendment to Employment Agreement dated December 19, 2008, by and between the Registrant and Joseph P. Pellegrino	10-K	3/31/09	10.39	
10.22	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	10.33	
10.23	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	10.34	
10.24	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	10.28	
10.25	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	10.29	
10.26	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.				X

**Table of Contents**

Exhibit Number	Exhibit Description	Incorporated By Reference			Filed Herewith
		Form	Date	Number	
21.1	List of Subsidiaries				X
23.1	Consent of Ernst & Young LLP				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
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.